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118TH CONGRESS
*1st Session*

HOUSE OF REPRESENTATIVES

REPT. 118–231
Part 1

# HEALTH CARE PRICE TRANSPARENCY ACT OF 2023

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R E P O R T

OF THE

## COMMITTEE ON WAYS AND MEANS HOUSE OF REPRESENTATIVES

together with

DISSENTING VIEWS

SEPTEMBER 29, 2023.—Ordered to be printed

# HEALTH CARE PRICE TRANSPARENCY ACT OF 2023

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Mr. SMITH of Missouri, from the Committee on Ways and Means, submitted the following

# R E P O R T

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## DISSENTING VIEWS

[To accompany H.R. 4822]

The Committee on Ways and Means, to whom was referred the bill (H.R. 4822) to improve price transparency with respect to certain health care services, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

CONTENTS



53–576

The amendment is as follows:
Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

(a) SHORT TITLE.—This Act may be cited as the "Health Care Price Transparency Act of 2023".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:



# TITLE I—HEALTH CARE PRICE TRANSPARENCY FOR PATIENTS

**SEC. 101. REQUIRING CERTAIN FACILITIES UNDER THE MEDICARE PROGRAM TO DISCLOSE CERTAIN INFORMATION RELATING TO CHARGES AND PRICES.**

(a) IN GENERAL.—Part E of title XVIII of the Social Security Act (42 U.S.C. 1395x et seq.) is amended by adding at the end the following new section:

**"SEC. 1899C. HEALTH CARE PROVIDER PRICE TRANSPARENCY.**

"(a) HOSPITAL PRICE TRANSPARENCY.—

"(1) IN GENERAL.—Beginning January 1, 2026, each specified hospital (as defined in paragraph (6)) that receives payment under this title for furnishing items and services shall comply with the price transparency requirement described in paragraph (2).

"(2) REQUIREMENT DESCRIBED.—

"(A) IN GENERAL.—For purposes of paragraph (1), the price transparency requirement described in this paragraph is, with respect to a specified hospital, that such hospital, in accordance with a method and format established by the Secretary under subparagraph (C), compile and make public (without subscription and free of charge) for each year—

"(i) one or more lists, in a format specified by the Secretary (which may be a machine-readable format), of the hospital's standard charges (including the information described in subparagraph (B)) for each item and service furnished by such hospital; and

"(ii) information in a consumer-friendly format (as specified by the Secretary)—

"(I) on the hospital's prices (including the information described in subparagraph (B)) for as many of the Centers for Medicare & Medicaid Services-specified shoppable services that are furnished by the hospital, and as many additional hospital-selected shoppable services (or all such additional services, if such hospital furnishes fewer than 300 shoppable services) as may be necessary for a combined total of at least 300 shoppable services; and

"(II) that includes, with respect to each Centers for Medicare & Medicaid Services-specified shoppable service that is not furnished by the hospital, an indication that such service is not so furnished.

"(B) INFORMATION DESCRIBED.—For purposes of subparagraph (A), the information described in this subparagraph is, with respect to standard charges and prices (as applicable) made public by a specified hospital, the following:

"(i) A description of each item or service, accompanied by, as applicable, the Healthcare Common Procedure Coding System code, the diag-

nosis-related group, the national drug code, or other identifier used or approved by the Centers for Medicare & Medicaid Services.

"(ii) The gross charge, expressed as a dollar amount, for each such item or service, when provided in, as applicable, the inpatient setting and outpatient department setting.

"(iii) The discounted cash price, expressed as a dollar amount, for each such item or service when provided in, as applicable, the inpatient setting and outpatient department setting (or, in the case no discounted cash price is available for an item or service, the median price charged by the hospital for such item or service when provided in such settings for the previous three years, expressed as a dollar amount).

"(iv) Any other information the Secretary may require for purposes of promoting public awareness of specified hospital standard charges or prices in advance of receiving an item or service from such a hospital, except information that is duplicative of any other reporting requirement under this section. Such information may include any current payer-specific negotiated charges, clearly associated with the name of the third party payer and plan and expressed as a dollar amount, that apply to each such item or service when provided in, as applicable, the inpatient setting and outpatient department setting.

"(C) METHOD AND FORMAT.—Not later than January 1, 2026, the Secretary shall establish one or more methods and formats for specified facilities to use in compiling and making public standard charges and prices (as applicable) pursuant to subparagraph (A). Any such method and format—

"(i) may be similar to any template made available by the Centers for Medicare & Medicaid Services as of the date of the enactment of this subparagraph;

"(ii) shall meet such standards as determined appropriate by the Secretary in order to ensure the accessibility and usability of such charges and prices; and

"(iii) shall be updated as determined appropriate by the Secretary, in consultation with stakeholders.

"(3) DEEMED COMPLIANCE WITH SHOPPABLE SERVICES REQUIREMENT FOR HOSPITALS WITH A PRICE ESTIMATOR TOOL.—

"(A) IN GENERAL.—With respect to each year until the effective date of regulations implementing the provisions of sections 2799A–1(f) and 2799B–6 of the Public Health Service Act (relating to advanced explanations of benefits), including regulations on establishing data transfer standards to effectuate such provisions, a specified hospital shall be deemed to have complied with the requirement described in paragraph (2)(A)(ii)(I) (relating to shoppable services) if such hospital maintains a price estimator tool described in subparagraph (B).

"(B) PRICE ESTIMATOR TOOL DESCRIBED.—For purposes of subparagraph (A), the price estimator tool described in this subparagraph is, with respect to a specified hospital, a tool that meets the following requirements:

"(i) Such tool allows an individual to immediately obtain a price estimate (taking into account whether such individual is covered under any plan, coverage, or program described in clause (iv)(III)) and the discounted cash price charged by a specified hospital, for each Centers for Medicare & Medicaid Services-specified shoppable service that is furnished by such hospital, and for each additional shoppable service as such hospital may select, such that price estimates are available through such tool for at least 300 shoppable services (or for all such services, if such hospital furnishes fewer than 300 shoppable services).

"(ii) Such tool allows an individual to obtain such an estimate by billing code and by service description.

"(iii) Such tool is prominently displayed on the public internet website of such hospital.

"(iv) Such tool does not require an individual seeking such an estimate to create an account or otherwise input personal information, except that such tool may require that such individual provide information specified by the Secretary, which may include the following:

"(I) The name of such individual.

"(II) The date of birth of such individual.

"(III) In the case such individual is covered under a group health plan, group or individual health insurance coverage, a Federal health care program, or the program established under chapter 89 of title 5, United States Code, an identifying number assigned by such plan, coverage, or program to such individual.

"(IV) In the case of an individual described in subclause (III), an indication as to whether such individual is the primary insured individual under such plan, coverage, or program (and, if such individual is not the primary insured individual, a description of the individual's relationship to such primary insured individual).

"(V) Any other information specified by the Secretary.

"(v) Such tool contains a statement confirming the accuracy and completeness of information presented through such tool as of the date such request is made.

"(vi) Such tool meets any other requirement specified by the Secretary.

"(4) MONITORING COMPLIANCE.—The Secretary shall, through notice and comment rulemaking and in consultation with the Inspector General of the Department of Health and Human Services, establish a process to monitor compliance with this subsection. Such process shall ensure that each specified hospital's compliance with this subsection is reviewed not less frequently than once every 3 years.

"(5) ENFORCEMENT.—

"(A) IN GENERAL.—In the case of a specified hospital that fails to comply with the requirements of this subsection—

"(i) the Secretary shall notify such hospital of such failure not later than 30 days after the date on which the Secretary determines such failure exists; and

"(ii) upon request of the Secretary, the hospital shall submit to the Secretary, not later than 45 days after the date of such request, a corrective action plan to comply with such requirements.

"(B) CIVIL MONETARY PENALTY.—

"(i) IN GENERAL.—In addition to any other enforcement actions or penalties that may apply under another provision of law, a specified hospital that has received a notification under subparagraph (A)(i) and fails to comply with the requirements of this subsection by the date that is 90 days after such notification (or, in the case of such a hospital that has submitted a corrective action plan described in subparagraph (A)(ii) in response to a request so described, by the date that is 90 days after the Secretary identifies the failure of such hospital to satisfactorily complete such corrective action plan) shall be subject to a civil monetary penalty of an amount specified by the Secretary for each subsequent day during which such failure is ongoing. Such amount shall not exceed—

"(I) in the case of a specified hospital that is a hospital or critical access hospital with 30 or fewer beds, $300 per day; and

"(II) in the case of any specified hospital and except as provided in clause (iii), $2,000,000 for a 1-year period.

"(ii) INCREASE AUTHORITY.—In applying this subparagraph with respect to violations occurring in 2029 or a subsequent year, the Secretary may through notice and comment rulemaking increase—

"(I) the limitation on the per day amount of any penalty applicable to a specified hospital that is a hospital or critical access hospital with 30 or fewer beds under clause (i)(I);

"(II) the limitation on the amount of any penalty applicable for a 1-year period under clause (i)(II); and

"(III) the limitation on the increase of any penalty applied under clause (iii).

"(iii) PERSISTENT NONCOMPLIANCE.—In the case of a specified hospital (other than a specified hospital that is a hospital or critical access hospital with 30 or fewer beds) that the Secretary has determined to be knowingly and willfully noncompliant with the provisions of this subsection two or more times during a 1-year period, the Secretary may increase any penalty otherwise applicable under this subparagraph by not more than $1,000,000 and may require such hospital to complete such additional corrective actions plans as the Secretary may specify.

"(iv) APPLICATION OF CERTAIN PROVISIONS.—The provisions of section 1128A (other than subsections (a) and (b) of such section) shall apply to a civil monetary penalty imposed under this subparagraph in the same manner as such provisions apply to a civil monetary penalty imposed under subsection (a) of such section.

"(v) AUTHORITY TO WAIVE OR REDUCE PENALTY.—The Secretary may waive or reduce any penalty otherwise applicable with respect to a specified hospital under this subparagraph if the Secretary determines

that imposition of such penalty would result in a significant hardship for such hospital (such as in the case of a hospital located in a rural or underserved area where imposition of such penalty may result in, or contribute to, a lack of access to care for individuals in such area).

"(C) PUBLICATION OF HOSPITAL PRICE TRANSPARENCY INFORMATION.—Beginning on January 1, 2026, the Secretary shall make publicly available on the public website of the Centers for Medicare & Medicaid Services information with respect to compliance with the requirements of this subsection and enforcement activities undertaken by the Secretary under this subsection. Such information shall be updated not less than annually and include, with respect to each year—

"(i) the number of reviews of compliance with this subsection undertaken by the Secretary;

"(ii) the number of notifications described in subparagraph (A)(i) sent by the Secretary;

"(iii) the identify of each specified hospital that was sent such a notification and a description of the nature of such hospital's noncompliance with this subsection;

"(iv) the amount of any civil monetary penalty imposed on such hospital under subparagraph (B);

"(v) whether such hospital subsequently came into compliance with this subsection; and

"(vi) any other information as determined by the Secretary.

"(6) DEFINITIONS.—For purposes of this subsection:

"(A) DISCOUNTED CASH PRICE.—The term 'discounted cash price' means the charge that applies to an individual who pays cash, or cash equivalent, for a specified hospital-furnished item or service.

"(B) FEDERAL HEALTH CARE PROGRAM.—The term 'Federal health care program' has the meaning given such term in section 1128B.

"(C) GROSS CHARGE.—The term 'gross charge' means the charge for an individual item or service that is reflected on a specified hospital's chargemaster, absent any discounts.

"(D) GROUP HEALTH PLAN; GROUP HEALTH INSURANCE COVERAGE; INDIVIDUAL HEALTH INSURANCE COVERAGE.—The terms 'group health plan', 'group health insurance coverage', and 'individual health insurance coverage' have the meaning given such terms in section 2791 of the Public Health Service Act.

"(E) PAYER-SPECIFIC NEGOTIATED CHARGE.—The term 'payer-specific negotiated charge' means the charge that a specified hospital has negotiated with a third party payer for an item or service.

"(F) SHOPPABLE SERVICE.—The term 'shoppable service' means a service that can be scheduled by a health care consumer in advance and includes all ancillary items and services customarily furnished as part of such service.

"(G) SPECIFIED HOSPITAL.—The term 'specified hospital' means a hospital (as defined in section 1861(e)), a critical access hospital (as defined in section 1861(mmm)(1)), or a rural emergency hospital (as defined in section 1861(kkk)).

"(H) THIRD PARTY PAYER.—The term 'third party payer' means an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service.

"(b) AMBULATORY SURGICAL CENTER PRICE TRANSPARENCY.—

"(1) IN GENERAL.—Beginning January 1, 2028, each ambulatory surgical center that receives payment under this title for furnishing items and services shall comply with the price transparency requirement described in paragraph (2).

"(2) REQUIREMENT DESCRIBED.—

"(A) IN GENERAL.—For purposes of paragraph (1), the price transparency requirement described in this subsection is, with respect to an ambulatory surgical center, that such surgical center in accordance with a method and format established by the Secretary under subparagraph (C)), compile and make public (without subscription and free of charge), for each year—

"(i) one or more lists, in a format specified by the Secretary (which may be machine-readable), of the ambulatory surgical center's standard charges (including the information described in subparagraph (B)) for each item and service furnished by such surgical center;

"(ii) information on the ambulatory surgical center's prices (including the information described in subparagraph (B)) for as many of the Centers for Medicare & Medicaid Services-specified shoppable services that

are furnished by such surgical center, and as many additional ambulatory surgical center-selected shoppable services (or all such additional services, if such surgical center furnishes fewer than 300 shoppable services) as may be necessary for a combined total of at least 300 shoppable services; and

"(iii) with respect to each Centers for Medicare & Medicaid Services-specified shoppable service that is not furnished by the ambulatory surgical center, an indication that such service is not so furnished.

"(B) INFORMATION DESCRIBED.—For purposes of subparagraph (A), the information described in this subparagraph is, with respect to standard charges and prices (as applicable) made public by an ambulatory surgical center, the following:

"(i) A description of each item or service, accompanied by, as applicable, the Healthcare Common Procedure Coding System code, the diagnosis-related group, the national drug code, or other identifier used or approved by the Centers for Medicare & Medicaid Services.

"(ii) The gross charge, expressed as a dollar amount, for each such item or service.

"(iii) The discounted cash price, expressed as a dollar amount, for each such item or service (or, in the case no discounted cash price is available for an item or service, the gross charge for such item or service for the previous three years, expressed as a dollar amount).

"(iv) Any other information the Secretary may require that is not duplicative of any other reporting requirement under this subsection for purposes of promoting public awareness of ambulatory surgical center prices in advance of receiving an item or service from such an ambulatory surgical center, which may include any current payer-specific negotiated charges, clearly associated with the name of the third party payer and plan and expressed as a dollar amount, that applies to each such item or service.

"(C) METHOD AND FORMAT.—Not later than January 1, 2028, the Secretary shall establish one or more methods and formats for ambulatory surgical centers to use in making public standard charges and prices (as applicable) pursuant to subparagraph (A). Any such method and format—

"(i) may be similar to any template made available by the Centers for Medicare & Medicaid Services as of the date of the enactment of this paragraph;

"(ii) shall meet such standards as determined appropriate by the Secretary in order to ensure the accessibility and usability of such charges and prices; and

"(iii) shall be updated as determined appropriate by the Secretary, in consultation with stakeholders.

"(3) DEEMED COMPLIANCE WITH SHOPPABLE SERVICES REQUIREMENT FOR AMBULATORY SURGICAL CENTERS WITH A PRICE ESTIMATOR TOOL.—

"(A) IN GENERAL.—With respect to each year until the effective date of regulations implementing the provisions of sections 2799A–1(f) and 2799B–6 of the Public Health Service Act (relating to advanced explanations of benefits), including regulations on establishing data transfer standards to effectuate such provisions, an ambulatory surgical center shall be deemed to have complied with the requirement described in subsection (b)(2)(A) (relating to shoppable services) if such surgical center maintains a price estimator tool described in subparagraph (B).

"(B) PRICE ESTIMATOR TOOL DESCRIBED.—For purposes of subparagraph (A), the price estimator tool described in this subparagraph is, with respect to an ambulatory surgical center, a tool that meets the following requirements:

"(i) Such tool allows an individual to immediately obtain a price estimate (taking into account whether such individual is covered under any plan, coverage, or program described in clause (iv)(III)) for each Centers for Medicare & Medicaid Services-specified shoppable service that is furnished by such surgical center, and for each additional shoppable service as such surgical center may select, such that price estimates are available through such tool for at least 300 shoppable services (or for all such services, if such surgical center furnishes fewer than 300 shoppable services).

"(ii) Such tool allows an individual to obtain such an estimate by billing code and by service description.

"(iii) Such tool is prominently displayed on the public internet website of such ambulatory surgical center.

"(iv) Such tool does not require an individual seeking such an estimate to create an account or otherwise input personal information, except that such tool may require that such individual provide information specified by the Secretary, which may include the following:

"(I) The name of such individual.

"(II) The date of birth of such individual.

"(III) In the case such individual is covered under a group health plan, group or individual health insurance coverage, a Federal health care program, or the program established under chapter 89 of title 5, United States Code, an identifying number assigned by such plan, coverage, or program to such individual.

"(IV) In the case of an individual described in subclause (III), an indication as to whether such individual is the primary insured individual under such plan, coverage, or program (and, if such individual is not the primary insured individual, a description of the individual's relationship to such primary insured individual).

"(V) Any other information specified by the Secretary.

"(v) Such tool contains a statement confirming the accuracy and completeness of information presented through such tool as of the date such request is made.

"(vi) Such tool meets any other requirement specified by the Secretary.

"(4) MONITORING COMPLIANCE.—The Secretary shall, through notice and comment rulemaking and in consultation with the Inspector General of the Department of Health and Human Services, establish a process to monitor compliance with this subsection. Such process shall ensure that each ambulatory surgical center's compliance with this subsection is reviewed not less frequently than once every 3 years.

"(5) ENFORCEMENT.—

"(A) IN GENERAL.—In the case of an ambulatory surgical center that fails to comply with the requirements of this subsection—

"(i) the Secretary shall notify such ambulatory surgical center of such failure not later than 30 days after the date on which the Secretary determines such failure exists; and

"(ii) upon request of the Secretary, the ambulatory surgical center shall submit to the Secretary, not later than 45 days after the date of such request, a corrective action plan to comply with such requirements.

"(B) CIVIL MONETARY PENALTY.—

"(i) IN GENERAL.—In addition to any other enforcement actions or penalties that may apply under another provision of law, an ambulatory surgical center that has received a notification under subparagraph (A)(i) and fails to comply with the requirements of this subsection by the date that is 90 days after such notification (or, in the case of an ambulatory surgical center that has submitted a corrective action plan described in subparagraph (A)(ii) in response to a request so described, by the date that is 90 days after such submission) shall be subject to a civil monetary penalty of an amount specified by the Secretary for each subsequent day during which such failure is ongoing (not to exceed $300 per day).

"(ii) INCREASE AUTHORITY.—In applying this subparagraph with respect to violations occurring in 2029 or a subsequent year, the Secretary may through notice and comment rulemaking increase the limitation on the per day amount of any penalty applicable to an ambulatory surgical center under clause (i).

"(iii) APPLICATION OF CERTAIN PROVISIONS.—The provisions of section 1128A (other than subsections (a) and (b) of such section) shall apply to a civil monetary penalty imposed under this subparagraph in the same manner as such provisions apply to a civil monetary penalty imposed under subsection (a) of such section.

"(iv) AUTHORITY TO WAIVE OR REDUCE PENALTY.—The Secretary may waive or reduce any penalty otherwise applicable with respect to an ambulatory surgical center under this subparagraph if the Secretary determines that imposition of such penalty would result in a significant hardship for such ambulatory surgical center (such as in the case of an ambulatory surgical center located in a rural or underserved area where imposition of such penalty may result in, or contribute to, a lack of access to care for individuals in such area).

"(6) DEFINITIONS.—For purposes of this section:

"(A) DISCOUNTED CASH PRICE.—The term 'discounted cash price' means the charge that applies to an individual who pays cash, or cash equivalent, for a item or service furnished by an ambulatory surgical center.

"(B) FEDERAL HEALTH CARE PROGRAM.—The term 'Federal health care program' has the meaning given such term in section 1128B.

"(C) GROSS CHARGE.—The term 'gross charge' means the charge for an individual item or service that is reflected on a specified surgical center's chargemaster, absent any discounts.

"(D) GROUP HEALTH PLAN; GROUP HEALTH INSURANCE COVERAGE; INDIVIDUAL HEALTH INSURANCE COVERAGE.—The terms 'group health plan', 'group health insurance coverage', and 'individual health insurance coverage' have the meaning given such terms in section 2791 of the Public Health Service Act.

"(E) PAYER-SPECIFIC NEGOTIATED CHARGE.—The term 'payer-specific negotiated charge' means the charge that a specified surgical center has negotiated with a third party payer for an item or service.

"(F) SHOPPABLE SERVICE.—The term 'shoppable service' means a service that can be scheduled by a health care consumer in advance and includes all ancillary items and services customarily furnished as part of such service.

"(G) THIRD PARTY PAYER.—The term 'third party payer' means an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service.

"(c) IMAGING SERVICES PRICE TRANSPARENCY.—

"(1) IN GENERAL.—Beginning January 1, 2028, each provider of services and supplier that receives payment under this title for furnishing a specified imaging service shall—

"(A) make publicly available (in a form and manner specified by the Secretary) on an Internet website the information described in paragraph (2) with respect to each such service that such provider of services or supplier furnishes; and

"(B) ensure that such information is updated not less frequently than annually.

"(2) INFORMATION DESCRIBED.—For purposes of paragraph (1), the information described in this subsection is, with respect to a provider of services or supplier and a specified imaging service, the following:

"(A) The discounted cash price for such service (or, if no such price exists, the gross charge for such service).

"(B) If required by the Secretary, the deidentified minimum negotiated rate in effect between such provider or supplier and any group health plan or group or individual health insurance coverage for such service and the deidentified maximum negotiated rate in effect between such provider or supplier and any such plan or coverage for such service.

"(3) METHOD AND FORMAT.—Not later than January 1, 2028, the Secretary shall establish one or more methods and formats for each provider of services and supplier to use in compiling and making public standard charges and prices (as applicable) pursuant to paragraph (1). Any such method and format—

"(A) may be similar to any template made available by the Centers for Medicare & Medicaid Services as of the date of the enactment of this subsection;

"(B) shall meet such standards as determined appropriate by the Secretary in order to ensure the accessibility and usability of such charges and prices; and

"(C) shall be updated as determined appropriate by the Secretary, in consultation with stakeholders.

"(4) MONITORING COMPLIANCE.—The Secretary shall, through notice and comment rulemaking and in consultation with the Inspector General of the Department of Health and Human Services, establish a process to monitor compliance with this subsection.

"(5) SPECIFICATION OF SERVICES.—Not later than January 1, 2028, the Secretary shall publish a list of at least 50 imaging services that the Secretary determines are shoppable (or all such services, if the Secretary determines that fewer than 50 such services are shoppable) between providers of services and suppliers of such services. The Secretary shall update such list as determined appropriate by the Secretary.

"(6) ENFORCEMENT.—

"(A) IN GENERAL.—In the case that the Secretary determines that a provider of services or supplier is not in compliance with paragraph (1)—

"(i) not later than 30 days after such determination, the Secretary shall notify such provider or supplier of such determination;

"(ii) upon request of the Secretary, such provider or supplier shall submit to the Secretary, not later than 45 days after the date of such request, a corrective action plan to comply with such paragraph; and

"(iii) if such provider or supplier continues to fail to comply with such paragraph after the date that is 90 days after such notification is sent (or, in the case of such a provider or supplier that has submitted a corrective action plan described in clause (ii) in response to a request so described, after the date that is 90 days after such submission), the Secretary may impose a civil monetary penalty in an amount not to exceed $300 for each subsequent day during which such failure to comply or failure to submit is ongoing.

"(B) INCREASE AUTHORITY.—In applying this paragraph with respect to violations occurring in 2029 or a subsequent year, the Secretary may through notice and comment rulemaking increase the amount of the civil monetary penalty under subparagraph (A)(iii).

"(C) APPLICATION OF CERTAIN PROVISIONS.—The provisions of section 1128A (other than subsections (a) and (b) of such section) shall apply to a civil monetary penalty imposed under this paragraph in the same manner as such provisions apply to a civil monetary penalty imposed under subsection (a) of such section.

"(D) AUTHORITY TO WAIVE OR REDUCE PENALTY.—The Secretary may waive or reduce any penalty otherwise applicable with respect to a provider of services or supplier under this subparagraph if the Secretary determines that imposition of such penalty would result in a significant hardship for such provider or supplier (such as in the case of a provider or supplier located in a rural or underserved area where imposition of such penalty may result in, or contribute to, a lack of access to care for individuals in such area).

"(E) CLARIFICATION OF NONAPPLICABILITY OF OTHER ENFORCEMENT PROVISIONS.—Notwithstanding any other provision of this title, this paragraph shall be the sole means of enforcing the provisions of this subsection.

"(7) DEFINITIONS.—In this subsection:

"(A) GROUP HEALTH PLAN; GROUP HEALTH INSURANCE COVERAGE; INDIVIDUAL HEALTH INSURANCE COVERAGE.—The terms 'group health plan', 'group health insurance coverage', and 'individual health insurance coverage' have the meaning given such terms in section 2791 of the Public Health Service Act.

"(B) SPECIFIED IMAGING SERVICE.—the term 'specified imaging service' means an imaging service that is included on the list published by the Secretary under subsection (e).

"(d) CLINICAL LABORATORY PRICE TRANSPARENCY.—

"(1) IN GENERAL.—Beginning January 1, 2028, each applicable laboratory that receives payment under this title for furnishing a specified clinical diagnostic laboratory test shall—

"(A) make publicly available (in a manner and form specified by the Secretary) on an Internet website the information described in paragraph (2) with respect to each such specified clinical diagnostic laboratory test that such laboratory is so available to furnish; and

"(B) ensure that such information is updated not less frequently than annually.

"(2) INFORMATION DESCRIBED.—For purposes of paragraph (1), the information described in this subsection is, with respect to an applicable laboratory and a specified clinical diagnostic laboratory test, the following:

"(A) The discounted cash price for such test (or, if no such price exists, the gross charge for such test).

"(B) If required by the Secretary, the deidentified minimum negotiated rate in effect between such laboratory and any group health plan or group or individual health insurance coverage for such test and the deidentified maximum negotiated rate in effect between such laboratory and any such plan or coverage for such test.

"(3) METHOD AND FORMAT.—Not later than January 1, 2028, the Secretary shall establish one or more methods and formats for each provider of services and supplier to use in compiling and making public standard charges and prices (as applicable) pursuant to paragraph (1). Any such method and format—

"(A) may be similar to any template made available by the Centers for Medicare & Medicaid Services as of the date of the enactment of this subsection;

"(B) shall meet such standards as determined appropriate by the Secretary in order to ensure the accessibility and usability of such charges and prices; and

"(C) shall be updated as determined appropriate by the Secretary, in consultation with stakeholders.

"(4) MONITORING COMPLIANCE.—The Secretary shall, through notice and comment rulemaking and in consultation with the Inspector General of the Department of Health and Human Services, establish a process to monitor compliance with this subsection.

"(5) ENFORCEMENT.—

"(A) IN GENERAL.—In the case that the Secretary determines that an applicable laboratory is not in compliance with paragraph (1)—

"(i) not later than 30 days after such determination, the Secretary shall notify such laboratory of such determination;

"(ii) upon request of the Secretary, such laboratory shall submit to the Secretary, not later than 45 days after such request is sent, a corrective action plan to comply with such subsection; and

"(iii) if such laboratory continues to fail to comply with such paragraph after the date that is 90 days after such notification is sent (or, in the case of such a laboratory that has submitted a corrective action plan described in clause(ii) in response to a request so described, after the date that is 90 days after such submission), the Secretary may impose a civil monetary penalty in an amount not to exceed $300 for each subsequent day during which such failure to comply is ongoing.

"(B) INCREASE AUTHORITY.—In applying this paragraph with respect to violations occurring in 2029 or a subsequent year, the Secretary may through notice and comment rulemaking increase the amount of the civil monetary penalty under subparagraph (A)(iii).

"(C) APPLICATION OF CERTAIN PROVISIONS.—The provisions of section 1128A (other than subsections (a) and (b) of such section) shall apply to a civil monetary penalty imposed under this paragraph in the same manner as such provisions apply to a civil monetary penalty imposed under subsection (a) of such section.

"(D) AUTHORITY TO WAIVE OR REDUCE PENALTY.—The Secretary may waive or reduce any penalty otherwise applicable with respect to an applicable laboratory under this paragraph if the Secretary determines that imposition of such penalty would result in a significant hardship for such laboratory (such as in the case of an applicable laboratory located in a rural or underserved area where imposition of such penalty may result in, or contribute to, a lack of access to care for individuals in such area).

"(E) CLARIFICATION OF NONAPPLICABILITY OF OTHER ENFORCEMENT PROVISIONS.—Notwithstanding any other provision of this title, this subsection shall be the sole means of enforcing the provisions of this section.

"(6) DEFINITIONS.—In this subsection:

"(A) APPLICABLE LABORATORY.—The term 'applicable laboratory' has the meaning given such term in section 414.502, of title 42, Code of Federal Regulations (or any successor regulation).

"(B) GROUP HEALTH PLAN; GROUP HEALTH INSURANCE COVERAGE; INDIVIDUAL HEALTH INSURANCE COVERAGE.—The terms 'group health plan', 'group health insurance coverage', and 'individual health insurance coverage' have the meaning given such terms in section 2791 of the Public Health Service Act.

"(C) SPECIFIED CLINICAL DIAGNOSTIC LABORATORY TEST.—The term 'specified clinical diagnostic laboratory test' means a clinical diagnostic laboratory test that is included on the list of shoppable services specified by the Centers for Medicare & Medicaid Services pursuant to section 180.60 of title 45, Code of Federal Regulations (or a successor regulation), other than such a test that is an advanced diagnostic laboratory test (as defined in section 1834A(d)(5)).".

(b) PUBLICATION OF HOSPITAL COMPLIANCE WITH PRICE TRANSPARENCY REQUIREMENTS.—Section 1886 of the Social Security Act (42 U.S.C. 1395ww) is amended by adding at the end the following new subsection:

"(u) PUBLICATION OF HOSPITAL COMPLIANCE WITH PRICE TRANSPARENCY REQUIREMENTS.—

"(1) IN GENERAL.—Beginning January 1, 2026, the Secretary shall, for each hospital with respect to which the Secretary has conducted a review of such hospital's compliance with the provisions of section 1899C(a) and found such hospital noncompliant with such provisions—

"(A) indicate such noncompliance on such hospital's entry on the Hospital Compare internet website (or a successor website); and

"(B) specify whether such hospital—

"(i) submitted a corrective action plan described in subsection (a)(5)(A)(ii) of such section (and, if so, the date such plan was received by the Secretary); or

"(ii) was subject to a civil monetary penalty imposed under subsection (a)(5)(B) of such section (and, if so, the date of the imposition of such penalty and the amount of such penalty).

"(2) ADDITIONS AND UPDATES.—The Secretary shall update any specification described in subparagraph (A) or (B) of paragraph (1) with respect to such hospital—

"(A) in the case of the specification described in such paragraph (1)(A), as soon as practicable after sending the notification described in section 1899C(a)(5)(A)(i); and

"(B) in the case of the specification described in such paragraph (1)(B)(ii), as soon as practicable after the imposition of a civil monetary penalty described in such paragraph.".

(c) CONFORMING AMENDMENT.—Section 2718(e) of the Public Health Service Act (42 U.S.C. 300gg–18(e)) is amended by adding at the end the following new sentence: "The preceding sentence shall not apply beginning January 1, 2026.".

(d) FUNDING.—

(1) IN GENERAL.—In addition to funds otherwise available, out of any moneys in the Treasury not otherwise appropriated, there are appropriated $10,000,000 for fiscal year 2024, to remain available until expended, for purposes of—

(A) implementing the amendment made by this subsection (a); and

(B) monitoring the compliance of entities with such amendment.

(2) REPORT ON EXPENDITURES.—Not later than 5 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report that—

(A) describes activities undertaken funded through funds made available under paragraph (1), including a specification of the amount of such funds expended for each such activity; and

(B) identifies all entities with which the Secretary has entered into contracts for purposes of implementing the amendment made by this subsection (a), monitoring compliance of entities with such amendment, or providing technical assistance to entities to promote compliance with such amendment.

(e) IMPLEMENTATION.—

(1) ACCESSIBILITY.—In implementing section 1899C(a)(2)(A)(ii) of the Social Security Act (as added by subsection (a)), the Secretary of Health and Human Services shall through rulemaking ensure that information made available pursuant to such amendment by an entity is so made available in plain, easily understandable language and that such entity provides access to such interpretation services, translations, and other assistive services to make such information accessible to individuals with limited English proficiency and individuals with disabilities.

(2) TECHNICAL ASSISTANCE.—The Secretary of Health and Human Services shall, to the extent practicable, provide technical assistance to entities making public standard charges and prices (as applicable) pursuant to the amendment made by subsection (a).

**SEC. 102. PROMOTING HEALTH COVERAGE PRICE TRANSPARENCY.**

(a) PRICE TRANSPARENCY REQUIREMENTS.—

(1) IRC.—

(A) IN GENERAL.—Section 9819 of the Internal Revenue Code of 1986 (26. U.S.C. 9816) is amended to read as follows:

**"SEC. 9819. PRICE TRANSPARENCY REQUIREMENTS.**

"(a) COST SHARING TRANSPARENCY.—

"(1) IN GENERAL.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Health Care Price Transparency Act of 2023, a group health plan shall permit individuals to learn the amount of cost-sharing (including deductibles, copayments, and coinsurance) under the individual's plan or coverage that the individual would be responsible for paying with respect to the furnishing of a specific item or service by a provider in a timely manner upon the request of the individual. At a minimum, such information shall include the information specified in paragraph (2) and shall be made

available to such individual through a self-service tool that meets the requirements of paragraph (3) or, at the option of such individual, through a paper disclosure or phone or other electronic disclosure (as selected by such individual and provided at no cost to such individual) that meets such requirements as the Secretary may specify.

"(2) SPECIFIED INFORMATION.—For purposes of paragraph (1), the information specified in this paragraph is, with respect to an item or service for which benefits are available under a group health plan furnished by a health care provider to a participant or beneficiary of such plan, the following:

"(A) If such provider is a participating provider with respect to such item or service, the in-network rate (as defined in subsection (c)) for such item or service.

"(B) If such provider is not described in subparagraph (A), the maximum allowed amount for such item or service.

"(C) The estimated amount of cost sharing (including deductibles, copayments, and coinsurance) that the participant or beneficiary will incur for such item or service (which, in the case such item or service is to be furnished by a provider described in subparagraph (B), shall be calculated using the maximum amount described in such subparagraph).

"(D) The amount the participant or beneficiary has already accumulated with respect to any deductible or out of pocket maximum, whether for items and services furnished by a participating provider or for items and services furnished by a provider that is not a participating provider, under the plan (broken down, in the case separate deductibles or maximums apply to separate participants and beneficiaries enrolled in the plan, by such separate deductibles or maximums, in addition to any cumulative deductible or maximum).

"(E) In the case such plan imposes any frequency or volume limitations with respect to such item or service (excluding medical necessity determinations), the amount that such participant or beneficiary has accrued towards such limitation with respect to such item or service.

"(F) Any prior authorization, concurrent review, step therapy, fail first, or similar requirements applicable to coverage of such item or service under such plan.

The Secretary may provide that information described in any of subparagraphs (A) through (F) not be treated as information specified in this paragraph, and specify additional information that shall be treated as information specified in this paragraph, if determined appropriate by the Secretary.

"(3) SELF-SERVICE TOOL.—For purposes of paragraph (1), a self-service tool established by a group health plan meets the requirements of this paragraph if such tool—

"(A) is based on an Internet website;

"(B) provides for real-time responses to requests described in paragraph (1);

"(C) is updated in a manner such that information provided through such tool is timely and accurate at the time such request is made;

"(D) allows such a request to be made with respect to an item or service furnished by—

"(i) a specific provider that is a participating provider with respect to such item or service;

"(ii) all providers that are participating providers with respect to such item or service; or

"(iii) a provider that is not described in clause (ii);

"(E) provides that such a request may be made with respect to an item or service through use of the billing code for such item or service or through use of a descriptive term for such item or service; and

"(F) meets any other requirement determined appropriate by the Secretary.

The Secretary may require such tool, as a condition of complying with subparagraph (E), to link multiple billing codes to a single descriptive term if the Secretary determines that the billing codes to be so linked correspond to similar items and services.

"(b) RATE AND PAYMENT INFORMATION.—

"(1) IN GENERAL.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Health Care Price Transparency Act of 2023, each group health plan (other than a grandfathered health plan (as defined in section 1251(e) of the Patient Protection and Affordable Care Act)) shall, not less frequently than once every 3 months (or, in the case of information described in paragraph (2)(B), not less frequently than monthly),

make available to the public the rate and payment information described in paragraph (2) in accordance with paragraph (3).

"(2) RATE AND PAYMENT INFORMATION DESCRIBED.—For purposes of paragraph (1), the rate and payment information described in this paragraph is, with respect to a group health plan, the following:

"(A) With respect to each item or service (other than a drug) for which benefits are available under such plan, the in-network rate in effect with each provider that is a participating provider with respect to such item or service, other than such a rate in effect with a provider that, during the 1-year period ending 10 business days before the date of the publication of such information, did not submit any claim for such item or service to such plan.

"(B) With respect to each drug (identified by national drug code) for which benefits are available under such plan, the average amount paid by such plan (net of rebates, discounts, and price concessions) for such drug dispensed or administered during the 90-day period beginning 180 days before such date of publication to each provider that was a participating provider with respect to such drug, broken down by each such provider, other than such an amount paid to a provider that, during such period, submitted fewer than 20 claims for such drug to such plan.

"(C) With respect to each item or service for which benefits are available under such plan, the amount billed, and the amount allowed by the plan, for each such item or service furnished during the 90-day period specified in subparagraph (B) by a provider that was not a participating provider with respect to such item or service, broken down by each such provider, other than items and services with respect to which fewer than 20 claims for such item or service were submitted to such plan during such period.

"(3) MANNER OF PUBLICATION.—Rate and payment information required to be made available under this subsection shall be so made available in dollar amounts through 3 separate machine-readable files (or any successor technology, such as application program interface technology, determined appropriate by the Secretary) corresponding to the information described in each of subparagraphs (A) through (C) of paragraph (2) that meet such requirements as specified by the Secretary. Such requirements shall ensure that such files are limited to an appropriate size, do not include disclosure of unnecessary duplicative information contained in other files made available under this subsection, are made available in a widely-available format through a publicly-available website that allows for information contained in such files to be compared across group health plans, and are accessible to individuals at no cost and without the need to establish a user account or provide other credentials.

"(4) USER INSTRUCTIONS.—Each group health plan shall make available to the public instructions written in plain language explaining how individuals may search for information described in paragraph (2) in files submitted in accordance with paragraph (3). The Secretary shall develop and publish a template that such a plan may use in developing instructions for purposes of the preceding sentence.

"(5) ATTESTATION.—Each group health plan shall post, along with rate and payment information made public by such plan, an attestation that such information is complete and accurate.

"(c) DEFINITIONS.—In this section:

"(1) PARTICIPATING PROVIDER.—The term 'participating provider' has the meaning given such term in section 9816.

"(2) IN-NETWORK RATE.—The term 'in-network rate' means, with respect to a health plan and an item or service furnished by a provider that is a participating provider with respect to such plan and item or service, the contracted rate in effect between such plan and such provider for such item or service.".

(B) CLERICAL AMENDMENT.—The item relating to section 9819 of the table of sections for subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended to read as follows:

"Sec. 9819. Price transparency requirements.".

(2) PHSA.—Section 2799A–4 of the Public Health Service Act (42 U.S.C. 300gg–114) is amended to read as follows:

**"SEC. 2799A–4. PRICE TRANSPARENCY REQUIREMENTS.**

"(a) COST SHARING TRANSPARENCY.—

"(1) IN GENERAL.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Health Care Price Transparency Act of 2023, a group health plan or a health insurance issuer offering group or individual health insurance coverage shall permit individuals to learn the

amount of cost-sharing (including deductibles, copayments, and coinsurance) under the individual's plan or coverage that the individual would be responsible for paying with respect to the furnishing of a specific item or service by a provider in a timely manner upon the request of the individual. At a minimum, such information shall include the information specified in paragraph (2) and shall be made available to such individual through a self-service tool that meets the requirements of paragraph (3) or, at the option of such individual, through a paper disclosure or phone or other electronic disclosure (as selected by such individual and provided at no cost to such individual) that meets such requirements as the Secretary may specify.

"(2) SPECIFIED INFORMATION.—For purposes of paragraph (1), the information specified in this paragraph is, with respect to an item or service for which benefits are available under a group health plan or group or individual health insurance coverage furnished by a health care provider to a participant or beneficiary of such plan, or enrollee in such coverage, the following:

"(A) If such provider is a participating provider with respect to such item or service, the in-network rate (as defined in subsection (c)) for such item or service.

"(B) If such provider is not described in subparagraph (A), the maximum allowed amount for such item or service.

"(C) The estimated amount of cost sharing (including deductibles, copayments, and coinsurance) that the participant, beneficiary, or enrollee will incur for such item or service (which, in the case such item or service is to be furnished by a provider described in subparagraph (B), shall be calculated using the maximum amount described in such subparagraph).

"(D) The amount the participant, beneficiary, or enrollee has already accumulated with respect to any deductible or out of pocket maximum, whether for items and services furnished by a participating provider or for items and services furnished by a provider that is not a participating provider, under the plan or coverage (broken down, in the case separate deductibles or maximums apply to separate participants, beneficiaries or enrollees enrolled in the plan or coverage, by such separate deductibles or maximums, in addition to any cumulative deductible or maximum).

"(E) In the case such plan or coverage imposes any frequency or volume limitations with respect to such item or service (excluding medical necessity determinations), the amount that such participant, beneficiary, or enrollee has accrued towards such limitation with respect to such item or service.

"(F) Any prior authorization, concurrent review, step therapy, fail first, or similar requirements applicable to coverage of such item or service under such plan or coverage.

The Secretary may provide that information described in any of subparagraphs (A) through (F) not be treated as information specified in this paragraph, and specify additional information that shall be treated as information specified in this paragraph, if determined appropriate by the Secretary.

"(3) SELF-SERVICE TOOL.—For purposes of paragraph (1), a self-service tool established by a group health plan or group or individual health insurance coverage meets the requirements of this paragraph if such tool—

"(A) is based on an Internet website;

"(B) provides for real-time responses to requests described in paragraph (1);

"(C) is updated in a manner such that information provided through such tool is timely and accurate at the time such request is made;

"(D) allows such a request to be made with respect to an item or service furnished by—

"(i) a specific provider that is a participating provider with respect to such item or service;

"(ii) all providers that are participating providers with respect to such item or service; or

"(iii) a provider that is not described in clause (ii);

"(E) provides that such a request may be made with respect to an item or service through use of the billing code for such item or service or through use of a descriptive term for such item or service; and

"(F) meets any other requirement determined appropriate by the Secretary.

The Secretary may require such tool, as a condition of complying with subparagraph (E), to link multiple billing codes to a single descriptive term if the Secretary determines that the billing codes to be so linked correspond to similar items and services.

"(b) RATE AND PAYMENT INFORMATION.—

"(1) IN GENERAL.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Health Care Price Transparency Act of 2023, each group health plan or group or individual health insurance coverage (other than a grandfathered health plan (as defined in section 1251(e) of the Patient Protection and Affordable Care Act)) shall, not less frequently than once every 3 months (or, in the case of information described in paragraph (2)(B), not less frequently than monthly), make available to the public the rate and payment information described in paragraph (2) in accordance with paragraph (3).

"(2) RATE AND PAYMENT INFORMATION DESCRIBED.—For purposes of paragraph (1), the rate and payment information described in this paragraph is, with respect to a group health plan or group or individual health insurance coverage, the following:

"(A) With respect to each item or service (other than a drug) for which benefits are available under such plan or coverage, the in-network rate in effect with each provider that is a participating provider with respect to such item or service, other than such a rate in effect with a provider that, during the 1-year period ending 10 business days before the date of the publication of such information, did not submit any claim for such item or service to such plan or coverage.

"(B) With respect to each drug (identified by national drug code) for which benefits are available under such plan, the average amount paid by such plan or coverage (net of rebates, discounts, and price concessions) for such drug dispensed or administered during the 90-day period beginning 180 days before such date of publication to each provider that was a participating provider with respect to such drug, broken down by each such provider, other than such an amount paid to a provider that, during such period, submitted fewer than 20 claims for such drug to such plan or coverage.

"(C) With respect to each item or service for which benefits are available under such plan or coverage, the amount billed, and the amount allowed by the plan or coverage, for each such item or service furnished during the 90-day period specified in subparagraph (B) by a provider that was not a participating provider with respect to such item or service, broken down by each such provider, other than items and services with respect to which fewer than 20 claims for such item or service were submitted to such plan or coverage during such period.

"(3) MANNER OF PUBLICATION.—Rate and payment information required to be made available under this subsection shall be so made available in dollar amounts through 3 separate machine-readable files (or any successor technology, such as application program interface technology, determined appropriate by the Secretary) corresponding to the information described in each of subparagraphs (A) through (C) of paragraph (2) that meet such requirements as specified by the Secretary. Such requirements shall ensure that such files are limited to an appropriate size, do not include disclosure of unnecessary duplicative information contained in other files made available under this subsection, are made available in a widely-available format through a publicly-available website that allows for information contained in such files to be compared across group health plans and group and individual health insurance coverage, and are accessible to individuals at no cost and without the need to establish a user account or provide other credentials.

"(4) USER INSTRUCTIONS.—Each group health plan and group or individual health insurance coverage shall make available to the public instructions written in plain language explaining how individuals may search for information described in paragraph (2) in files submitted in accordance with paragraph (3). The Secretary shall develop and publish a template that such a plan or coverage may use in developing instructions for purposes of the preceding sentence.

"(5) ATTESTATION.—Each group health plan and group or individual health insurance coverage shall post, along with rate and payment information made public by such plan or coverage, an attestation that such information is complete and accurate.

"(c) DEFINITIONS.—In this section:

"(1) PARTICIPATING PROVIDER.—The term 'participating provider' has the meaning given such term in section 2791A–1(a)(3)(G)(ii).

"(2) IN-NETWORK RATE.—The term 'in-network rate' means, with respect to a health plan or coverage and an item or service furnished by a provider that is a participating provider with respect to such plan and item or service, the contracted rate in effect between such plan or coverage and such provider for such item or service.".

(3) ERISA.—

(A) IN GENERAL.—Section 719 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185h) is amended to read as follows:

**"SEC. 719. PRICE TRANSPARENCY REQUIREMENTS.**

"(a) COST SHARING TRANSPARENCY.—

"(1) IN GENERAL.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Health Care Price Transparency Act of 2023, a group health plan or a health insurance issuer offering group health insurance coverage shall permit individuals to learn the amount of cost-sharing (including deductibles, copayments, and coinsurance) under the individual's plan or coverage that the individual would be responsible for paying with respect to the furnishing of a specific item or service by a provider in a timely manner upon the request of the individual. At a minimum, such information shall include the information specified in paragraph (2) and shall be made available to such individual through a self-service tool that meets the requirements of paragraph (3) or, at the option of such individual, through a paper disclosure or phone or other electronic disclosure (as selected by such individual and provided at no cost to such individual) that meets such requirements as the Secretary may specify.

"(2) SPECIFIED INFORMATION.—For purposes of paragraph (1), the information specified in this paragraph is, with respect to an item or service for which benefits are available under a group health plan or group health insurance coverage furnished by a health care provider to a participant or beneficiary of such plan, or enrollee in such coverage, the following:

"(A) If such provider is a participating provider with respect to such item or service, the in-network rate (as defined in subsection (c)) for such item or service.

"(B) If such provider is not described in subparagraph (A), the maximum allowed amount for such item or service.

"(C) The estimated amount of cost sharing (including deductibles, copayments, and coinsurance) that the participant, beneficiary, or enrollee will incur for such item or service (which, in the case such item or service is to be furnished by a provider described in subparagraph (B), shall be calculated using the maximum amount described in such subparagraph).

"(D) The amount the participant, beneficiary, or enrollee has already accumulated with respect to any deductible or out of pocket maximum, whether for items and services furnished by a participating provider or for items and services furnished by a provider that is not a participating provider, under the plan or coverage (broken down, in the case separate deductibles or maximums apply to separate participants, beneficiaries or enrollees enrolled in the plan or coverage, by such separate deductibles or maximums, in addition to any cumulative deductible or maximum).

"(E) In the case such plan or coverage imposes any frequency or volume limitations with respect to such item or service (excluding medical necessity determinations), the amount that such participant, beneficiary, or enrollee has accrued towards such limitation with respect to such item or service.

"(F) Any prior authorization, concurrent review, step therapy, fail first, or similar requirements applicable to coverage of such item or service under such plan or coverage.

The Secretary may provide that information described in any of subparagraphs (A) through (F) not be treated as information specified in this paragraph, and specify additional information that shall be treated as information specified in this paragraph, if determined appropriate by the Secretary.

"(3) SELF-SERVICE TOOL.—For purposes of paragraph (1), a self-service tool established by a group health plan or group health insurance coverage meets the requirements of this paragraph if such tool—

"(A) is based on an Internet website;

"(B) provides for real-time responses to requests described in paragraph (1);

"(C) is updated in a manner such that information provided through such tool is timely and accurate at the time such request is made;

"(D) allows such a request to be made with respect to an item or service furnished by—

"(i) a specific provider that is a participating provider with respect to such item or service;

"(ii) all providers that are participating providers with respect to such item or service; or

"(iii) a provider that is not described in clause (ii);

"(E) provides that such a request may be made with respect to an item or service through use of the billing code for such item or service or through use of a descriptive term for such item or service; and

"(F) meets any other requirement determined appropriate by the Secretary.

The Secretary may require such tool, as a condition of complying with subparagraph (E), to link multiple billing codes to a single descriptive term if the Secretary determines that the billing codes to be so linked correspond to similar items and services.

"(b) RATE AND PAYMENT INFORMATION.—

"(1) IN GENERAL.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Health Care Price Transparency Act of 2023, each group health plan or group health insurance coverage (other than a grandfathered health plan (as defined in section 1251(e) of the Patient Protection and Affordable Care Act)) shall, not less frequently than once every 3 months (or, in the case of information described in paragraph (2)(B), not less frequently than monthly), make available to the public the rate and payment information described in paragraph (2) in accordance with paragraph (3).

"(2) RATE AND PAYMENT INFORMATION DESCRIBED.—For purposes of paragraph (1), the rate and payment information described in this paragraph is, with respect to a group health plan or group health insurance coverage, the following:

"(A) With respect to each item or service (other than a drug) for which benefits are available under such plan or coverage, the in-network rate in effect with each provider that is a participating provider with respect to such item or service, other than such a rate in effect with a provider that, during the 1-year period ending 10 business days before the date of the publication of such information, did not submit any claim for such item or service to such plan or coverage.

"(B) With respect to each drug (identified by national drug code) for which benefits are available under such plan, the average amount paid by such plan or coverage (net of rebates, discounts, and price concessions) for such drug dispensed or administered during the 90-day period beginning 180 days before such date of publication to each provider that was a participating provider with respect to such drug, broken down by each such provider, other than such an amount paid to a provider that, during such period, submitted fewer than 20 claims for such drug to such plan or coverage.

"(C) With respect to each item or service for which benefits are available under such plan or coverage, the amount billed, and the amount allowed by the plan or coverage, for each such item or service furnished during the 90-day period specified in subparagraph (B) by a provider that was not a participating provider with respect to such item or service, broken down by each such provider, other than items and services with respect to which fewer than 20 claims for such item or service were submitted to such plan or coverage during such period.

"(3) MANNER OF PUBLICATION.—Rate and payment information required to be made available under this subsection shall be so made available in dollar amounts through 3 separate machine-readable files (or any successor technology, such as application program interface technology, determined appropriate by the Secretary) corresponding to the information described in each of subparagraphs (A) through (C) of paragraph (2) that meet such requirements as specified by the Secretary. Such requirements shall ensure that such files are limited to an appropriate size, do not include disclosure of unnecessary duplicative information contained in other files made available under this subsection, are made available in a widely-available format through a publicly-available website that allows for information contained in such files to be compared across group health plans and group and individual health insurance coverage, and are accessible to individuals at no cost and without the need to establish a user account or provide other credentials.

"(4) USER INSTRUCTIONS.—Each group health plan and group health insurance coverage shall make available to the public instructions written in plain language explaining how individuals may search for information described in paragraph (2) in files submitted in accordance with paragraph (3). The Secretary shall develop and publish a template that such a plan or coverage may use in developing instructions for purposes of the preceding sentence.

"(5) ATTESTATION.—Each group health plan and group health insurance coverage shall post, along with rate and payment information made public by such plan or coverage, an attestation that such information is complete and accurate.

"(c) DEFINITIONS.—In this section:

"(1) PARTICIPATING PROVIDER.—The term 'participating provider' has the meaning given such term in section 716(a)(3)(G)(ii).

"(2) IN-NETWORK RATE.—The term 'in-network rate' means, with respect to a health plan or coverage and an item or service furnished by a provider that is a participating provider with respect to such plan and item or service, the contracted rate in effect between such plan or coverage and such provider for such item or service.".

(B) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by striking the item relating to section 719 and inserting the following new item:

"Sec. 719. Price transparency requirements.".

(b) ACCESSIBILITY THROUGH IMPLEMENTATION.—In implementing the amendments made by subsection (a), the Secretary of the Treasury, the Secretary of Health and Human Services, and the Secretary of Labor shall take reasonable steps to ensure the accessibility of information made available pursuant to such amendments, including reasonable steps to ensure that such information is provided in plain, easily understandable language and that interpretation, translations, and assistive services are provided by group health plans and health insurance issuers offering group or individual health insurance coverage to make such information accessible to those with limited English proficiency and those with disabilities.

(c) CONTINUED APPLICABILITY OF RULES FOR PREVIOUS YEARS.—Nothing in the amendments made by subsection (a) may be construed as affecting the applicability of the rule entitled "Transparency in Coverage" published by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services on November 12, 2020 (85 Fed. Reg. 72158) for any plan year beginning before the date that is 2 years after the date of the enactment of this Act.

**SEC. 103. OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.**

(a) IRC.—

(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following:

**"SEC. 9826. OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.**

"(a) IN GENERAL.—For plan years beginning on or after the date that is 3 years after the date of enactment of this section, a group health plan, or an entity or subsidiary providing pharmacy benefits management services on behalf of such a plan, shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan, from making the report described in subsection (b).

"(b) ANNUAL REPORT.—

"(1) IN GENERAL.—With respect to plan years beginning on or after the date that is 3 years after the date of enactment of this section, for each such plan year, a group health plan, or an entity providing pharmacy benefits management services on behalf of such a plan, shall submit to the plan sponsor (as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974) of such plan a report in a machine-readable format. Each such report shall include, with respect to such plan provided for such plan year—

"(A) to the extent feasible, information collected from drug manufacturers (or an entity administering copay assistance on behalf of such manufacturers) by such plan (or entity or subsidiary providing pharmacy benefits management services on behalf of such plan) on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the participants and beneficiaries in such plan;

"(B) a list of each drug covered by such plan that was dispensed during the plan year, including, with respect to each such drug during such plan year—

"(i) the brand name, chemical entity, and National Drug Code;

"(ii) the number of participants and beneficiaries for whom the drug was dispensed during the plan year, the total number of prescription claims for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, disaggregated by dispensing channel (such as retail, mail order, or specialty pharmacy);

"(iii) the wholesale acquisition cost, listed as cost per days supply and cost per pill, or in the case of a drug in another form, per dosage unit;

"(iv) the total out-of-pocket spending by participants and beneficiaries on such drug, including participant and beneficiary spending through copayments, coinsurance, and deductibles;

"(v) for any drug for which gross spending of the group health plan exceeded $10,000 during the plan year—

"(I) a list of all other drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class as such drug; and

"(II) the rationale for the formulary placement of such drug in that therapeutic category or class, if applicable;

"(vi) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration for claims incurred for such drug during the plan year;

"(vii) the total net spending, after deducting rebates, price concessions, alternative discounts or other remuneration from drug manufacturers, by the health plan on such drug; and

"(viii) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, incurred by the health plan and its participants and beneficiaries after manufacturer rebates, fees, and other remuneration for such drug dispensed during the plan year;

"(C) a list of each therapeutic category or class of drugs that were dispensed under the health plan during the plan year, and, with respect to each such therapeutic category or class of drugs, during the plan year—

"(i) total gross spending by the plan, before manufacturer rebates, fees, or other manufacturer remuneration;

"(ii) the number of participants and beneficiaries who were dispensed a drug covered by such plan in that category or class, broken down by each such drug (identified by National Drug Code);

"(iii) if applicable to that category or class, a description of the formulary tiers and utilization management (such as prior authorization or step therapy) employed for drugs in that category or class; and

"(iv) the total out-of-pocket spending by participants and beneficiaries, including participant and beneficiary spending through copayments, coinsurance, and deductibles;

"(D) total gross spending on prescription drugs by the plan during the plan year, before rebates and other manufacturer fees or remuneration;

"(E) total amount received, or expected to be received, by the health plan in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug spending under that health plan during the plan year;

"(F) the total net spending on prescription drugs by the health plan during the plan year; and

"(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm for the referral of the group health plan's business to the pharmacy benefits manager.

"(2) PRIVACY REQUIREMENTS.—Entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and shall restrict the use and disclosure of such information according to such privacy regulations.

"(3) DISCLOSURE AND REDISCLOSURE.—

"(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).

"(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents an entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such entity may not restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, the Comptroller General of the United States, or applicable State agencies.

"(C) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required of plan

sponsors who are drug manufacturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

"(4) REPORT TO GAO.—A group health plan, or an entity providing pharmacy benefits management services on behalf of a group health plan, shall submit to the Comptroller General of the United States each of the first 4 reports submitted to a plan sponsor under paragraph (1) with respect to such plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (2), the disclosure and redisclosure standards under paragraph (3), the standards specified pursuant to paragraph (5), and such other information that the Comptroller General determines necessary to carry out the study under section 103(d) of the Health Care Price Transparency Act of 2023.

"(5) STANDARD FORMAT.—Not later than 18 months after the date of enactment of this section, the Secretary shall specify through rulemaking standards for entities required to submit reports under paragraph (4) to submit such reports in a standard format.

"(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a group health plan or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary of the Treasury to a report described in subsection (b)(1) or information related to compliance with subsection (a) or (b) by such plan or other entity subject to such subsections.

"(d) DEFINITION.—In this section, the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.".

(2) CLERICAL AMENDMENT.—The table of sections for subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

"Sec. 9826. Oversight of pharmacy benefits manager services.".

(b) PHSA.—Title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.) is amended—

(1) in part D (42 U.S.C. 300gg–111 et seq.), by adding at the end the following new section:

**"SEC. 2799A–11. OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.**

"(a) IN GENERAL.—For plan years beginning on or after the date that is 3 years after the date of enactment of this section, a group health plan or health insurance issuer offering group health insurance coverage, or an entity or subsidiary providing pharmacy benefits management services on behalf of such a plan or issuer, shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or issuer, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan or issuer, from making the report described in subsection (b).

"(b) ANNUAL REPORT.—

"(1) IN GENERAL.—With respect to plan years beginning on or after the date that is 3 years after the date of enactment of this section, for each such plan year, a group health plan or health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefits management services on behalf of such a plan or an issuer, shall submit to the plan sponsor (as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974) of such plan or coverage a report in a machine-readable format. Each such report shall include, with respect to such plan or coverage provided for such plan year—

"(A) to the extent feasible, information collected from drug manufacturers (or an entity administering copay assistance on behalf of such manufacturers) by such plan or issuer (or entity or subsidiary providing pharmacy benefits management services on behalf of such plan or issuer) on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the participants, beneficiaries, and enrollees in such plan or coverage;

"(B) a list of each drug covered by such plan or coverage that was dispensed during the plan year, including, with respect to each such drug during such plan year—

"(i) the brand name, chemical entity, and National Drug Code;

"(ii) the number of participants, beneficiaries, and enrollees for whom the drug was dispensed during the plan year, the total number of prescription claims for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, disaggregated by dispensing channel (such as retail, mail order, or specialty pharmacy);

"(iii) the wholesale acquisition cost, listed as cost per days supply and cost per pill, or in the case of a drug in another form, per dosage unit;

"(iv) the total out-of-pocket spending by participants, beneficiaries, and enrollees on such drug, including participant, beneficiary, and enrollee spending through copayments, coinsurance, and deductibles;

"(v) for any drug for which gross spending of the group health plan or health insurance coverage exceeded $10,000 during the plan year—

"(I) a list of all other drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class as such drug; and

"(II) the rationale for the formulary placement of such drug in that therapeutic category or class, if applicable;

"(vi) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration for claims incurred for such drug during the plan year;

"(vii) the total net spending, after deducting rebates, price concessions, alternative discounts or other remuneration from drug manufacturers, by the health plan or health insurance coverage on such drug; and

"(viii) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, incurred by the health plan or health insurance coverage and its participants, beneficiaries, and enrollees, after manufacturer rebates, fees, and other remuneration for such drug dispensed during the plan year;

"(C) a list of each therapeutic category or class of drugs that were dispensed under the health plan or health insurance coverage during the plan year, and, with respect to each such therapeutic category or class of drugs, during the plan year—

"(i) total gross spending by the plan or coverage, before manufacturer rebates, fees, or other manufacturer remuneration;

"(ii) the number of participants, beneficiaries, and enrollees who were dispensed a drug covered by such plan or coverage in that category or class, broken down by each such drug (identified by National Drug Code);

"(iii) if applicable to that category or class, a description of the formulary tiers and utilization management (such as prior authorization or step therapy) employed for drugs in that category or class; and

"(iv) the total out-of-pocket spending by participants, beneficiaries, and enrollees, including participant, beneficiary, and enrollee spending through copayments, coinsurance, and deductibles;

"(D) total gross spending on prescription drugs by the plan or coverage during the plan year, before rebates and other manufacturer fees or remuneration;

"(E) total amount received, or expected to be received, by the health plan or health insurance coverage in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug spending under that health plan or health insurance coverage during the plan year;

"(F) the total net spending on prescription drugs by the health plan or health insurance coverage during the plan year; and

"(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm for the referral of the group health plan's or health insurance issuer's business to the pharmacy benefits manager.

"(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage and entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and shall restrict the use and disclosure of such information according to such privacy regulations.

"(3) DISCLOSURE AND REDISCLOSURE.—

"(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).

"(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such issuer or entity may not restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, the Comptroller General of the United States, or applicable State agencies.

"(C) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required of plan sponsors who are drug manufacturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

"(4) REPORT TO GAO.—A group health plan or health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 4 reports submitted to a plan sponsor under paragraph (1) with respect to such coverage or plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (2), the disclosure and redisclosure standards under paragraph (3), the standards specified pursuant to paragraph (5), and such other information that the Comptroller General determines necessary to carry out the study under section 103(d) of the Health Care Price Transparency Act of 2023.

"(5) STANDARD FORMAT.—Not later than 18 months after the date of enactment of this section, the Secretary shall specify through rulemaking standards for health insurance issuers and entities required to submit reports under paragraph (4) to submit such reports in a standard format.

"(c) ENFORCEMENT.—

"(1) IN GENERAL.—Notwithstanding section 2723, the Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall enforce this section.

"(2) FAILURE TO PROVIDE TIMELY INFORMATION.—A health insurance issuer or an entity providing pharmacy benefits management services that violates subsection (a) or fails to provide information required under subsection (b) shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

"(3) FALSE INFORMATION.—A health insurance issuer or entity providing pharmacy benefits management services that knowingly provides false information under this section shall be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalty shall be in addition to other penalties as may be prescribed by law.

"(4) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsection (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

"(5) WAIVERS.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that has made a good-faith effort to comply with this section.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary of Health and Human Services to a report described in subsection (b)(1) or information related to compliance with subsection (a) or (b) by such issuer, plan, or other entity subject to such subsections.

"(e) DEFINITION.—In this section, the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act."; and

(2) in section 2723 of such Act (42 U.S.C. 300gg–22)—

(A) in subsection (a)—

(i) in paragraph (1), by inserting "(other than subsections (a) and (b) of section 2799A–11)" after "part D"; and

(ii) in paragraph (2), by inserting "(other than subsections (a) and (b) of section 2799A–11)" after "part D"; and

(B) in subsection (b)—

(i) in paragraph (1), by inserting "(other than subsections (a) and (b) of section 2799A–11)" after "part D";

(ii) in paragraph (2)(A), by inserting "(other than subsections (a) and (b) of section 2799A–11)" after "part D"; and

(iii) in paragraph (2)(C)(ii), by inserting "(other than subsections (a) and (b) of section 2799A–11)" after "part D".

(c) ERISA.—

(1) IN GENERAL.—Subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1021 et seq.) is amended—

(A) in subpart B of part 7 (29 U.S.C. 1185 et seq.), by adding at the end the following:

**"SEC. 726. OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.**

"(a) IN GENERAL.—For plan years beginning on or after the date that is 3 years after the date of enactment of this section, a group health plan or health insurance issuer offering group health insurance coverage, or an entity or subsidiary providing pharmacy benefits management services on behalf of such a plan or issuer, shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or issuer, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan or issuer, from making the report described in subsection (b).

"(b) ANNUAL REPORT.—

"(1) IN GENERAL.—With respect to plan years beginning on or after the date that is 3 years after the date of enactment of this section, for each such plan year, a group health plan or health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefits management services on behalf of such a plan or an issuer, shall submit to the plan sponsor (as defined in section 3(16)(B)) of such plan or coverage a report in a machine-readable format. Each such report shall include, with respect to such plan or coverage provided for such plan year—

"(A) to the extent feasible, information collected from drug manufacturers (or an entity administering copay assistance on behalf of such manufacturers) by such plan or issuer (or entity or subsidiary providing pharmacy benefits management services on behalf of such plan or issuer) on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the participants, beneficiaries, and enrollees in such plan or coverage;

"(B) a list of each drug covered by such plan or coverage that was dispensed during the plan year, including, with respect to each such drug during such plan year—

"(i) the brand name, chemical entity, and National Drug Code;

"(ii) the number of participants, beneficiaries, and enrollees for whom the drug was dispensed during the plan year, the total number of prescription claims for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, disaggregated by dispensing channel (such as retail, mail order, or specialty pharmacy);

"(iii) the wholesale acquisition cost, listed as cost per days supply and cost per pill, or in the case of a drug in another form, per dosage unit;

"(iv) the total out-of-pocket spending by participants, beneficiaries, and enrollees on such drug, including participant, beneficiary, and enrollee spending through copayments, coinsurance, and deductibles;

"(v) for any drug for which gross spending of the group health plan or health insurance coverage exceeded $10,000 during the plan year—

"(I) a list of all other drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class as such drug; and

"(II) the rationale for the formulary placement of such drug in that therapeutic category or class, if applicable;

"(vi) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration for claims incurred for such drug during the plan year;

"(vii) the total net spending, after deducting rebates, price concessions, alternative discounts or other remuneration from drug manufacturers, by the health plan or health insurance coverage on such drug; and

"(viii) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, incurred by the health plan or health insurance coverage and its participants, beneficiaries, and enrollees, after manufacturer rebates, fees, and other remuneration for such drug dispensed during the plan year;

"(C) a list of each therapeutic category or class of drugs that were dispensed under the health plan or health insurance coverage during the plan year, and, with respect to each such therapeutic category or class of drugs, during the plan year—

"(i) total gross spending by the plan or coverage, before manufacturer rebates, fees, or other manufacturer remuneration;

"(ii) the number of participants, beneficiaries, and enrollees who were dispensed a drug covered by such plan or coverage in that category or class, broken down by each such drug (identified by National Drug Code);

"(iii) if applicable to that category or class, a description of the formulary tiers and utilization management (such as prior authorization or step therapy) employed for drugs in that category or class; and

"(iv) the total out-of-pocket spending by participants, beneficiaries, and enrollees, including participant, beneficiary, and enrollee spending through copayments, coinsurance, and deductibles;

"(D) total gross spending on prescription drugs by the plan or coverage during the plan year, before rebates and other manufacturer fees or remuneration;

"(E) total amount received, or expected to be received, by the health plan or health insurance coverage in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug spending under that health plan or health insurance coverage during the plan year;

"(F) the total net spending on prescription drugs by the health plan or health insurance coverage during the plan year; and

"(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm for the referral of the group health plan's or health insurance issuer's business to the pharmacy benefits manager.

"(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage and entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and shall restrict the use and disclosure of such information according to such privacy regulations.

"(3) DISCLOSURE AND REDISCLOSURE.—

"(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).

"(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such issuer or entity may not restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, the Comptroller General of the United States, or applicable State agencies.

"(C) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required of plan sponsors who are drug manufacturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

"(4) REPORT TO GAO.—A group health plan or health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 4 reports submitted to a plan sponsor under paragraph (1) with respect to such coverage or plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (2), the disclosure and redisclosure standards under paragraph (3), the standards specified pursuant to paragraph (5), and such other information that the Comptroller General determines necessary to carry out the study under section 103(d) of the Health Care Price Transparency Act of 2023.

"(5) STANDARD FORMAT.—Not later than 18 months after the date of enactment of this section, the Secretary shall specify through rulemaking standards

for health insurance issuers and entities required to submit reports under paragraph (4) to submit such reports in a standard format.

"(c) ENFORCEMENT.—

"(1) IN GENERAL.—Notwithstanding section 502, the Secretary, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, shall enforce this section.

"(2) FAILURE TO PROVIDE TIMELY INFORMATION.—A health insurance issuer or an entity providing pharmacy benefits management services that violates subsection (a) or fails to provide information required under subsection (b) shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

"(3) FALSE INFORMATION.—A health insurance issuer or entity providing pharmacy benefits management services that knowingly provides false information under this section shall be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalty shall be in addition to other penalties as may be prescribed by law.

"(4) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsection (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

"(5) WAIVERS.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that has made a good-faith effort to comply with this section.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary of Labor to a report described in subsection (b)(1) or information related to compliance with subsection (a) or (b) by such issuer, plan, or other entity subject to such subsections.

"(e) DEFINITION.—In this section, the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act."; and

(B) in section 502 (29 U.S.C. 1132)—

(i) in subsection (a)—

(I) in paragraph (6), by striking "or (9)" and inserting "(9), or (13)";

(II) in paragraph (10), by striking at the end "or";

(III) in paragraph (11), at the end by striking the period and inserting "; or"; and

(IV) by adding at the end the following new paragraph:

"(12) by the Secretary, in consultation with the Secretary of Health and Human Services, and the Secretary of the Treasury, to enforce section 726.";

(ii) in subsection (b)(3), by inserting "and subsections (a)(12) and (c)(13)" before ", the Secretary is not"; and

(iii) in subsection (c), by adding at the end the following new paragraph:

"(13) SECRETARIAL ENFORCEMENT AUTHORITY RELATING TO OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.—

"(A) FAILURE TO PROVIDE TIMELY INFORMATION.—The Secretary, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, may impose a penalty against any group health plan or health insurance issuer offering group health insurance coverage, or entity providing pharmacy benefits management services on behalf of such plan or coverage, that violates section 726(a) or fails to provide information required under section 726(b), in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

"(B) FALSE INFORMATION.—The Secretary, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, may impose a penalty against a group health plan or health insurance issuer offering group health coverage, or an entity providing pharmacy benefits management services on behalf of such plan or coverage, that knowingly provides false information under section 726 in an amount not to exceed $100,000 for each item of false information. Such penalty shall be in addition to other penalties as may be prescribed by law.

"(C) WAIVERS.—The Secretary may waive penalties under subparagraph (A), or extend the period of time for compliance with a requirement of section 726, for an entity in violation of such section that has made a good-faith effort to comply with such section.".

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.) is amended by inserting after the item relating to section 725 the following new item:

"Sec. 726. Oversight of pharmacy benefits manager services.".

(d) GAO STUDY.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on—

(A) pharmacy networks of group health plans, health insurance issuers, and entities providing pharmacy benefits management services under such group health plan or group or individual health insurance coverage, including networks that have pharmacies that are under common ownership (in whole or part) with group health plans, health insurance issuers, or entities providing pharmacy benefits management services or pharmacy benefits administrative services under group health plan or group or individual health insurance coverage;

(B) as it relates to pharmacy networks that include pharmacies under common ownership described in subparagraph (A)—

(i) whether such networks are designed to encourage enrollees of a plan or coverage to use such pharmacies over other network pharmacies for specific services or drugs, and if so, the reasons the networks give for encouraging use of such pharmacies; and

(ii) whether such pharmacies are used by enrollees disproportionately more in the aggregate or for specific services or drugs compared to other network pharmacies;

(C) whether group health plans and health insurance issuers offering group or individual health insurance coverage have options to elect different network pricing arrangements in the marketplace with entities that provide pharmacy benefits management services, the prevalence of electing such different network pricing arrangements;

(D) pharmacy network design parameters that encourage enrollees in the plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies that are wholly or partially-owned by that issuer or entity; and

(E) the degree to which mail order, specialty, or retail pharmacies that dispense prescription drugs to an enrollee in a group health plan or health insurance coverage that are under common ownership (in whole or part) with group health plans, health insurance issuers, or entities providing pharmacy benefits management services or pharmacy benefits administrative services under group health plan or group or individual health insurance coverage receive reimbursement that is greater than the median price charged to the group health plan or health insurance issuer when the same drug is dispensed to enrollees in the plan or coverage by other pharmacies included in the pharmacy network of that plan, issuer, or entity that are not wholly or partially owned by the health insurance issuer or entity providing pharmacy benefits management services.

(2) REQUIREMENT.—The Comptroller General of the United States shall ensure that the report under paragraph (1) does not contain information that would allow a reader to identify a specific plan or entity providing pharmacy benefits management services or otherwise contain commercial or financial information that is privileged or confidential.

(3) DEFINITIONS.—In this subsection, the terms "group health plan", "health insurance coverage", and "health insurance issuer" have the meanings given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91).

**SEC. 104. REPORTS ON HEALTH CARE TRANSPARENCY TOOLS AND DATA REQUIREMENTS.**

(a) INITIAL REPORT.—Not later than December 31, 2024, the Comptroller General of the United States shall submit to the Committees (as defined in subsection (d)) an initial report that—

(1) identifies and describes health care transparency tools and Federal health care reporting requirements (as described in subsection (d)) that are in effect as of the date of the submission of such initial report, including the frequency of reports with respect to each such requirement and whether any such requirements are duplicative;

(2) reviews how such reporting requirements are enforced;

(3) analyzes whether the public availability of health care transparency tools, and the publication of data pursuant to such reporting requirements, has—

(A) been utilized and valued by consumers, including reasons for such utilization (or lack thereof); and

(B) assisted health insurance plan sponsors and fiduciaries improve benefits, lower health care costs for plan participants, and meet fiduciary requirements;

(4) includes recommendations to the Committees, the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury to—

(A) improve the efficiency, accuracy, and usability of health care transparency tools;

(B) streamline Federal health care reporting requirements to eliminate duplicative requirements and reduce the burden on entities required to submit reports pursuant to such provisions;

(C) improve the accuracy and efficiency of such reports while maintaining the integrity and usability of the data provided by such reports;

(D) address any gaps in data provided by such reports; and

(E) ensure that the data and information reported is comparable and usable to consumers, including patients, plan sponsors, and policy makers.

(b) FINAL REPORT.—Not later than December 31, 2028, the Comptroller General of the United States shall submit to the Committees a report that includes—

(1) the information provided in the initial report, along with any updates to such information; and

(2) any new information with respect to health care transparency tools that have been released following the submission of such initial report, or new reporting requirements in effect as of the date of the submission of the final report.

(c) REPORT ON EXPANDING PRICE TRANSPARENCY REQUIREMENTS.—Not later than December 31, 2025, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, health care provider groups, and patient advocacy groups, shall submit to the Committees a report that includes recommendations to expand price transparency reporting requirements to additional care settings, with an emphasis on settings where shoppable services (as defined in subsection (d)) are furnished.

(d) DEFINITIONS.—In this section:

(1) COMMITTEES.—The term "Committees" means the Committee on Ways and Means, the Committee on Energy and Commerce, and the Committee on Education and the Workforce of the House of Representatives, and the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate.

(2) FEDERAL HEALTH CARE REPORTING REQUIREMENTS.—The term "Federal health care reporting requirements" includes regulatory and statutory requirements with respect to the reporting and publication of health care price, cost access, and quality data, including requirements established by the Consolidated Appropriations Act of 2021 (Public Law 116–260), this Act, and other reporting and publication requirements with respect to transparency in health care as identified by the Comptroller General of the United States.

(3) SHOPPABLE SERVICE.—The term "shoppable service" means a service that can be scheduled by a health care consumer in advance and includes all ancillary items and services customarily furnished as part of such service.

**SEC. 105. REPORT ON INTEGRATION IN MEDICARE.**

(a) REQUIRED MA AND PDP REPORTING.—

(1) MA PLANS.—Section 1857(e) of the Social Security Act (42 U.S.C. 1395w–27(e)) is amended by adding at the end the following new paragraph:

"(6) REQUIRED DISCLOSURE OF CERTAIN INFORMATION RELATING TO HEALTH CARE PROVIDER OWNERSHIP.—

"(A) IN GENERAL.—For plan year 2025 and for every third plan year thereafter, each MA organization offering an MA plan under this part during such plan year shall submit to the Secretary, at a time and in a manner specified by the Secretary—

"(i) the taxpayer identification number for each health care provider that was a specified health care provider with respect to such organization during such year;

"(ii) the total amount of incentive-based payments made to, and the total amount of shared losses recoupments collected from, such specified health care providers during such plan year; and

"(iii) the total amount of incentive-based payments made to, and the total amount of shared losses recoupments collected from, providers of services and suppliers not described in clause (ii) during such plan year.

"(B) DEFINITION.—For purposes of this paragraph, the term 'specified health care provider' means, with respect to an MA organization and a plan

year, a provider of services or supplier with respect to which such organization (or any person with an ownership or control interest (as defined in section 1124(a)(3)) in such organization) is a person with an ownership or control interest (as so defined).".

(2) PRESCRIPTION DRUG PLANS.—Section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)) is amended by adding at the end the following new paragraph:

"(9) PROVISION OF INFORMATION RELATING TO PHARMACY OWNERSHIP.—

"(A) IN GENERAL.—For plan year 2025 and for every third plan year thereafter, each PDP sponsor offering a prescription drug plan under this part during such plan year shall submit to the Secretary, at a time and in a manner specified by the Secretary, the taxpayer identification number and National Provider Identifier for each pharmacy that was a specified pharmacy with respect to such sponsor during such year.

"(B) DEFINITION.—For purposes of this paragraph, the term 'specified pharmacy' means, with respect to an PDP sponsor offering a prescription drug plan and a plan year, a pharmacy with respect to which—

"(i) such sponsor (or any person with an ownership or control interest (as defined in section 1124(a)(3)) in such sponsor) is a person with an ownership or control interest (as so defined); or

"(ii) a pharmacy benefit manager offering services under such plan (or any person with an ownership or control interest (as so defined) in such sponsor) is a person with an ownership or control interest (as so defined).".

(b) MEDPAC REPORTS.—Part E of title XVIII of the Social Security Act (42 U.S.C. 1395x et seq.), as amended by section 101, is further amended by adding at the end the following new section:

**"SEC. 1899D. REPORTS ON VERTICAL INTEGRATION UNDER MEDICARE.**

"(a) IN GENERAL.—Not later than June 15, 2029, and every 3 years thereafter, the Medicare Payment Advisory Commission shall submit to Congress a report on the state of vertical integration in the health care sector during the applicable year with respect to entities participating in the Medicare program, including health care providers, pharmacies, prescription drug plan sponsors, Medicare Advantage organizations, and pharmacy benefit managers. Such report shall include—

"(1) with respect to Medicare Advantage organizations, the evaluation described in subsection (b);

"(2) with respect to prescription drug plans, pharmacy benefit managers, and pharmacies, the comparisons and evaluations described in subsection (c);

"(3) with respect to Medicare Advantage plans under which benefits are available for physician-administered drugs, the information described in subsection (d); and

"(4) the identifications described in subsection (e); and

"(5) an analysis of the impact of such integration on health care access, price, quality, and outcomes.

"(b) MEDICARE ADVANTAGE ORGANIZATIONS.—For purposes of subsection (a)(1), the evaluation described in this subsection is, with respect to Medicare Advantage organizations and an applicable year, an evaluation, taking into account patient acuity and the types of areas serviced by such organization, of—

"(1) the average number of qualifying diagnoses made during such year with respect to enrollees of a Medicare Advantage plan offered by such organization who, during such year, received a health risk assessment from a specified health care provider;

"(2) the average risk score for such enrollees who received such an assessment during such year;

"(3) any relationship between such risk scores for such enrollees receiving such an assessment from such a provider during such year and incentive payments made to such providers;

"(4) the average risk score for enrollees of such plan who received any item or service from a specified health care provider during such year;

"(5) any relationship between the risk scores of enrollees under such plan and whether the enrollees have received any item or service from a specified provider; and

"(6) any relationship between the risk scores of enrollees under such plan that have received any item or service from a specified provider and incentive payments made under the plan to specified providers.

"(c) PRESCRIPTION DRUG PLANS.—For purposes of subsection (a)(2), the comparisons and evaluations described in this subsection are, with respect to prescription drug plans and an applicable year, the following:

"(1) For each covered part D drug for which benefits are available under such a plan, a comparison of the average negotiated rate in effect with specified pharmacies with such rates in effect for in-network pharmacies that are not specified pharmacies.

"(2) Comparisons of the following:

"(A) The total amount paid by pharmacy benefit managers to specified pharmacies for covered part D drugs and the total amount so paid to pharmacies that are not specified pharmacies for such drugs.

"(B) The total amount paid by such sponsors to specified pharmacy benefit managers as reimbursement for covered part D drugs and the total amount so paid to pharmacy benefit managers that are not specified pharmacy benefit managers as such reimbursement.

"(C) Fees paid under by plan to specified pharmacy benefit managers compared to such fees paid to pharmacy benefit managers that are not specified pharmacy benefit managers.

"(3) An evaluation of the total amount of direct and indirect remuneration for covered part D drugs passed through to prescription drug plan sponsors and the total amount retained by pharmacy benefit managers (including entities under contract with such a manager).

"(4) To the extent that the available data permits, an evaluation of fees charged by rebate aggregators that are affiliated with plan sponsors.

"(d) PHYSICIAN-ADMINISTERED DRUGS.—For purposes of subsection (a)(3), the information described in this subsection is, with respect to physician-administered drugs for which benefits are available under a Medicare Advantage plan during an applicable year, the following:

"(1) With respect to each such plan, an identification of each drug for which benefits were available under such plan only when administered by a health care provider that acquired such drug from an affiliated pharmacy.

"(2) An evaluation of the difference between the total number of drugs administered by a health care provider that were acquired from affiliated pharmacies compared to the number of such drugs so administered that were acquired from pharmacies other than affiliated pharmacies, and an evaluation of the difference in payments for such drugs so administered when acquired from a specified pharmacy and when acquired from a pharmacy that is not a specified pharmacy.

"(3) An evaluation of the dollar value of all such drugs that were not so administered because of a delay attributable to an affiliated pharmacy compared to the dollar value of all such drugs that were not so administered because of a delay attributable to pharmacy that is not an affiliated pharmacy.

"(4) The number of enrollees administered such a drug that was acquired from an affiliated pharmacy.

"(5) The number of enrollees furnished such a drug that was acquired from a pharmacy that is not an affiliated pharmacy.

"(e) IDENTIFICATIONS.—For purposes of subsection (a)(4), the identifications described in this subsection are, with respect to an applicable year, identifications of each health care entity participating under the Medicare program with respect to which another health care entity so participating is a person with an ownership or control interest (as defined in section 1124(a)(3)).

"(f) DEFINITIONS.—In this section:

"(1) AFFILIATED PHARMACY.—The term 'affiliated pharmacy' means, with respect to a Medicare Advantage plan offered by a Medicare Advantage organization, a pharmacy with respect to which such organization (or any person with an ownership or control interest (as defined in section 1124(a)(3)) in such organization) is a person with an ownership or control interest (as so defined).

"(2) APPLICABLE YEAR.—The term 'applicable year' means, with respect to a report submitted under subsection (a), the first calendar year beginning at least 4 years prior to the date of the submission of such report.

"(3) COVERED PART D DRUG.—The term 'covered part D drug' has the meaning given such term in section 1860D–2(e).

"(4) DIRECT AND INDIRECT REMUNERATION.—The term 'direct and indirect remuneration' has the meaning given such term in section 423.308 of title 42, Code of Federal Regulations (or any successor regulation).

"(5) QUALIFYING DIAGNOSIS.—The term 'qualifying diagnosis' means, with respect to an enrollee of a Medicare Advantage plan, a diagnosis that is taken into account in calculating a risk score for such enrollee under the risk adjustment methodology established by the Secretary pursuant to section 1853(a)(3).

"(6) RISK SCORE.—The term 'risk score' means, with respect to an enrollee of a Medicare Advantage plan, the score calculated for such individual using the methodology described in paragraph (5).

"(7) PHYSICIAN-ADMINISTERED DRUG.—The term 'physician-administered drug' means a drug furnished to an individual that, had such individual been enrolled under part B and not enrolled under part C, would have been payable under section 1842(o).

"(8) SPECIFIED HEALTH CARE PROVIDER.—The term 'specified health care provider' means, with respect to a Medicare Advantage plan offered by a Medicare Advantage organization, a health care provider with respect to which such organization (or any person with an ownership or control interest (as defined in section 1124(a)(3)) in such organization) is a person with an ownership or control interest (as so defined).

"(9) SPECIFIED PHARMACY.—The term 'specified pharmacy' means, with respect to a prescription drug plan offered by a prescription drug plan sponsor, a pharmacy with respect to which—

"(A) such sponsor (or any person with an ownership or control interest (as defined in section 1124(a)(3)) in such sponsor) is a person with an ownership or control interest (as so defined); or

"(B) a pharmacy benefit manager offering services under such plan (or any person with an ownership or control interest (as so defined) in such sponsor) is a person with an ownership or control interest (as so defined).

"(10) SPECIFIED PHARMACY BENEFIT MANAGER.—The term 'specified pharmacy benefit manager' means, with respect to a prescription drug plan offered by a prescription drug plan sponsor, a pharmacy benefit manager with respect to which such sponsor (or any person with an ownership or control interest (as defined in section 1124(a)(3)) in such sponsor) is a person with an ownership or control interest (as so defined).".

# TITLE II—FAIR PRICES FOR PATIENTS

**SEC. 201. LIMITATION ON COST SHARING TO NET PRICE AMOUNT UNDER MEDICARE PART D.**

(a) IN GENERAL.—Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102) is amended—

(1) in subsection (b)—

(A) in paragraph (2)(A), by striking "(8) and (9)" and inserting "(8), (9), and (10)";

(B) in paragraph (9)(B)(ii), by striking "For a plan year" and inserting "Subject to paragraph (10), for a plan year"; and

(C) by adding at the end the following new paragraph:

"(10) LIMITATION ON COST SHARING TO NET PRICE AMOUNT.—

"(A) IN GENERAL.—For a plan year beginning on or after January 1, 2027, the coverage provides benefits for a supply of a covered part D drug dispensed by a pharmacy, for costs in excess of the deductible specified in paragraph (1) and prior to an individual reaching the out-of-pocket threshold under paragraph (4), with cost-sharing for a month's supply that does not exceed the average net price for such a supply of such drug during such plan year (or, if lower, the applicable cash price for such a supply of such drug so dispensed by such pharmacy).

"(B) DEFINITIONS.—In this paragraph:

"(i) APPLICABLE CASH PRICE.—The term 'applicable cash price' means, with respect to a supply of a covered part D drug dispensed by a pharmacy, the price that such pharmacy would charge for such supply of such drug dispensed to an individual without benefits for such drug under any Federal health care program (as defined in section 1128B), a group health plan or group or individual health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act), or the program established under chapter 89 of title 5, United States Code.

"(ii) AVERAGE NET PRICE.—The term 'average net price' means, with respect to a supply of a covered part D drug, a prescription drug plan, and a plan year, the average amount paid under such plan (including any amounts paid by an individual enrolled under such plan as cost sharing for such drug) as payment for such a supply of such drug dispensed during such year, less any rebates or other forms of remuneration received under such plan with respect to such drug."; and

(2) in subsection (c), by adding at the end the following new paragraph:

"(7) COST SHARING LIMITED TO NET PRICE.—The coverage is provided in accordance with subsection (b)(10).".

(b) CONFORMING AMENDMENT TO COST-SHARING FOR LOW-INCOME INDIVIDUALS.—Section 1860D–14(a)(1)(D)(iii) of the Social Security Act (42 U.S.C. 1395w–

114(a)(1)(D)(iii)) is amended by adding at the end the following new sentence: "For plan year 2027 and subsequent plan years, the copayment amount applicable under this clause to a supply of a covered part D drug dispensed to the individual may not exceed the amount provided under section 1860D–2(b)(10).".

(c) GAO REPORT.—Not later than January 1, 2029, the Comptroller General of the United States shall submit to Congress a report containing—

(1) an analysis of compliance with the amendments made by this section;

(2) an analysis of enforcement of such amendments;

(3) recommendations with respect to improving such enforcement; and

(4) recommendations relating to improving public disclosure, and public awareness of, the requirements of such amendments.

**SEC. 202. REQUIRING A SEPARATE IDENTIFICATION NUMBER AND AN ATTESTATION FOR EACH OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.**

(a) IN GENERAL.—Section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)) is amended by adding at the end the following new paragraph:

"(23) USE OF UNIQUE HEALTH IDENTIFIERS; ATTESTATION.—

"(A) IN GENERAL.—No payment may be made under this subsection (or under an applicable payment system pursuant to paragraph (21)) for items and services furnished on or after January 1, 2026, by an off-campus outpatient department of a provider (as defined in subparagraph (C)) unless—

"(i) such department has obtained, and such items and services are billed under, a standard unique health identifier for health care providers (as described in section 1173(b)) that is separate from such identifier for such provider; and

"(ii) such provider has submitted to the Secretary, during the 2-year period ending on the date such items and services are so furnished, an attestation that such department is compliant with the requirements described in section 413.65 of title 42, Code of Federal Regulations (or a successor regulation).

"(B) PROCESS FOR SUBMISSION AND REVIEW.—Not later than 1 year after the date of enactment of this paragraph, the Secretary shall, through notice and comment rulemaking, establish a process for each provider with an off-campus outpatient department of a provider to submit an attestation pursuant to subparagraph (A)(ii), and for the Secretary to review each such attestation and determine, through site visits, remote audits, or other means (as determined appropriate by the Secretary), whether such department is compliant with the requirements described in such subparagraph.

"(C) OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER DEFINED.—For purposes of this paragraph, the term 'off-campus outpatient department of a provider' means a department of a provider (as defined in section 413.65 of title 42, Code of Federal Regulations, or any successor regulation) that is not located—

"(i) on the campus (as defined in such section) of such provider; or

"(ii) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section).".

(b) HHS OIG ANALYSIS.—Not later than January 1, 2030, the Inspector General of the Department of Health and Human Services shall submit to Congress—

(1) an analysis of the process established by the Secretary of Health and Human Services to conduct the reviews and determinations described in section 1833(t)(23)(B) of the Social Security Act, as added by subsection (a) of this section; and

(2) recommendations based on such analysis, as the Inspector General determines appropriate.

**SEC. 203. PARITY IN MEDICARE PAYMENTS FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES FURNISHED OFF-CAMPUS.**

(a) IN GENERAL.—Section 1833(t)(16) of the Social Security Act (42 U.S.C. 1395l(t)(16)) is amended by adding at the end the following new subparagraph:

"(H) PARITY IN FEE SCHEDULE AMOUNT FOR CERTAIN SERVICES FURNISHED BY AN OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.—

"(i) IN GENERAL.—Subject to clause (iii), in the case of specified OPD services (as defined in clause (v)) that are furnished during 2025 or a subsequent year by an off-campus outpatient department of a provider (as defined in clause (iv)) (or, in the case of an off-campus outpatient department of a provider that is a hospital described in section 1886(d)(1)(B)(v), or is located in a rural area or a health professional shortage area, such services that are furnished during 2026 or a subsequent year), there shall be substituted for the amount otherwise determined under this subsection for such service and year an amount equal

to the payment amount that would have been payable under the applicable payment system under this part (other than under this subsection) had such services been furnished by such a department subject to such payment system pursuant to paragraph (21)(C).

"(ii) NOT BUDGET NEUTRAL IMPLEMENTATION.—In making any budget neutrality adjustments under this subsection for 2025 or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

"(iii) TRANSITION.—The Secretary shall provide for a 4-year phase-in of the application of clause (i), with clause (i) being fully applicable for specified OPD services beginning with 2028 (or in the case of an off-campus outpatient department of a provider that is a hospital described in section 1886(d)(1)(B)(v), or is located in a rural area or a health professional shortage area, beginning with 2029).

"(iv) OFF-CAMPUS DEPARTMENT OF A PROVIDER.—For purposes of this subparagraph, the term 'off-campus outpatient department of a provider' means a department of a provider (as defined in section 413.65(a)(2) of title 42, Code of Federal Regulations) that is not located—

"(I) on the campus (as such term is defined in such section) of such provider; or

"(II) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section).

"(v) OTHER DEFINITIONS.—For purposes of this subparagraph:

"(I) DESIGNATED AMBULATORY PAYMENT CLASSIFICATION GROUP.—The term 'designated ambulatory payment classification group' means an ambulatory payment classification group for drug administration services.

"(II) HEALTH PROFESSIONAL SHORTAGE AREA.—The term 'health professional shortage area' has the meaning given such term in section 332(a)(1)(A) of the Public Health Service Act.

"(III) RURAL AREA.—The term 'rural area' has the meaning given such term in section 1886(d)(2)(D).

"(IV) SPECIFIED OPD SERVICES.—The term 'specified OPD services' means covered OPD services assigned to a designated ambulatory payment classification group.".

(b) IMPLEMENTATION.—Section 1833(t)(12) of the Social Security Act (42 U.S.C. 1395l(t)(12)) is amended—

(1) in subparagraph (D), by striking "and" at the end;

(2) in subparagraph (E), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following new subparagraph:

"(F) the determination of any payment amount under paragraph (16)(H), including the transition under clause (iii) of such paragraph.".

# TITLE III—PATIENT-FOCUSED INVESTMENTS

**SEC. 301. ESTABLISHING REQUIREMENTS WITH RESPECT TO THE USE OF PRIOR AUTHORIZATION UNDER MEDICARE ADVANTAGE PLANS.**

(a) IN GENERAL.—Section 1852 of the Social Security Act (42 U.S.C. 1395w–22) is amended by adding at the end the following new subsection:

"(o) PRIOR AUTHORIZATION REQUIREMENTS.—

"(1) IN GENERAL.—In the case of a Medicare Advantage plan that imposes any prior authorization requirement with respect to any applicable item or service (as defined in paragraph (5)) during a plan year, such plan shall—

"(A) beginning with the third plan year beginning after the date of the enactment of this subsection—

"(i) establish the electronic prior authorization program described in paragraph (2); and

"(ii) meet the enrollee protection standards specified pursuant to paragraph (4); and

"(B) beginning with the fourth plan year beginning after the date of the enactment of this subsection, meet the transparency requirements specified in paragraph (3).

"(2) ELECTRONIC PRIOR AUTHORIZATION PROGRAM.—

"(A) IN GENERAL.—For purposes of paragraph (1)(A), the electronic prior authorization program described in this paragraph is a program that provides for the secure electronic transmission of—

"(i) a prior authorization request from a provider of services or supplier to a Medicare Advantage plan with respect to an applicable item or service to be furnished to an individual and a response, in accordance with this paragraph, from such plan to such provider or supplier; and

"(ii) any attachment relating to such request or response.

"(B) ELECTRONIC TRANSMISSION.—

"(i) EXCLUSIONS.—For purposes of this paragraph, a facsimile, a proprietary payer portal that does not meet standards specified by the Secretary, or an electronic form shall not be treated as an electronic transmission described in subparagraph (A).

"(ii) STANDARDS.—An electronic transmission described in subparagraph (A) shall comply with—

"(I) applicable technical standards adopted by the Secretary pursuant to section 1173; and

"(II) other requirements to promote the standardization and streamlining of electronic transactions under this part specified by the Secretary.

"(iii) DEADLINE FOR SPECIFICATION OF ADDITIONAL REQUIREMENTS.—Not later than July 1, 2024, the Secretary shall finalize requirements described in clause (ii)(II).

"(C) REAL-TIME DECISIONS.—

"(i) IN GENERAL.—Subject to clause (iv), the program described in subparagraph (A) shall provide for real-time decisions (as defined by the Secretary in accordance with clause (v)) by a Medicare Advantage plan with respect to prior authorization requests for applicable items and services identified by the Secretary pursuant to clause (ii) if such requests are submitted with all medical or other documentation required by such plan.

"(ii) IDENTIFICATION OF ITEMS AND SERVICES.—

"(I) IN GENERAL.—For purposes of clause (i), the Secretary shall identify, not later than the date on which the initial announcement described in section 1853(b)(1)(B)(i) for the third plan year beginning after the date of the enactment of this subsection is required to be announced, applicable items and services for which prior authorization requests are routinely approved.

"(II) UPDATES.—The Secretary shall consider updating the applicable items and services identified under subclause (I) based on the information described in paragraph (3)(A)(i) (if available and determined practicable to utilize by the Secretary) and any other information determined appropriate by the Secretary not less frequently than biennially. The Secretary shall announce any such update that is to apply with respect to a plan year not later than the date on which the initial announcement described in section 1853(b)(1)(B)(i) for such plan year is required to be announced.

"(iii) REQUEST FOR INFORMATION.—The Secretary shall issue a request for information for purposes of initially identifying applicable items and services under clause (ii)(I).

"(iv) EXCEPTION FOR EXTENUATING CIRCUMSTANCES.—In the case of a prior authorization request submitted to a Medicare Advantage plan for an individual enrolled in such plan during a plan year with respect to an item or service identified by the Secretary pursuant to clause (ii) for such plan year, such plan may, in lieu of providing a real-time decision with respect to such request in accordance with clause (i), delay such decision under extenuating circumstances (as specified by the Secretary), provided that such decision is provided no later than 72 hours after receipt of such request (or, in the case that the provider of services or supplier submitting such request has indicated that such delay may seriously jeopardize such individual's life, health, or ability to regain maximum function, no later than 24 hours after receipt of such request).

"(v) DEFINITION OF REAL-TIME DECISION.—In establishing the definition of a real-time decision for purposes of clause (i), the Secretary shall take into account current medical practice, technology, health care industry standards, and other relevant information relating to how quick-

ly a Medicare Advantage plan may provide responses with respect to prior authorization requests.

"(vi) IMPLEMENTATION.—The Secretary shall use notice and comment rulemaking for each of the following:

"(I) Establishing the definition of a 'real-time decision' for purposes of clause (i).

"(II) Updating such definition.

"(III) Initially identifying applicable items or services pursuant to clause (ii)(I).

"(IV) Updating applicable items and services so identified as described in clause (ii)(II).

"(3) TRANSPARENCY REQUIREMENTS.—

"(A) IN GENERAL.—For purposes of paragraph (1)(B), the transparency requirements specified in this paragraph are, with respect to a Medicare Advantage plan, the following:

"(i) The plan, annually and in a manner specified by the Secretary, shall submit to the Secretary the following information:

"(I) A list of all applicable items and services that were subject to a prior authorization requirement under the plan during the previous plan year.

"(II) The percentage and number of specified requests (as defined in subparagraph (F)) approved during the previous plan year by the plan in an initial determination and the percentage and number of specified requests denied during such plan year by such plan in an initial determination (both in the aggregate and categorized by each item and service).

"(III) The percentage and number of specified requests submitted during the previous plan year that were made with respect to an item or service identified by the Secretary pursuant to paragraph (2)(C)(ii) for such plan year, and the percentage and number of such requests that were subject to an exception under paragraph (2)(C)(iv) (categorized by each item and service).

"(IV) The percentage and number of specified requests submitted during the previous plan year that were made with respect to an item or service identified by the Secretary pursuant to paragraph (2)(C)(ii) for such plan year that were approved (categorized by each item and service).

"(V) The percentage and number of specified requests that were denied during the previous plan year by the plan in an initial determination and that were subsequently appealed.

"(VI) The number of appeals of specified requests resolved during the preceding plan year, and the percentage and number of such resolved appeals that resulted in approval of the furnishing of the item or service that was the subject of such request, categorized by each applicable item and service and categorized by each level of appeal (including judicial review).

"(VII) The percentage and number of specified requests that were denied, and the percentage and number of specified requests that were approved, by the plan during the previous plan year through the utilization of decision support technology, artificial intelligence technology, machine-learning technology, clinical decision-making technology, or any other technology specified by the Secretary.

"(VIII) The average and the median amount of time (in hours) that elapsed during the previous plan year between the submission of a specified request to the plan and a determination by the plan with respect to such request for each such item and service, excluding any such requests that were not submitted with the medical or other documentation required to be submitted by the plan.

"(IX) The percentage and number of specified requests that were excluded from the calculation described in subclause (VIII) based on the plan's determination that such requests were not submitted with the medical or other documentation required to be submitted by the plan.

"(X) Information on each occurrence during the previous plan year in which, during a surgical or medical procedure involving the furnishing of an applicable item or service with respect to which such plan had approved a prior authorization request, the provider of services or supplier furnishing such item or service determined that a different or additional item or service was medically nec-

essary, including a specification of whether such plan subsequently approved the furnishing of such different or additional item or service.

"(XI) A disclosure and description of any technology described in subclause (VII) that the plan utilized during the previous plan year in making determinations with respect to specified requests.

"(XII) The number of grievances (as described in subsection (f)) received by such plan during the previous plan year that were related to a prior authorization requirement.

"(XIII) Such other information as the Secretary determines appropriate.

"(ii) The plan shall provide—

"(I) to each provider or supplier who seeks to enter into a contract with such plan to furnish applicable items and services under such plan, the list described in clause (i)(I) and any policies or procedures used by the plan for making determinations with respect to prior authorization requests;

"(II) to each such provider and supplier that enters into such a contract, access to the criteria used by the plan for making such determinations and an itemization of the medical or other documentation required to be submitted by a provider or supplier with respect to such a request; and

"(III) to an enrollee of the plan, upon request, access to the criteria used by the plan for making determinations with respect to prior authorization requests for an item or service.

"(B) OPTION FOR PLAN TO PROVIDE CERTAIN ADDITIONAL INFORMATION.—As part of the information described in subparagraph (A)(i) provided to the Secretary during a plan year, a Medicare Advantage plan may elect to include information regarding the percentage and number of specified requests made with respect to an individual and an item or service that were denied by the plan during the preceding plan year in an initial determination based on such requests failing to demonstrate that such individuals met the clinical criteria established by such plan to receive such items or services.

"(C) REGULATIONS.—The Secretary shall, through notice and comment rulemaking, establish requirements for Medicare Advantage plans regarding the provision of—

"(i) access to criteria described in subparagraph (A)(ii)(II) to providers of services and suppliers in accordance with such subparagraph; and

"(ii) access to such criteria to enrollees in accordance with subparagraph (A)(ii)(III).

"(D) PUBLICATION OF INFORMATION.—The Secretary shall publish information described in subparagraph (A)(i) and subparagraph (B) on a public website of the Centers for Medicare & Medicaid Services. Such information shall be so published on an individual plan level and may in addition be aggregated in such manner as determined appropriate by the Secretary.

"(E) MEDPAC REPORT.—Not later than 3 years after the date information is first submitted under subparagraph (A)(i), the Medicare Payment Advisory Commission shall submit to Congress a report on such information that includes a descriptive analysis of the use of prior authorization. As appropriate, the Commission should report on statistics including the frequency of appeals and overturned decisions. The Commission shall provide recommendations, as appropriate, on any improvement that should be made to the electronic prior authorization programs of Medicare Advantage plans.

"(F) SPECIFIED REQUEST DEFINED.—For purposes of this paragraph, the term 'specified request' means a prior authorization request made with respect to an applicable item or service.

"(4) ENROLLEE PROTECTION STANDARDS.—For purposes of paragraph (1)(A)(ii), with respect to the use of prior authorization by Medicare Advantage plans for applicable items and services, the enrollee protection standards specified in this paragraph are—

"(A) the adoption of transparent prior authorization programs developed in consultation with enrollees and with providers and suppliers with contracts in effect with such plans for furnishing such items and services under such plans;

"(B) allowing for the waiver or modification of prior authorization requirements based on the performance of such providers and suppliers in demonstrating compliance with such requirements, such as adherence to evidence-based medical guidelines and other quality criteria; and

"(C) conducting annual reviews of such items and services for which prior authorization requirements are imposed under such plans through a process that takes into account input from enrollees and from providers and suppliers with such contracts in effect and is based on consideration of prior authorization data from previous plan years and analyses of current coverage criteria.

"(5) APPLICABLE ITEM OR SERVICE DEFINED.—For purposes of this subsection, the term 'applicable item or service' means, with respect to a Medicare Advantage plan, any item or service for which benefits are available under such plan, other than a covered part D drug.

"(6) REPORTS TO CONGRESS.—

"(A) GAO.—Not later than the end of the fourth plan year beginning on or after the date of the enactment of this subsection, the Comptroller General of the United States shall submit to Congress a report containing an evaluation of the implementation of the requirements of this subsection and an analysis of issues in implementing such requirements faced by Medicare Advantage plans.

"(B) HHS.—Not later than the end of the fifth plan year beginning after the date of the enactment of this subsection, and biennially thereafter through the date that is 10 years after such date of enactment, the Secretary shall submit to Congress a report containing a description of the information submitted under paragraph (3)(A)(i) during—

"(i) in the case of the first such report, the fourth plan year beginning after the date of the enactment of this subsection; and

"(ii) in the case of a subsequent report, the 2 plan years preceding the year of the submission of such report.".

(b) ENSURING TIMELY RESPONSES FOR ALL PRIOR AUTHORIZATION REQUESTS SUBMITTED UNDER PART C.—Section 1852(g) of the Social Security Act (42 U.S.C. 1395w–22(g)) is amended—

(1) in paragraph (1)(A), by inserting "and in accordance with paragraph (6)" after "paragraph (3)";

(2) in paragraph (3)(B)(iii), by inserting "(or, subject to subsection (o), with respect to prior authorization requests submitted on or after the first day of the third plan year beginning after the date of the enactment of the Health Care Price Transparency Act of 2023, not later than 24 hours)" after "72 hours"; and

(3) by adding at the end the following new paragraph:

"(6) TIMEFRAME FOR RESPONSE TO PRIOR AUTHORIZATION REQUESTS.—Subject to paragraph (3) and subsection (o), in the case of an organization determination made with respect to a prior authorization request for an item or service to be furnished to an individual submitted on or after the first day of the third plan year beginning after the date of the enactment of this paragraph, the organization shall notify the enrollee (and the physician involved, as appropriate) of such determination no later than 7 days (or such shorter timeframe as the Secretary may specify through notice and comment rulemaking, taking into account enrollee and stakeholder feedback) after receipt of such request.".

(c) RULE OF CONSTRUCTION.—None of the amendments made by this section may be construed to affect the finalization of the proposed rule entitled "Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program" published on December 13, 2022 (87 Fed. Reg. 76238), or application of such rule so finalized, for plan years before the third plan year beginning on or after the date of the enactment of this Act.

(d) FUNDING.—The Secretary of Health and Human Services shall provide for the transfer, from the Federal Hospital Insurance Trust Fund established under section 1817 of the Social Security Act (42 U.S.C. 1395i) and the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of such Act (42 U.S.C. 1395t) (in such proportion as determined appropriate by the Secretary) to the Centers for Medicare & Medicaid Services Program Management Account, of $25,000,000 for fiscal year 2024, to remain available until expended, for purposes of carrying out the amendments made by this section.

**SEC. 302. EXTENSION OF CERTAIN DIRECT SPENDING REDUCTIONS.**

Section 251A(6)(D) of the Balanced Budget and Emergency Deficit Control Act of 1985 (2 U.S.C. 901a(6)(D)) is amended—

(1) in clause (i), by striking "; and" and inserting a semicolon;
(2) in clause (ii), by striking "second 6 months in which such order is effective for such fiscal year, the payment reduction shall be 0 percent." and inserting "2 month period beginning on the day after the last day of the period described in clause (i) in which such order is effective for such fiscal year, the payment reduction shall be 1.5 percent; and"; and
(3) by adding at the end the following new clause:
"(iii) with respect to the last 4 months in which such order is effective for such fiscal year, the payment reduction shall be 0 percent.".

## I. SUMMARY AND BACKGROUND

### A. PURPOSE AND SUMMARY

The bill, H.R. 4822, the "Health Care Price Transparency Act of 2023," as ordered reported by the Committee on Ways and Means on July 26, 2023, to improve price transparency with respect to certain health care services, and for other purposes.

### B. BACKGROUND AND NEED FOR LEGISLATION

*Hospital Price Transparency*

The Affordable Care Act (ACA) (P.L. 111–148) amended the Public Health Service Act (PHSA) to add section 2718(e), which states:

> Each hospital operating within the United States shall for each year establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1395ww(d)(4) of this title.[1]

The Obama Administration implemented this provision by requiring hospitals to publish their gross charges (their so-called "chargemaster" rates). In 2018—and effective January 1, 2019, the Trump Administration finalized a rule that required hospitals to publicly post their chargemasters online and sought comment on additional price transparency measures. In June 2019, President Trump issued the Executive Order on *Improving Price and Quality Transparency in American Healthcare to Put Patients First*, which required the Department of Health and Human Services (HHS) to promulgate rulemaking within 60 days requiring hospitals to publish negotiated rates for shoppable services.[2] In August 2019, the Trump Administration, acting through the Centers for Medicare & Medicaid Services (CMS), promulgated the required proposed rule, and the rule was finalized in November 2019 with an effective date of January 1, 2021.

H.R. 4822 would codify this hospital price transparency rule in Part E of title XVIII of the Social Security Act (SSA). Legislative action was necessary to codify these price transparency rules in this manner for several reasons. First, the existing hospital price transparency authority in the PHSA is far too vague. Additionally, having been placed in the PHSA (which generally does not contain these kinds of hospital requirements) and in a chapter dedicated to health insurance policy, the current provision is ill-situated. Be-

[1] https://uscode.house.gov/view.xhtml?req=(title:42%20section:300gg-18%20edition:prelim).
[2] https://www.federalregister.gov/documents/2019/06/27/2019-13945/improving-price-and-quality-transparency-in-american-healthcare-to-put-patients-first.

cause the provision applies to "each hospital operating in the United States," its requirements necessarily apply to hospitals that choose not to participate in federal health programs like Medicare and Medicaid, resulting in a private sector mandate. Second, as a consequence of the vagueness of Sec. 2718(e), the Trump hospital price transparency rule's specific requirements were necessarily developed solely by the Executive Branch, a future administration could significantly alter the provisions of the rule. Third, the Committee was made aware of independent analyses of hospital compliance with the Trump hospital price transparency rule that suggested less than one quarter of hospitals were fully compliant. Fourth, Sec. 2718(e) only required hospitals to publish prices, omitting other kinds of providers of health care services.

*Health Insurer Price Transparency*

*Establishing Requirements with respect to the use of prior authorization under Medicare Advantage plans*

Medicare Advantage (MA) is a private plan option for Medicare beneficiaries that covers all traditional Medicare benefits, but coinsurance, deductibles, and benefit management tools may be different than in traditional Medicare. As required by statute, MA plans must cover the services included under traditional Medicare (Parts A and B). The Centers for Medicare & Medicaid Services (CMS) stipulates that, "plans may not impose limitations, waiting periods or exclusions from coverage due to pre-existing conditions that are not present in original Medicare."[3] MA plans manage the provision of Medicare benefits to enrollees, however, and while many MA plans cover additional supplemental benefits beyond those in traditional Medicare, they also may impose additional requirements like referrals or prior authorization before paying for the services.

MA plans use prior authorization to require a health care provider to receive advance approval of payment for the service for the purpose of reducing inappropriate utilization of health care services.[4] Health insurers contend that the primary goal of prior authorization is to promote evidence-based care, protect patient safety, and reduce unnecessary spending. MA plans establish criteria for prior authorization, which must follow the medical necessity requirements and coverage standards under traditional Medicare. Insurers report that they base prior authorization criteria on peer-reviewed evidence-based programs, federal studies and guidelines, internal plan data, and proprietary software, among other factors. Critics, however, contend that these prior authorization criteria lack transparency.[5] [6] Data on the use of organizational determinations (which include prior authorizations per CMS regulations),

[3] Medicare Managed Care Manual Chapter 4—Benefits and Beneficiary Protections, Ctrs. For Medicare & Medicaid Servs. (Apr. 22, 2016), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.

[4] Kaye Pestaina & Karen Pollitz, Examining Prior Authorization in Health Insurance, Kaiser Fam. Found. (May 20, 2022), https://www.kff.org/policy-watch/examining-prior-authorization-in health-insurance/.

[5] Key Results of Industry Survey on Prior Authorization, AHIP at 7, https://www.ahip.org/documents/Prior-Authorization-SurveyResults.pdf (last visited July 21, 2022).

[6] A. Mark Fendrick, Reframe The Role Of Prior Authorization To Reduce Low-Value Care, Health Affairs (July 11, 2022), https://www.healthaffairs.org/do/10.1377/forefront.20220708.54139/.

how frequently they are used, and under what circumstances are not collected by the HHS Secretary under current law.

The goal of prior authorization is to ensure payments are made for only medically appropriate and covered services; however, the process may be burdensome for both beneficiaries and health care providers, creating barriers to care. Physicians report that prior authorizations impact the quality of care, causing harmful delays in needed health care services. Prior authorizations can also result in inappropriate denials of care. The HHS Office of Inspector General (OIG) has studied prior authorization and potential incentives for MA plans to deny access to services to avoid paying for medical procedures.[7] One HHS OIG study found that 13 percent of prior authorizations led to denials that in fact met Medicare coverage rules.[8] HHS OIG determined that these inappropriate denials were most often a result of: (1) MA plans using clinical criteria that were not included in the traditional Medicare coverage rules; and (2) MA plans claiming that they did not have sufficient documentation to approve the claim (HHS OIG found sufficient documentation in the patient's medical record to support coverage of the service).[9] OIG also found that "denied requests that meet Medicare coverage rules may prevent or delay beneficiaries from receiving medically necessary care and can burden providers." CMS audits of MA plans, for example, have found persistent challenges with inappropriate denials of services.[10] If a service is denied through prior authorization, the beneficiary or health care provider can appeal the plan decision with the plan through an independent review entity. The beneficiary also retains the ability to appeal through the administrative law judge or federal court processes.[11] HHS OIG found that when denials were appealed, the denial was often overturned: MA plans overturned 75 percent of their initial denials upon appeal from 2014 to 2016, and the independent review entities overturned even more denials. Still, beneficiaries often do not appeal prior authorization denials. Between 2014 and 2016, beneficiaries only appealed one percent of the initial denials.[12]

In addition to potential delays in care delivery, physicians report that prior authorization creates additional administrative burdens, taking resources away from direct patient care. Specifically, a 2021 AMA survey found 88 percent of physicians experienced a high or

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[7] See Office of Inspector General, Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care, U.S. Dept. of Health & Human Servs. (Apr. 2022), https://oig.hhs.gov/oei/reports/OEI-18 00260.pdf.

[8] Office of Inspector General, Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care, U.S. Dept. of Health & Human Servs. at 9 (Apr. 2022), https://oig.hhs.gov/oei/reports/OEI 18 00260.pdf.

[9] Ibid.

[10] See Office of Inspector General, Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials, U.S. Dept. Of Health & Human Servs. (Sept. 2018), https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf.

[11] See generally Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 1, 2020), https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.

[12] Office of Inspector General, Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials, U.S. Dept. of Health & Human Servs. at 7 (Sept. 2018), https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf.

extremely high burden with conducting prior authorizations.[13] In addition, 40 percent of physicians reported that they have a staff member dedicated just to prior authorizations and that they complete 41 prior authorizations per physician per week on average.[14] One study of physician practices quantified the cost to be $6.72 for each prior authorization.[15]

Unlike in Medicare Part D, MA plans are not required to use electronic prior authorization systems and often rely on manual, labor-intensive prior authorization communications. These manual processes can exacerbate delays and administrative burdens for providers. A recent Council for Affordable Quality Healthcare (CAQH) report found that only 26 percent of prior authorizations were fully electronic, whereas 35 percent were fully manual (e.g., phone, mail, fax).[16] CAQH further estimated that transitioning to a fully electronic prior authorization system would save over $400 million annually.[17]

## C. Legislative History

*Background*

H.R. 4822 was introduced on July 24, 2023, and was referred to the Committee on Energy and Commerce, the Committee on Ways and Means, the Committee on Education and Workforce, and the Committee on the Budget.

*Committee Hearings*

On Tuesday, May 16, the Committee held a full Committee Hearing, "*Health Care Price Transparency: A Patient's Right to Know.*"

On Wednesday, May 17, the Committee held a Health Sub-Committee Hearing, "*Why Health Care is Unaffordable: Anticompetitive and Consolidated Markets.*"

*Committee Action*

The Committee on Ways and Means marked up H.R. 4822, the "Price Transparency Act of 2023," on July 26, 2023, and ordered the bill, as amended, favorably reported (with a quorum being present).

## D. Designated Hearing

Pursuant to clause 3(c)(6) of rule XIII, the following hearings were used to develop and consider H.R. 4822:

(1) Committee on Ways and Means Full Committee Hearing "*Health Care Price Transparency: A Patient's Right to Know.*"

(2) Committee on Ways and Means Health Sub-Committee Hearing, "*Why Health Care is Unaffordable: Anticompetitive and Consolidated Markets.*"

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[13] 2021 AMA prior authorization (PA) physician survey, Am. Med. Assoc. (2022), https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

[14] Ibid.

[15] Ryan P. Carlisle et al., Administrative Burden and Costs of Prior Authorizations in a Dermatology Department, 156:10 JAMA Dermatology at 1074 (2020) https://doi.org/10.1001/jamadermatol.2020.1852.

[16] 2021 CAQH Index: Working Together: Advances in Automation During Unprecedented Times, Council for Affordable Quality Healthcare at 18 (2022), https://www.caqh.org/sites/default/files/explorations/index/2021-caqh-index.pdf.

[17] Ibid.

## II. EXPLANATION OF THE BILL

### A. PRICE TRANSPARENCY ACT OF 2023

#### PRESENT LAW

*Section 101*

*Hospital Price Transparency*

Under the Trump hospital price transparency rule promulgated pursuant to Sec. 2718(e) of the PHSA, hospitals are required to publish prices of medical services in two formats. The first is a machine-readable file containing the following information related to prices for services: gross prices, cash prices, payer-specific negotiated rates, and the de-identified maximum and minimum negotiated rates. The second format is a consumer-friendly display of prices for at least 300 shoppable services. A hospital may provide an online price estimator tool in lieu of publishing prices in the second, consumer-friendly format. CMS will send noncompliant hospitals a written warning notice detailing the specific violation(s). Generally, if noncompliance continues after the notice, CMS will request that the hospital submit a corrective action plan (CAP) within 45 days of the request, which must be completed within 90 days. If noncompliance persists, or if a hospital fails to submit a CAP within 45 days or fails to comply within 90 days of submitting its CAP, CMS may impose a civil monetary penalty (CMP). The CMP amounts, initially $300 per day of noncompliance, are currently tied to a hospital's bed count. For hospitals with 30 or fewer beds, the maximum daily CMP is $300, for a maximum calendar year CMP of $109,500. For hospitals with 31–550 beds, the maximum daily CMP is $10 per bed per day, a range of $310–$5,500. This provides for a maximum calendar year CMP between $113,150 and $2,007,500. For hospitals with 550 or more beds, the maximum daily CMP is $5,500, providing for a maximum calendar year CMP of $2,007,500.

*Ambulatory Surgical Center Price Transparency*

Under current law, ambulatory surgical centers are not required to publish their prices.

*Clinical Laboratory Price Transparency*

Under current law, clinical laboratories are not required to publish their prices.

*Imaging Services Price Transparency*

Under current law, providers of imaging services are not required to publish their prices.

*Sec. 102*

The Department of Health and Human Services is responsible for regulating Medicare Part D Plans.

Pharmacy benefits managers ("PBMs") are third-party administrators that manage prescription drug benefits for Medicare Part D plans. PBMs typically process prescription drug claims, maintain prescription drug formularies on behalf of the plan or issuer, contract with pharmacies for reimbursement, and negotiate prices

with drug manufacturers. Although plans and issuers are required to provide certain patient protections as a stipulation of participating in the Medicare Part D prescription drug benefit program [18] there is currently no Federal law protecting patients from paying more than the negotiated rate during the coverage phase.

*Health Insurer Price Transparency*

Under the Patient Protection and Affordable Care Act ("PPACA"),[19] individual market health insurance coverage must meet various requirements to qualify for certification to be offered through an Exchange ("Exchange coverage").[20] Among these requirements, Exchange coverage must permit individuals to learn the amount of cost-sharing (including deductibles, copayments, and coinsurance) under the individual's plan or coverage that the individual would be responsible for paying with respect to the furnishing of a specific item or service by a participating provider in a timely manner upon the request of the individual. At a minimum, such information must be made available to such individual through an internet website and such other means for individuals without access to the internet.[21] This transparency requirement also applies to group health plans and to health insurance issuers offering group or individual health insurance coverage.[22]

In 2020, the Department of the Treasury, the Department of Labor ("DOL"), and the Department of Health and Human Services ("HHS") (collectively, "the Departments") adopted final rules under the authority described above imposing additional transparency requirements on group health plans and issuers of individual and group health insurance coverage,[23] the Transparency in Coverage Final Rules ("TiC Final Rules").[24] The TiC Final Rules require plans and issuers to make the information described below available in the formats described below.[25]

*Self Service Tool*

Plans and issuers must make available to participants, beneficiaries, and enrollees a "self-service tool" that provides estimated cost-sharing information for a covered item or service from a particular provider or providers.[26] The self-service tool must be available over the internet, and plans and issuers must make the required information available in paper form,[27] upon request.

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[18] Provide Statute Citation.

[19] Pub. L. No. 111–148, March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111–152, March 30, 2010.

[20] An Exchange is established under section 1311 of the PPACA.

[21] Sec. 1311(e)(3)(C) of the PPACA. These requirements do not apply to grandfathered coverage as provided under section 1251 of the PPACA.

[22] Sec. 2715A of the Public Health Service Act ("PHSA"); sec. 9815.

[23] The Departments cooperate on implementing analogous requirements applicable to both group health plans and health insurance issuers under their respective authorities. See section 104 of the Health Insurance Portability and Accountability Act ("HIPAA") of 1996, Pub. L. No. 104–191, August 21, 1996; Notice of Signing of a Memorandum of Understanding among the Department of the Treasury, DOL, and HHS, 64 Fed. Reg. 70164, December 15, 1999. For simplicity, this discussion refers to "plans and issuers" when group health plans and issuers of group and individual health insurance coverage are collectively subject to a particular requirement.

[24] T.D. 9929, 85 Fed. Reg. 72158, Nov. 12, 2020.

[25] These requirements do not apply to health reimbursement arrangements or other account-based plans.

[26] The information made available must include 500 specified items and services for plan years beginning on or after January 1, 2023, and all items and services for plan years beginning on or after January 1, 2024.

[27] The TiC Final Rules set forth detailed requirements for the use of the paper method.

Plans and issuers are required to make the following information available:

- An estimate of the participant's, beneficiary's, or enrollee's cost-sharing liability for a requested covered item or service;[28]
- Accumulated amounts;[29]
- The in-network rate for the item or service;
- The out-of-network allowed amount or any other rate that provides a more accurate estimate of an amount the plan or issuer will pay for the requested covered item or service, generally reflected as a dollar amount, if the request for cost-sharing information is for a covered item or service furnished by an out-of-network provider;
- If applicable, notification that coverage of a specific item or service is subject to a prerequisite; and
- A notice including specified plain language disclaimers.

This information must be made available in plain language, without subscription or other fee, through a self-service tool on an internet website that provides real-time responses based on cost-sharing information that is accurate at the time of the request.

The tool must allow users to search for cost-sharing information for a covered item or service provided by a specific in-network provider or by all in-network providers by inputting:

- A billing code or a descriptive term, at the option of the user;
- The name of the in-network provider, if the user seeks cost-sharing information with respect to a specific in-network provider; and
- Other factors utilized by the plan or issuer that are relevant for determining the applicable cost-sharing information (such as location of service, facility name, or dosage).

The tool must allow users to search for an out-of-network allowed amount, percentage of billed charges, or other rate that provides a reasonably accurate estimate of the amount a plan or issuer will pay for a covered item or service provided by out-of-network providers by inputting:

- A billing code or descriptive term, at the option of the user; and
- Other factors utilized by the plan or issuer that are relevant for determining the applicable out-of-network allowed amount or other rate (such as the location in which the covered item or service will be sought or provided).

The tool must allow users to refine and reorder search results based on geographic proximity of in-network providers, and the amount of the participant's, beneficiary's, or enrollee's estimated cost-sharing liability for the covered item or service, to the extent the search for cost-sharing information for covered items or services returns multiple results.

The TiC Final Rules also include standards to prevent unnecessary duplication and permit a plan or issuer to satisfy these requirements by entering into a written agreement under which an-

[28] The TiC Final Rules also include detailed provisions regarding the reporting of information on bundled payment arrangements.

[29] Accumulated amounts are generally defined to mean the amount of financial responsibility a participant, beneficiary, or enroleee has incurred at the time a request for cost-sharing information is made, with respect to a deductible or out-of-pocket limit.

other party provides the required information, though the plan or issuer remains ultimately responsible for providing this information.

*Machine-Readable Files*

Plans and issuers must make publicly available three machine-readable files: (1) the in-network rate machine-readable file, which includes including price information for in-network provider rates for covered items and services; (2) the out-of-network allowed amount machine-readable file, which includes information, on out-of-network allowed amounts and billed charges for covered items and services; and (3) the prescription-drug machine readable file, which includes information on negotiated rates and historical net prices for covered prescription drugs. These files must be updated on a monthly basis.

The in-network rate machine-readable file must include the following information, with an exception for prescription drugs that are subject to a fee-for-service reimbursement arrangement, in addition to plan or issuer identifying information:

- A billing code and a plain language description for each billing code for each covered item or service;
- All applicable rates, including for bundled payment arrangements,[30] which must be:
  - Associated with the National Provider Identifier ("NPI"), Taxpayer Identification Number ("TIN"), and Place of Service Code for each in-network provider.
  - Associated with the last date of the contract term or expiration date for each provider-specific applicable rate that applies to each covered item or service; and
  - Indicated with a notation where a reimbursement arrangement other than a standard fee-for-service model (such as capitation or a bundled payment arrangement) applies.

The out-of-network allowed amount machine-readable file is required to include, in addition to plan or issuer identifying information:

- A billing code and a plain language description for each billing code for each covered item or service; and
- Unique out-of-network allowed amounts and billed charges with respect to covered items or services furnished by out-of-network providers during the 90-day time period that begins 180 days prior to the publication date of the machine-readable file (except that this data must be omitted in relation to a particular item or service and provider when inclusion would require the reporting of out-of-network allowed amounts in connection with fewer than 20 different claims for payments under a single plan or coverage). Each unique out-of-network allowed amount must be reflected as a dollar amount and associated with the NPI, TIN, and Place of Service Code for each out-of-network provider.

[30] If the plan or issuer does not use negotiated rates for provider reimbursement, then the plan or issuer should disclose derived amounts to the extent these amounts are already calculated in the normal course of business. If the plan or issuer uses underlying fee schedule rates for calculating cost sharing, then the plan or issuer should include the underlying fee schedule rates in addition to the negotiated rate or derived amount.

The prescription drug machine-readable file is required to include, in addition to plan or issuer identifying information:

- The National Drug Code ("NDC"), and the proprietary and nonproprietary name assigned to the NDC by the Food and Drug Administration ("FDA"), for each covered item or service under each coverage option offered by a plan that is a prescription drug;
- Negotiated rates, which must be:
  - Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider;
  - Associated with the NPI, TIN, and Place of Service Code for each in-network provider; and
  - Associated with the last date of the contract term for each provider-specific negotiated rate that applies to each NDC; and
- Historical net prices[31] that are:
  - Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider;
  - Associated with the NPI, TIN, and Place of Service Code for each in-network provider; and
  - Associated with the 90-day time period that begins 180 days prior to the publication date of the machine-readable file for each provider-specific historical net price that applies to each NDC (except that such data must be omitted in relation to a particular NDC and provider when inclusion would require the reporting of historical net prices calculated using fewer than 20 different claims for payment).

The machine-readable files must be available in a form and manner as specified in guidance issued by the Departments. The machine-readable files must be publicly available and accessible to any person free of charge and without conditions, such as establishment of a user account, password, or other credentials, or submission of personally identifiable information to access the file.

The TiC Final Rules include standards to prevent unnecessary duplication and permit plans and issuers to satisfy these requirements by entering into a written agreement under which another party provides the required information, though the plan or issuer remains ultimately responsible for providing this information.

In addition, plans and issuers may satisfy the allowed amount file requirement by disclosing out-of-network allowed amounts made available by, or otherwise obtained from, an issuer, a service provider, or other party with which the plan or issuer has entered into a written agreement to provide the information, provided the minimum claim threshold described above is independently met for each item or service and for each plan or coverage included in an aggregated file. Under such circumstances, health insurance issuers, service providers, or other parties with which the plan or issuer has contracted may aggregate out-of-network allowed amounts for more than one plan or insurance policy or contract.

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[31] Historical net price means the retrospective average amount a plan or issuer paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug.

*Subsequent Changes in Law and Guidance*

The Consolidated Appropriations Act, 2021 ("2021 CAA"),[32] also includes transparency requirements. The 2021 CAA requires plans and issuers to offer price comparison guidance by telephone and make available on the plan's or issuer's website a "price comparison tool" that (to the extent practicable) allows an individual enrolled under the plan or coverage, with respect to participating providers, to compare the amount of cost-sharing for which the individual would be responsible under such plan or coverage with respect to the furnishing of a specific item or service by any such provider.[33]

In addition, the 2021 CAA includes reporting requirements primarily related to prescription drug expenditures, requiring that plans and issuers submit detailed information to the Departments regarding prescription drug coverage, including, for example, the 50 most frequently dispensed brand prescription drugs, and the total number of paid claims for each such drug; the 50 most costly prescription drugs by total annual spending, and the annual amount spent by the plan or coverage for each such drug; and the 50 prescription drugs with the greatest increase in plan expenditures over the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan or coverage in each such plan year.[34] Additionally, the 2021 CAA requires the Departments to issue biannual public reports on prescription drug reimbursements under group health plans and group and individual health insurance coverage, prescription drug pricing trends, and the impact of prescription costs on premium rates.

Based on the rationale that the price comparison guidance required by the 2021 CAA is largely duplicative of the internet-based self-service tool requirement of the TiC Final Rules (with the exception of the requirement in the 2021 CAA that information be available by telephone), the Departments indicated in guidance that they intend to propose rulemaking regarding whether compliance with the internet-based self-service tool requirements of the TiC Final Rules satisfies the similar requirements set forth in the 2021 CAA.[35] In addition, the Departments stated that they intend to propose rulemaking requiring that the same pricing information that is available through the online tool or in paper form, as described in the TiC Final Rules, also be provided over the telephone upon request.

Finally, in response to the enactment of the drug price reporting provisions in the 2021 CAA and stakeholder concerns, the Departments announced they are deferring enforcement of the prescription drug machine-readable file requirement in the TiC Final Rules

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[32] Pub. L. No. 116 260, December 27, 2020.

[33] Sec. 9819, sec. 719 of the Employee Retirement Income Security Act ("ERISA"), and sec. 2799A–4 of the PHSA, as added by section 114 of division BB of the 2021 CAA. These provisions apply to health plans that are grandfathered under section 1251 of the PPACA, unlike the requirements of section 1311 of the PPACA.

[34] See sec. 9825, sec. 725 of ERISA, and sec. 2799A–10 of the PHSA, as added by section 204 of division BB of the 2021 CAA.

[35] FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49, August 20, 2021, available at https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf.

while they consider whether the prescription drug machine-readable file requirement remains appropriate.[36]

*Sec. 103*

The Departments are responsible for regulating group and individual health insurance and group health plans.

Pharmacy benefits managers (PBMs) are third-party administrators that manage prescription drug benefits for a group health plan or health insurance issuer. PBMs typically process prescription drug claims, maintain prescription drug formularies on behalf of the plan or issuer, contract with pharmacies for reimbursement, and negotiate prices with drug manufacturers.[37] Although plans and issuers are required to report information related to prescription drug benefits to the Departments,[38] there is currently no Federal law requiring PBMs to make similar reports to health insurance plans and issuers in general, or to group health plan sponsors.

*Sec. 104*

*Reports on Health Care Transparency Tools and Data Requirements*

Currently, there is no central repository or reviewer of information related to transparency requirements to which health care providers are subject. Consequently, there has been little formal work done to improve the efficiency, accuracy, and usability of health care transparency tools.

*Sec. 105*

*Report on Integration in Medicare*

Medicare Advantage (MA) Organizations are currently not required to report:

- Taxpayer identification number for each health care provider they own.
- The total amount of incentive payments made to, and the total amount of shared losses recoupments collected from, health care providers owned by the plan and not owned by the plan.

Prescription Drug Plans (PDPs) are not currently required to report:

- The taxpayer identification number and National Provider Identifier for each pharmacy they own.

*Section 202*

Currently, hospital outpatient departments (HOPDs) billing Medicare are required to submit different modifier codes to distinguish what type of facility the billing facility is for the purposes of payment.

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[36] Ibid.

[37] For a discussion of PBMs and certain required disclosures in the individual health insurance market context, see Patient Protection and Affordable Care Act; HHS, Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards, Final Rule, 86 Fed. Reg. 24140, May 5, 2021.

[38] See sec. 9825, sec. 725 of ERISA, and sec. 2799A–10 of the PHSA, as added by sec. 204 of division BB of the 2021 CAA; see also 45 C.F.R. sec. 184.50 (PBM reporting provision implementing section 1150A of the Social Security Act related to health insurance offered by qualified health plans, which are typically offered an on Exchange created under section 1311 of the PPACA).

*Section 203*

Medicare historically pays hospital outpatient departments (HOPDs) at rates determined by the Outpatient Prospective Payment System (OPPS). The Bipartisan Budget Act of 2015 (BBA15) changed this payment for "new" off-campus HOPDs, instead paying qualifying facilities based on other "applicable payment system" for certain non-emergency services. Additionally, in the 2019 OPPS payment rule, CMS reduced HOPD payments for an evaluation and management clinic visit code to align payments to all off-campus HOPDs with Medicare reimbursements under the Physician Fee Schedule-regardless of whether the facility was subject to the changes made in the Bipartisan Budget Act of 2015.

*Sec. 301*

*Establishing Requirements with respect to the use of prior authorization under Medicare Advantage plans*

Medicare Advantage (MA or Part C), an alternative to original (Parts A and B) fee-for-service (FFS) Medicare, allows beneficiaries to choose to receive their Medicare covered benefits through a private plan. Under contracts with the Secretary of Health and Human Services (HHS Secretary), MA plans agree to provide the Medicare covered benefits (and may also provide Part D outpatient prescription drug benefits, as well as other supplemental benefits) to beneficiaries who enroll in their plan, in exchange for a capitated or per person monthly payment.

In general, for Medicare to pay for an item or service, it must meet several criteria: it must be eligible for one of the defined Medicare benefit categories (e.g., hospital care, physicians' services); it must not be an item that is specifically statutorily excluded (e.g., hearing aids); and it must be "reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member." Alternatively, an item or service may be specified in statute as being covered by Medicare even if it would not otherwise meet the above criteria (e.g., preventive services).

Exactly which specific items and services are considered "reasonable and necessary" and covered by the Medicare program can be determined either nationally or locally. A National Coverage Determination (NCD) is a policy developed by the HHS Secretary that a particular item or service is reasonable and necessary, and therefore covered by Medicare nationally. In the absence of an NCD, or in concert with one, Medicare administrative contractors (MACs) may issue local coverage determinations (LCDs) that establish whether a particular item or service is reasonable and necessary, and therefore covered by Medicare within the MAC's service area.

In general, the coverage criteria including the national and local determinations that apply to original Medicare also apply to MA plans. However, there are situations where MA plans are allowed to standardize benefits or delay implementation. For example, if an MA plan service area spans more than one MAC region and therefore is subject to more than one coverage determination, the MA plan can choose to standardize its coverage policy based on the coverage determination that is most beneficial to the enrollee.

MA plans are paid a per-person monthly (capitated) amount by Medicare. Payments to plans are risk adjusted to take into account the demographic and health history of those who actually enroll in the plan.

Prior authorization for MA plans is described by HHS as a "process through which a physician or other health care provider is required to obtain advance approval from the plan that payment will be made for a service or item furnished to an enrollee. Unless specified otherwise with respect to a particular item or service, the enrollee is not responsible for obtaining (prior) authorizations." To satisfy a prior authorization requirement, a physician or health care provider must demonstrate compliance with coverage and payment rules and receive a determination from the MA plan before an item or service is provided to the beneficiary, rather than after. If a prior authorization is denied (i.e., the MA organizational determination was to deny the request), an individual, or his or her health care provider, may appeal the decision through a process that allows for multiple levels of review or appeal.

MA organizations are required to establish procedures for making determinations regarding whether an enrollee is entitled to receive an item or service, and the amount of cost sharing required, if any. MA organizations also are required to have procedures for making timely organizational determinations, meaning prior authorization adjudications. Determinations and appeals (i.e. reconsiderations of the determination) are required, per regulation, to be done within 14 days from the receipt of the organizational determination. The plan can extend this timeline if it needs additional information and must notify the beneficiary as to the reason for the timeline extension. Determinations may be done on an expedited basis at an enrollee's or physician's request, if making a determination or reconsideration under a normal timeframe could seriously jeopardize the life or health of the enrollee or the enrollee's ability to retain maximum function. Under an expedited determination or reconsideration, the plan is required to notify the enrollee and physician by a time determined by the HHS Secretary, but not later than 72 hours from receipt of the request.

Medicare statutes specify requirements and limitations with respect to MA plans' use of prior authorizations. Regardless of any prior authorization policy, MA plans are required to provide coverage for emergency services that meet the statutory definition of an emergency. In addition to coverage related requirements, MA plans are also subject to certain statutory disclosure requirements. Plans are required to disclose specified information, in a clear, accurate, and standardized format, to each enrollee at the time of enrollment and yearly thereafter, including "rules regarding prior authorization or other review requirements that could result in nonpayment." At the same time, plans are also required to disclose all plan appeal or grievance rights and procedures.

*Section 302*

The two percent sequestration of Medicare payments started by the Budget Control Act of 2011 is set to expire at the end of 2031.

REASONS FOR CHANGE

*Sec. 101*

*Hospital, ASC, Clinical Laboratory, and Imaging Provider Price Transparency*

The Committee believes consumers of health care services have a right to know the price of a service before they receive it, and therefore believes that it is important to codify and improve existing health care provider price transparency requirements. The Committee observes that the current statutory basis for the hospital price transparency requirements is suboptimal, as it is located in a part of U.S. Code that does not generally include such hospital requirements. This concerns the Committee for two reasons. First, the current statutory location is confusing, given that requirements for hospitals are typically located in Medicare, and hospitals may find it difficult to follow and comply with two sets of statutory requirements. Second, the Committee observes that the current provision's applicability to "all hospitals operating in the United States" imposes a private sector mandate, as it imposes requirements on hospitals that choose not to participate in Federal health programs. Additionally, the Committee believes the current provision is far too vague, deferring almost totally to the Executive Branch in developing specific requirements. The Committee is also concerned by reports that that CMS is failing to hold hospitals accountable for compliance with the hospital price transparency requirements, only auditing a relatively small number of hospitals annually and imposing few and low CMPs. Finally, the Committee observes that the current requirements only pertain to hospitals and not to other settings of care that provide shoppable services.

*Sec. 102*

*Health Insurer Price Transparency*

The Committee believes that the TiC final rules have the potential to greatly enhance health cost transparency for individuals, families, and employers. The Committee therefore believes it is appropriate to codify the regulations requiring plans and issuers to make these disclosures, including the prescription drug machine-readable file, to ensure that families and businesses may continue to benefit from increased health coverage price transparency.

*Sec. 103*

The Committee believes that the particular business models PBMs employ are not well understood, including the impact that PBM activities have on drug prices. The Committee therefore believes it is appropriate to require that PBMs provide detailed information to employers, to allow employers to better assess whether PBMs the value of the services provided by the PBM, and the cost of those services to the employer and its employees and their families.

*Sec. 104*

*Report on Health Care Transparency Tools and Data Requirements*

Health care providers may be subject to a variety of transparency requirements related to their prices as well as their financial transactions and ownership, and such requirements may be imposed by government health agencies or a variety of other federal agencies that regulate such transactions. Some providers may be required to comply with a variety of statutory, regulatory, and sub-regulatory requirements, which may be misaligned and result in unnecessary burden. The Committee is concerned that, to date, there has been little formal work focused on identifying all transparency requirements imposed by government on health care providers.

*Sec. 105*

*Report on Integration in Medicare*

The Committee is concerned with the consistent trend of health insurance plans purchasing health care providers and pharmacy benefit managers purchasing pharmacies and the impact this vertical integration may have on patient costs, outcomes, and quality of care.

*Sec. 201*

The Committee believes Medicare Part D beneficiaries should not pay more in cost sharing for prescription drugs during the coverage phase than the rate paid by the prescription drug plan.

*Section 202*

The Committee believes that the current requirements for identifying billing sites of service are inadequate and may lead to overpayments for patients and the Medicare program. While HOPDs are required to use modifier codes on their billing forms to designate, for example, if they are a facility that should be subject to the BBA15 payment changes and thus be paid a different amount than otherwise applicable, the practice of submitting the appropriate modifier is fundamentally self-attested and likely misused. Requiring HOPDs to bill with their own separate National Provider Identifier number, will remove a level of potential obscurity and improve transparency regarding which services are being performed at each specific HOPD.

*Section 203*

The Committee believes that better aligning Medicare payment rates across different sites of service will significantly reduce costs for Medicare beneficiaries, as patients would be responsible for paying their copays based on less expensive Part B services. Additionally, evidence shows that payment differentials for drug administration services has in part driven more services being performed at the highest-cost settings of care. The Medicare Payment Advisory Commission (MedPAC) reported in their June 2023 report that chemotherapy administration in freestanding clinician offices, typically the lowest-cost setting of care, fell 14.2 percent, while the volume in HOPDs, typically the highest-cost setting of care for ambu-

latory services, increased 21.0 percent. Aligning payment rates to eliminate these perverse spending trends will both lower patient cost-sharing and lower Medicare program spending by billions of dollars.

*Sec. 301*

*Establishing Requirements with respect to the use of prior authorization under Medicare Advantage plans*

The Committee believes that streamlining and modernizing prior authorizations improves efficiencies in the health care system, reducing unnecessary bureaucracy for patients, providers, and plans. This bill will lower barriers to patient care, reduce paperwork burdens for patients and providers and improve transparency.

To make the prior authorization process more efficient, this bill would require electronic prior authorization and speed up the timelines for prior authorization decisions. The bill would require the Secretary to promulgate rules by the third plan year after the date of enactment on the use of electronic prior authorizations, moving prior authorizations into the electronic age instead of the current time-consuming, inefficient practices of phones, fax, and paper transactions. For routinely approved services, MA plans would be required to make real-time decisions; exceptions must be determined within 24 hours for expedited requests or 72 hours for traditional requests. For non-routinely approved decisions, plans must decide prior authorizations in seven days for traditional requests and 24 hours for expedited requests (the current requirement is 14 days and 72 hours, respectively).

The bill also would require additional transparency provisions that require MA organizations to provide detailed data on prior authorization use and denials on the plan level, and to disclose information about the criteria that MA plans use when making prior authorization decisions to Medicare beneficiaries, providers, and suppliers, including determinations made using decision-support technology, artificial intelligence, machine-learning technology, clinical decision-making technology, and other technologies.

*Section 302*

An extension of the existing two percent sequestration of Medicare payments as required by the Budget Control Act of 2011 will continue to save the federal government billions of dollars.

EXPLANATION OF PROVISION

*Sec. 101*

The provision creates a new section 1899C of the Social Security Act and places within this new section price transparency requirements for hospitals, ambulatory surgical centers (ASCs), clinical laboratories, and providers of imaging services.

*Hospital Price Transparency*

The provision generally codifies the existing hospital price transparency rule, with key improvements. The provision requires hospitals to publish their gross charges, cash prices, and allows the Secretary of HHS to require the publication of negotiated rates. Unlike under current law, publication of the de-identified minimum

and maximum negotiated rates is not required. The provision also requires hospitals to publish a consumer-friendly list of 300 shoppable services and allows hospitals to be deemed compliant with this requirement if they offer a price estimator tool that meets certain requirements. Hospitals may be deemed compliant by using such a tool until HHS finalizes rules implementing sections 2799A–1(f) and 2799B–6 of the PHSA related to the advanced explanations of benefits.

The provision requires HHS to review each hospital's compliance no less than once every three years and provides for an enforcement process. The provision authorizes HHS to levy civil monetary penalties (CMP) on noncompliant hospitals. For hospitals with 30 or fewer beds, a maximum CMP of $300 per day may be levied; for other hospitals, a maximum annual CMP of $2,000,000. In the case of a hospital that is found to be knowingly and willfully noncompliant, the provision authorizes the Secretary to levy an additional CMP up to $1,000,000 on such hospitals with 31 or more beds and/or request an additional corrective action plan. The provision further allows the Secretary to waive or reduce any penalty otherwise applicable under the provision if the Secretary determines the imposition of such penalty would result in a significant hardship for the hospital, such as in the event the Secretary finds that imposing a CMP would harm patient access to care.

The provision requires information related to compliance with the provision to be published on the public website of the Centers for Medicare & Medicaid Services (CMS), including the number of reviews of noncompliance undertaken by the Secretary, the number of notifications sent by the Secretary, the identified of each hospital sent a notification and the nature of the noncompliance, the amount of any CMP imposed on such hospital, and whether such hospital subsequently came into compliance.

*Ambulatory Surgical Center Price Transparency*

The provision generally extends the provision's hospital price transparency requirements to ASCs, with maximum CMPs not to exceed $300 per day.

*Imaging Services Price Transparency*

The provision imposes price transparency requirements on providers of imaging services under the Medicare Program. The provision requires each provider of imaging services receiving payment under Medicare to publish the discounted cash price for services. The provision allows Secretary to require publication of the de-identified minimum and maximum negotiated rates. The provision requires the Secretary to publish a list of at least 50 shoppable imaging services. The provision enumerates an enforcement process similar to the hospital price transparency enforcement process and allows for CMPs not to exceed $300 per day for noncompliance.

*Clinical Laboratory Price Transparency*

The provision imposes price transparency requirements on clinical laboratories under the Medicare Program. The provision requires each clinical laboratory receiving payment under Medicare to publish the discounted cash price for services. The provision allows the Secretary to require publication of the de-identified min-

imum and maximum negotiated rates. The provision enumerates an enforcement process similar to the hospital price transparency enforcement process and allows for CMPs not to exceed $300 per day for noncompliance.

*Publication of Hospital Compliance with Price Transparency Requirements*

The provision requires the Secretary to indicate on the CMS Hospital Compare website any hospital noncompliance identified, along with details related to the noncompliance and any associated penalty imposed.

*Conforming Amendment*

The provision sunsets applicability of the current section 2718(e) of the PHSA.

*Funding*

The provision appropriates $10,000,000, to remain available until expended, for the purposes of implementing the provision and monitoring compliance with the provision.

*Report on Expenditures*

The provision requires the Secretary, no later than five years after the date of enactment of the Act, to submit to the Committee, and to the House Committee on Energy & Commerce and Senate Finance Committee a report that describes the manner in which the Secretary utilized the funding provided in the Act and identifies all entities with whom the Secretary contracted in carrying out the provision.

*Implementation*

The provision requires the Secretary to ensure price transparency information is made available in plain language and that entities provide access to interpretation services, translations, and other assistive services. The provision requires the Secretary to provide technical assistance to providers required under the provision to publish price information.

*Effective Date*

The hospital price transparency provision is effective January 1, 2026.

The ASC price transparency provision is effective January 1, 2028.

The imaging services price transparency provision is effective January 1, 2028.

The clinical laboratory price transparency provision is effective January 1, 2028.

The conforming amendment related to applicability of Section 2718(e) of the PHSA is effective after January 1, 2026.

*Sec. 102*

*Health Insurer Price Transparency*

The provision generally codifies the TiC Final Rules, with certain changes, in place of the 2021 CAA price comparison provision de-

scribed above. In particular, the provision requires plans and issuers to make the information described below available in the formats described below.

*Self Service Tool*

A plan or issuer is required to permit individuals to learn the amount of cost-sharing (including deductibles, copayments, and coinsurance) under the individual's plan or coverage that the individual would be responsible for paying with respect to the furnishing of a specific item or service by a provider in a timely manner upon the request of the individual according to the parameters described below.

The disclosure must include the following specified information:

- If the provider is a participating provider with respect to the item or service, the in-network rate for such item or service;
- If the provider is not such a participating provider, the maximum allowed amount for the item or service;
- The estimated amount of cost-sharing (including deductibles, copayments, and coinsurance) that the participant, beneficiary, or enrollee will incur for the item or service, calculated, for providers that are not participating providers, using the maximum allowed amount;
- The amount the participant, beneficiary, or enrollee had already accumulated with respect to any deductible or out of pocket maximum, for participating and non-participating providers, broken down for separate individuals if separate deductibles or maximums apply to separate individuals under the plan, in addition to any cumulative amount;
- If the plan or coverage imposes any applicable frequency or volume limitations (excluding medical necessity determinations), the amount that the participant, beneficiary, or enrollee has accrued towards such limitation with respect to the item or service; and
- Any prior authorization, concurrent review, step therapy, fail first, or similar requirements applicable to the item or service.

The Departments are authorized to modify these requirements by providing that information described in any of the categories above not be treated as information required to be disclosed, and may designate additional information that must be disclosed, if determined appropriate by the Departments.[39]

The plan or issuer must make this information available through a self-service tool that meets the following requirements. The self-service tool must:

- Be based on an internet website;
- Provide for real-time responses to requests;
- Be updated to be timely and accurate;
- Allow individuals to make requests by:
  - A specific participating provider;
  - All participating providers; or
  - All providers that are not participating providers;

[39] For simplicity, and to reflect the coordinated approach taken by the Departments, this discussion generally refers to "the Departments" where the statute refers to the Secretaries of the Treasury, Labor, and HHS individually.

- Provide that a request may be made by billing code or descriptive term; and
- Meet any other requirements determined appropriate by the Secretary.

The Departments may require such tool to link multiple billing codes to a single descriptive term if the Departments determine that the billing codes to be so linked correspond to similar items and services.

At the option of the individual, the information described above must also be available in paper format, over the phone, or through other electronic disclosure, at no cost to the individual, as meets such requirements as the Departments may specify.

*Machine-Readable Files*

The provision requires that each plan or issuer make available to the public the following information:

- In-network rate information for each item and service for which benefits are available under the plan or coverage, other than a drug, other than a rate that is in effect for a provider that did not submit any claim for the relevant item or service within the one-year period ending 10 business days before the date of publication.
- In-network drug price information for each drug (identified by NDC) for which benefits are available under the plan or coverage, including the average amount paid by the plan (net of rebates, discounts, and price concessions) for such drug dispensed or administered during the 90-day period beginning 180 days before the date of publication, broken down by each provider, other than amounts paid to a provider that, during such period, submitted fewer than 20 claims for such drug to such plan or coverage.
- Out-of-network price information, including, for each item or service for which benefits are available, the amount billed, and the amount allowed, broken down by provider, for each item or service furnished during the same 90-day period as applicable for prescription drug information, other than items or services for which fewer than 20 claims were submitted during the relevant period for such plan or coverage.

This information must be made available for plan years beginning on or after the date that is no later than two years after the date of enactment. The information related to in-network rates and out-of-network price information must be made available every three months thereafter, in machine-readable file format (or successor technology, such as application program interface technology, as determined to be appropriate by the Departments) as two separate files that meet requirements specified by the Departments. Information related to prescription drug prices must be made available every month thereafter, in the same format as the other two files.

The requirements specified by the Departments must ensure that such files are limited to an appropriate size, do not contain information that is unnecessarily duplicative of information contained in other files made available pursuant to the machine-readable file requirement, are made available in a widely-available format through a publicly-available website that allows for information

contained in such files to be compared across plans and coverages, and are accessible to individuals at no cost and without the need to establish a user account or provide other credentials. The machine-readable file requirement does not apply to grandfathered plans.

Each plan or issuer must also make available to the public instructions written in plain language explaining how individuals may search for this information. The Departments are required to develop and publish a template that a plan or issuer may use in developing these instructions. The provision requires plans and issuers to post, along with rate and payment information made public by such plan or issuer, an attestation that such information is complete and accurate.

Finally, the provision requires that the Departments take reasonable steps to ensure the accessibility of the information made available under the provision, including reasonable steps to ensure that such information is provided in plain, easily understandable language and that interpretation, translations, and assistive services are provided to make the information accessible to those with limited English proficiency and those with disabilities.

*Section 103*

The provision prohibits a group health plan or issuer of group health insurance coverage, or an entity or subsidiary providing pharmacy benefits management services ("PBM services")[40] on behalf of such a plan or issuer, from entering into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or issuer, or an entity or subsidiary providing PBM services on behalf of a plan or issuer, from making reports related to PBM services, as described below.

Plans or issuers, or entities providing PBM services on behalf of a plan or issuer, must submit these reports to plan sponsors[41] at least annually and make the reports available to the plan sponsor in a machine-readable format. The report must include, with respect to the plan or coverage for the plan year:

- To the extent feasible, information collected from drug manufacturers by the PBM on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the participants, beneficiaries, and enrollees in such plan or coverage;
- A list of each drug covered by such plan or coverage that was dispensed during the plan year, including, with respect to each drug during the plan year:
  - The brand name, chemical entity, and NDC;
  - The number of participants, beneficiaries, and enrollees for whom the drug was dispensed during the plan year, the total number of prescription claims for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, disaggregated by

[40] For simplicity, this discussion generally refers to entities covered by the disclosure requirements in this provision simply as "PBMs".

[41] As defined in section 3(16)(B) of ERISA.

dispensing channel (such as retail, mail order, or specialty pharmacy);

- The wholesale acquisition cost, listed as cost per days supply and cost per pill, or in the case of a drug in another form, per dosage unit;
- The total out-of-pocket spending by participants, beneficiaries, and enrollees on such drug, including spending through copayments, coinsurance, and deductibles;
- For any drug for which the plan's or coverage's gross spending exceeded $10,000 during the plan year: (1) a list of all other drugs in the same therapeutic category or class; and (2) the rationale (if applicable) for preferred formulary placement of such drug in that therapeutic category or class;
- The amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration for claims incurred for such drug during the plan year;
- The total net spending, after deducting rebates, price concessions, alternative discounts or other remuneration from drug manufacturers, by the plan or coverage on such drug; and
- The net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, incurred by the plan or coverage and its participants, beneficiaries, and enrollees after manufacturer rebates, fees, and other remuneration for such drug dispensed during the plan year.
- A list of each therapeutic category or class of drugs that were dispensed during the plan year, and, with respect to each such therapeutic category or class of drugs, during the plan year:
- Total gross spending by the plan or coverage, before manufacturer rebates, fees, or other manufacturer remuneration;
- The number of participants, beneficiaries, and enrollees who were dispensed a drug cover by such plan in that category or class, broken down by each such drug (identified by NDC);
- If applicable, a description of the formulary tiers and utilization management (such as prior authorization or step therapy) employed for drugs in that category or class; and
- The total out-of-pocket spending by participants, beneficiaries, and enrollees including through copayments, coinsurance, and deductibles;
- Total gross spending on prescription drugs by the plan or coverage during the plan year, before rebates and other manufacturer fees or remuneration;
- Total amount received, or expected to be received, by the plan or coverage in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug spending under the plan or coverage during the plan year;
- The total net spending on prescription drugs by the plan or coverage during the plan year; and
- Amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm for the referral of the plan's or coverage's business to the PBM.

PBMs are required to report the information in a manner consistent with the privacy, security, and breach notification regulations promulgated under HIPAA[42] and follow HIPAA use and disclosure restrictions.[43] In addition, group health plans receiving reports may disclose this information only to business associates as defined in HHS regulations.[44]

The provision provides enforcement authority to DOL and HHS, in consultation with the Secretary of the Treasury, and provides for a $10,000 per day civil penalty for periods of noncompliance with the contracting and reporting requirements described above and a $100,000 per item civil penalty for knowingly providing false information. DOL and HHS may extend timelines or waive the noncompliance period penalty for entities that have made a good faith effort at compliance.

The Departments also are required to issue rules defining a limited form of the report described above for use by plan sponsors who are drug manufacturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

Finally, the Comptroller General is directed to submit a report to Congress not later than three years after the date of enactment. The report must include information on:

- Pharmacy networks of group health plans, health insurance issuers, and PBMs under such group health plan or group or individual health insurance coverage, including networks that have pharmacies that are under common ownership with group health plans, health insurance issuers, or entities providing PBM or pharmacy benefits administrative services under group health plan or health insurance coverage;
- As it relates to pharmacy networks that include pharmacies under common ownership:
    - Whether such networks are designed to encourage enrollees of a plan or coverage to use such pharmacies over other network pharmacies for specific services or drugs, and if so, the reasons the networks give for encouraging use of such pharmacies; and
    - Whether such pharmacies are used by enrollees disproportionately more in the aggregate or for specific services or drugs compared to other network pharmacies;
- Whether plans and issuers have options to elect different network pricing arrangements in the marketplace with entities that provide PBM services, the prevalence of electing such different network pricing arrangements;
- Pharmacy network design parameters that encourage enrollees in the plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies that are wholly or partially owned by that issuer or entity; and

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[42] Pub. L. No. 104–191, sec. 264(c), August 21, 1996.

[43] The provision permits PBMs to place reasonable restrictions on the public disclosure of this information, except that the PBM may not restrict disclosure to the Departments, the Comptroller General of the United States, or applicable State agencies. PBMs are also required to submit the first four reports (and other reports as requested) to the Comptroller General. The Departments are required to specify standards for a standard format for these reports not later than eighteen months after the date of enactment.

[44] See 45 C.F.R. sec. 160.103.

- The degree to which mail order, specialty, or retail pharmacies that dispense prescription drugs to an enrollee in a plan or coverage that are under common ownership with group health plans, health insurance issuers, or entities providing PBM or pharmacy benefits administrative services under plan or coverage receive reimbursement that is greater than the median price charged to the plan or issuer when the same drug is dispensed to enrollees in the plan or coverage by other pharmacies included in the pharmacy network of that plan, issuer, or entity that are not owned by the issuer or entity providing PBM services.

The Comptroller General is required to ensure that this report does not contain information that could be used to identify a specific plan or entity providing PBM services or otherwise contain commercial or financial information that is privileged or confidential.

*Section 104*

The provision would require the Comptroller General of the United States to submit to Congress a report that identifies all health care price transparency tools and federal health reporting requirements, reviews how they are enforced, and analyze whether public information resulting from these requirements has been utilized by consumers and lowered health care costs. The provision further requires the Comptroller General to include in the report recommendations to Congress and the Secretaries of HHS, Labor, and Treasury to improve and streamline transparency tools and various reporting requirements, improve the accuracy of public reporting, and address any gaps in existing data.

The provision further requires the Comptroller General, in consultation with the HHS Secretary and health care providers and patient advocates, to submit to Congress a report containing recommendations related to expansion of price transparency tools and reporting requirements, emphasizing settings of care that provide shoppable services.

*Sec. 105*

*Report on Integration in Medicare*

The provision requires Medicare Advantage Organizations to report:

- Taxpayer identification number for each health care provider they own
- The total amount of incentive payments made to, and the total amount of shared losses recoupments collected from, health care providers owned by the plan and not owned by the plan.

The provision requires Prescription Drug Plans (PDPs) to report:

- The taxpayer identification number and National Provider Identifier for each pharmacy they own.

Additionally, the Medicare Payment Advisory Commission is required to submit a report to Congress on the state of vertical integration in the health care sector every three years with respect to entities participating in the Medicare program, including health

care providers, pharmacies, prescription drug plan sponsors, Medicare Advantage Organizations, and pharmacy benefit managers.

*Section 201*

The provision prohibits a Medicare Part D plan from charging more in cost sharing than the plan negotiated for the price of the drug.

*Section 202*

This provision requires hospital outpatient departments (HOPDs) to obtain and use separate NPIs when billing Medicare and requires the HHS Office of the Inspector General to review the compliance of previous Medicare site-neutral payment policies.

*Section 203*

This section requires Medicare to reimburse off-campus hospital outpatient departments (HOPDs) administering Medicare Part B drugs at the same rate it reimburses physicians under the Medicare Physician Fee Schedule.

*Section 302*

This section extends a 1.5 percent sequestration of Medicare payments for the first two months of 2032.

*Section 202*

This section is effective January 1, 2026.

*Section 203*

Payment changes made in this section are effective beginning in 2025, with a four-year phase-in to the complete rate in 2028, and an additional one-year delay for HOPDs located in rural or health professional shortage areas (HPSAs) and for the 11 specially designated cancer hospitals.

*Section 302*

This extension of sequestration is effective January 1, 2032.

EFFECTIVE DATE

*Health Insurer Price Transparency*

The provision is generally effective for plan years that begin on or after the date that is two years after the date of enactment. In addition, the provision specifies that nothing in the provision may be construed as affecting the applicability of the TiC Final Rules for any period prior to the effective date.

*Section 103*

The provision applies to plan years beginning on or after the date that is three years after the date of enactment.

*Section 201*

The provision applies to plan years beginning on or after January 1, 2027.

*Section 202*

This section is effective January 1, 2026.

*Section 203*

Payment changes made in this section are effective beginning in 2025, with a four-year phase-in to the complete rate in 2028, and an additional one-year delay for HOPDs located in rural or health professional shortage areas (HPSAs) and for the 11 specially designated cancer hospitals.

*Sec. 301*

*Establishing Requirements with respect to the use of prior authorization under Medicare Advantage plans*

Provisions begin to take effect the third plan year after enactment.

*Section 302*

This extension of sequestration is effective January 1, 2032.

## III. VOTE OF THE COMMITTEE

In compliance with the Rules of the House of Representatives, the following statement is made concerning the vote of the Committee on Ways and Means during the markup consideration of H.R. 4822, the "Health Care Price Transparency Act of 2023," on July 26, 2023.

The vote on the amendment offered by Mr. Doggett to the amendment in the nature of a substitute to H.R. 4822, which would require the Medicare Advantage and Medicare Part D plans to provide a similar consumer price transparency tool as required of group health plans. This amendment would also apply Section 202 of the No Surprises Act within the Consolidated Appropriations Act of 2021 to Medicare Advantage agents and brokers. Finally, the amendment would require additional data reporting to be accompanied with Medicare Advantage encounter data was not agreed to by a roll call vote of 16 yeas to 25 nays (with a quorum being present). The vote was as follows:

| Representative | Yea | Nay | Present | Representative | Yea | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Smith (MO) | | X | | Mr. Neal | X | | |
| Mr. Buchanan | | X | | Mr. Doggett | X | | |
| Mr. Smith (NE) | | X | | Mr. Thompson | X | | |
| Mr. Kelly | | X | | Mr. Larson | X | | |
| Mr. Schweikert | | X | | Mr. Blumenauer | X | | |
| Mr. LaHood | | X | | Mr. Pascrell | X | | |
| Dr. Wenstrup | | X | | Mr. Davis | X | | |
| Mr. Arrington | | X | | Ms. Sanchez | X | | |
| Dr. Ferguson | | X | | Mr. Higgins | X | | |
| Mr. Estes | | X | | Ms. Sewell | | | |
| Mr. Smucker | | X | | Ms. DelBene | X | | |
| Mr. Hern | | X | | Ms. Chu | X | | |
| Ms. Miller | | X | | Ms. Moore | X | | |
| Dr. Murphy | | X | | Mr. Kildee | X | | |
| Mr. Kustoff | | X | | Mr. Beyer | X | | |
| Mr. Fitzpatrick | | X | | Mr. Evans | | | |
| Mr. Steube | | X | | Mr. Schneider | X | | |
| Ms. Tenney | | X | | Mr. Panetta | X | | |
| Mrs. Fischbach | | X | | | | | |
| Mr. Moore | | X | | | | | |

| Representative | Yea | Nay | Present | Representative | Yea | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mrs. Steel | | X | | | | | |
| Ms. Van Duyne | | X | | | | | |
| Mr. Feenstra | | X | | | | | |
| Ms. Malliotakis | | X | | | | | |
| Mr. Carey | | X | | | | | |

In compliance with the Rules of the House of Representatives, the following statement is made concerning the vote of the Committee on Ways and Means during the markup consideration of H.R. 4822, the "Health Care Price Transparency Act of 2023," on July 26, 2023.

The vote on the amendment offered by Mr. Pascrell to the amendment in the nature of a substitute to H.R. 4822, which would require reporting by certain investors with respect to certain specified medical care providers under new provisions of the Internal Revenue Code of 1986 under section 6039J was not agreed to by a roll call vote of 16 yeas to 25 nays (with a quorum being present). The vote was as follows:

| Representative | Yea | Nay | Present | Representative | Yea | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Smith (MO) | | X | | Mr. Neal | X | | |
| Mr. Buchanan | | X | | Mr. Doggett | X | | |
| Mr. Smith (NE) | | X | | Mr. Thompson | X | | |
| Mr. Kelly | | X | | Mr. Larson | X | | |
| Mr. Schweikert | | X | | Mr. Blumenauer | X | | |
| Mr. LaHood | | X | | Mr. Pascrell | X | | |
| Dr. Wenstrup | | X | | Mr. Davis | X | | |
| Mr. Arrington | | X | | Ms. Sanchez | X | | |
| Dr. Ferguson | | X | | Mr. Higgins | X | | |
| Mr. Estes | | X | | Ms. Sewell | | | |
| Mr. Smucker | | X | | Ms. DelBene | X | | |
| Mr. Hern | | X | | Ms. Chu | X | | |
| Ms. Miller | | X | | Ms. Moore | X | | |
| Dr. Murphy | | X | | Mr. Kildee | X | | |
| Mr. Kustoff | | X | | Mr. Beyer | X | | |
| Mr. Fitzpatrick | | X | | Mr. Evans | | | |
| Mr. Steube | | X | | Mr. Schneider | X | | |
| Ms. Tenney | | X | | Mr. Panetta | X | | |
| Mrs. Fischbach | | X | | | | | |
| Mr. Moore | | X | | | | | |
| Mrs. Steel | | X | | | | | |
| Ms. Van Duyne | | X | | | | | |
| Mr. Feenstra | | X | | | | | |
| Ms. Malliotakis | | X | | | | | |
| Mr. Carey | | X | | | | | |

In compliance with the Rules of the House of Representatives, the following statement is made concerning the vote of the Committee on Ways and Means during the markup consideration of H.R. 4822, the "Health Care Price Transparency Act of 2023," on July 26, 2023.

The vote on the amendment offered by Ms. DelBene to the amendment in the nature of a substitute to H.R. 4822, which would exempt dedicated cancer centers from Medicare reimbursement revisions under Section 203 of the amendment in the nature of a substitute to H.R. 4822 was not agreed to by a roll call vote of 15 yeas to 25 nays (with a quorum being present). The vote was as follows:

| Representative | Yea | Nay | Present | Representative | Yea | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Smith (MO) | | X | | Mr. Neal | X | | |

| Representative | Yea | Nay | Present | Representative | Yea | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Buchanan | | X | | Mr. Doggett | | | |
| Mr. Smith (NE) | | X | | Mr. Thompson | X | | |
| Mr. Kelly | | X | | Mr. Larson | X | | |
| Mr. Schweikert | | X | | Mr. Blumenauer | X | | |
| Mr. LaHood | | X | | Mr. Pascrell | X | | |
| Dr. Wenstrup | | X | | Mr. Davis | X | | |
| Mr. Arrington | | X | | Ms. Sanchez | X | | |
| Dr. Ferguson | | X | | Mr. Higgins | X | | |
| Mr. Estes | | X | | Ms. Sewell | | | |
| Mr. Smucker | | X | | Ms. DelBene | X | | |
| Mr. Hern | | X | | Ms. Chu | X | | |
| Ms. Miller | | X | | Ms. Moore | X | | |
| Dr. Murphy | | X | | Mr. Kildee | X | | |
| Mr. Kustoff | | X | | Mr. Beyer | X | | |
| Mr. Fitzpatrick | | X | | Mr. Evans | | | |
| Mr. Steube | | X | | Mr. Schneider | X | | |
| Ms. Tenney | | X | | Mr. Panetta | X | | |
| Mrs. Fischbach | | X | | | | | |
| Mr. Moore | | X | | | | | |
| Mrs. Steel | | X | | | | | |
| Ms. Van Duyne | | X | | | | | |
| Mr. Feenstra | | X | | | | | |
| Ms. Malliotakis | | X | | | | | |
| Mr. Carey | | X | | | | | |

In compliance with the Rules of the House of Representatives, the following statement is made concerning the vote of the Committee on Ways and Means during the markup consideration of H.R. 4822, the "Health Care Price Transparency Act of 2023," on July 26, 2023.

The vote on the amendment offered by Ms. Chu to the amendment in the nature of a substitute to H.R. 4822, which would add to H.R. 4822 a prohibition on the use of any information disclosed, submitted, or otherwise made available for the purpose of prosecuting or investigating a patient or provider for accessing or performing comprehensive sexual and reproductive healthcare was not agreed to by a roll call vote of 16 yeas to 25 nays (with a quorum being present). The vote was as follows:

| Representative | Yea | Nay | Present | Representative | Yea | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Smith (MO) | | X | | Mr. Neal | X | | |
| Mr. Buchanan | | X | | Mr. Doggett | | | |
| Mr. Smith (NE) | | X | | Mr. Thompson | X | | |
| Mr. Kelly | | X | | Mr. Larson | X | | |
| Mr. Schweikert | | X | | Mr. Blumenauer | X | | |
| Mr. LaHood | | X | | Mr. Pascrell | X | | |
| Dr. Wenstrup | | X | | Mr. Davis | X | | |
| Mr. Arrington | | X | | Ms. Sanchez | X | | |
| Dr. Ferguson | | X | | Mr. Higgins | X | | |
| Mr. Estes | | X | | Ms. Sewell | | | |
| Mr. Smucker | | X | | Ms. DelBene | X | | |
| Mr. Hern | | X | | Ms. Chu | X | | |
| Ms. Miller | | X | | Ms. Moore | X | | |
| Dr. Murphy | | X | | Mr. Kildee | X | | |
| Mr. Kustoff | | X | | Mr. Beyer | X | | |
| Mr. Fitzpatrick | | X | | Mr. Evans | X | | |
| Mr. Steube | | X | | Mr. Schneider | X | | |
| Ms. Tenney | | X | | Mr. Panetta | X | | |
| Mrs. Fischbach | | X | | | | | |
| Mr. Moore | | X | | | | | |
| Mrs. Steel | | X | | | | | |
| Ms. Van Duyne | | X | | | | | |
| Mr. Feenstra | | X | | | | | |

| Representative | Yea | Nay | Present | Representative | Yea | Nay | Present |
|---|---|---|---|---|---|---|---|
| Ms. Malliotakis | | X | | | | | |
| Mr. Carey | | X | | | | | |

In compliance with the Rules of the House of Representatives, the following statement is made concerning the vote of the Committee on Ways and Means during the markup consideration of H.R. 4822, the "Health Care Price Transparency Act of 2023," on July 26, 2023.

H.R. 4822 was ordered favorably reported to the House of Representatives as amended by a roll call vote of 25 yeas to 16 nays (with a quorum being present). The vote was as follows:

| Representative | Yea | Nay | Present | Representative | Yea | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Smith (MO) | X | | | Mr. Neal | | X | |
| Mr. Buchanan | X | | | Mr. Doggett | | X | |
| Mr. Smith (NE) | X | | | Mr. Thompson | | X | |
| Mr. Kelly | X | | | Mr. Larson | | X | |
| Mr. Schweikert | X | | | Mr. Blumenauer | | X | |
| Mr. LaHood | X | | | Mr. Pascrell | | X | |
| Dr. Wenstrup | X | | | Mr. Davis | | X | |
| Mr. Arrington | X | | | Ms. Sanchez | | X | |
| Dr. Ferguson | X | | | Mr. Higgins | | X | |
| Mr. Estes | X | | | Ms. Sewell | | | |
| Mr. Smucker | X | | | Ms. DelBene | | X | |
| Mr. Hern | X | | | Ms. Chu | | X | |
| Ms. Miller | X | | | Ms. Moore | | | |
| Dr. Murphy | X | | | Mr. Kildee | | X | |
| Mr. Kustoff | X | | | Mr. Beyer | | X | |
| Mr. Fitzpatrick | X | | | Mr. Evans | | X | |
| Mr. Steube | X | | | Mr. Schneider | | X | |
| Ms. Tenney | X | | | Mr. Panetta | | X | |
| Mrs. Fischbach | X | | | | | | |
| Mr. Moore | X | | | | | | |
| Mrs. Steel | X | | | | | | |
| Ms. Van Duyne | X | | | | | | |
| Mr. Feenstra | X | | | | | | |
| Ms. Malliotakis | X | | | | | | |
| Mr. Carey | X | | | | | | |

## IV. BUDGET EFFECTS OF THE BILL

### A. Committee Estimate of Budgetary Effects

In compliance with clause 3(d) of rule XIII of the Rules of the House of Representatives, a cost estimate provided by the Congressional Budget Office pursuant to section 402 of the *Congressional Budget Act of 1974* was not made available to the Committee in time for the filing of this report. The Chairman of the Committee shall cause such estimate to be printed in the Congressional Record upon its receipt by the Committee.

### B. Statement Regarding New Budget Authority and Tax Expenditures Budget Authority

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that the bill involves no new or increased budget authority.

## V. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE

### A. Committee Oversight Findings and Recommendations

With respect to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee made findings and recommendations that are reflected in this report.

### B. Statement of General Performance Goals and Objectives

With respect to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee advises that the bill does not authorize funding, so no statement of general performance goals and objectives is required.

### C. Information Relating to Unfunded Mandates

This information is provided in accordance with section 423 of the Unfunded Mandates Reform Act of 1995 (Pub. L. No. 104–4). The Committee has determined that the bill does not contain Federal mandates on the private sector. The Committee has determined that the bill does not impose a Federal intergovernmental mandate on State, local, or tribal governments.

### D. Congressional Earmarks, Limited Tax Benefits, and Limited Tariff Benefits

With respect to clause 9 of rule XXI of the Rules of the House of Representatives, the Committee has carefully reviewed the provisions of the bill, and states that the provisions of the bill do not contain any congressional earmarks, limited tax benefits, or limited tariff benefits within the meaning of the rule.

### E. Duplication of Federal Programs

In compliance with clause 3(c)(5) of rule XIII of the Rules of the House of Representatives, the Committee states that no provision of the bill establishes or reauthorizes: (1) a program of the Federal Government known to be duplicative of another Federal program; (2) a program included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139; or (3) a program related to a program identified in the most recent Catalog of Federal Domestic Assistance, published pursuant to the Federal Program Information Act (Pub. L. No. 95–220, as amended by Pub. L. No. 98–169).

## VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

### A. Changes in Existing Law Made by the Bill, as Reported

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

## SOCIAL SECURITY ACT

* * * * * * *

## TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

* * * * * * *

### PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

* * * * * * *

#### PAYMENT OF BENEFITS

SEC. 1833. (a) Except as provided in section 1876, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—(1) in the case of services described in section 1832(a)(1)—80 percent of the reasonable charges for the services; except that (A) an organization which provides medical and other health services (or arranges for their availability) on a prepayment basis (and either is sponsored by a union or employer, or does not provide, or arrange for the provision of, any inpatient hospital services) may elect to be paid 80 percent of the reasonable cost of services for which payment may be made under this part on behalf of individuals enrolled in such organization in lieu of 80 percent of the reasonable charges for such services if the organization undertakes to charge such individuals no more than 20 percent of such reasonable cost plus any amounts payable by them as a result of subsection (b), (B) with respect to items and services described in section 1861(s)(10)(A), the amounts paid shall be 100 percent of the reasonable charges for such items and services, (C) with respect to expenses incurred for those physicians' services for which payment may be made under this part that are described in section 1862(a)(4), the amounts paid shall be subject to such limitations as may be prescribed by regulations, (D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i)(I) on the basis of a fee schedule under subsection (h)(1) (for tests furnished before January 1, 2017) or section 1834(d)(1), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (II) undersection 1834A (for tests furnished on or after January1, 2017), the amount paid shall be equal to 80 percent(or 100 percent, in the case of such tests for whichpayment is made on an assignment-related basis) ofthe lesser of the amount determined under such sectionor the amount of the charges billed for the tests, or (ii) for tests furnished before January 1, 2017,on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate,,(E) with

respect to services furnished to individuals who have been determined to have end stage renal disease, the amounts paid shall be determined subject to the provisions of section 1881,(F) with respect to clinical social worker services under section 1861(s)(2)(N), the amounts paid shall be 80 percent of the lesser of (i) the actual charge for the services or (ii) 75 percent of the amount determined for payment of a psychologist under clause (L),

(G) with respect to facility services furnished in connection with a surgical procedure specified pursuant to subsection (i)(1)(A) and furnished to an individual in an ambulatory surgical center described in such subsection, for services furnished beginning with the implementation date of a revised payment system for such services in such facilities specified in subsection (i)(2)(D), the amounts paid, subject to subsection (i)(9), shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system,

(H) with respect to services of a certified registered nurse anesthetist under section 1861(s)(11), the amounts paid shall be 80 percent of the least of the actual charge, the prevailing charge that would be recognized (or, for services furnished on or after January 1, 1992, the fee schedule amount provided under section 1848) if the services had been performed by an anesthesiologist, or the fee schedule for such services established by the Secretary in accordance with subsection (l), (I) with respect to covered items (described in section 1834(a)(13)), the amounts paid shall be the amounts described in section 1834(a)(1), and(J) with respect to expenses incurred for radiologist services (as defined in section 1834(b)(6)), subject to section 1848, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount provided under the fee schedule established under section 1834(b), (K) with respect to certified nurse-midwife services under section 1861(s)(2)(L), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph (but in no event shall such fee schedule exceed 65 percent of the prevailing charge that would be allowed for the same service performed by a physician, or, for services furnished on or after January 1, 1992, 65 percent (or 100 percent for services furnished on or after January 1, 2011) of the fee schedule amount provided under section 1848 for the same service performed by a physician), (L) with respect to qualified psychologist services under section 1861(s)(2)(M), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph, (M) with respect to prosthetic devices and orthotics and prosthetics (as defined in section 1834(h)(4)), the amounts paid shall be the amounts described in section 1834(h)(1), (N) with respect to expenses incurred for physicians' services (as defined in section 1848(j)(3)) other than personalized prevention plan services (as defined in section 1861(hhh)(1)), the amounts paid shall be 80 percent of the pay-

ment basis determined under section 1848(a)(1), (O) with respect to services described in section 1861(s)(2)(K) (relating to services furnished by physician assistants, nurse practitioners, or clinic nurse specialists), the amounts paid shall be equal to 80 percent of (i) the lesser of the actual charge or 85 percent of the fee schedule amount provided under section 1848, or (ii) in the case of services as an assistant at surgery, the lesser of the actual charge or 85 percent of the amount that would otherwise be recognized if performed by a physician who is serving as an assistant at surgery, (P) with respect to surgical dressings, the amounts paid shall be the amounts determined under section 1834(i), (Q) with respect to items or services for which fee schedules are established pursuant to section 1842(s), the amounts paid shall be 80 percent of the lesser of the actual charge or the fee schedule established in such section, (R) with respect to ambulance services, (i) the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary under section 1834(l) and (ii) with respect to ambulance services described in section 1834(l)(8), the amounts paid shall be the amounts determined under section 1834(g) for outpatient critical access hospital services, (S)(i) except as provided in clause (ii),subject to subparagraph (EE), with respect todrugs and biologicals (including intravenous immune globulin (as defined in section 1861(zz))) not paid on a cost or prospective payment basis as otherwise provided in this part (other than items and services described in subparagraph (B)), the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established in section 1842(o) (or, if applicable, under section 1847, 1847A, or 1847B), and(ii) with respect to insulin furnished on or after July 1, 2023, through an item of durable medical equipment covered under section 1861(n), the amounts paid shall be, subject to the fourth sentence of this subsection, 80 percent of the payment amount established under section 1847A (or section 1847B, if applicable) for such insulin, (T) with respect to medical nutrition therapy services (as defined in section 1861(vv)), the amount paid shall be 80 percent (or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual) of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) for the same services if furnished by a physician, (U) with respect to facility fees described in section 1834(m)(2)(B), the amounts paid shall be 80 percent of the lesser of the actual charge or the amounts specified in such section, (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1842(s) items), with respect to competitively priced items and services (described in section 1847(a)(2)) that are furnished in a competitive area, the amounts paid shall be the amounts described in section 1847(b)(5), (W) with respect to additional preventive services (as defined in section 1861(ddd)(1)), the amount paid

shall be (i) in the case of such services which are clinical diagnostic laboratory tests, the amount determined under subparagraph (D) (if such subparagraph were applied, by substituting "100 percent" for "80 percent"), and (ii) in the case of all other such services, 100 percent of the lesser of the actual charge for the service or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph, (X) with respect to personalized prevention plan services (as defined in section 1861(hhh)(1)), the amount paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined under the payment basis determined under section 1848, (Y) subject to subsection (dd), with respect to preventive services described in subparagraphs (A) and (B) of section 1861(ddd)(3) that are appropriate for the individual and, in the case of such services described in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population, the amount paid shall be 100 percent of (i) except as provided in clause (ii), the lesser of the actual charge for the services or the amount determined under the fee schedule that applies to such services under this part, and (ii) in the case of such services that are covered OPD services (as defined in subsection (t)(1)(B)), the amount determined under subsection (t), (Z) with respect to Federally qualified health center services for which payment is made under section 1834(o), the amounts paid shall be 80 percent of the lesser of the actual charge or the amount determined under such section, (AA) with respect to an applicable disposable device (as defined in paragraph (2) of section 1834(s)) furnished to an individual pursuant to paragraph (1) of such section, the amount paid shall be equal to 80 percent of the lesser of the actual charge or the amount determined under paragraph (3) of such section, (BB) with respect to home infusion therapy, the amount paid shall be an amount equal to 80 percent of the lesser of the actual charge for the services or the amount determined under section 1834(u), (CC) with respect to opioid use disorder treatment services furnished during an episode of care, the amount paid shall be equal to the amount payable under section 1834(w) less any copayment required as specified by the Secretary, (DD) with respect to a specified COVID–19 testing-related service described in paragraph (1) of subsection (cc) for which payment may be made under a specified outpatient payment provision described in paragraph (2) of such subsection, the amounts paid shall be 100 percent of the payment amount otherwise recognized under such respective specified outpatient payment provision for such service, (EE) with respect to a part B rebatable drug (as defined in paragraph (2) of section 1847A(i)) furnished on or after April 1, 2023, for which the payment amount for a calendar quarter under paragraph (3)(A)(ii)(I) of such section (or, in the case of a part B rebatable drug that is a selected drug (as defined in section 1192(c) for which, the payment amount described in section 1847A(b)(1)(B)) for such drug for such quarter exceeds the inflation-adjusted payment under paragraph (3)(A)(ii)(II) of such section for such quarter, the amounts paid shall be equal to the percent of the payment

amount under paragraph (3)(A)(ii)(I) of such section or section 1847A(b)(1)(B), as applicable, that equals the difference between (i) 100 percent, and (ii) the percent applied under section 1847A(i)(5)(B)(FF) with respect to marriage and family therapist services and mental health counselor services under section 1861(s)(2)(II), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist under subparagraph (L), (GG) with respect to lymphedema compression treatment items (as defined in section 1861(mmm)), the amount paid shall be equal to 80 percent of the lesser of the actual charge or the amount determined under the payment basis determined under section 1834(z), and (HH) with respect to items and services related to the administration of intravenous immune globulin furnished on or after January 1, 2024, as described in section 1861(zz), the amounts paid shall be the lesser of the 80 percent of the actual charge or the payment amount established under section 1842(o)(8);

(2) in the case of services described in section 1832(a)(2) (except those services described in subparagraphs (C), (D), (E), (F), (G), (H), and (I) of such section and unless otherwise specified in section 1881)—

(A) with respect to home health services (other than a covered osteoporosis drug) (as defined in section 1861(kk)), the amount determined under the prospective payment system under section 1895;

(B) with respect to other items and services (except those described in subparagraph (C), (D), or (E) of this paragraph and except as may be provided in section 1886 or section 1888(e)(9))—

(i) furnished before January 1, 1999, the lesser of—

(I) the reasonable cost of such services, as determined under section 1861(v), or

(II) the customary charges with respect to such services,—less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A), but in no case may the payment for such other services exceed 80 percent of such reasonable cost, or

(ii) if such services are furnished before January 1, 1999, by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this clause), free of charge or at nominal charges to the public, 80 percent of the amount determined in accordance with section 1814(b)(2), or

(iii) if such services are furnished on or after January 1, 1999, the amount determined under subsection (t), or

(iv) if (and for so long as) the conditions described in section 1814(b)(3) are met, the amounts determined under the reimbursement system described in such section;

(C) with respect to services described in the second sentence of section 1861(p), 80 percent of the reasonable charges for such services;

(D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i)(I)on the basis of a fee schedule determined under subsection(h)(1) (for tests furnished before January 1, 2017) or section 1834(d)(1), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1866) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (II) under section 1834A (for tests furnished on or after January 1, 2017), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1866) of the lesser of the amount determined under such section or the amount of the charges billed for the tests, or (ii) for tests furnished before January 1, 2017, on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate for such tests;

(E) with respect to—

(i) outpatient hospital radiology services (including diagnostic and therapeutic radiology, nuclear medicine and CAT scan procedures, magnetic resonance imaging, and ultrasound and other imaging services, but excluding screening mammography and, for services furnished on or after January 1, 2005, diagnostic mammography), and

(ii) effective for procedures performed on or after October 1, 1989, diagnostic procedures (as defined by the Secretary) described in section 1861(s)(3) (other than diagnostic x-ray tests and diagnostic laboratory tests),

the amount determined under subsection (n) or, for services or procedures performed on or after January 1, 1999, subsection (t);

(F) with respect to a covered osteoporosis drug (as defined in section 1861(kk)) furnished by a home health agency, 80 percent of the reasonable cost of such service, as determined under section 1861(v);

(G) with respect to items and services described in section 1861(s)(10)(A), the lesser of—

(i) the reasonable cost of such services, as determined under section 1861(v), or

(ii) the customary charges with respect to such services; and

(H) with respect to personalized prevention plan services (as defined in section 1861(hhh)(1)) furnished by an outpatient department of a hospital, the amount determined under paragraph (1)(X),

or, if such services are furnished by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this provision), free of charge or at nominal charges to the public, the amount determined in accordance with section 1814(b)(2);

(3) in the case of services described in section 1832(a)(2)(D)—

(A) except as provided in subparagraph (B), the costs which are reasonable and related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations, including those authorized under section 1861(v)(1)(A), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A), but in no case may the payment for such services (other than for items and services described in section 1861(s)(10)(A)) exceed 80 percent of such costs; or

(B) with respect to the services described in clause (ii) of section 1832(a)(2)(D) that are furnished to an individual enrolled with a MA plan under part C pursuant to a written agreement described in section 1853(a)(4), the amount (if any) by which—

(i) the amount of payment that would have otherwise been provided (I) under subparagraph (A) (calculated as if "100 percent" were substituted for "80 percent" in such subparagraph) for such services if the individual had not been so enrolled, or (II) in the case of such services furnished on or after the implementation date of the prospective payment system under section 1834(o), under such section (calculated as if "100 percent" were substituted for "80 percent" in such section) for such services if the individual had not been so enrolled; exceeds

(ii) the amount of the payments received under such written agreement for such services (not including any financial incentives provided for in such agreement such as risk pool payments, bonuses, or withholds),

less the amount the federally qualified health center may charge as described in section 1857(e)(3)(B);

(4) in the case of facility services described in section 1832(a)(2)(F), and outpatient hospital facility services furnished in connection with surgical procedures specified by the Secretary pursuant to section 1833(i)(1)(A), the applicable amount as determined under paragraph (2) or (3) of subsection (i) or subsection (t);

(5) in the case of covered items (described in section 1834(a)(13)) the amounts described in section 1834(a)(1);

(6) in the case of outpatient critical access hospital services, the amounts described in section 1834(g);

(7) in the case of prosthetic devices and orthotics and prosthetics (as described in section 1834(h)(4)), the amounts described in section 1834(h);

(8) in the case of—

(A) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished—

(i) by a rehabilitation agency, public health agency, clinic, comprehensive outpatient rehabilitation facility, or skilled nursing facility,

(ii) by a home health agency to an individual who is not homebound, or

(iii) by another entity under an arrangement with an entity described in clause (i) or (ii); and

(B) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished—

(i) by a hospital to an outpatient or to a hospital inpatient who is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness or is not so entitled to benefits under part A, or

(ii) by another entity under an arrangement with a hospital described in clause (i),

the amounts described in section 1834(k);

(9) in the case of services described in section 1832(a)(2)(E) that are not described in paragraph (8), the amounts described in section 1834(k); and

(10) with respect to rural emergency hospital services furnished on or after January 1, 2023, the amounts determined under section 1834(x).

Paragraph (3)(A) shall not apply to Federally qualified health center services furnished on or after the implementation date of the prospective payment system under section 1834(o). For services furnished on or after January 1, 2022, paragraph (1)(Y) shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test. The Secretary shall make such adjustments as may be necessary to the amounts paid as specified under paragraph (1)(S)(ii) for insulin furnished on or after July 1, 2023, through an item of durable medical equipment covered under section 1861(n), such that the amount of coinsurance payable by an individual enrolled under this part for a month's supply of such insulin does not exceed $35.

(b) Before applying subsection (a) with respect to expenses incurred by an individual during any calendar year, the total amount of the expenses incurred by such individual during such year (which would, except for this subsection, constitute incurred expenses from which benefits payable under subsection (a) are determinable) shall be reduced by a deductible of $75 for calendar years before 1991, $100 for 1991 through 2004, $110 for 2005, and for a subsequent year the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) ending with such subsequent year (rounded to the nearest $1); except that (1) such total amount shall not include expenses incurred for preventive services described in subparagraph (A) of section 1861(ddd)(3) that are rec-

ommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual., (2) such deductible shall not apply with respect to home health services (other than a covered osteoporosis drug (as defined in section 1861(kk))), (3) such deductible shall not apply with respect to clinical diagnostic laboratory tests for which payment is made under this part (A) under subsection (a)(1)(D)(i) or (a)(2)(D)(i) on an assignment-related basis, or to a provider having an agreement under section 1866, or (B) for tests furnished before January 1, 2017,on the basis of a negotiated rate determined under subsection (h)(6), (4) such deductible shall not apply to Federally qualified health center services, (5) such deductible shall not apply with respect to screening mammography (as described in section 1861(jj)), (6) such deductible shall not apply with respect to screening pap smear and screening pelvic exam (as described in section 1861(nn)), (7) such deductible shall not apply with respect to ultrasound screening for abdominal aortic aneurysm (as defined in section 1861(bbb)), (8) such deductible shall not apply with respect to colorectal cancer screening tests (as described in section 1861(pp)(1)), (9) such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1861(ww)), (10) such deductible shall not apply with respect to personalized prevention plan services (as defined in section 1861(hhh)(1)), (11) such deductible shall not apply with respect to any specified COVID–19 testing-related service described in paragraph (1) of subsection (cc) for which payment may be made under a specified outpatient payment provision described in paragraph (2) of such subsection, (12) such deductible shall not apply withrespect a COVID–19 vaccine and its administration describedin section 1861(s)(10)(A),, and (13) such deductible shall not apply with respect to insulin furnished on or after July 1, 2023, through an item of durable medical equipment covered under section 1861(n).. The total amount of the expenses incurred by an individual as determined under the preceding sentence shall, after the reduction specified in such sentence, be further reduced by an amount equal to the expenses incurred for the first three pints of whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished to the individual during the calendar year, except that such deductible for such blood shall in accordance with regulations be appropriately reduced to the extent that there has been a replacement of such blood (or equivalent quantities of packed red blood cells, as so defined); and for such purposes blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual shall be deemed replaced when the institution or other person furnishing such blood (or such equivalent quantities of packed red blood cells, as so defined) is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is made under this sentence. The deductible under the previous sentence for blood or blood cells furnished an individual in a year shall be reduced to the extent that a deductible has been imposed under section 1813(a)(2) to blood or blood cells furnished the individual in the year. Paragraph (1) of the first sentence of this subsection shall apply with respect to a colorectal cancer screening test regardless of the code that is billed

for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

(c)(1) Notwithstanding any other provision of this part, with respect to expenses incurred in a calendar year in connection with the treatment of mental, psychoneurotic, and personality disorders of an individual who is not an inpatient of a hospital at the time such expenses are incurred, there shall be considered as incurred expenses for purposes of subsections (a) and (b)—

(A) for expenses incurred in years prior to 2010, only 62½ percent of such expenses;

(B) for expenses incurred in 2010 or 2011, only 68¾ percent of such expenses;

(C) for expenses incurred in 2012, only 75 percent of such expenses;

(D) for expenses incurred in 2013, only 81¼ percent of such expenses; and

(E) for expenses incurred in 2014 or any subsequent calendar year, 100 percent of such expenses.

(2) For purposes of subparagraphs (A) through (D) of paragraph (1), the term "treatment" does not include brief office visits (as defined by the Secretary) for the sole purpose of monitoring or changing drug prescriptions used in the treatment of such disorders or partial hospitalization services or intensive outpatient services that are not directly provided by a physician

(d) No payment may be made under this part with respect to any services furnished an individual to the extent that such individual is entitled (or would be entitled except for section 1813) to have payment made with respect to such services under part A.

(e) No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

(f)(1) In establishing limits under subsection (a) on payment for rural health clinic services provided by rural health clinics (other than such clinics in hospitals with less than 50 beds), the Secretary shall establish such limit, for services provided prior to April 1, 2021—

(A) in 1988, after March 31, at $46 per visit, and

(B) in a subsequent year (before April 1, 2021), at the limit established under this paragraph for the previous year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) applicable to primary care services (as defined in section 1842(i)(4)) furnished as of the first day of that year.

(2) In establishing limits under subsection (a) on payment for rural health clinic services furnished on or after April 1, 2021, by a rural health clinic (other than a rural health clinic described in paragraph (3)(B)), the Secretary shall establish such limit, for services provided—

(A) in 2021, after March 31, at $100 per visit;

(B) in 2022, at $113 per visit;

(C) in 2023, at $126 per visit;
(D) in 2024, at $139 per visit;
(E) in 2025, at $152 per visit;
(F) in 2026, at $165 per visit;
(G) in 2027, at $178 per visit;
(H) in 2028, at $190 per visit; and
(I) in a subsequent year, at the limit established under this paragraph for the previous year increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of such subsequent year.

(3)(A) In establishing limits under subsection (a) on payment for rural health clinic services furnished on or after April 1, 2021, by a rural health clinic described in subparagraph (B), the Secretary shall establish such limit, with respect to each such rural health clinic, for services provided—

(i) in 2021, after March 31, at an amount equal to the greater of—

(I) with respect to a rural health clinic that had a per visit payment amount established for services furnished in 2020—

(aa) the per visit payment amount applicable to such rural health clinic for rural health clinic services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021; or

(bb) the limit described in paragraph (2)(A); and

(II) with respect to a rural health clinic that did not have a per visit payment amount established for services furnished in 2020—

(aa) the per visit payment amount applicable to such rural health clinic for rural health clinic services furnished in 2021; or

(bb) the limit described in paragraph (2)(A); and

(ii) in a subsequent year, at an amount equal to the greater of—

(I) the amount established under subclause (I) or (II) of clause (i), as applicable, or this subclause for the previous year with respect to such rural health clinic, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of such subsequent year; or

(II) the limit established under paragraph (2) for such subsequent year.

(B) A rural health clinic described in this subparagraph is a rural health clinic that—

(i) as of December 31, 2020, was in a hospital with less than 50 beds and after such date such hospital continues to have less than 50 beds (not taking into account any increase in the number of beds pursuant to a waiver under subsection (b)(1)(A) of section 1135 during the emergency period described in subsection (g)(1)(B) of such section); and

(ii)(I) as of December 31, 2020, was enrolled under section 1866(j) (including temporary enrollment during such emergency period for such emergency period); or

(II) submitted an application for enrollment under section 1866(j) (or a request for such a temporary enrollment for such emergency period) that was received not later than December 31, 2020.

(g)(1)(A) Subject to paragraphs (4) and (5), in the case of physical therapy services of the type described in section 1861(p) and speech-language pathology services of the type described in such section through the application of section 1861(ll)(2), but (except as provided in paragraph (6)) not described in subsection (a)(8)(B), and physical therapy services and speech-language pathology services of such type which are furnished by a physician or as incident to physicians' services, with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b). The preceding sentence shall not apply to expenses incurred with respect to services furnished after December 31, 2017.

(B) With respect to services furnished during 2018 or a subsequent year, in the case of physical therapy services of the type described in section 1861(p), speech-language pathology services of the type described in such section through the application of section 1861(ll)(2), and physical therapy services and speech-language pathology services of such type which are furnished by a physician or as incident to physicians' services, with respect to expenses incurred in any calendar year, any amount that is more than the amount specified in paragraph (2) for the year shall not be considered as incurred expenses for purposes of subsections (a) and (b) unless the applicable requirements of paragraph (7) are met.

(2) The amount specified in this paragraph—

(A) for 1999, 2000, and 2001, is $1,500, and

(B) for a subsequent year is the amount specified in this paragraph for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year;

except that if an increase under subparagraph (B) for a year is not a multiple of $10, it shall be rounded to the nearest multiple of $10.

(3)(A) Subject to paragraphs (4) and (5), in the case of occupational therapy services (of the type that are described in section 1861(p) (but (except as provided in paragraph (6)) not described in subsection (a)(8)(B)) through the operation of section 1861(g) and of such type which are furnished by a physician or as incident to physicians' services), with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b). The preceding sentence shall not apply to expenses incurred with respect to services furnished after December 31, 2017.

(B) With respect to services furnished during 2018 or a subsequent year, in the case of occupational therapy services (of the type that are described in section 1861(p) through the operation of section 1861(g) and of such type which are furnished by a physician or as incident to physicians' services), with respect to expenses incurred in any calendar year, any amount that is more than the amount specified in paragraph (2) for the year shall not be consid-

ered as incurred expenses for purposes of subsections (a) and (b) unless the applicable requirements of paragraph (7) are met.

(4) This subsection shall not apply to expenses incurred with respect to services furnished during 2000, 2001, 2002, 2004, and 2005.

(5)(A) With respect to expenses incurred during the period beginning on January 1, 2006, and ending on December 31, 2017, for services, the Secretary shall implement a process under which an individual enrolled under this part may, upon request of the individual or a person on behalf of the individual, obtain an exception from the uniform dollar limitation specified in paragraph (2), for services described in paragraphs (1) and (3) if the provision of such services is determined to be medically necessary and if the requirement of subparagraph (B) is met. Under such process, if the Secretary does not make a decision on such a request for an exception within 10 business days of the date of the Secretary's receipt of the request made in accordance with such requirement, the Secretary shall be deemed to have found the services to be medically necessary.

(B) In the case of outpatient therapy services for which an exception is requested under the first sentence of subparagraph (A), the claim for such services shall contain an appropriate modifier (such as the KX modifier used as of the date of the enactment of this subparagraph) indicating that such services are medically necessary as justified by appropriate documentation in the medical record involved.

(C)(i) In applying this paragraph with respect to a request for an exception with respect to expenses that would be incurred for outpatient therapy services (including services described in subsection (a)(8)(B)) that would exceed the threshold described in clause (ii) for a year, the request for such an exception, for services furnished on or after October 1, 2012, shall be subject to a manual medical review process that, subject to subparagraph (E), is similar to the manual medical review process used for certain exceptions under this paragraph in 2006.

(ii) The threshold under this clause for a year is $3,700. Such threshold shall be applied separately—

(I) for physical therapy services and speech-language pathology services; and

(II) for occupational therapy services.

(E)(i) In place of the manual medical review process under subparagraph (C)(i), the Secretary shall implement a process for medical review under this subparagraph under which the Secretary shall identify and conduct medical review for services described in subparagraph (C)(i) furnished by a provider of services or supplier (in this subparagraph referred to as a "therapy provider") using such factors as the Secretary determines to be appropriate.

(ii) Such factors may include the following:

(I) The therapy provider has had a high claims denial percentage for therapy services under this part or is less compliant with applicable requirements under this title.

(II) The therapy provider has a pattern of billing for therapy services under this part that is aberrant compared to peers or otherwise has questionable billing practices for such services, such as billing medically unlikely units of services in a day.

(III) The therapy provider is newly enrolled under this title or has not previously furnished therapy services under this part.

(IV) The services are furnished to treat a type of medical condition.

(V) The therapy provider is part of group that includes another therapy provider identified using the factors determined under this subparagraph.

(iii) For purposes of carrying out this subparagraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $5,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for fiscal years 2015 and 2016, to remain available until expended. Such funds may not be used by a contractor under section 1893(h) for medical reviews under this subparagraph.

(iv) The targeted review process under this subparagraph shall not apply to services for which expenses are incurred beyond the period for which the exceptions process under subparagraph (A) is implemented, except as such process is applied under paragraph (7)(B).

(6)(A) In applying paragraphs (1) and (3) to services furnished during the period beginning not later than October 1, 2012, and ending on December 31, 2017, the exclusion of services described in subsection (a)(8)(B) from the uniform dollar limitation specified in paragraph (2) shall not apply to such services furnished during 2012 through 2017.

(B)(i) With respect to outpatient therapy services furnished beginning on or after January 1, 2013, and before January 1, 2014, for which payment is made under section 1834(g), the Secretary shall count toward the uniform dollar limitations described in paragraphs (1) and (3) and the threshold described in paragraph (5)(C) the amount that would be payable under this part if such services were paid under section 1834(k)(1)(B) instead of being paid under section 1834(g).

(ii) Nothing in clause (i) shall be construed as changing the method of payment for outpatient therapy services under section 1834(g).

(7) For purposes of paragraphs (1)(B) and (3)(B), with respect to services described in such paragraphs, the requirements described in this paragraph are as follows:

(A) INCLUSION OF APPROPRIATE MODIFIER.—The claim for such services contains an appropriate modifier (such as the KX modifier described in paragraph (5)(B)) indicating that such services are medically necessary as justified by appropriate documentation in the medical record involved.

(B) TARGETED MEDICAL REVIEW FOR CERTAIN SERVICES ABOVE THRESHOLD.—

(i) IN GENERAL.—In the case where expenses that would be incurred for such services would exceed the threshold described in clause (ii) for the year, such services shall be subject to the process for medical review implemented under paragraph (5)(E).

(ii) THRESHOLD.—The threshold under this clause for—

(I) a year before 2028, is $3,000;

(II) 2028, is the amount specified in subclause (I) increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for 2028; and

(III) a subsequent year, is the amount specified in this clause for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year;

except that if an increase under subclause (II) or (III) for a year is not a multiple of $10, it shall be rounded to the nearest multiple of $10.

(iii) APPLICATION.—The threshold under clause (ii) shall be applied separately—

(I) for physical therapy services and speech-language pathology services; and

(II) for occupational therapy services.

(iv) FUNDING.—For purposes of carrying out this subparagraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account, of $5,000,000 for each fiscal year beginning with fiscal year 2018, to remain available until expended. Such funds may not be used by a contractor under section 1893(h) for medical reviews under this subparagraph.

(8) With respect to services furnished on or after January 1, 2013, where payment may not be made as a result of application of paragraphs (1) and (3), section 1879 shall apply in the same manner as such section applies to a denial that is made by reason of section 1862(a)(1).

(h)(1)(A) Subject to section 1834(d)(1), the Secretary shall establish fee schedules for clinical diagnostic laboratory tests (including prostate cancer screening tests under section 1861(oo) consisting of prostate-specific antigen blood tests) for which payment is made under this part, other than such tests performed by a provider of services for an inpatient of such provider.

(B) In the case of clinical diagnostic laboratory tests performed by a physician or by a laboratory (other than tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital), the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(C) In the case of clinical diagnostic laboratory tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital, the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(D) In this subsection, the term "qualified hospital laboratory" means a hospital laboratory, in a sole community hospital (as defined in section 1886(d)(5)(D)(iii)), which provides some clinical diagnostic laboratory tests 24 hours a day in order to serve a hospital emergency room which is available to provide services 24 hours a day and 7 days a week.

(2)(A)(i) Except as provided in clause (v), subparagraph (B), and paragraph (4), the Secretary shall set the fee schedules at 60 percent (or, in the case of a test performed by a qualified hospital laboratory (as defined in paragraph (1)(D)) for outpatients of such hospital, 62 percent) of the prevailing charge level determined pursuant to the third and fourth sentences of section 1842(b)(3) for similar clinical diagnostic laboratory tests for the applicable region, State, or area for the 12-month period beginning July 1, 1984, adjusted annually (to become effective on January 1 of each year) by, subject to clause (iv), a percentage increase or decrease equal to the percentage increase or decrease in the Consumer Price Index for All Urban Consumers (United States city average) minus, for each of the years 2009 and 2010, 0.5 percentage points, and, for tests furnished before the dateof enactment of section 1834A, subject to such other adjustments as the Secretary determines are justified by technological changes.

(ii) Notwithstanding clause (i)—

(I) any change in the fee schedules which would have become effective under this subsection for tests furnished on or after January 1, 1988, shall not be effective for tests furnished during the 3-month period beginning on January 1, 1988,

(II) the Secretary shall not adjust the fee schedules under clause (i) to take into account any increase in the consumer price index for 1988,

(III) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1991, 1992, and 1993 shall be 2 percent, and

(IV) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1994 and 1995, 1998 through 2002, and 2004 through 2008 shall be 0 percent.

(iii) In establishing fee schedules under clause (i) with respect to automated tests and tests (other than cytopathology tests) which before July 1, 1984, the Secretary made subject to a limit based on lowest charge levels under the sixth sentence of section 1842(b)(3) performed after March 31, 1988, the Secretary shall reduce by 8.3 percent the fee schedules otherwise established for 1988, and such reduced fee schedules shall serve as the base for 1989 and subsequent years.

(iv) After determining the adjustment to the fee schedules under clause (i), the Secretary shall reduce such adjustment—

(I) for 2011 and each subsequent year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(II) for each of 2011 through 2015, by 1.75 percentage points.

Subclause (I) shall not apply in a year where the adjustment to the fee schedules determined under clause (i) is 0.0 or a percentage decrease for a year. The application of the productivity adjustment under subclause (I) shall not result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year. The application of subclause (II) may result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year, and may result in payment rates for a year being less than such payment rates for the preceding year.

(v) The Secretary shall reduce by 2 percent the fee schedules otherwise determined under clause (i) for 2013, and such reduced fee schedules shall serve as the base for 2014 and subsequent years.

(B) The Secretary may make further adjustments or exceptions to the fee schedules to assure adequate reimbursement of (i) emergency laboratory tests needed for the provision of bona fide emergency services, and (ii) certain low volume high-cost tests where highly sophisticated equipment or extremely skilled personnel are necessary to assure quality.

(3) In addition to the amounts provided under the fee schedules (for tests furnished before January 1, 2017)or under section 1834A (for tests furnished on or afterJanuary 1, 2017), subject to subsection (b)(5) of such section, the Secretary shall provide for and establish (A) a nominal fee to cover the appropriate costs in collecting the sample on which a clinical diagnostic laboratory test was performed and for which payment is made under this part, except that not more than one such fee may be provided under this paragraph with respect to samples collected in the same encounter, and (B) a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). In establishing a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, the Secretary shall provide a method for computing the fee based on the number of miles traveled and the personnel costs associated with the collection of each individual sample, but the Secretary shall only be required to apply such method in the case of tests furnished during the period beginning on April 1, 1989, and ending on December 31, 1990, by a laboratory that establishes to the satisfaction of the Secretary (based on data for the 12-month period ending June 30, 1988) that (i) the laboratory is dependent upon payments under this title for at least 80 percent of its collected revenues for clinical diagnostic laboratory tests, (ii) at least 85 percent of its gross revenues for such tests are attributable to tests performed with respect to individuals who are homebound or who are residents in a nursing facility, and (iii) the laboratory provided such tests for residents in nursing facilities representing at least 20 percent of the number of such facilities in the State in which the laboratory is located.

(4)(A) In establishing any fee schedule under this subsection, the Secretary may provide for an adjustment to take into account, with respect to the portion of the expenses of clinical diagnostic laboratory tests attributable to wages, the relative difference between a region's or local area's wage rates and the wage rate presumed in the data on which the schedule is based.

(B) For purposes of subsections (a)(1)(D)(i) and (a)(2)(D)(i), the limitation amount for a clinical diagnostic laboratory test performed—

(i) on or after July 1, 1986, and before April 1, 1988, is equal to 115 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(ii) after March 31, 1988, and before January 1, 1990, is equal to the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iii) after December 31, 1989, and before January 1, 1991, is equal to 93 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iv) after December 31, 1990, and before January 1, 1994, is equal to 88 percent of such median,

(v) after December 31, 1993, and before January 1, 1995, is equal to 84 percent of such median,

(vi) after December 31, 1994, and before January 1, 1996, is equal to 80 percent of such median,

(vii) after December 31, 1995, and before January 1, 1998, is equal to 76 percent of such median, and

(viii) after December 31, 1997, is equal to 74 percent of such median (or 100 percent of such median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001, that the Secretary determines is a new test for which no limitation amount has previously been established under this subparagraph).

(5)(A) In the case of a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part on an assignment-related basis or under a provider agreement under section 1866, payment may be made only to the person or entity which performed or supervised the performance of such test; except that—

(i) if a physician performed or supervised the performance of such test, payment may be made to another physician with whom he shares his practice,

(ii) in the case of a test performed at the request of a laboratory by another laboratory, payment may be made to the referring laboratory but only if—

(I) the referring laboratory is located in, or is part of, a rural hospital,

(II) the referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both the referring laboratory and the entity performing such test are wholly-owned by a third entity, or

(III) not more than 30 percent of the clinical diagnostic laboratory tests for which such referring laboratory (but not including a laboratory described in subclause (II)), receives requests for testing during the year in which the test is performed are performed by another laboratory, and

(iii) in the case of a clinical diagnostic laboratory test provided under an arrangement (as defined in section 1861(w)(1)) made by a hospital, critical access hospital, or skilled nursing facility, payment shall be made to the hospital or skilled nursing facility.

(B) In the case of such a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part, and which is not described in subparagraph (A), payment may be made to the beneficiary only on the basis of the itemized bill of the person or entity which performed or supervised the performance of the test.

(C) Payment for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test per-

formed by a rural health clinic may only be made on an assignment-related basis or to a provider of services with an agreement in effect under section 1866.

(D) A person may not bill for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test performed by a rural health clinic, other than on an assignment-related basis. If a person knowingly and willfully and on a repeated basis bills for a clinical diagnostic laboratory test in violation of the previous sentence, the Secretary may apply sanctions against the person in the same manner as the Secretary may apply sanctions against a physician in accordance with paragraph (2) of section 1842(j) in the same manner such paragraphs apply with respect to a physician. Paragraph (4) of such section shall apply in this subparagraph in the same manner as such paragraph applies to such section.

(6) For tests furnished before January 1, 2017, inthe case of any diagnostic laboratory test payment for which is not made on the basis of a fee schedule under paragraph (1), the Secretary may establish a payment rate which is acceptable to the person or entity performing the test and which would be considered the full charge for such tests. Such negotiated rate shall be limited to an amount not in excess of the total payment that would have been made for the services in the absence of such rate.

(7) Notwithstanding paragraphs (1) and (4)and section 1834A, the Secretary shall establish a national minimum payment amount under this part for a diagnostic or screening pap smear laboratory test (including all cervical cancer screening technologies that have been approved by the Food and Drug Administration as a primary screening method for detection of cervical cancer) equal to $14.60 for tests furnished in 2000. For such tests furnished in subsequent years, such national minimum payment amount shall be adjusted annually as provided in paragraph (2).

(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as "new tests").

(B) Determinations under subparagraph (A) shall be made only after the Secretary—

(i) makes available to the public (through an Internet website and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and

recommendations (and data on which the recommendations are based);

(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

(i) set forth the criteria for making determinations under subparagraph (A); and

(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

(E) For purposes of this paragraph:

(i) The term "HCPCS" refers to the Health Care Procedure Coding System.

(ii) A code shall be considered to be "substantially revised" if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).

(9) Notwithstanding any other provision in this part, in the case of any diagnostic laboratory test for HbA1c that is labeled by the Food and Drug Administration for home use and is furnished on or after April 1, 2008, the payment rate for such test shall be the payment rate established under this part for a glycated hemoglobin test (identified as of October 1, 2007, by HCPCS code 83036 (and any succeeding codes)).

(i)(1) The Secretary shall, in consultation with appropriate medical organizations—

(A) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in an ambulatory surgical center (meeting the standards specified under section 1832(a)(2)(F)(i)), critical access hospital, or hospital outpatient department, and

(B) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital

inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in a physician's office.

The lists of procedures established under subparagraphs (A) and (B) shall be reviewed and updated not less often than every 2 years, in consultation with appropriate trade and professional organizations.

(2)(A) For services furnished prior to the implementation of the system described in subparagraph (D), subject to subparagraph (E), the amount of payment to be made for facility services furnished in connection with a surgical procedure specified pursuant to paragraph (1)(A) and furnished to an individual in an ambulatory surgical center described in such paragraph shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary's estimate of a fair fee which—

(i) takes into account the costs incurred by such centers, or classes of centers, generally in providing services furnished in connection with the performance of such procedure, as determined in accordance with a survey (based upon a representative sample of procedures and facilities) of the actual audited costs incurred by such centers in providing such services,

(ii) takes such costs into account in such a manner as will assure that the performance of the procedure in such a center will result in substantially less amounts paid under this title than would have been paid if the procedure had been performed on an inpatient basis in a hospital, and

(iii) in the case of insertion of an intraocular lens during or subsequent to cataract surgery includes payment which is reasonable and related to the cost of acquiring the class of lens involved.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(B) The amount of payment to be made under this part for facility services furnished, in connection with a surgical procedure specified pursuant to paragraph (1)(B), in a physician's office shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary's estimate of a fair fee which—

(i) takes into account additional costs, not usually included in the professional fee, incurred by physicians in securing, maintaining, and staffing the facilities and ancillary services appropriate for the performance of such procedure in the physician's office, and

(ii) takes such items into account in such a manner which will assure that the performance of such procedure in the physician's office will result in substantially less amounts paid under this title than would have been paid if the services had been furnished on an inpatient basis in a hospital.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(C)(i) Notwithstanding the second sentence of each of subparagraphs (A) and (B), except as otherwise specified in clauses (ii),

(iii), and (iv), if the Secretary has not updated amounts established under such subparagraphs or under subparagraph (D), with respect to facility services furnished during a fiscal year (beginning with fiscal year 1986 or a calendar year (beginning with 2006)), such amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(ii) In each of the fiscal years 1998 through 2002, the increase under this subparagraph shall be reduced (but not below zero) by 2.0 percentage points.

(iii) In fiscal year 2004, beginning with April 1, 2004, the increase under this subparagraph shall be the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with March 31, 2003, minus 3.0 percentage points.

(iv) In fiscal year 2005, the last quarter of calendar year 2005, and each of calendar years 2006 through 2009, the increase under this subparagraph shall be 0 percent.

(D)(i) Taking into account the recommendations in the report under section 626(d) of Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall implement a revised payment system for payment of surgical services furnished in ambulatory surgical centers.

(ii) In the year the system described in clause (i) is implemented, such system shall be designed to result in the same aggregate amount of expenditures for such services as would be made if this subparagraph did not apply, as estimated by the Secretary and taking into account reduced expenditures that would apply if subparagraph (E) were to continue to apply, as estimated by the Secretary.

(iii) The Secretary shall implement the system described in clause (i) for periods in a manner so that it is first effective beginning on or after January 1, 2006, and not later than January 1, 2008.

(iv) The Secretary may implement such system in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).

(v) In implementing the system described in clause (i) for 2011 and each subsequent year, any annual update under such system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). The application of the preceding sentence may result in such update being less than 0.0 for a year, and may result in payment rates under the system described in clause (i) for a year being less than such payment rates for the preceding year.

(vi) There shall be no administrative or judicial review under section 1869, 1878, or otherwise, of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, under this subparagraph.

(E) With respect to surgical procedures furnished on or after January 1, 2007, and before the effective date of the implementation of a revised payment system under subparagraph (D), if—

(i) the standard overhead amount under subparagraph (A) for a facility service for such procedure, without the application of any geographic adjustment, exceeds

(ii) the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department services under paragraph (3)(D) of section 1833(t) for such service for such year, determined without regard to geographic adjustment under paragraph (2)(D) of such section,

the Secretary shall substitute under subparagraph (A) the amount described in clause (ii) for the standard overhead amount for such service referred to in clause (i).

(3)(A) The aggregate amount of the payments to be made under this part for outpatient hospital facility services or critical access hospital services furnished before January 1, 1999, in connection with surgical procedures specified under paragraph (1)(A) shall be equal to the lesser of—

(i) the amount determined with respect to such services under subsection (a)(2)(B); or

(ii) the blend amount (described in subparagraph (B)).

(B)(i) The blend amount for a cost reporting period is the sum of—

(I) the cost proportion (as defined in clause (ii)(I)) of the amount described in subparagraph (A)(i), and

(II) the ASC proportion (as defined in clause (ii)(II)) of the standard overhead amount payable with respect to the same surgical procedure as if it were provided in an ambulatory surgical center in the same area, as determined under paragraph (2)(A), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A).

(ii) Subject to paragraph (4), in this paragraph:

(I) The term "cost proportion" means 75 percent for cost reporting periods beginning in fiscal year 1988, 50 percent for portions of cost reporting periods beginning on or after October 1, 1988, and ending on or before December 31, 1990, and 42 percent for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term "ASC proportion" means 25 percent for cost reporting periods beginning in fiscal year 1988, 50 percent for portions of cost reporting periods beginning on or after October 1, 1988, and ending on or before December 31, 1990, and 58 percent for portions of cost reporting periods beginning on or after January 1, 1991.

(4)(A) In the case of a hospital that—

(i) makes application to the Secretary and demonstrates that it specializes in eye services or eye and ear services (as determined by the Secretary),

(ii) receives more than 30 percent of its total revenues from outpatient services, and

(iii) on October 1, 1987—

(I) was an eye specialty hospital or an eye and ear specialty hospital, or

(II) was operated as an eye or eye and ear unit (as defined in subparagraph (B)) of a general acute care hospital which, on the date of the application described in clause (i), operates less than 20 percent of the beds that the hos-

pital operated on October 1, 1987, and has sold or otherwise disposed of a substantial portion of the hospital's other acute care operations,

the cost proportion and ASC proportion in effect under subclauses (I) and (II) of paragraph (3)(B)(ii) for cost reporting periods beginning in fiscal year 1988 shall remain in effect for cost reporting periods beginning on or after October 1, 1988, and before January 1, 1995.

(B) For purposes of this subparagraph (A)(iii)(II), the term "eye or eye and ear unit" means a physically separate or distinct unit containing separate surgical suites devoted solely to eye or eye and ear services.

(5)(A) The Secretary is authorized to provide by regulations that in the case of a surgical procedure, specified by the Secretary pursuant to paragraph (1)(A), performed in an ambulatory surgical center described in such paragraph, there shall be paid (in lieu of any amounts otherwise payable under this part) with respect to the facility services furnished by such center and with respect to all related services (including physicians' services, laboratory, X-ray, and diagnostic services) a single all-inclusive fee established pursuant to subparagraph (B), if all parties furnishing all such services agree to accept such fee (to be divided among the parties involved in such manner as they shall have previously agreed upon) as full payment for the services furnished.

(B) In implementing this paragraph, the Secretary shall establish with respect to each surgical procedure specified pursuant to paragraph (1)(A) the amount of the all-inclusive fee for such procedure, taking into account such factors as may be appropriate. The amount so established with respect to any surgical procedure shall be reviewed periodically and may be adjusted by the Secretary, when appropriate, to take account of varying conditions in different areas.

(6) Any person, including a facility having an agreement under section 1832(a)(2)(F)(i), who knowingly and willfully presents, or causes to be presented, a bill or request for payment, for an intraocular lens inserted during or subsequent to cataract surgery for which payment may be made under paragraph (2)(A)(iii), is subject to a civil money penalty of not to exceed $2,000. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(7)(A) For purposes of paragraph (2)(D)(iv), the Secretary may provide, in the case of an ambulatory surgical center that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to a year, any annual increase provided under the system established under paragraph (2)(D) for such year shall be reduced by 2.0 percentage points. A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing any annual increase factor for a subsequent year.

(B) Except as the Secretary may otherwise provide, the provisions of subparagraphs (B), (C), (D), and (E) of paragraph (17) of section 1833(t) shall apply with respect to services of ambulatory

surgical centers under this paragraph in a similar manner to the manner in which they apply under such paragraph and, for purposes of this subparagraph, any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ambulatory surgical center, the setting of such a center, or services of such a center, respectively.

(8) The Secretary shall conduct a similar type of review as required under paragraph (22) of section 1833(t)), including the second sentence of subparagraph (C) of such paragraph, to payment for services under this subsection, and make such revisions under this paragraph, in an appropriate manner (as determined by the Secretary).

(9) In the case of a part B rebatable drug (as defined in paragraph (2) of section 1847A(i)) for which payment under this subsection is not packaged into a payment for a service furnished on or after April 1, 2023, under the revised payment system under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section 1847A(i)(5) and paragraph (1)(EE) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1847A(i)(5) and subsection (a) apply under such section and subsection.

(10) TEMPORARY ADDITIONAL PAYMENTS FOR NON-OPIOID TREATMENTS FOR PAIN RELIEF.—

(A) IN GENERAL.—In the case of surgical services furnished on or after January 1, 2025, and before January 1, 2028, the payment system described in paragraph (2)(D)(i) shall provide, in a budget-neutral manner, for an additional payment for a non-opioid treatment for pain relief (as defined in clause (iv) of subsection (t)(16)(G)) furnished as part of such services in the amount specified in clause (ii) of such subsection, subject to the limitation under clause (iii) of such subsection.

(B) TRANSITION.—A drug or biological that meets the requirements of section 416.174 of title 42, Code of Federal Regulations (or any successor regulation) and is a non-opioid treatment for pain relief (as defined in clause (iv) of subsection (t)(16)(G)) shall receive additional payment in the amount specified in clause (ii) of such subsection, subject to the limitation under clause (iii) of such subsection.

(j) Whenever a final determination is made that the amount of payment made under this part either to a provider of services or to another person pursuant to an assignment under section 1842(b)(3)(B)(ii) was in excess of or less than the amount of payment that is due, and payment of such excess or deficit is not made (or effected by offset) within 30 days of the date of the determination, interest shall accrue on the balance of such excess or deficit not paid or offset (to the extent that the balance is owed by or owing to the provider) at a rate determined in accordance with the regulations of the Secretary of the Treasury applicable to charges for late payments (or, in the case of such a determination made with respect to a payment made on or after the date of the enactment of the CARES Act and during the period at the end of the emergency sentence described in section 1135(g)(1)(B) under the

program described in section 421.214 of title 42, Code of Federal Regulations (or any successor regulation), at a rate of 4 percent).

(k) With respect to services described in section 1861(s)(10)(B), the Secretary may provide, instead of the amount of payment otherwise provided under this part, for payment of such an amount or amounts as reasonably reflects the general cost of efficiently providing such services.

(l)(1)(A) The Secretary shall establish a fee schedule for services of certified registered nurse anesthetists under section 1861(s)(11).

(B) In establishing the fee schedule under this paragraph the Secretary may utilize a system of time units, a system of base and time units, or any appropriate methodology.

(C) The provisions of this subsection shall not apply to certain services furnished in certain hospitals in rural areas under the provisions of section 9320(k) of the Omnibus Budget Reconciliation Act of 1986, as amended by section 6132 of the Omnibus Budget Reconciliation Act of 1989.

(2) Except as provided in paragraph (3), the fee schedule established under paragraph (1) shall be initially based on audited data from cost reporting periods ending in fiscal year 1985 and such other data as the Secretary determines necessary.

(3)(A) In establishing the initial fee schedule for those services, the Secretary shall adjust the fee schedule to the extent necessary to ensure that the estimated total amount which will be paid under this title for those services plus applicable coinsurance in 1989 will equal the estimated total amount which would be paid under this title for those services in 1989 if the services were included as inpatient hospital services and payment for such services was made under part A in the same manner as payment was made in fiscal year 1987, adjusted to take into account changes in prices and technology relating to the administration of anesthesia.

(B) The Secretary shall also reduce the prevailing charge of physicians for medical direction of a certified registered nurse anesthetist, or the fee schedule for services of certified registered nurse anesthetists, or both, to the extent necessary to ensure that the estimated total amount which will be paid under this title plus applicable coinsurance for such medical direction and such services in 1989 and 1990 will not exceed the estimated total amount which would have been paid plus applicable coinsurance but for the enactment of the amendments made by section 9320 of the Omnibus Budget Reconciliation Act of 1986. A reduced prevailing charge under this subparagraph shall become the prevailing charge but for subsequent years for purposes of applying the economic index under the fourth sentence of section 1842(b)(3).

(4)(A) Except as provided in subparagraphs (C) and (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, by a certified registered nurse anesthetist who is not medically directed—

(i) the conversion factor shall be—

(I) for services furnished in 1991, $15.50,

(II) for services furnished in 1992, $15.75,

(III) for services furnished in 1993, $16.00,

(IV) for services furnished in 1994, $16.25,

(V) for services furnished in 1995, $16.50,

(VI) for services furnished in 1996, $16.75, and

(VII) for services furnished in calendar years after 1996, the previous year's conversion factor increased by the update determined under section 1848(d) for physician anesthesia services for that year;

(ii) the payment areas to be used shall be the fee schedule areas used under section 1848 (or, in the case of services furnished during 1991, the localities used under section 1842(b)) for purposes of computing payments for physicians' services that are anesthesia services;

(iii) the geographic adjustment factors to be applied to the conversion factor under clause (i) for services in a fee schedule area or locality is—

(I) in the case of services furnished in 1991, the geographic work index value and the geographic practice cost index value specified in section 1842(q)(1)(B) for physicians' services that are anesthesia services furnished in the area or locality, and

(II) in the case of services furnished after 1991, the geographic work index value, the geographic practice cost index value, and the geographic malpractice index value used for determining payments for physicians' services that are anesthesia services under section 1848,

with 70 percent of the conversion factor treated as attributable to work and 30 percent as attributable to overhead for services furnished in 1991 (and the portions attributable to work, practice expenses, and malpractice expenses in 1992 and thereafter being the same as is applied under section 1848).

(B)(i) Except as provided in clause (ii) and subparagraph (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, and before January 1, 1994, by a certified registered nurse anesthetist who is medically directed, the Secretary shall apply the same methodology specified in subparagraph (A).

(ii) The conversion factor used under clause (i) shall be—

(I) for services furnished in 1991, $10.50,

(II) for services furnished in 1992, $10.75, and

(III) for services furnished in 1993, $11.00.

(iii) In the case of services of a certified registered nurse anesthetist who is medically directed or medically supervised by a physician which are furnished on or after January 1, 1994, the fee schedule amount shall be one-half of the amount described in section 1848(a)(5)(B) with respect to the physician.

(C) Notwithstanding subclauses (I) through (V) of subparagraph (A)(i)—

(i) in the case of a 1990 conversion factor that is greater than $16.50, the conversion factor for a calendar year after 1990 and before 1996 shall be the 1990 conversion factor reduced by the product of the last digit of the calendar year and one-fifth of the amount by which the 1990 conversion factor exceeds $16.50; and

(ii) in the case of a 1990 conversion factor that is greater than $15.49 but less than $16.51, the conversion factor for a calendar year after 1990 and before 1996 shall be the greater of—

(I) the 1990 conversion factor, or

(II) the conversion factor specified in subparagraph (A)(i) for the year involved.

(D) Notwithstanding subparagraph (C), in no case may the conversion factor used to determine payment for services in a fee schedule area or locality under this subsection, as adjusted by the adjustment factors specified in subparagraphs (A)(iii), exceed the conversion factor used to determine the amount paid for physicians' services that are anesthesia services in the area or locality.

(5)(A) Payment for the services of a certified registered nurse anesthetist (for which payment may otherwise be made under this part) may be made on the basis of a claim or request for payment presented by the certified registered nurse anesthetist furnishing such services, or by a hospital, critical access hospital, physician, group practice, or ambulatory surgical center with which the certified registered nurse anesthetist furnishing such services has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, critical access hospital, physician, group practice, or ambulatory surgical center.

(B) No hospital or critical access hospital that presents a claim or request for payment for services of a certified nurse anesthetist under this part may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital or critical access hospital for purposes of this title.

(6) If an adjustment under paragraph (3)(B) results in a reduction in the reasonable charge for a physicians' service and a nonparticipating physician furnishes the service to an individual entitled to benefits under this part after the effective date of the reduction, the physician's actual charge is subject to a limit under section 1842(j)(1)(D).

(m)(1) In the case of physicians' services furnished in a year to an individual, who is covered under the insurance program established by this part and who incurs expenses for such services, in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area as identified by the Secretary prior to the beginning of such year, in addition to the amount otherwise paid under this part, there also shall be paid to the physician (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6)) (on a monthly or quarterly basis) from the Federal Supplementary Medical Insurance Trust Fund an amount equal to 10 percent of the payment amount for the service under this part.

(2) For each health professional shortage area identified in paragraph (1) that consists of an entire county, the Secretary shall provide for the additional payment under paragraph (1) without any requirement on the physician to identify the health professional shortage area involved. The Secretary may implement the previous sentence using the method specified in subsection (u)(4)(C).

(3) The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a list of the health professional shortage areas identified in paragraph (1) that consist of a partial county to facilitate the additional payment under paragraph (1) in such areas.

(4) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, respecting—

(A) the identification of a county or area;

(B) the assignment of a specialty of any physician under this paragraph;

(C) the assignment of a physician to a county under this subsection; or

(D) the assignment of a postal ZIP Code to a county or other area under this subsection.

(n)(1)(A) The aggregate amount of the payments to be made for all or part of a cost reporting period for services described in subsection (a)(2)(E)(i) furnished under this part on or after October 1, 1988, and before January 1, 1999, and for services described in subsection (a)(2)(E)(ii) furnished under this part on or after October 1, 1989, and before January 1, 1999, shall be equal to the lesser of—

(i) the amount determined with respect to such services under subsection (a)(2)(B), or

(ii) the blend amount for radiology services and diagnostic procedures determined in accordance with subparagraph (B).

(B)(i) The blend amount for radiology services and diagnostic procedures for a cost reporting period is the sum of—

(I) the cost proportion (as defined in clause (ii)) of the amount described in subparagraph (A)(i); and

(II) the charge proportion (as defined in clause (ii)(II)) of 62 percent (for services described in subsection (a)(2)(E)(i)), or (for procedures described in subsection (a)(2)(E)(ii)), 42 percent or such other percent established by the Secretary (or carriers acting pursuant to guidelines issued by the Secretary) based on prevailing charges established with actual charge data, of the prevailing charge or (for services described in subsection (a)(2)(E)(i) furnished on or after January 1, 1989) the fee schedule amount established for participating physicians for the same services as if they were furnished in a physician's office in the same locality as determined under section 1842(b), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A).

(ii) In this subparagraph:

(I) The term "cost proportion" means 50 percent, except that such term means 65 percent in the case of outpatient radiology services for portions of cost reporting periods which occur in fiscal year 1989 and in the case of diagnostic procedures described in subsection (a)(2)(E)(ii) for portions of cost reporting periods which occur in fiscal year 1990, and such term means 42 percent in the case of outpatient radiology services for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term "charge proportion" means 100 percent minus the cost proportion.

(o)(1) In the case of shoes described in section 1861(s)(12)—

(A) no payment may be made under this part, with respect to any individual for any year, for the furnishing of—

(i) more than one pair of custom molded shoes (including inserts provided with such shoes) and 2 additional pairs of inserts for such shoes, or

(ii) more than one pair of extra-depth shoes (not including inserts provided with such shoes) and 3 pairs of inserts for such shoes, and

(B) with respect to expenses incurred in any calendar year, no more than the amount of payment applicable under paragraph (2) shall be considered as incurred expenses for purposes of subsections (a) and (b).

Payment for shoes (or inserts) under this part shall be considered to include payment for any expenses for the fitting of such shoes (or inserts).

(2)(A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra-depth shoes, and inserts shall be the amount determined for such items by the Secretary under section 1834(h).

(B) The Secretary may establish payment amounts for shoes and inserts that are lower than the amount established under section 1834(h) if the Secretary finds that shoes and inserts of an appropriate quality are readily available at or below the amount established under such section.

(C) In accordance with procedures established by the Secretary, an individual entitled to benefits with respect to shoes described in section 1861(s)(12) may substitute modification of such shoes instead of obtaining one (or more, as specified by the Secretary) pair of inserts (other than the original pair of inserts with respect to such shoes). In such case, the Secretary shall substitute, for the payment amount established under section 1834(h), a payment amount that the Secretary estimates will assure that there is no net increase in expenditures under this subsection as a result of this subparagraph.

(3) In this title, the term "shoes" includes, except for purposes of subparagraphs (A)(ii) and (B) of paragraph (2), inserts for extra-depth shoes.

(q)(1) Each request for payment, or bill submitted, for an item or service furnished by an entity for which payment may be made under this part and for which the entity knows or has reason to believe there has been a referral by a referring physician (within the meaning of section 1877) shall include the name and unique physician identification number for the referring physician.

(2)(A) In the case of a request for payment for an item or service furnished by an entity under this part on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included, payment may be denied under this part.

(B) In the case of a request for payment for an item or service furnished by an entity under this part not submitted on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included—

(i) if the entity knowingly and willfully fails to provide such information promptly upon request of the Secretary or a carrier, the entity may be subject to a civil money penalty in an amount not to exceed $2,000, and

(ii) if the entity knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection to provide the information

required under paragraph (1), the entity may be subject to exclusion from participation in the programs under this Act for a period not to exceed 5 years, in accordance with the procedures of subsections (c), (f), and (g) of section 1128.

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under clause (i) in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(r)(1) With respect to services described in section 1861(s)(2)(K)(ii) (relating to nurse practitioner or clinical nurse specialist services), payment may be made on the basis of a claim or request for payment presented by the nurse practitioner or clinical nurse specialist furnishing such services, or by a hospital, critical access hospital, skilled nursing facility or nursing facility (as defined in section 1919(a)), physician, group practice, or ambulatory surgical center with which the nurse practitioner or clinical nurse specialist has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, physician, group practice, or ambulatory surgical center.

(2) No hospital or critical access hospital that presents a claim or request for payment under this part for services described in section 1861(s)(2)(K)(ii) may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital for purposes of this title.

(s) The Secretary may not provide for payment under subsection (a)(1)(A) with respect to an organization unless the organization provides assurances satisfactory to the Secretary that the organization meets the requirement of section 1866(f) (relating to maintaining written policies and procedures respecting advance directives).

(t) PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.—

(1) AMOUNT OF PAYMENT.—

(A) IN GENERAL.—With respect to covered OPD services (as defined in subparagraph (B)) furnished during a year beginning with 1999, the amount of payment under this part shall be determined under a prospective payment system established by the Secretary in accordance with this subsection.

(B) DEFINITION OF COVERED OPD SERVICES.—For purposes of this subsection, the term "covered OPD services"—

(i) means hospital outpatient services designated by the Secretary;

(ii) subject to clause (iv), includes inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (I) is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness, or (II) is not so entitled;

(iii) includes implantable items described in paragraph (3), (6), or (8) of section 1861(s);

(iv) does not include any therapy services described in subsection (a)(8) or ambulance services, for which payment is made under a fee schedule described in

section 1834(k) or section 1834(l) and does not include screening mammography (as defined in section 1861(jj)), diagnostic mammography, or personalized prevention plan services (as defined in section 1861(hhh)(1)); and

(v) does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of such paragraph).

(2) SYSTEM REQUIREMENTS.—Under the payment system—

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner;

(E) the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and temporary additional payments for non-opioid treatments for pain relief under paragraph (16)(G), and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals;

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not; and

(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive inten-

sity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.

For purposes of subparagraph (B), items and services within a group shall not be treated as "comparable with respect to the use of resources" if the highest median cost (or mean cost, if elected by the Secretary under subparagraph (C)) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the group; except that the Secretary may make exceptions in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act.

(3) CALCULATION OF BASE AMOUNTS.—

(A) AGGREGATE AMOUNTS THAT WOULD BE PAYABLE IF DEDUCTIBLES WERE DISREGARDED.—The Secretary shall estimate the sum of—

(i) the total amounts that would be payable from the Trust Fund under this part for covered OPD services in 1999, determined without regard to this subsection, as though the deductible under section 1833(b) did not apply, and

(ii) the total amounts of copayments estimated to be paid under this subsection by beneficiaries to hospitals for covered OPD services in 1999, as though the deductible under section 1833(b) did not apply.

(B) UNADJUSTED COPAYMENT AMOUNT.—

(i) IN GENERAL.—For purposes of this subsection, subject to clause (ii), the "unadjusted copayment amount" applicable to a covered OPD service (or group of such services) is 20 percent of the national median of the charges for the service (or services within the group) furnished during 1996, updated to 1999 using the Secretary's estimate of charge growth during the period.

(ii) ADJUSTED TO BE 20 PERCENT WHEN FULLY PHASED IN.—If the pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year would be equal to or exceed 80 percent, then the unadjusted copayment amount shall be 20 percent of amount determined under subparagraph (D).

(iii) RULES FOR NEW SERVICES.—The Secretary shall establish rules for establishment of an unadjusted copayment amount for a covered OPD service not furnished during 1996, based upon its classification within a group of such services.

(C) CALCULATION OF CONVERSION FACTORS.—

(i) FOR 1999.—

(I) IN GENERAL.—The Secretary shall establish a 1999 conversion factor for determining the medicare OPD fee schedule amounts for each covered

OPD service (or group of such services) furnished in 1999. Such conversion factor shall be established on the basis of the weights and frequencies described in paragraph (2)(C) and in such a manner that the sum for all services and groups of the products (described in subclause (II) for each such service or group) equals the total projected amount described in subparagraph (A).

(II) PRODUCT DESCRIBED.—The Secretary shall determine for each service or group the product of the medicare OPD fee schedule amounts (taking into account appropriate adjustments described in paragraphs (2)(D) and (2)(E)) and the estimated frequencies for such service or group.

(ii) SUBSEQUENT YEARS.—Subject to paragraph (8)(B), the Secretary shall establish a conversion factor for covered OPD services furnished in subsequent years in an amount equal to the conversion factor established under this subparagraph and applicable to such services furnished in the previous year increased by the OPD fee schedule increase factor specified under clause (iv) for the year involved.

(iii) ADJUSTMENT FOR SERVICE MIX CHANGES.—Insofar as the Secretary determines that the adjustments for service mix under paragraph (2) for a previous year (or estimates that such adjustments for a future year) did (or are likely to) result in a change in aggregate payments under this subsection during the year that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service mix, the Secretary may adjust the conversion factor computed under this subparagraph for subsequent years so as to eliminate the effect of such coding or classification changes.

(iv) OPD FEE SCHEDULE INCREASE FACTOR.—For purposes of this subparagraph, subject to paragraph (17) and subparagraph (F) of this paragraph, the "OPD fee schedule increase factor" for services furnished in a year is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) to hospital discharges occurring during the fiscal year ending in such year, reduced by 1 percentage point for such factor for services furnished in each of 2000 and 2002. In applying the previous sentence for years beginning with 2000, the Secretary may substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year.

(D) CALCULATION OF MEDICARE OPD FEE SCHEDULE AMOUNTS.—The Secretary shall compute a medicare OPD fee schedule amount for each covered OPD service (or

group of such services) furnished in a year, in an amount equal to the product of—

(i) the conversion factor computed under subparagraph (C) for the year, and

(ii) the relative payment weight (determined under paragraph (2)(C)) for the service or group.

(E) PRE-DEDUCTIBLE PAYMENT PERCENTAGE.—The pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year is equal to the ratio of—

(i) the medicare OPD fee schedule amount established under subparagraph (D) for the year, minus the unadjusted copayment amount determined under subparagraph (B) for the service or group, to

(ii) the medicare OPD fee schedule amount determined under subparagraph (D) for the year for such service or group.

(F) PRODUCTIVITY AND OTHER ADJUSTMENT.—After determining the OPD fee schedule increase factor under subparagraph (C)(iv), the Secretary shall reduce such increase factor—

(i) for 2012 and subsequent years, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(ii) for each of 2010 through 2019, by the adjustment described in subparagraph (G).

The application of this subparagraph may result in the increase factor under subparagraph (C)(iv) being less than 0.0 for a year, and may result in payment rates under the payment system under this subsection for a year being less than such payment rates for the preceding year.

(G) OTHER ADJUSTMENT.—For purposes of subparagraph (F)(ii), the adjustment described in this subparagraph is—

(i) for each of 2010 and 2011, 0.25 percentage point;

(ii) for each of 2012 and 2013, 0.1 percentage point;

(iii) for 2014, 0.3 percentage point;

(iv) for each of 2015 and 2016, 0.2 percentage point; and

(v) for each of 2017, 2018, and 2019, 0.75 percentage point.

(4) MEDICARE PAYMENT AMOUNT.—The amount of payment made from the Trust Fund under this part for a covered OPD service (and such services classified within a group) furnished in a year is determined, subject to paragraph (7), as follows:

(A) FEE SCHEDULE ADJUSTMENTS.—The medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or group and year is adjusted for relative differences in the cost of labor and other factors determined by the Secretary, as computed under paragraphs (2)(D) and (2)(E).

(B) SUBTRACT APPLICABLE DEDUCTIBLE.—Reduce the adjusted amount determined under subparagraph (A) by the amount of the deductible under section 1833(b), to the extent applicable.

(C) APPLY PAYMENT PROPORTION TO REMAINDER.—The amount of payment is the amount so determined under subparagraph (B) multiplied by the pre-deductible payment percentage (as determined under paragraph (3)(E)) for the service or group and year involved, plus the amount of any reduction in the copayment amount attributable to paragraph (8)(C).

(5) OUTLIER ADJUSTMENT.—

(A) IN GENERAL.—Subject to subparagraph (D), the Secretary shall provide for an additional payment for each covered OPD service (or group of services) for which a hospital's charges, adjusted to cost, exceed—

(i) a fixed multiple of the sum of—

(I) the applicable medicare OPD fee schedule amount determined under paragraph (3)(D), as adjusted under paragraph (4)(A) (other than for adjustments under this paragraph or paragraph (6)); and

(II) any transitional pass-through payment under paragraph (6); and

(ii) at the option of the Secretary, such fixed dollar amount as the Secretary may establish.

(B) AMOUNT OF ADJUSTMENT.—The amount of the additional payment under subparagraph (A) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the applicable cutoff point under such subparagraph.

(C) LIMIT ON AGGREGATE OUTLIER ADJUSTMENTS.—

(i) IN GENERAL.—The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the term "applicable percentage" means a percentage specified by the Secretary up to (but not to exceed)—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, 3.0 percent.

(D) TRANSITIONAL AUTHORITY.—In applying subparagraph (A) for covered OPD services furnished before January 1, 2002, the Secretary may—

(i) apply such subparagraph to a bill for such services related to an outpatient encounter (rather than for a specific service or group of services) using OPD fee schedule amounts and transitional pass-through payments covered under the bill; and

(ii) use an appropriate cost-to-charge ratio for the hospital involved (as determined by the Secretary),

rather than for specific departments within the hospital.

(E) EXCLUSION OF SEPARATE DRUG AND BIOLOGICAL APCS FROM OUTLIER PAYMENTS.—No additional payment shall be made under subparagraph (A) in the case of ambulatory payment classification groups established separately for drugs or biologicals.

(6) TRANSITIONAL PASS-THROUGH FOR ADDITIONAL COSTS OF INNOVATIVE MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.—

(A) IN GENERAL.—The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services):

(i) CURRENT ORPHAN DRUGS.—A drug or biological that is used for a rare disease or condition with respect to which the drug or biological has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this subsection is implemented.

(ii) CURRENT CANCER THERAPY DRUGS AND BIOLOGICALS AND BRACHYTHERAPY.—A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy or temperature monitored cryoablation, if payment for such drug, biological, or device as an outpatient hospital service under this part was being made on such first date.

(iii) CURRENT RADIOPHARMACEUTICAL DRUGS AND BIOLOGICAL PRODUCTS.—A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures if payment for the drug or biological as an outpatient hospital service under this part was being made on such first date.

(iv) NEW MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.—A medical device, drug, or biological not described in clause (i), (ii), or (iii) if—

(I) payment for the device, drug, or biological as an outpatient hospital service under this part was not being made as of December 31, 1996; and

(II) the cost of the drug or biological or the average cost of the category of devices is not insignificant in relation to the OPD fee schedule amount (as calculated under paragraph (3)(D)) payable for the service (or group of services) involved.

(B) USE OF CATEGORIES IN DETERMINING ELIGIBILITY OF A DEVICE FOR PASS-THROUGH PAYMENTS.—The following provisions apply for purposes of determining whether a medical device qualifies for additional payments under clause (ii) or (iv) of subparagraph (A):

(i) ESTABLISHMENT OF INITIAL CATEGORIES.—

(I) IN GENERAL.—The Secretary shall initially establish under this clause categories of medical devices based on type of device by April 1, 2001. Such categories shall be established in a manner such that each medical device that meets the requirements of clause (ii) or (iv) of subparagraph (A) as of January 1, 2001, is included in such a category and no such device is included in more than one category. For purposes of the preceding sentence, whether a medical device meets such requirements as of such date shall be determined on the basis of the program memoranda issued before such date.

(II) AUTHORIZATION OF IMPLEMENTATION OTHER THAN THROUGH REGULATIONS.—The categories may be established under this clause by program memorandum or otherwise, after consultation with groups representing hospitals, manufacturers of medical devices, and other affected parties.

(ii) ESTABLISHING CRITERIA FOR ADDITIONAL CATEGORIES.—

(I) IN GENERAL.—The Secretary shall establish criteria that will be used for creation of additional categories (other than those established under clause (i)) through rulemaking (which may include use of an interim final rule with comment period).

(II) STANDARD.—Such categories shall be established under this clause in a manner such that no medical device is described by more than one category. Such criteria shall include a test of whether the average cost of devices that would be included in a category and are in use at the time the category is established is not insignificant, as described in subparagraph (A)(iv)(II).

(III) DEADLINE.—Criteria shall first be established under this clause by July 1, 2001. The Secretary may establish in compelling circumstances categories under this clause before the date such criteria are established.

(IV) ADDING CATEGORIES.—The Secretary shall promptly establish a new category of medical devices under this clause for any medical device that meets the requirements of subparagraph (A)(iv) and for which none of the categories in effect (or that were previously in effect) is appropriate.

(iii) PERIOD FOR WHICH CATEGORY IS IN EFFECT.—Subject to subparagraph (K), a category of medical devices established under clause (i) or (ii) shall be in effect for a period of at least 2 years, but not more than 3 years, that begins—

(I) in the case of a category established under clause (i), on the first date on which payment was made under this paragraph for any device described by such category (including payments made during the period before April 1, 2001); and

(II) in the case of any other category, on the first date on which payment is made under this paragraph for any medical device that is described by such category.

(iv) REQUIREMENTS TREATED AS MET.—A medical device shall be treated as meeting the requirements of subparagraph (A)(iv), regardless of whether the device meets the requirement of subclause (I) of such subparagraph, if—

(I) the device is described by a category established and in effect under clause (i); or

(II) the device is described by a category established and in effect under clause (ii) and an application under section 515 of the Federal Food, Drug, and Cosmetic Act has been approved with respect to the device, or the device has been cleared for market under section 510(k) of such Act, or the device is exempt from the requirements of section 510(k) of such Act pursuant to subsection (l) or (m) of section 510 of such Act or section 520(g) of such Act.

Nothing in this clause shall be construed as requiring an application or prior approval (other than that described in subclause (II)) in order for a covered device described by a category to qualify for payment under this paragraph.

(C) LIMITED PERIOD OF PAYMENT.—

(i) DRUGS AND BIOLOGICALS.—Subject to subparagraph (G), the payment under this paragraph with respect to a drug or biological shall only apply during a period of at least 2 years, but not more than 3 years, that begins—

(I) on the first date this subsection is implemented in the case of a drug or biological described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a drug or biological described in subparagraph (A)(iv) and for which payment under this part is made as an outpatient hospital service before such first date; or

(II) in the case of a drug or biological described in subparagraph (A)(iv) not described in subclause (I), on the first date on which payment is made under this part for the drug or biological as an outpatient hospital service.

(ii) MEDICAL DEVICES.—Payment shall be made under this paragraph with respect to a medical device only if such device—

(I) is described by a category of medical devices established and in effect under subparagraph (B); and

(II) is provided as part of a service (or group of services) paid for under this subsection and provided during the period for which such category is in effect under such subparagraph.

(D) AMOUNT OF ADDITIONAL PAYMENT.—Subject to subparagraph (E)(iii), the amount of the payment under this paragraph with respect to a device, drug, or biological provided as part of a covered OPD service is—

(i) subject to subparagraph (H), in the case of a drug or biological, the amount by which the amount determined under section 1842(o) (or if the drug or biological is covered under a competitive acquisition contract under section 1847B, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary for purposes of this paragraph) for the drug or biological exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the drug or biological; or

(ii) in the case of a medical device, the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the device.

(E) LIMIT ON AGGREGATE ANNUAL ADJUSTMENT.—

(i) IN GENERAL.—The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year. This clause shall not apply for 2018 or 2020.

(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the term "applicable percentage" means—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

(iii) UNIFORM PROSPECTIVE REDUCTION IF AGGREGATE LIMIT PROJECTED TO BE EXCEEDED.—If the Secretary estimates before the beginning of a year that the amount of the additional payments under this paragraph for the year (or portion thereof) as determined under clause (i) without regard to this clause will exceed the limit established under such clause, the Secretary shall reduce pro rata the amount of each of the additional payments under this paragraph for that year (or portion thereof) in order to ensure that the aggregate additional payments under this paragraph (as so estimated) do not exceed such limit.

(F) LIMITATION OF APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD.—

(i) IN GENERAL.—The Secretary may not publish regulations that apply a functional equivalence standard to a drug or biological under this paragraph.

(ii) APPLICATION.—Clause (i) shall apply to the application of a functional equivalence standard to a drug or biological on or after the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 unless—

(I) such application was being made to such drug or biological prior to such date of enactment; and

(II) the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this title.

(iii) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed to effect the Secretary's authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of Food and Drugs.

(G) PASS-THROUGH EXTENSION FOR CERTAIN DRUGS AND BIOLOGICALS.—In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, such pass-through status shall be extended for a 2-year period beginning on October 1, 2018.

(H) TEMPORARY PAYMENT RULE FOR CERTAIN DRUGS AND BIOLOGICALS.—In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, the payment amount for such drug or biological under this subsection that is furnished during the period beginning on October 1, 2018, and ending on March 31, 2019, shall be the greater of—

(i) the payment amount that would otherwise apply under subparagraph (D)(i) for such drug or biological during such period; or

(ii) the payment amount that applied under such subparagraph (D)(i) for such drug or biological on December 31, 2017.

(I) SPECIAL PAYMENT ADJUSTMENT RULES FOR LAST QUARTER OF 2018.—In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment amount for a covered OPD service (or group of services) beginning January 1, 2018, the following rules shall apply with respect to payment amounts under this subsection for covered a OPD

service (or group of services) furnished during the period beginning on October 1, 2018, and ending on December 31, 2018:

(i) The Secretary shall remove the packaged costs of such drug or biological (as determined by the Secretary) from the payment amount under this subsection for the covered OPD service (or group of services) with which it is packaged.

(ii) The Secretary shall not make any adjustments to payment amounts under this subsection for a covered OPD service (or group of services) for which no costs were removed under clause (i).

(J) ADDITIONAL PASS-THROUGH EXTENSION AND SPECIAL PAYMENT ADJUSTMENT RULE FOR CERTAIN DIAGNOSTIC RADIOPHARMACEUTICALS.—In the case of a drug or biological furnished in the context of a clinical study on diagnostic imaging tests approved under a coverage with evidence development determination whose period of pass-through status under this paragraph concluded on December 31, 2018, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2019, the Secretary shall—

(i) extend such pass-through status for such drug or biological for the 9-month period beginning on January 1, 2020;

(ii) remove, during such period, the packaged costs of such drug or biological (as determined by the Secretary) from the payment amount under this subsection for the covered OPD service (or group of services) with which it is packaged; and

(iii) not make any adjustments to payment amounts under this subsection for a covered OPD service (or group of services) for which no costs were removed under clause (ii).

(K) PASS-THROUGH EXTENSION FOR CERTAIN DEVICES.—

(i) IN GENERAL.—In the case of a device whose period of pass-through status under this paragraph will end on December 31, 2022, such pass-through status shall be extended for a 1–year period beginning on January 1, 2023.

(ii) NO ADJUSTMENT FOR PACKAGED COSTS.—For purposes of the 1–year period described in clause (i), the Secretary shall not remove the packaged costs of such device (as determined by the Secretary) from the payment amount under this subsection for a covered OPD service (or group of services) with which it is packaged.

(iii) NO APPLICATION OF AGGREGATE LIMIT OR BUDGET NEUTRALITY.—Notwithstanding any other provision of this subsection, this subparagraph shall not be taken into account—

(I) in applying the limit on annual aggregate adjustments under subparagraph (E) for 2023; or

(II) in making any budget neutrality adjustments under this subsection for 2023.

(7) TRANSITIONAL ADJUSTMENT TO LIMIT DECLINE IN PAYMENT.—

(A) BEFORE 2002.—Subject to subparagraph (D), for covered OPD services furnished before January 1, 2002, for which the PPS amount (as defined in subparagraph (E)) is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in subparagraph (F)), the amount of payment under this subsection shall be increased by 80 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.71 and the pre-BBA amount, exceeds (II) the product of 0.70 and the PPS amount;

(iii) at least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.63 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iv) less than 70 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 21 percent of the pre-BBA amount.

(B) 2002.—Subject to subparagraph (D), for covered OPD services furnished during 2002, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 70 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.61 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iii) less than 80 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 13 percent of the pre-BBA amount.

(C) 2003.—Subject to subparagraph (D), for covered OPD services furnished during 2003, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 60 percent of the amount of such difference; or

(ii) less than 90 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 6 percent of the pre-BBA amount.

(D) HOLD HARMLESS PROVISIONS.—

(i) TEMPORARY TREATMENT FOR CERTAIN RURAL HOSPITALS.—(I) In the case of a hospital located in a rural area and that has not more than 100 beds or a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) located in a rural area, for covered OPD services furnished before January 1, 2006, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(II) In the case of a hospital located in a rural area and that has not more than 100 beds and that is not a sole community hospital (as defined in section 1886(d)(5)(D)(iii)), for covered OPD services furnished on or after January 1, 2006, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the applicable percentage of the amount of such difference. For purposes of the preceding sentence, the applicable percentage shall be 95 percent with respect to covered OPD services furnished in 2006, 90 percent with respect to such services furnished in 2007, and 85 percent with respect to such services furnished in 2008, 2009, 2010, 2011, or 2012.

(III) In the case of a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) that has not more than 100 beds, for covered OPD services furnished on or after January 1, 2009, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by 85 percent of the amount of such difference. In the case of covered OPD services furnished on or after January 1, 2010, and before March 1, 2012, the preceding sentence shall be applied without regard to the 100-bed limitation.

(ii) PERMANENT TREATMENT FOR CANCER HOSPITALS AND CHILDREN'S HOSPITALS.—In the case of a hospital described in clause (iii) or (v) of section 1886(d)(1)(B), for covered OPD services for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(E) PPS AMOUNT DEFINED.—In this paragraph, the term "PPS amount" means, with respect to covered OPD services, the amount payable under this title for such services (determined without regard to this paragraph), including amounts payable as copayment under paragraph (8), coinsurance under section 1866(a)(2)(A)(ii), and the deductible under section 1833(b).

(F) PRE-BBA AMOUNT DEFINED.—

(i) IN GENERAL.—In this paragraph, the "pre-BBA amount" means, with respect to covered OPD services furnished by a hospital in a year, an amount equal to the product of the reasonable cost of the hospital for such services for the portions of the hospital's cost re-

porting period (or periods) occurring in the year and the base OPD payment-to-cost ratio for the hospital (as defined in clause (ii)).

(ii) BASE PAYMENT-TO-COST-RATIO DEFINED.—For purposes of this subparagraph, the "base payment-to-cost ratio" for a hospital means the ratio of—

(I) the hospital's reimbursement under this part for covered OPD services furnished during the cost reporting period ending in 1996 (or in the case of a hospital that did not submit a cost report for such period, during the first subsequent cost reporting period ending before 2001 for which the hospital submitted a cost report), including any reimbursement for such services through cost-sharing described in subparagraph (E), to

(II) the reasonable cost of such services for such period.

The Secretary shall determine such ratios as if the amendments made by section 4521 of the Balanced Budget Act of 1997 were in effect in 1996.

(G) INTERIM PAYMENTS.—The Secretary shall make payments under this paragraph to hospitals on an interim basis, subject to retrospective adjustments based on settled cost reports.

(H) NO EFFECT ON COPAYMENTS.—Nothing in this paragraph shall be construed to affect the unadjusted copayment amount described in paragraph (3)(B) or the copayment amount under paragraph (8).

(I) APPLICATION WITHOUT REGARD TO BUDGET NEUTRALITY.—The additional payments made under this paragraph—

(i) shall not be considered an adjustment under paragraph (2)(E); and

(ii) shall not be implemented in a budget neutral manner.

(8) COPAYMENT AMOUNT.—

(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), the copayment amount under this subsection is the amount by which the amount described in paragraph (4)(B) exceeds the amount of payment determined under paragraph (4)(C).

(B) ELECTION TO OFFER REDUCED COPAYMENT AMOUNT.—The Secretary shall establish a procedure under which a hospital, before the beginning of a year (beginning with 1999), may elect to reduce the copayment amount otherwise established under subparagraph (A) for some or all covered OPD services to an amount that is not less than 20 percent of the medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service involved. Under such procedures, such reduced copayment amount may not be further reduced or increased during the year involved and the hospital may disseminate information on the reduction of copayment amount effected under this subparagraph.

(C) LIMITATION ON COPAYMENT AMOUNT.—

(i) TO INPATIENT HOSPITAL DEDUCTIBLE AMOUNT.—In no case shall the copayment amount for a procedure performed in a year exceed the amount of the inpatient hospital deductible established under section 1813(b) for that year.

(ii) TO SPECIFIED PERCENTAGE.—The Secretary shall reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed the following percentage:

(I) For procedures performed in 2001, on or after April 1, 2001, 57 percent.

(II) For procedures performed in 2002 or 2003, 55 percent.

(III) For procedures performed in 2004, 50 percent.

(IV) For procedures performed in 2005, 45 percent.

(V) For procedures performed in 2006 and thereafter, 40 percent.

(D) NO IMPACT ON DEDUCTIBLES.—Nothing in this paragraph shall be construed as affecting a hospital's authority to waive the charging of a deductible under section 1833(b).

(E) COMPUTATION IGNORING OUTLIER AND PASS-THROUGH ADJUSTMENTS.—The copayment amount shall be computed under subparagraph (A) as if the adjustments under paragraphs (5) and (6) (and any adjustment made under paragraph (2)(E) in relation to such adjustments) had not occurred.

(F) PART B REBATABLE DRUGS.—In the case of a part B rebatable drug (as defined in paragraph (2) of section 1847A(i), except if such drug does not have a copayment amount as a result of application of subparagraph (E)) for which payment under this part is not packaged into a payment for a covered OPD service (or group of services) furnished on or after April 1, 2023, and the payment for such drug under this subsection is the same as the amount for a calendar quarter under paragraph (3)(A)(ii)(I) of section 1847A(i), under the system under this subsection, in lieu of calculation of the copayment amount and the amount of payment otherwise applicable under this subsection (other than the application of the limitation described in subparagraph (C)), the provisions of section 1847A(i)(5) and paragraph (1)(EE) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1847A(i)(5) and subsection (a) apply under such section and subsection.

(9) PERIODIC REVIEW AND ADJUSTMENTS COMPONENTS OF PROSPECTIVE PAYMENT SYSTEM.—

(A) PERIODIC REVIEW.—The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments de-

scribed in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

(B) BUDGET NEUTRALITY ADJUSTMENT.—If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).

(C) UPDATE FACTOR.—If the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.

(10) SPECIAL RULE FOR AMBULANCE SERVICES.—The Secretary shall pay for hospital outpatient services that are ambulance services on the basis described in section 1861(v)(1)(U), or, if applicable, the fee schedule established under section 1834(l).

(11) SPECIAL RULES FOR CERTAIN HOSPITALS.—In the case of hospitals described in clause (iii) or (v) of section 1886(d)(1)(B)—

(A) the system under this subsection shall not apply to covered OPD services furnished before January 1, 2000; and

(B) the Secretary may establish a separate conversion factor for such services in a manner that specifically takes into account the unique costs incurred by such hospitals by virtue of their patient population and service intensity.

(12) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise of—

(A) the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F);

(B) the calculation of base amounts under paragraph (3);

(C) periodic adjustments made under paragraph (6);

(D) the establishment of a separate conversion factor under paragraph (8)(B); [and]

(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6)**[**.**]***; and*

*(F) the determination of any payment amount under paragraph (16)(H), including the transition under clause (iii) of such paragraph.*

(13) AUTHORIZATION OF ADJUSTMENT FOR RURAL HOSPITALS.—

(A) STUDY.—The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals located in rural areas by ambulatory payment classification groups (APCs) exceed those costs incurred by hospitals located in urban areas.

(B) AUTHORIZATION OF ADJUSTMENT.—Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals located in rural areas exceed those costs incurred by hospitals located in urban areas, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs by January 1, 2006.

(14) DRUG APC PAYMENT RATES.—

(A) IN GENERAL.—The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)—

(i) in 2004, in the case of—

(I) a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug;

(ii) in 2005, in the case of—

(I) a sole source drug shall in no case be less than 83 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug; or

(iii) in a subsequent year, shall be equal, subject to subparagraph (E)—

(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

(B) SPECIFIED COVERED OUTPATIENT DRUG DEFINED.—

(i) IN GENERAL.—In this paragraph, the term "specified covered outpatient drug" means, subject to clause (ii), a covered outpatient drug (as defined in section 1927(k)(2)) for which a separate ambulatory payment classification group (APC) has been established and that is—

(I) a radiopharmaceutical; or

(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

(ii) EXCEPTION.—Such term does not include—

(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

(C) PAYMENT FOR DESIGNATED ORPHAN DRUGS DURING 2004 AND 2005.—The amount of payment under this subsection for an orphan drug designated by the Secretary under subparagraph (B)(ii)(III) that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 shall equal such amount as the Secretary may specify.

(D) ACQUISITION COST SURVEY FOR HOSPITAL OUTPATIENT DRUGS.—

(i) ANNUAL GAO SURVEYS IN 2004 AND 2005.—

(I) IN GENERAL.—The Comptroller General of the United States shall conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug. Not later than April 1, 2005, the Comptroller General shall furnish data from such surveys to the Secretary for use in setting the payment rates under subparagraph (A) for 2006.

(II) RECOMMENDATIONS.—Upon the completion of such surveys, the Comptroller General shall recommend to the Secretary the frequency and

methodology of subsequent surveys to be conducted by the Secretary under clause (ii).

(ii) SUBSEQUENT SECRETARIAL SURVEYS.—The Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates under subparagraph (A).

(iii) SURVEY REQUIREMENTS.—The surveys conducted under clauses (i) and (ii) shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. With respect to the surveys conducted under clause (i), the Comptroller General shall report to Congress on the justification for the size of the sample used in order to assure the validity of such estimates.

(iv) DIFFERENTIATION IN COST.—In conducting surveys under clause (i), the Comptroller General shall determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals based on the volume of covered OPD services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).

(v) COMMENT ON PROPOSED RATES.—Not later than 30 days after the date the Secretary promulgated proposed rules setting forth the payment rates under subparagraph (A) for 2006, the Comptroller General shall evaluate such proposed rates and submit to Congress a report regarding the appropriateness of such rates based on the surveys the Comptroller General has conducted under clause (i).

(E) ADJUSTMENT IN PAYMENT RATES FOR OVERHEAD COSTS.—

(i) MEDPAC REPORT ON DRUG APC DESIGN.—The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

(I) a description and analysis of the data available with regard to such expenses;

(II) a recommendation as to whether such a payment adjustment should be made; and

(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

(ii) ADJUSTMENT AUTHORIZED.—The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i).

(F) CLASSES OF DRUGS.—For purposes of this paragraph:

(i) SOLE SOURCE DRUGS.—The term "sole source drug" means—

(I) a biological product (as defined under section 1861(t)(1)); or

(II) a single source drug (as defined in section 1927(k)(7)(A)(iv)).

(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—The term "innovator multiple source drug" has the meaning given such term in section 1927(k)(7)(A)(ii).

(iii) NONINNOVATOR MULTIPLE SOURCE DRUGS.—The term "noninnovator multiple source drug" has the meaning given such term in section 1927(k)(7)(A)(iii).

(G) REFERENCE AVERAGE WHOLESALE PRICE.—The term "reference average wholesale price" means, with respect to a specified covered outpatient drug, the average wholesale price for the drug as determined under section 1842(o) as of May 1, 2003.

(H) INAPPLICABILITY OF EXPENDITURES IN DETERMINING CONVERSION, WEIGHTING, AND OTHER ADJUSTMENT FACTORS.—Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.

(15) PAYMENT FOR NEW DRUGS AND BIOLOGICALS UNTIL HCPCS CODE ASSIGNED.—With respect to payment under this part for an outpatient drug or biological that is covered under this part and is furnished as part of covered OPD services for which a HCPCS code has not been assigned, the amount provided for payment for such drug or biological under this part shall be equal to 95 percent of the average wholesale price for the drug or biological.

(16) MISCELLANEOUS PROVISIONS.—

(A) APPLICATION OF RECLASSIFICATION OF CERTAIN HOSPITALS.—If a hospital is being treated as being located in a rural area under section 1886(d)(8)(E), that hospital shall be treated under this subsection as being located in that rural area.

(B) THRESHOLD FOR ESTABLISHMENT OF SEPARATE APCS FOR DRUGS.—The Secretary shall reduce the threshold for the establishment of separate ambulatory payment classification groups (APCs) with respect to drugs or biologicals to $50 per administration for drugs and biologicals furnished in 2005 and 2006.

(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY AND THERAPEUTIC RADIOPHARMACEUTICALS AT CHARGES ADJUSTED TO COST.—Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy consisting of a seed or seeds (or radioactive source) furnished on or after January 1, 2004, and before January 1, 2010, and for therapeutic radiopharmaceuticals furnished on or after January 1, 2008, and before January 1, 2010, the payment basis for the device or therapeutic radiopharmaceutical under this subsection shall be equal to the hos-

pital's charges for each device or therapeutic radiopharmaceutical furnished, adjusted to cost. Charges for such devices or therapeutic radiopharmaceuticals shall not be included in determining any outlier payment under this subsection.

(D) SPECIAL PAYMENT RULE.—

(i) IN GENERAL.—In the case of covered OPD services furnished on or after April 1, 2013, in a hospital described in clause (ii), if—

(I) the payment rate that would otherwise apply under this subsection for stereotactic radiosurgery, complete course of treatment of cranial lesion(s) consisting of 1 session that is multisource Cobalt 60 based (identified as of January 1, 2013, by HCPCS code 77371 (and any succeeding code) and reimbursed as of such date under APC 0127 (and any succeeding classification group)); exceeds

(II) the payment rate that would otherwise apply under this subsection for linear accelerator based stereotactic radiosurgery, complete course of therapy in one session (identified as of January 1, 2013, by HCPCS code G0173 (and any succeeding code) and reimbursed as of such date under APC 0067 (and any succeeding classification group)),

the payment rate for the service described in subclause (I) shall be reduced to an amount equal to the payment rate for the service described in subclause (II).

(ii) HOSPITAL DESCRIBED.—A hospital described in this clause is a hospital that is not—

(I) located in a rural area (as defined in section 1886(d)(2)(D));

(II) classified as a rural referral center under section 1886(d)(5)(C); or

(III) a sole community hospital (as defined in section 1886(d)(5)(D)(iii)).

(iii) NOT BUDGET NEUTRAL.—In making any budget neutrality adjustments under this subsection for 2013 (with respect to covered OPD services furnished on or after April 1, 2013, and before January 1, 2014) or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(E) APPLICATION OF APPROPRIATE USE CRITERIA FOR CERTAIN IMAGING SERVICES.—For provisions relating to the application of appropriate use criteria for certain imaging services, see section 1834(q).

(F) PAYMENT INCENTIVE FOR THE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY.—Notwithstanding the previous provisions of this subsection:

(i) LIMITATION ON PAYMENT FOR FILM X-RAY IMAGING SERVICES.—In the case of an imaging service that is an X-ray taken using film and that is furnished during 2017 or a subsequent year, the payment amount for

such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 20 percent.

(ii) PHASED-IN LIMITATION ON PAYMENT FOR COMPUTED RADIOGRAPHY IMAGING SERVICES.—In the case of an imaging service that is an X-ray taken using computed radiography technology (as defined in section 1848(b)(9)(C))—

(I) in the case of such a service furnished during 2018, 2019, 2020, 2021, or 2022, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 7 percent; and

(II) in the case of such a service furnished during 2023 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 10 percent.

(iii) APPLICATION WITHOUT REGARD TO BUDGET NEUTRALITY.—The reductions made under this subparagraph—

(I) shall not be considered an adjustment under paragraph (2)(E); and

(II) shall not be implemented in a budget neutral manner.

(iv) IMPLEMENTATION.—In order to implement this subparagraph, the Secretary shall adopt appropriate mechanisms which may include use of modifiers.

(G) TEMPORARY ADDITIONAL PAYMENTS FOR NON-OPIOID TREATMENTS FOR PAIN RELIEF.—

(i) IN GENERAL.—Notwithstanding any other provision of this subsection, with respect to a non-opioid treatment for pain relief (as defined in clause (iv)) furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for such non-opioid treatment for pain relief into a payment for a covered OPD service (or group of services), and shall make an additional payment as specified in clause (ii) for such non-opioid treatment for pain relief.

(ii) AMOUNT OF PAYMENT.—Subject to the limitation under clause (iii), the amount of the payment specified in this clause is, with respect to a non-opioid treatment for pain relief that is—

(I) a drug or biological product, the amount of payment for such drug or biological determined under section 1847A that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological; or

(II) a medical device, the amount of the hospital's charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the device.

(iii) LIMITATION.—The additional payment amount specified in clause (ii) shall not exceed the estimated average of 18 percent of the OPD fee schedule amount for the OPD service (or group of services) with which the non-opioid treatment for pain relief is furnished, as determined by the Secretary.

(iv) DEFINITION OF NON-OPIOID TREATMENT FOR PAIN RELIEF.—In this subparagraph, the term "non-opioid treatment for pain relief" means a drug, biological product, or medical device that—

(I) in the case of a drug or biological product, has a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors;

(II) in case of a medical device, is used to deliver a therapy to reduce postoperative pain, or produce postsurgical or regional analgesia, and has—

(aa) an application under section 515 of the Federal Food, Drug, and Cosmetic Act that has been approved with respect to the device, been cleared for market under section 510(k) of such Act, or is exempt from the requirements of section 510(k) of such Act pursuant to subsection (l) or (m) or section 510 of such Act or section 520(g) of such Act; and

(bb) demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal;

(III) does not receive transitional pass-through payment under paragraph (6); and

(IV) has payment that is packaged into a payment for a covered OPD service (or group of services).

*(H) PARITY IN FEE SCHEDULE AMOUNT FOR CERTAIN SERVICES FURNISHED BY AN OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.—*

*(i) IN GENERAL.—Subject to clause (iii), in the case of specified OPD services (as defined in clause (v)) that are furnished during 2025 or a subsequent year by an off-campus outpatient department of a provider (as defined in clause (iv)) (or, in the case of an off-campus*

*outpatient department of a provider that is a hospital described in section 1886(d)(1)(B)(v), or is located in a rural area or a health professional shortage area, such services that are furnished during 2026 or a subsequent year), there shall be substituted for the amount otherwise determined under this subsection for such service and year an amount equal to the payment amount that would have been payable under the applicable payment system under this part (other than under this subsection) had such services been furnished by such a department subject to such payment system pursuant to paragraph (21)(C).*

*(ii) NOT BUDGET NEUTRAL IMPLEMENTATION.—In making any budget neutrality adjustments under this subsection for 2025 or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.*

*(iii) TRANSITION.—The Secretary shall provide for a 4-year phase-in of the application of clause (i), with clause (i) being fully applicable for specified OPD services beginning with 2028 (or in the case of an off-campus outpatient department of a provider that is a hospital described in section 1886(d)(1)(B)(v), or is located in a rural area or a health professional shortage area, beginning with 2029).*

*(iv) OFF-CAMPUS DEPARTMENT OF A PROVIDER.—For purposes of this subparagraph, the term "off-campus outpatient department of a provider" means a department of a provider (as defined in section 413.65(a)(2) of title 42, Code of Federal Regulations) that is not located—*

*(I) on the campus (as such term is defined in such section) of such provider; or*

*(II) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section).*

*(v) OTHER DEFINITIONS.—For purposes of this subparagraph:*

*(I) DESIGNATED AMBULATORY PAYMENT CLASSIFICATION GROUP.—The term "designated ambulatory payment classification group" means an ambulatory payment classification group for drug administration services.*

*(II) HEALTH PROFESSIONAL SHORTAGE AREA.—The term "health professional shortage area" has the meaning given such term in section 332(a)(1)(A) of the Public Health Service Act.*

*(III) RURAL AREA.—The term "rural area" has the meaning given such term in section 1886(d)(2)(D).*

*(IV) SPECIFIED OPD SERVICES.—The term "specified OPD services" means covered OPD services assigned to a designated ambulatory payment classification group.*

(17) QUALITY REPORTING.—

(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

(i) IN GENERAL.—For purposes of paragraph (3)(C)(iv) for 2009 and each subsequent year, in the case of a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to such a year, the OPD fee schedule increase factor under paragraph (3)(C)(iv) for such year shall be reduced by 2.0 percentage points.

(ii) NON-CUMULATIVE APPLICATION.—A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing the OPD fee schedule increase factor for a subsequent year.

(B) FORM AND MANNER OF SUBMISSION.—Each subsection (d) hospital shall submit data on measures selected under this paragraph to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this paragraph.

(C) DEVELOPMENT OF OUTPATIENT MEASURES.—

(i) IN GENERAL.—The Secretary shall develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

(ii) CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing the Secretary from selecting measures that are the same as (or a subset of) the measures for which data are required to be submitted under section 1886(b)(3)(B)(viii).

(D) REPLACEMENT OF MEASURES.—For purposes of this paragraph, the Secretary may replace any measures or indicators in appropriate cases, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice.

(E) AVAILABILITY OF DATA.—The Secretary shall establish procedures for making data submitted under this paragraph available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(18) AUTHORIZATION OF ADJUSTMENT FOR CANCER HOSPITALS.—

(A) STUDY.—The Secretary shall conduct a study to determine if, under the system under this subsection, costs

incurred by hospitals described in section 1886(d)(1)(B)(v) with respect to ambulatory payment classification groups exceed those costs incurred by other hospitals furnishing services under this subsection (as determined appropriate by the Secretary). In conducting the study under this subparagraph, the Secretary shall take into consideration the cost of drugs and biologicals incurred by such hospitals.

(B) AUTHORIZATION OF ADJUSTMENT.—Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals described in section 1886(d)(1)(B)(v) exceed those costs incurred by other hospitals furnishing services under this subsection, the Secretary shall, subject to subparagraph (C), provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs effective for services furnished on or after January 1, 2011.

(C) TARGET PCR ADJUSTMENT.—In applying section 419.43(i) of title 42 of the Code of Federal Regulations to implement the appropriate adjustment under this paragraph for services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage points less than the target PCR that would otherwise apply. In addition to the percentage point reduction under the previous sentence, the Secretary may consider making an additional percentage point reduction to such target PCR that takes into account payment rates for applicable items and services described in paragraph (21)(C) other than for services furnished by hospitals described in section 1886(d)(1)(B)(v). In making any budget neutrality adjustments under this subsection for 2018 or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(19) FLOOR ON AREA WAGE ADJUSTMENT FACTOR FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES IN FRONTIER STATES.—

(A) IN GENERAL.—Subject to subparagraph (B), with respect to covered OPD services furnished on or after January 1, 2011, the area wage adjustment factor applicable under the payment system established under this subsection to any hospital outpatient department which is located in a frontier State (as defined in section 1886(d)(3)(E)(iii)(II)) may not be less than 1.00. The preceding sentence shall not be applied in a budget neutral manner.

(B) LIMITATION.—This paragraph shall not apply to any hospital outpatient department located in a State that receives a non-labor related share adjustment under section 1886(d)(5)(H).

(20) NOT BUDGET NEUTRAL APPLICATION OF REDUCED EXPENDITURES RESULTING FROM QUALITY INCENTIVES FOR COMPUTED TOMOGRAPHY.—The Secretary shall not take into account the reduced expenditures that result from the application of section 1834(p) in making any budget neutrality adjustments this subsection.

(21) SERVICES FURNISHED BY AN OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.—

(A) APPLICABLE ITEMS AND SERVICES.—For purposes of paragraph (1)(B)(v) and this paragraph, the term "applicable items and services" means items and services other than items and services furnished by a dedicated emergency department (as defined in section 489.24(b) of title 42 of the Code of Federal Regulations).

(B) OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.—

(i) IN GENERAL.—For purposes of paragraph (1)(B)(v) and this paragraph, subject to the subsequent provisions of this subparagraph, the term "off-campus outpatient department of a provider" means a department of a provider (as defined in section 413.65(a)(2) of title 42 of the Code of Federal Regulations, as in effect as of the date of the enactment of this paragraph) that is not located—

(I) on the campus (as defined in such section 413.65(a)(2)) of such provider; or

(II) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section 413.65(a)(2)).

(ii) EXCEPTION.—For purposes of paragraph (1)(B)(v) and this paragraph, the term "off-campus outpatient department of a provider" shall not include a department of a provider (as so defined) that was billing under this subsection with respect to covered OPD services furnished prior to the date of the enactment of this paragraph.

(iii) DEEMED TREATMENT FOR 2017.—For purposes of applying clause (ii) with respect to applicable items and services furnished during 2017, a department of a provider (as so defined) not described in such clause is deemed to be billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015, if the Secretary received from the provider prior to December 2, 2015, an attestation (pursuant to section 413.65(b)(3) of title 42 of the Code of Federal Regulations) that such department was a department of a provider (as so defined).

(iv) ALTERNATIVE EXCEPTION BEGINNING WITH 2018.—For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2018 or a subsequent year, the term "off-campus outpatient department of a provider" also shall not include a department of a provider (as so defined) that is not described in clause (ii) if—

(I) the Secretary receives from the provider an attestation (pursuant to such section 413.65(b)(3)) not later than December 31, 2016 (or, if later, 60 days after the date of the enactment of this clause), that such department met the requirements of a department of a provider specified in

section 413.65 of title 42 of the Code of Federal Regulations;

(II) the provider includes such department as part of the provider on its enrollment form in accordance with the enrollment process under section 1866(j); and

(III) the department met the mid-build requirement of clause (v) and the Secretary receives, not later than 60 days after the date of the enactment of this clause, from the chief executive officer or chief operating officer of the provider a written certification that the department met such requirement.

(v) MID-BUILD REQUIREMENT DESCRIBED.—The mid-build requirement of this clause is, with respect to a department of a provider, that before November 2, 2015, the provider had a binding written agreement with an outside unrelated party for the actual construction of such department.

(vi) EXCLUSION FOR CERTAIN CANCER HOSPITALS.—For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2017 or a subsequent year, the term "off-campus outpatient department of a provider" also shall not include a department of a provider (as so defined) that is not described in clause (ii) if the provider is a hospital described in section 1886(d)(1)(B)(v) and—

(I) in the case of a department that met the requirements of section 413.65 of title 42 of the Code of Federal Regulations after November 1, 2015, and before the date of the enactment of this clause, the Secretary receives from the provider an attestation that such department met such requirements not later than 60 days after such date of enactment; or

(II) in the case of a department that meets such requirements after such date of enactment, the Secretary receives from the provider an attestation that such department meets such requirements not later than 60 days after the date such requirements are first met with respect to such department.

(vii) AUDIT.—Not later than December 31, 2018, the Secretary shall audit the compliance with requirements of clause (iv) with respect to each department of a provider to which such clause applies. Not later than 2 years after the date the Secretary receives an attestation under clause (vi) relating to compliance of a department of a provider with requirements referred to in such clause, the Secretary shall audit the compliance with such requirements with respect to the department. If the Secretary finds as a result of an audit under this clause that the applicable requirements were not met with respect to such department, the de-

partment shall not be excluded from the term "off-campus outpatient department of a provider" under such clause.

(viii) IMPLEMENTATION.—For purposes of implementing clauses (iii) through (vii):

(I) Notwithstanding any other provision of law, the Secretary may implement such clauses by program instruction or otherwise.

(II) Subchapter I of chapter 35 of title 44, United States Code, shall not apply.

(III) For purposes of carrying out this subparagraph with respect to clauses (iii) and (iv) (and clause (vii) insofar as it relates to clause (iv)), $10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until December 31, 2018. For purposes of carrying out this subparagraph with respect to clause (vi) (and clause (vii) insofar as it relates to such clause), $2,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until expended.

(C) AVAILABILITY OF PAYMENT UNDER OTHER PAYMENT SYSTEMS.—Payments for applicable items and services furnished by an off-campus outpatient department of a provider that are described in paragraph (1)(B)(v) shall be made under the applicable payment system under this part (other than under this subsection) if the requirements for such payment are otherwise met.

(D) INFORMATION NEEDED FOR IMPLEMENTATION.—Each hospital shall provide to the Secretary such information as the Secretary determines appropriate to implement this paragraph and paragraph (1)(B)(v) (which may include reporting of information on a hospital claim using a code or modifier and reporting information about off-campus outpatient departments of a provider on the enrollment form described in section 1866(j)).

(E) LIMITATIONS.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(i) The determination of the applicable items and services under subparagraph (A) and applicable payment systems under subparagraph (C).

(ii) The determination of whether a department of a provider meets the term described in subparagraph (B).

(iii) Any information that hospitals are required to report pursuant to subparagraph (D).

(iv) The determination of an audit under subparagraph (B)(vii).

(22) REVIEW AND REVISIONS OF PAYMENTS FOR NON-OPIOID ALTERNATIVE TREATMENTS.—

(A) IN GENERAL.—With respect to payments made under this subsection for covered OPD services (or groups of serv-

ices), including covered OPD services assigned to a comprehensive ambulatory payment classification, the Secretary—

(i) shall, as soon as practicable, conduct a review (part of which may include a request for information) of payments for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives;

(ii) may, as the Secretary determines appropriate, conduct subsequent reviews of such payments; and

(iii) shall consider the extent to which revisions under this subsection to such payments (such as the creation of additional groups of covered OPD services to classify separately those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management.

(B) PRIORITY.—In conducting the review under clause (i) of subparagraph (A) and considering revisions under clause (iii) of such subparagraph, the Secretary shall focus on covered OPD services (or groups of services) assigned to a comprehensive ambulatory payment classification, ambulatory payment classifications that primarily include surgical services, and other services determined by the Secretary which generally involve treatment for pain management.

(C) REVISIONS.—If the Secretary identifies revisions to payments pursuant to subparagraph (A)(iii), the Secretary shall, as determined appropriate, begin making such revisions for services furnished on or after January 1, 2020. Revisions under the previous sentence shall be treated as adjustments for purposes of application of paragraph (9)(B).

(D) RULES OF CONSTRUCTION.—Nothing in this paragraph shall be construed to preclude the Secretary—

(i) from conducting a demonstration before making the revisions described in subparagraph (C); or

(ii) prior to implementation of this paragraph, from changing payments under this subsection for covered OPD services (or groups of services) which include opioids or non-opioid alternatives for pain management.

*(23) USE OF UNIQUE HEALTH IDENTIFIERS; ATTESTATION.—*

*(A) IN GENERAL.—No payment may be made under this subsection (or under an applicable payment system pursuant to paragraph (21)) for items and services furnished on or after January 1, 2026, by an off-campus outpatient department of a provider (as defined in subparagraph (C)) unless—*

*(i) such department has obtained, and such items and services are billed under, a standard unique*

*health identifier for health care providers (as described in section 1173(b)) that is separate from such identifier for such provider; and*

*(ii) such provider has submitted to the Secretary, during the 2-year period ending on the date such items and services are so furnished, an attestation that such department is compliant with the requirements described in section 413.65 of title 42, Code of Federal Regulations (or a successor regulation).*

*(B) PROCESS FOR SUBMISSION AND REVIEW.—Not later than 1 year after the date of enactment of this paragraph, the Secretary shall, through notice and comment rulemaking, establish a process for each provider with an off-campus outpatient department of a provider to submit an attestation pursuant to subparagraph (A)(ii), and for the Secretary to review each such attestation and determine, through site visits, remote audits, or other means (as determined appropriate by the Secretary), whether such department is compliant with the requirements described in such subparagraph.*

*(C) OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER DEFINED.—For purposes of this paragraph, the term "off-campus outpatient department of a provider" means a department of a provider (as defined in section 413.65 of title 42, Code of Federal Regulations, or any successor regulation) that is not located—*

*(i) on the campus (as defined in such section) of such provider; or*

*(ii) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section).*

(u) INCENTIVE PAYMENTS FOR PHYSICIAN SCARCITY AREAS.—

(1) IN GENERAL.—In the case of physicians' services furnished on or after January 1, 2005, and before July 1, 2008—

(A) by a primary care physician in a primary care scarcity county (identified under paragraph (4)); or

(B) by a physician who is not a primary care physician in a specialist care scarcity county (as so identified),

in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid an amount equal to 5 percent of the payment amount for the service under this part.

(2) DETERMINATION OF RATIOS OF PHYSICIANS TO MEDICARE BENEFICIARIES IN AREA.—Based upon available data, the Secretary shall establish for each county or equivalent area in the United States, the following:

(A) NUMBER OF PHYSICIANS PRACTICING IN THE AREA.—The number of physicians who furnish physicians' services in the active practice of medicine or osteopathy in that county or area, other than physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services. Of such number, the number of such physicians who are—

(i) primary care physicians; or

(ii) physicians who are not primary care physicians.

(B) NUMBER OF MEDICARE BENEFICIARIES RESIDING IN THE AREA.—The number of individuals who are residing in the county and are entitled to benefits under part A or enrolled under this part, or both (in this subsection referred to as "individuals").

(C) DETERMINATION OF RATIOS.—

(i) PRIMARY CARE RATIO.—The ratio (in this paragraph referred to as the "primary care ratio") of the number of primary care physicians (determined under subparagraph (A)(i)), to the number of individuals determined under subparagraph (B).

(ii) SPECIALIST CARE RATIO.—The ratio (in this paragraph referred to as the "specialist care ratio") of the number of other physicians (determined under subparagraph (A)(ii)), to the number of individuals determined under subparagraph (B).

(3) RANKING OF COUNTIES.—The Secretary shall rank each such county or area based separately on its primary care ratio and its specialist care ratio.

(4) IDENTIFICATION OF COUNTIES.—

(A) IN GENERAL.—The Secretary shall identify—

(i) those counties and areas (in this paragraph referred to as "primary care scarcity counties") with the lowest primary care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph; and

(ii) those counties and areas (in this subsection referred to as "specialist care scarcity counties") with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph.

(B) PERIODIC REVISIONS.—The Secretary shall periodically revise the counties or areas identified in subparagraph (A) (but not less often than once every three years) unless the Secretary determines that there is no new data available on the number of physicians practicing in the county or area or the number of individuals residing in the county or area, as identified in paragraph (2).

(C) IDENTIFICATION OF COUNTIES WHERE SERVICE IS FURNISHED.—For purposes of paying the additional amount specified in paragraph (1), if the Secretary uses the 5-digit postal ZIP Code where the service is furnished, the dominant county of the postal ZIP Code (as determined by the United States Postal Service, or otherwise) shall be used to determine whether the postal ZIP Code is in a scarcity county identified in subparagraph (A) or revised in subparagraph (B).

(D) SPECIAL RULE.—With respect to physicians' services furnished on or after January 1, 2008, and before July 1, 2008, for purposes of this subsection, the Secretary shall

use the primary care scarcity counties and the specialty care scarcity counties (as identified under the preceding provisions of this paragraph) that the Secretary was using under this subsection with respect to physicians' services furnished on December 31, 2007.

(E) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting—

116.(i) the identification of a county or area;

(ii) the assignment of a specialty of any physician under this paragraph;

(iii) the assignment of a physician to a county under paragraph (2); or

(iv) the assignment of a postal ZIP Code to a county or other area under this subsection.

(5) RURAL CENSUS TRACTS.—To the extent feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), as an equivalent area for purposes of qualifying as a primary care scarcity county or specialist care scarcity county under this subsection.

(6) PHYSICIAN DEFINED.—For purposes of this paragraph, the term "physician" means a physician described in section 1861(r)(1) and the term "primary care physician" means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

(7) PUBLICATION OF LIST OF COUNTIES; POSTING ON WEBSITE.—With respect to a year for which a county or area is identified or revised under paragraph (4), the Secretary shall identify such counties or areas as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the applicable year. The Secretary shall post the list of counties identified or revised under paragraph (4) on the Internet website of the Centers for Medicare & Medicaid Services.

(v) INCREASE OF FQHC PAYMENT LIMITS.—In the case of services furnished by Federally qualified health centers (as defined in section 1861(aa)(4)), the Secretary shall establish payment limits with respect to such services under this part for services furnished—

(1) in 2010, at the limits otherwise established under this part for such year increased by $5; and

(2) in a subsequent year, at the limits established under this subsection for the previous year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year.

(w) METHODS OF PAYMENT.—The Secretary may develop alternative methods of payment for items and services provided under clinical trials and comparative effectiveness studies sponsored or supported by an agency of the Department of Health and Human Services, as determined by the Secretary, to those that would otherwise apply under this section, to the extent such alternative methods are necessary to preserve the scientific validity of such

trials or studies, such as in the case where masking the identity of interventions from patients and investigators is necessary to comply with the particular trial or study design.

(x) INCENTIVE PAYMENTS FOR PRIMARY CARE SERVICES.—

(1) IN GENERAL.—In the case of primary care services furnished on or after January 1, 2011, and before January 1, 2016, by a primary care practitioner, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) DEFINITIONS.—In this subsection:

(A) PRIMARY CARE PRACTITIONER.—The term "primary care practitioner" means an individual—

(i) who—

(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)); and

(ii) for whom primary care services accounted for at least 60 percent of the allowed charges under this part for such physician or practitioner in a prior period as determined appropriate by the Secretary.

(B) PRIMARY CARE SERVICES.—The term "primary care services" means services identified, as of January 1, 2009, by the following HCPCS codes (and as subsequently modified by the Secretary):

(i) 99201 through 99215.

(ii) 99304 through 99340.

(iii) 99341 through 99350.

(3) COORDINATION WITH OTHER PAYMENTS.—The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively. The amount of the additional payment for a service under this subsection and subsection (z) shall be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.

(4) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting the identification of primary care practitioners under this subsection.

(y) INCENTIVE PAYMENTS FOR MAJOR SURGICAL PROCEDURES FURNISHED IN HEALTH PROFESSIONAL SHORTAGE AREAS.—

(1) IN GENERAL.—In the case of major surgical procedures furnished on or after January 1, 2011, and before January 1, 2016, by a general surgeon in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area as identified by the Secretary prior to the beginning of the year involved, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a

monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) DEFINITIONS.—In this subsection:

(A) GENERAL SURGEON.—In this subsection, the term "general surgeon" means a physician (as described in section 1861(r)(1)) who has designated CMS specialty code 02–General Surgery as their primary specialty code in the physician's enrollment under section 1866(j).

(B) MAJOR SURGICAL PROCEDURES.—The term "major surgical procedures" means physicians' services which are surgical procedures for which a 10-day or 90-day global period is used for payment under the fee schedule under section 1848(b).

(3) COORDINATION WITH OTHER PAYMENTS.—The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively. The amount of the additional payment for a service under this subsection and subsection (z) shall be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.

(4) APPLICATION.—The provisions of paragraph (2) and (4) of subsection (m) shall apply to the determination of additional payments under this subsection in the same manner as such provisions apply to the determination of additional payments under subsection (m).

(z) INCENTIVE PAYMENTS FOR PARTICIPATION IN ELIGIBLE ALTERNATIVE PAYMENT MODELS.—

(1) PAYMENT INCENTIVE.—

(A) IN GENERAL.—In the case of covered professional services furnished by an eligible professional during a year that is in the period beginning with 2019 and ending with 2025 and for which the professional is a qualifying APM participant with respect to such year, in addition to the amount of payment that would otherwise be made for such covered professional services under this part for such year, there also shall be paid to such professional an amount equal to 5 percent (or, with respect to 2025, 3.5 percent) of the estimated aggregate payment amounts for such covered professional services under this part for the preceding year. For purposes of the previous sentence, the payment amount for the preceding year may be an estimation for the full preceding year based on a period of such preceding year that is less than the full year. The Secretary shall establish policies to implement this subparagraph in cases in which payment for covered professional services furnished by a qualifying APM participant in an alternative payment model—

(i) is made to an eligible alternative payment entity rather than directly to the qualifying APM participant; or

(ii) is made on a basis other than a fee-for-service basis (such as payment on a capitated basis).

(B) FORM OF PAYMENT.—Payments under this subsection shall be made in a lump sum, on an annual basis, as soon as practicable.

(C) TREATMENT OF PAYMENT INCENTIVE.—Payments under this subsection shall not be taken into account for purposes of determining actual expenditures under an alternative payment model and for purposes of determining or rebasing any benchmarks used under the alternative payment model.

(D) COORDINATION.—The amount of the additional payment under this subsection or subsection (m) shall be determined without regard to any additional payment under subsection (m) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (x) shall be determined without regard to any additional payment under subsection (x) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (y) shall be determined without regard to any additional payment under subsection (y) and this subsection, respectively.

(2) QUALIFYING APM PARTICIPANT.—For purposes of this subsection, the term "qualifying APM participant" means the following:

(A) 2019 AND 2020.—With respect to 2019 and 2020, an eligible professional for whom the Secretary determines that at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(B) 2021 THROUGH 2025.—With respect to each of 2021 through 2025, an eligible professional described in either of the following clauses:

(i) MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional for whom the Secretary determines that at least 50 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(ii) COMBINATION ALL-PAYER AND MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional—

(I) for whom the Secretary determines, with respect to items and services furnished by such professional during the most recent period for which data are available (which may be less than a year), that at least 50 percent of the sum of—

(aa) payments described in clause (i); and

(bb) all other payments, regardless of payer (other than payments made by the Secretary of Defense or the Secretary of Veterans Affairs and other than payments made under title XIX in a State in which no medical home

or alternative payment model is available under the State program under that title),

meet the requirement described in clause (iii)(I) with respect to payments described in item (aa) and meet the requirement described in clause (iii)(II) with respect to payments described in item (bb);

(II) for whom the Secretary determines at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity; and

(III) who provides to the Secretary such information as is necessary for the Secretary to make a determination under subclause (I), with respect to such professional.

(iii) REQUIREMENT.—For purposes of clause (ii)(I)—

(I) the requirement described in this subclause, with respect to payments described in item (aa) of such clause, is that such payments are made to an eligible alternative payment entity; and

(II) the requirement described in this subclause, with respect to payments described in item (bb) of such clause, is that such payments are made under arrangements in which—

(aa) quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i) apply;

(bb) certified EHR technology is used; and

(cc) the eligible professional participates in an entity that—

(AA) bears more than nominal financial risk if actual aggregate expenditures exceeds expected aggregate expenditures; or

(BB) with respect to beneficiaries under title XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1115A(c).

(C) BEGINNING IN 2026.—With respect to 2026 and each subsequent year, an eligible professional described in either of the following clauses:

(i) MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional for whom the Secretary determines that at least 75 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(ii) COMBINATION ALL-PAYER AND MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional—

(I) for whom the Secretary determines, with respect to items and services furnished by such professional during the most recent period for which data are available (which may be less than a year), that at least 75 percent of the sum of—

(aa) payments described in clause (i); and

(bb) all other payments, regardless of payer (other than payments made by the Secretary of Defense or the Secretary of Veterans Affairs and other than payments made under title XIX in a State in which no medical home or alternative payment model is available under the State program under that title),

meet the requirement described in clause (iii)(I) with respect to payments described in item (aa) and meet the requirement described in clause (iii)(II) with respect to payments described in item (bb);

(II) for whom the Secretary determines at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity; and

(III) who provides to the Secretary such information as is necessary for the Secretary to make a determination under subclause (I), with respect to such professional.

(iii) REQUIREMENT.—For purposes of clause (ii)(I)—

(I) the requirement described in this subclause, with respect to payments described in item (aa) of such clause, is that such payments are made to an eligible alternative payment entity; and

(II) the requirement described in this subclause, with respect to payments described in item (bb) of such clause, is that such payments are made under arrangements in which—

(aa) quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i) apply;

(bb) certified EHR technology is used; and

(cc) the eligible professional participates in an entity that—

(AA) bears more than nominal financial risk if actual aggregate expenditures exceeds expected aggregate expenditures; or

(BB) with respect to beneficiaries under title XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1115A(c).

(D) USE OF PATIENT APPROACH.—The Secretary may base the determination of whether an eligible professional is a qualifying APM participant under this subsection and the

determination of whether an eligible professional is a partial qualifying APM participant under section 1848(q)(1)(C)(iii) by using counts of patients in lieu of using payments and using the same or similar percentage criteria (as specified in this subsection and such section, respectively), as the Secretary determines appropriate. With respect to 2023, 2024, and 2025, the Secretary shall use the same percentage criteria for counts of patients that are used in 2022.

(3) ADDITIONAL DEFINITIONS.—In this subsection:

(A) COVERED PROFESSIONAL SERVICES.—The term "covered professional services" has the meaning given that term in section 1848(k)(3)(A).

(B) ELIGIBLE PROFESSIONAL.—The term "eligible professional" has the meaning given that term in section 1848(k)(3)(B) and includes a group that includes such professionals.

(C) ALTERNATIVE PAYMENT MODEL (APM).—The term "alternative payment model" means, other than for purposes of subparagraphs (B)(ii)(I)(bb) and (C)(ii)(I)(bb) of paragraph (2), any of the following:

(i) A model under section 1115A (other than a health care innovation award).

(ii) The shared savings program under section 1899.

(iii) A demonstration under section 1866C.

(iv) A demonstration required by Federal law.

(D) ELIGIBLE ALTERNATIVE PAYMENT ENTITY.—The term "eligible alternative payment entity" means, with respect to a year, an entity that—

(i) participates in an alternative payment model that—

(I) requires participants in such model to use certified EHR technology (as defined in subsection (o)(4)); and

(II) provides for payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i); and

(ii)(I) bears financial risk for monetary losses under such alternative payment model that are in excess of a nominal amount; or

(II) is a medical home expanded under section 1115A(c).

(4) LIMITATION.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, of the following:

(A) The determination that an eligible professional is a qualifying APM participant under paragraph (2) and the determination that an entity is an eligible alternative payment entity under paragraph (3)(D).

(B) The determination of the amount of the 5 percent (or, with respect to 2025, 3.5 percent) payment incentive under paragraph (1)(A), including any estimation as part of such determination.

(aa) MEDICAL REVIEW OF SPINAL SUBLUXATION SERVICES.—

(1) IN GENERAL.—The Secretary shall implement a process for the medical review (as described in paragraph (2)) of treatment by a chiropractor described in section 1861(r)(5) by means of manual manipulation of the spine to correct a subluxation (as described in such section) of an individual who is enrolled under this part and apply such process to such services furnished on or after January 1, 2017, focusing on services such as—

(A) services furnished by a such a chiropractor whose pattern of billing is aberrant compared to peers; and

(B) services furnished by such a chiropractor who, in a prior period, has a services denial percentage in the 85th percentile or greater, taking into consideration the extent that service denials are overturned on appeal.

(2) MEDICAL REVIEW.—

(A) PRIOR AUTHORIZATION MEDICAL REVIEW.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary shall use prior authorization medical review for services described in paragraph (1) that are furnished to an individual by a chiropractor described in section 1861(r)(5) that are part of an episode of treatment that includes more than 12 services. For purposes of the preceding sentence, an episode of treatment shall be determined by the underlying cause that justifies the need for services, such as a diagnosis code.

(ii) ENDING APPLICATION OF PRIOR AUTHORIZATION MEDICAL REVIEW.—The Secretary shall end the application of prior authorization medical review under clause (i) to services described in paragraph (1) by such a chiropractor if the Secretary determines that the chiropractor has a low denial rate under such prior authorization medical review. The Secretary may subsequently reapply prior authorization medical review to such chiropractor if the Secretary determines it to be appropriate and the chiropractor has, in the time period subsequent to the determination by the Secretary of a low denial rate with respect to the chiropractor, furnished such services described in paragraph (1).

(iii) EARLY REQUEST FOR PRIOR AUTHORIZATION REVIEW PERMITTED.—Nothing in this subsection shall be construed to prevent such a chiropractor from requesting prior authorization for services described in paragraph (1) that are to be furnished to an individual before the chiropractor furnishes the twelfth such service to such individual for an episode of treatment.

(B) TYPE OF REVIEW.—The Secretary may use pre-payment review or post-payment review of services described in section 1861(r)(5) that are not subject to prior authorization medical review under subparagraph (A).

(C) RELATIONSHIP TO LAW ENFORCEMENT ACTIVITIES.—The Secretary may determine that medical review under this subsection does not apply in the case where potential fraud may be involved.

(3) NO PAYMENT WITHOUT PRIOR AUTHORIZATION.—With respect to a service described in paragraph (1) for which prior authorization medical review under this subsection applies, the following shall apply:

(A) PRIOR AUTHORIZATION DETERMINATION.—The Secretary shall make a determination, prior to the service being furnished, of whether the service would or would not meet the applicable requirements of section 1862(a)(1)(A).

(B) DENIAL OF PAYMENT.—Subject to paragraph (5), no payment may be made under this part for the service unless the Secretary determines pursuant to subparagraph (A) that the service would meet the applicable requirements of such section 1862(a)(1)(A).

(4) SUBMISSION OF INFORMATION.—A chiropractor described in section 1861(r)(5) may submit the information necessary for medical review by fax, by mail, or by electronic means. The Secretary shall make available the electronic means described in the preceding sentence as soon as practicable.

(5) TIMELINESS.—If the Secretary does not make a prior authorization determination under paragraph (3)(A) within 14 business days of the date of the receipt of medical documentation needed to make such determination, paragraph (3)(B) shall not apply.

(6) APPLICATION OF LIMITATION ON BENEFICIARY LIABILITY.—Where payment may not be made as a result of the application of paragraph (2)(B), section 1879 shall apply in the same manner as such section applies to a denial that is made by reason of section 1862(a)(1).

(7) REVIEW BY CONTRACTORS.—The medical review described in paragraph (2) may be conducted by medicare administrative contractors pursuant to section 1874A(a)(4)(G) or by any other contractor determined appropriate by the Secretary that is not a recovery audit contractor.

(8) MULTIPLE SERVICES.—The Secretary shall, where practicable, apply the medical review under this subsection in a manner so as to allow an individual described in paragraph (1) to obtain, at a single time rather than on a service-by-service basis, an authorization in accordance with paragraph (3)(A) for multiple services.

(9) CONSTRUCTION.—With respect to a service described in paragraph (1) that has been affirmed by medical review under this subsection, nothing in this subsection shall be construed to preclude the subsequent denial of a claim for such service that does not meet other applicable requirements under this Act.

(10) IMPLEMENTATION.—

(A) AUTHORITY.—The Secretary may implement the provisions of this subsection by interim final rule with comment period.

(B) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to medical review under this subsection.

(bb) ADDITIONAL PAYMENTS FOR CERTAIN RURAL HEALTH CLINICS WITH PHYSICIANS OR PRACTITIONERS RECEIVING DATA 2000 WAIVERS.—

(1) IN GENERAL.—In the case of a rural health clinic with respect to which, beginning on or after January 1, 2019, rural health clinic services (as defined in section 1861(aa)(1)) are furnished for the treatment of opioid use disorder by a physician or practitioner who meets the requirements described in paragraph (3), the Secretary shall, subject to availability of funds under paragraph (4), make a payment (at such time and in such manner as specified by the Secretary) to such rural health clinic after receiving and approving an application described in paragraph (2). Such payment shall be in an amount determined by the Secretary, based on an estimate of the average costs of training for purposes of receiving a waiver described in paragraph (3)(B). Such payment may be made only one time with respect to each such physician or practitioner.

(2) APPLICATION.—In order to receive a payment described in paragraph (1), a rural health clinic shall submit to the Secretary an application for such a payment at such time, in such manner, and containing such information as specified by the Secretary. A rural health clinic may apply for such a payment for each physician or practitioner described in paragraph (1) furnishing services described in such paragraph at such clinic.

(3) REQUIREMENTS.—For purposes of paragraph (1), the requirements described in this paragraph, with respect to a physician or practitioner, are the following:

(A) The physician or practitioner is employed by or working under contract with a rural health clinic described in paragraph (1) that submits an application under paragraph (2).

(B) The physician or practitioner first receives a waiver under section 303(h) of the Controlled Substances Act on or after January 1, 2019.

(4) FUNDING.—For purposes of making payments under this subsection, there are appropriated, out of amounts in the Treasury not otherwise appropriated, $2,000,000, which shall remain available until expended.

(cc) SPECIFIED COVID–19 TESTING-RELATED SERVICES.—For purposes of subsection (a)(1)(DD):

(1) DESCRIPTION.—

(A) IN GENERAL.—A specified COVID–19 testing-related service described in this paragraph is a medical visit that—

(i) is in any of the categories of HCPCS evaluation and management service codes described in subparagraph (B);

(ii) is furnished during any portion of the emergency period (as defined in section 1135(g)(1)(B)) (beginning on or after the date of enactment of this subsection);

(iii) results in an order for or administration of a clinical diagnostic laboratory test described in section 1852(a)(1)(B)(iv)(IV); and

(iv) relates to the furnishing or administration of such test or to the evaluation of such individual for purposes of determining the need of such individual for such test.

(B) CATEGORIES OF HCPCS CODES.—For purposes of subparagraph (A), the categories of HCPCS evaluation and management services codes are the following:

(i) Office and other outpatient services.

(ii) Hospital observation services.

(iii) Emergency department services.

(iv) Nursing facility services.

(v) Domiciliary, rest home, or custodial care services.

(vi) Home services.

(vii) Online digital evaluation and management services.

(2) SPECIFIED OUTPATIENT PAYMENT PROVISION.—A specified outpatient payment provision described in this paragraph is any of the following:

(A) The hospital outpatient prospective payment system under subsection (t).

(B) The physician fee schedule under section 1848.

(C) The prospective payment system developed under section 1834(o).

(D) Section 1834(g), with respect to an outpatient critical access hospital service.

(E) The payment basis determined in regulations pursuant to section 1833(a)(3) for rural health clinic services.

(dd) SPECIAL COINSURANCE RULE FOR CERTAIN COLORECTAL CANCER SCREENING TESTS.—

(1) IN GENERAL.—In the case of a colorectal cancer screening test to which paragraph (1)(Y) of subsection (a) would not apply but for the third sentence of such subsection that is furnished during a year beginning on or after January 1, 2022, and before January 1, 2030, the amount paid shall be equal to the specified percent (as defined in paragraph (2)) for such year of the lesser of the actual charge for the service or the amount determined under the fee schedule that applies to such test under this part (or, in the case such test is a covered OPD service (as defined in subsection (t)(1)(B)), the amount determined under subsection (t)).

(2) SPECIFIED PERCENT DEFINED.—For purposes of paragraph (1), the term "specified percent" means—

(A) for 2022, 80 percent;

(B) for 2023 through 2026, 85 percent; and

(C) for 2027 through 2029, 90 percent.

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## PART C—MEDICARE+CHOICE PROGRAM

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### BENEFITS AND BENEFICIARY PROTECTIONS

SEC. 1852. (a) BASIC BENEFITS.—

(1) REQUIREMENT.—

(A) IN GENERAL.—Except as provided in section 1859(b)(3) for MSA plans and except as provided in paragraph (6) for MA regional plans, each Medicare+Choice plan shall provide to members enrolled under this part, through providers and other persons that meet the appli-

cable requirements of this title and part A of title XI, benefits under the original medicare fee-for-service program option (and, for plan years before 2006, additional benefits required under section 1854(f)(1)(A)).

(B) BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION DEFINED.—

(i) IN GENERAL.—For purposes of this part, the term "benefits under the original medicare fee-for-service program option" means, subject to subsection (m), those items and services (other than hospice care or coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d)) for which benefits are available under parts A and B to individuals entitled to benefits under part A and enrolled under part B, with cost-sharing for those services as required under parts A and B or, subject to clause (iii), an actuarially equivalent level of cost-sharing as determined in this part.

(ii) SPECIAL RULE FOR REGIONAL PLANS.—In the case of an MA regional plan in determining an actuarially equivalent level of cost-sharing with respect to benefits under the original medicare fee-for-service program option, there shall only be taken into account, with respect to the application of section 1858(b)(2), such expenses only with respect to subparagraph (A) of such section.

(iii) LIMITATION ON VARIATION OF COST SHARING FOR CERTAIN BENEFITS.—Subject to clause (v), cost-sharing for services described in clause (iv) shall not exceed the cost-sharing required for those services under parts A and B.

(iv) SERVICES DESCRIBED.—The following services are described in this clause:

(I) Chemotherapy administration services.

(II) Renal dialysis services (as defined in section 1881(b)(14)(B)).

(III) Skilled nursing care.

(IV) Clinical diagnostic laboratory test administered during any portion of the emergency period defined in paragraph (1)(B) of section 1135(g) beginning on or after the date of the enactment of the Families First Coronavirus Response Act for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19 and the administration of such test.

(V) Specified COVID–19 testing-related services (as described in section 1833(cc)(1)) for which payment would be payable under a specified outpatient payment provision described in section 1833(cc)(2).

(VI) A COVID–19 vaccine and its administration described in section 1861(s)(10)(A).

(VII) A drug or biological product that is a selected drug (as referred to in section 1192(c)).

(VIII) Such other services that the Secretary determines appropriate (including services that the Secretary determines require a high level of predictability and transparency for beneficiaries).

(v) EXCEPTION.—In the case of services described in clause (iv), other than subclauses (IV), (V), and (VI) of such clause, for which there is no cost-sharing required under parts A and B, cost-sharing may be required for those services in accordance with clause (i).

(vi) PROHIBITION OF APPLICATION OF CERTAIN REQUIREMENTS FOR COVID–19 TESTING.—In the case of a product or service described in subclause (IV) or (V), respectively, of clause (iv) that is administered or furnished during any portion of the emergency period described in such subclause beginning on or after the date of the enactment of this clause, an MA plan may not impose any prior authorization or other utilization management requirements with respect to the coverage of such a product or service under such plan.

(2) SATISFACTION OF REQUIREMENT.—

(A) IN GENERAL.—A Medicare+Choice plan (other than an MSA plan) offered by a Medicare+Choice organization satisfies paragraph (1)(A), with respect to benefits for items and services furnished other than through a provider or other person that has a contract with the organization offering the plan, if the plan provides payment in an amount so that—

(i) the sum of such payment amount and any cost sharing provided for under the plan, is equal to at least

(ii) the total dollar amount of payment for such items and services as would otherwise be authorized under parts A and B (including any balance billing permitted under such parts).

(B) REFERENCE TO RELATED PROVISIONS.—For provision relating to—

(i) limitations on balance billing against Medicare+Choice organizations for non-contract providers, see sections 1852(k) and 1866(a)(1)(O), and

(ii) limiting actuarial value of enrollee liability for covered benefits, see section 1854(e).

(C) ELECTION OF UNIFORM COVERAGE DETERMINATION.—In the case of a Medicare+Choice organization that offers a Medicare+Choice plan in an area in which more than one local coverage determination is applied with respect to different parts of the area, the organization may elect to have the local coverage determination for the part of the area that is most beneficial to Medicare+Choice enrollees (as identified by the Secretary) apply with respect to all Medicare+Choice enrollees enrolled in the plan.

(3) SUPPLEMENTAL BENEFITS.—

(A) BENEFITS INCLUDED SUBJECT TO SECRETARY'S APPROVAL.—Subject to subparagraph (D), each Medicare+Choice organization may provide to individuals enrolled under this part, other than under an MSA plan

(without affording those individuals an option to decline the coverage), supplemental health care benefits that the Secretary may approve. The Secretary shall approve any such supplemental benefits unless the Secretary determines that including such supplemental benefits would substantially discourage enrollment by Medicare+Choice eligible individuals with the organization.

(B) AT ENROLLEES' OPTION.—

(i) IN GENERAL.—Subject to clause (ii), a Medicare+Choice organization may provide to individuals enrolled under this part supplemental health care benefits that the individuals may elect, at their option, to have covered.

(ii) SPECIAL RULE FOR MSA PLANS.—A Medicare+Choice organization may not provide, under an MSA plan, supplemental health care benefits that cover the deductible described in section 1859(b)(2)(B). In applying the previous sentence, health benefits described in section 1882(u)(2)(B) shall not be treated as covering such deductible.

(C) APPLICATION TO MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLANS.—Nothing in this paragraph shall be construed as preventing a Medicare+Choice private fee-for-service plan from offering supplemental benefits that include payment for some or all of the balance billing amounts permitted consistent with section 1852(k) and coverage of additional services that the plan finds to be medically necessary. Such benefits may include reductions in cost-sharing below the actuarial value specified in section 1854(e)(4)(B).

(D) EXPANDING SUPPLEMENTAL BENEFITS TO MEET THE NEEDS OF CHRONICALLY ILL ENROLLEES.—

(i) IN GENERAL.—For plan year 2020 and subsequent plan years, in addition to any supplemental health care benefits otherwise provided under this paragraph, an MA plan, including a specialized MA plan for special needs individuals (as defined in section 1859(b)(6)), may provide supplemental benefits described in clause (ii) to a chronically ill enrollee (as defined in clause (iii)).

(ii) SUPPLEMENTAL BENEFITS DESCRIBED.—

(I) IN GENERAL.—Supplemental benefits described in this clause are supplemental benefits that, with respect to a chronically ill enrollee, have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee and may not be limited to being primarily health related benefits.

(II) AUTHORITY TO WAIVE UNIFORMITY REQUIREMENTS.—The Secretary may, only with respect to supplemental benefits provided to a chronically ill enrollee under this subparagraph, waive the uniformity requirements under this part, as determined appropriate by the Secretary.

(iii) CHRONICALLY ILL ENROLLEE DEFINED.—In this subparagraph, the term "chronically ill enrollee" means an enrollee in an MA plan that the Secretary determines—

(I) has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee;

(II) has a high risk of hospitalization or other adverse health outcomes; and

(III) requires intensive care coordination.

(4) ORGANIZATION AS SECONDARY PAYER.—Notwithstanding any other provision of law, a Medicare+Choice organization may (in the case of the provision of items and services to an individual under a Medicare+Choice plan under circumstances in which payment under this title is made secondary pursuant to section 1862(b)(2)) charge or authorize the provider of such services to charge, in accordance with the charges allowed under a law, plan, or policy described in such section—

(A) the insurance carrier, employer, or other entity which under such law, plan, or policy is to pay for the provision of such services, or

(B) such individual to the extent that the individual has been paid under such law, plan, or policy for such services.

(5) NATIONAL COVERAGE DETERMINATIONS AND LEGISLATIVE CHANGES IN BENEFITS.—If there is a national coverage determination or legislative change in benefits required to be provided under this part made in the period beginning on the date of an announcement under section 1853(b) and ending on the date of the next announcement under such section and the Secretary projects that the determination will result in a significant change in the costs to a Medicare+Choice organization of providing the benefits that are the subject of such national coverage determination and that such change in costs was not incorporated in the determination of the annual Medicare+Choice capitation rate under section 1853 included in the announcement made at the beginning of such period, then, unless otherwise required by law—

(A) such determination or legislative change in benefits shall not apply to contracts under this part until the first contract year that begins after the end of such period, and

(B) if such coverage determination or legislative change provides for coverage of additional benefits or coverage under additional circumstances, section 1851(i)(1) shall not apply to payment for such additional benefits or benefits provided under such additional circumstances until the first contract year that begins after the end of such period.

The projection under the previous sentence shall be based on an analysis by the Chief Actuary of the Centers for Medicare & Medicaid Services of the actuarial costs associated with the coverage determination or legislative change in benefits.

(6) SPECIAL BENEFIT RULES FOR REGIONAL PLANS.—In the case of an MA plan that is an MA regional plan, benefits under the plan shall include the benefits described in paragraphs (1) and (2) of section 1858(b).

(7) LIMITATION ON COST-SHARING FOR DUAL ELIGIBLES AND QUALIFIED MEDICARE BENEFICIARIES.—In the case of an individual who is a full-benefit dual eligible individual (as defined in section 1935(c)(6)) or a qualified medicare beneficiary (as defined in section 1905(p)(1)) and who is enrolled in a specialized Medicare Advantage plan for special needs individuals described in section 1859(b)(6)(B)(ii), the plan may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under title XIX if the individual were not enrolled in such plan.

(b) ANTIDISCRIMINATION.—

(1) BENEFICIARIES.—A Medicare Advantage organization may not deny, limit, or condition the coverage or provision of benefits under this part, for individuals permitted to be enrolled with the organization under this part, based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act. The Secretary shall not approve a plan of an organization if the Secretary determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals with the organization.

(2) PROVIDERS.—A Medicare+Choice organization shall not discriminate with respect to participation, reimbursement, or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification. This paragraph shall not be construed to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan.

(c) DISCLOSURE REQUIREMENTS.—

(1) DETAILED DESCRIPTION OF PLAN PROVISIONS.—A Medicare+Choice organization shall disclose, in clear, accurate, and standardized form to each enrollee with a Medicare+Choice plan offered by the organization under this part at the time of enrollment and at least annually thereafter, the following information regarding such plan:

(A) SERVICE AREA.—The plan's service area.

(B) BENEFITS.—Benefits offered under the plan, including information described in section 1851(d)(3)(A) and exclusions from coverage and, if it is an MSA plan, a comparison of benefits under such a plan with benefits under other Medicare+Choice plans.

(C) ACCESS.—The number, mix, and distribution of plan providers, out-of-network coverage (if any) provided by the plan, and any point-of-service option (including the supplemental premium for such option).

(D) OUT-OF-AREA COVERAGE.—Out-of-area coverage provided by the plan.

(E) EMERGENCY COVERAGE.—Coverage of emergency services, including—

(i) the appropriate use of emergency services, including use of the 911 telephone system or its local equiva-

lent in emergency situations and an explanation of what constitutes an emergency situation;

(ii) the process and procedures of the plan for obtaining emergency services; and

(iii) the locations of (I) emergency departments, and (II) other settings, in which plan physicians and hospitals provide emergency services and post-stabilization care.

(F) SUPPLEMENTAL BENEFITS.—Supplemental benefits available from the organization offering the plan, including—

(i) whether the supplemental benefits are optional,

(ii) the supplemental benefits covered, and

(iii) the Medicare+Choice monthly supplemental beneficiary premium for the supplemental benefits.

(G) PRIOR AUTHORIZATION RULES.—Rules regarding prior authorization or other review requirements that could result in nonpayment.

(H) PLAN GRIEVANCE AND APPEALS PROCEDURES.—All plan appeal or grievance rights and procedures.

(I) QUALITY IMPROVEMENT PROGRAM.—A description of the organization's quality improvement program under subsection (e).

(2) DISCLOSURE UPON REQUEST.—Upon request of a Medicare+Choice eligible individual, a Medicare+Choice organization must provide the following information to such individual:

(A) The general coverage information and general comparative plan information made available under clauses (i) and (ii) of section 1851(d)(2)(A).

(B) Information on procedures used by the organization to control utilization of services and expenditures.

(C) Information on the number of grievances, redeterminations, and appeals and on the disposition in the aggregate of such matters.

(D) An overall summary description as to the method of compensation of participating physicians.

(d) ACCESS TO SERVICES.—

(1) IN GENERAL.—A Medicare+Choice organization offering a Medicare+Choice plan may select the providers from whom the benefits under the plan are provided so long as—

(A) the organization makes such benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits;

(B) when medically necessary the organization makes such benefits available and accessible 24 hours a day and 7 days a week;

(C) the plan provides for reimbursement with respect to services which are covered under subparagraphs (A) and (B) and which are provided to such an individual other than through the organization, if—

(i) the services were not emergency services (as defined in paragraph (3)), but (I) the services were medi-

cally necessary and immediately required because of an unforeseen illness, injury, or condition, and (II) it was not reasonable given the circumstances to obtain the services through the organization,

(ii) the services were renal dialysis services and were provided other than through the organization because the individual was temporarily out of the plan's service area, or

(iii) the services are maintenance care or post-stabilization care covered under the guidelines established under paragraph (2);

(D) the organization provides access to appropriate providers, including credentialed specialists, for medically necessary treatment and services; and

(E) coverage is provided for emergency services (as defined in paragraph (3)) without regard to prior authorization or the emergency care provider's contractual relationship with the organization.

(2) GUIDELINES RESPECTING COORDINATION OF POST-STABILIZATION CARE.—A Medicare+Choice plan shall comply with such guidelines as the Secretary may prescribe relating to promoting efficient and timely coordination of appropriate maintenance and post-stabilization care of an enrollee after the enrollee has been determined to be stable under section 1867.

(3) DEFINITION OF EMERGENCY SERVICES.—In this subsection—

(A) IN GENERAL.—The term "emergency services" means, with respect to an individual enrolled with an organization, covered inpatient and outpatient services that—

(i) are furnished by a provider that is qualified to furnish such services under this title, and

(ii) are needed to evaluate or stabilize an emergency medical condition (as defined in subparagraph (B)).

(B) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON.—The term "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

(i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

(ii) serious impairment to bodily functions, or

(iii) serious dysfunction of any bodily organ or part.

(4) ASSURING ACCESS TO SERVICES IN MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLANS.—In addition to any other requirements under this part, in the case of a Medicare+Choice private fee-for-service plan, the organization offering the plan must demonstrate to the Secretary that the organization has sufficient number and range of health care professionals and providers willing to provide services under the terms of the plan. Subject to paragraphs (5) and (6), the Secretary shall find that an organization has met such requirement with respect to any cat-

egory of health care professional or provider if, with respect to that category of provider—

(A) the plan has established payment rates for covered services furnished by that category of provider that are not less than the payment rates provided for under part A, part B, or both, for such services, or

(B) the plan has contracts or agreements (other than deemed contracts or agreements under subsection (j)(6)) with a sufficient number and range of providers within such category to meet the access standards in subparagraphs (A) through (E) of paragraph (1),

or a combination of both. The previous sentence shall not be construed as restricting the persons from whom enrollees under such a plan may obtain covered benefits, except that, if a plan entirely meets such requirement with respect to a category of health care professional or provider on the basis of subparagraph (B), it may provide for a higher beneficiary copayment in the case of health care professionals and providers of that category who do not have contracts or agreements (other than deemed contracts or agreements under subsection (j)(6)) to provide covered services under the terms of the plan.

(5) REQUIREMENT OF CERTAIN NONEMPLOYER MEDICARE ADVANTAGE PRIVATE FEE-FOR-SERVICE PLANS TO USE CONTRACTS WITH PROVIDERS.—

(A) IN GENERAL.—For plan year 2011 and subsequent plan years, in the case of a Medicare Advantage private fee-for-service plan not described in paragraph (1) or (2) of section 1857(i) operating in a network area (as defined in subparagraph (B)), the plan shall meet the access standards under paragraph (4) in that area only through entering into written contracts as provided for under subparagraph (B) of such paragraph and not, in whole or in part, through the establishment of payment rates meeting the requirements under subparagraph (A) of such paragraph.

(B) NETWORK AREA DEFINED.—For purposes of subparagraph (A), the term "network area" means, for a plan year, an area which the Secretary identifies (in the Secretary's announcement of the proposed payment rates for the previous plan year under section 1853(b)(1)(B)) as having at least 2 network-based plans (as defined in subparagraph (C)) with enrollment under this part as of the first day of the year in which such announcement is made.

(C) NETWORK-BASED PLAN DEFINED.—

(i) IN GENERAL.—For purposes of subparagraph (B), the term "network-based plan" means—

(I) except as provided in clause (ii), a Medicare Advantage plan that is a coordinated care plan described in section 1851(a)(2)(A)(i);

(II) a network-based MSA plan; and

(III) a reasonable cost reimbursement plan under section 1876.

(ii) EXCLUSION OF NON-NETWORK REGIONAL PPOS.—The term "network-based plan" shall not include an MA regional plan that, with respect to the area, meets

access adequacy standards under this part substantially through the authority of section 422.112(a)(1)(ii) of title 42, Code of Federal Regulations, rather than through written contracts.

(6) REQUIREMENT OF ALL EMPLOYER MEDICARE ADVANTAGE PRIVATE FEE-FOR-SERVICE PLANS TO USE CONTRACTS WITH PROVIDERS.—For plan year 2011 and subsequent plan years, in the case of a Medicare Advantage private fee-for-service plan that is described in paragraph (1) or (2) of section 1857(i), the plan shall meet the access standards under paragraph (4) only through entering into written contracts as provided for under subparagraph (B) of such paragraph and not, in whole or in part, through the establishment of payment rates meeting the requirements under subparagraph (A) of such paragraph.

(e) QUALITY IMPROVEMENT PROGRAM.—

(1) IN GENERAL.—Each MA organization shall have an ongoing quality improvement program for the purpose of improving the quality of care provided to enrollees in each MA plan offered by such organization.

(2) CHRONIC CARE IMPROVEMENT PROGRAMS.—As part of the quality improvement program under paragraph (1), each MA organization shall have a chronic care improvement program. Each chronic care improvement program shall have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions that meet criteria established by the organization for participation under the program.

(3) DATA.—

(A) COLLECTION, ANALYSIS, AND REPORTING.—

(i) IN GENERAL.—Except as provided in clauses (ii) and (iii) with respect to plans described in such clauses and subject to subparagraph (B), as part of the quality improvement program under paragraph (1), each MA organization shall provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality. With respect to MA private fee-for-service plans and MSA plans, the requirements under the preceding sentence may not exceed the requirements under this subparagraph with respect to MA local plans that are preferred provider organization plans, except that, for plan year 2010, the limitation under clause (iii) shall not apply and such requirements shall apply only with respect to administrative claims data.

(ii) SPECIAL REQUIREMENTS FOR SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—In addition to the data required to be collected, analyzed, and reported under clause (i) and notwithstanding the limitations under subparagraph (B), as part of the quality improvement program under paragraph (1), each MA organization offering a specialized Medicare Advantage plan for special needs individuals shall provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality with respect to the requirements described in paragraphs (2) through (5) of sub-

section (f). Such data may be based on claims data and shall be at the plan level.

(iii) APPLICATION TO LOCAL PREFERRED PROVIDER ORGANIZATIONS AND MA REGIONAL PLANS.—Clause (i) shall apply to MA organizations with respect to MA local plans that are preferred provider organization plans and to MA regional plans only insofar as services are furnished by providers or services, physicians, and other health care practitioners and suppliers that have contracts with such organization to furnish services under such plans.

(iv) DEFINITION OF PREFERRED PROVIDER ORGANIZATION PLAN.—In this subparagraph, the term "preferred provider organization plan" means an MA plan that—

(I) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(II) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and

(III) is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

(B) LIMITATIONS.—

(i) TYPES OF DATA.—The Secretary shall not collect under subparagraph (A) data on quality, outcomes, and beneficiary satisfaction to facilitate consumer choice and program administration other than the types of data that were collected by the Secretary as of November 1, 2003.

(ii) CHANGES IN TYPES OF DATA.—Subject to subclause (iii), the Secretary may only change the types of data that are required to be submitted under subparagraph (A) after submitting to Congress a report on the reasons for such changes that was prepared in consultation with MA organizations and private accrediting bodies.

(iii) CONSTRUCTION.—Nothing in the subsection shall be construed as restricting the ability of the Secretary to carry out the duties under section 1851(d)(4)(D).

(4) TREATMENT OF ACCREDITATION.—

(A) IN GENERAL.—The Secretary shall provide that a Medicare+Choice organization is deemed to meet all the requirements described in any specific clause of subparagraph (B) if the organization is accredited (and periodically reaccredited) by a private accrediting organization under a process that the Secretary has determined assures that the accrediting organization applies and enforces standards that meet or exceed the standards established under section 1856 to carry out the requirements in such clause.

(B) REQUIREMENTS DESCRIBED.—The provisions described in this subparagraph are the following:

(i) Paragraphs (1) through (3) of this subsection (relating to quality improvement programs).

(ii) Subsection (b) (relating to antidiscrimination).

(iii) Subsection (d) (relating to access to services).

(iv) Subsection (h) (relating to confidentiality and accuracy of enrollee records).

(v) Subsection (i) (relating to information on advance directives).

(vi) Subsection (j) (relating to provider participation rules).

(vii) The requirements described in section 1860D–4(j), to the extent such requirements apply under section 1860D–21(c).

(C) TIMELY ACTION ON APPLICATIONS.—The Secretary shall determine, within 210 days after the date the Secretary receives an application by a private accrediting organization and using the criteria specified in section 1865(a)(2), whether the process of the private accrediting organization meets the requirements with respect to any specific clause in subparagraph (B) with respect to which the application is made. The Secretary may not deny such an application on the basis that it seeks to meet the requirements with respect to only one, or more than one, such specific clause.

(D) CONSTRUCTION.—Nothing in this paragraph shall be construed as limiting the authority of the Secretary under section 1857, including the authority to terminate contracts with Medicare+Choice organizations under subsection (c)(2) of such section.

(f) GRIEVANCE MECHANISM.—Each Medicare+Choice organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the organization provides health care services) and enrollees with Medicare+Choice plans of the organization under this part.

(g) COVERAGE DETERMINATIONS, RECONSIDERATIONS, AND APPEALS.—

(1) DETERMINATIONS BY ORGANIZATION.—

(A) IN GENERAL.—A Medicare+Choice organization shall have a procedure for making determinations regarding whether an individual enrolled with the plan of the organization under this part is entitled to receive a health service under this section and the amount (if any) that the individual is required to pay with respect to such service. Subject to paragraph (3) *and in accordance with paragraph (6)*, such procedures shall provide for such determination to be made on a timely basis.

(B) EXPLANATION OF DETERMINATION.—Such a determination that denies coverage, in whole or in part, shall be in writing and shall include a statement in understandable language of the reasons for the denial and a description of the reconsideration and appeals processes.

(2) RECONSIDERATIONS.—

(A) IN GENERAL.—The organization shall provide for reconsideration of a determination described in paragraph

(1)(B) upon request by the enrollee involved. The reconsideration shall be within a time period specified by the Secretary, but shall be made, subject to paragraph (3), not later than 60 days after the date of the receipt of the request for reconsideration.

(B) PHYSICIAN DECISION ON CERTAIN RECONSIDERATIONS.—A reconsideration relating to a determination to deny coverage based on a lack of medical necessity shall be made only by a physician with appropriate expertise in the field of medicine which necessitates treatment who is other than a physician involved in the initial determination.

(3) EXPEDITED DETERMINATIONS AND RECONSIDERATIONS.—

(A) RECEIPT OF REQUESTS.—

(i) ENROLLEE REQUESTS.—An enrollee in a Medicare+Choice plan may request, either in writing or orally, an expedited determination under paragraph (1) or an expedited reconsideration under paragraph (2) by the Medicare+Choice organization.

(ii) PHYSICIAN REQUESTS.—A physician, regardless whether the physician is affiliated with the organization or not, may request, either in writing or orally, such an expedited determination or reconsideration.

(B) ORGANIZATION PROCEDURES.—

(i) IN GENERAL.—The Medicare+Choice organization shall maintain procedures for expediting organization determinations and reconsiderations when, upon request of an enrollee, the organization determines that the application of the normal time frame for making a determination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) EXPEDITION REQUIRED FOR PHYSICIAN REQUESTS.—In the case of a request for an expedited determination or reconsideration made under subparagraph (A)(ii), the organization shall expedite the determination or reconsideration if the request indicates that the application of the normal time frame for making a determination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(iii) TIMELY RESPONSE.—In cases described in clauses (i) and (ii), the organization shall notify the enrollee (and the physician involved, as appropriate) of the determination or reconsideration under time limitations established by the Secretary, but not later than 72 hours *(or, subject to subsection (o), with respect to prior authorization requests submitted on or after the first day of the third plan year beginning after the date of the enactment of the Health Care Price Transparency Act of 2023, not later than 24 hours)* of the time of receipt of the request for the determination or reconsideration (or receipt of the information nec-

essary to make the determination or reconsideration), or such longer period as the Secretary may permit in specified cases.

(4) INDEPENDENT REVIEW OF CERTAIN COVERAGE DENIALS.—The Secretary shall contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm denial of coverage, in whole or in part. The provisions of section 1869(c)(5) shall apply to independent outside entities under contract with the Secretary under this paragraph.

(5) APPEALS.—An enrollee with a Medicare+Choice plan of a Medicare+Choice organization under this part who is dissatisfied by reason of the enrollee's failure to receive any health service to which the enrollee believes the enrollee is entitled and at no greater charge than the enrollee believes the enrollee is required to pay is entitled, if the amount in controversy is $100 or more, to a hearing before the Secretary to the same extent as is provided in section 205(b), and in any such hearing the Secretary shall make the organization a party. If the amount in controversy is $1,000 or more, the individual or organization shall, upon notifying the other party, be entitled to judicial review of the Secretary's final decision as provided in section 205(g), and both the individual and the organization shall be entitled to be parties to that judicial review. In applying subsections (b) and (g) of section 205 as provided in this paragraph, and in applying section 205(l) thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively. The provisions of section 1869(b)(1)(E)(iii) shall apply with respect to dollar amounts specified in the first 2 sentences of this paragraph in the same manner as they apply to the dollar amounts specified in section 1869(b)(1)(E)(i).

*(6) TIMEFRAME FOR RESPONSE TO PRIOR AUTHORIZATION REQUESTS.—Subject to paragraph (3) and subsection (o), in the case of an organization determination made with respect to a prior authorization request for an item or service to be furnished to an individual submitted on or after the first day of the third plan year beginning after the date of the enactment of this paragraph, the organization shall notify the enrollee (and the physician involved, as appropriate) of such determination no later than 7 days (or such shorter timeframe as the Secretary may specify through notice and comment rulemaking, taking into account enrollee and stakeholder feedback) after receipt of such request.*

(h) CONFIDENTIALITY AND ACCURACY OF ENROLLEE RECORDS.—Insofar as a Medicare+Choice organization maintains medical records or other health information regarding enrollees under this part, the Medicare+Choice organization shall establish procedures—

(1) to safeguard the privacy of any individually identifiable enrollee information;

(2) to maintain such records and information in a manner that is accurate and timely; and

(3) to assure timely access of enrollees to such records and information.

(i) INFORMATION ON ADVANCE DIRECTIVES.—Each Medicare+Choice organization shall meet the requirement of section 1866(f) (relating to maintaining written policies and procedures respecting advance directives).

(j) RULES REGARDING PROVIDER PARTICIPATION.—

(1) PROCEDURES.—Insofar as a Medicare+Choice organization offers benefits under a Medicare+Choice plan through agreements with physicians, the organization shall establish reasonable procedures relating to the participation (under an agreement between a physician and the organization) of physicians under such a plan. Such procedures shall include—

(A) providing notice of the rules regarding participation,

(B) providing written notice of participation decisions that are adverse to physicians, and

(C) providing a process within the organization for appealing such adverse decisions, including the presentation of information and views of the physician regarding such decision.

(2) CONSULTATION IN MEDICAL POLICIES.—A Medicare+Choice organization shall consult with physicians who have entered into participation agreements with the organization regarding the organization's medical policy, quality, and medical management procedures.

(3) PROHIBITING INTERFERENCE WITH PROVIDER ADVICE TO ENROLLEES.—

(A) IN GENERAL.—Subject to subparagraphs (B) and (C), a Medicare+Choice organization (in relation to an individual enrolled under a Medicare+Choice plan offered by the organization under this part) shall not prohibit or otherwise restrict a covered health care professional (as defined in subparagraph (D)) from advising such an individual who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the plan, if the professional is acting within the lawful scope of practice.

(B) CONSCIENCE PROTECTION.—Subparagraph (A) shall not be construed as requiring a Medicare+Choice plan to provide, reimburse for, or provide coverage of a counseling or referral service if the Medicare+Choice organization offering the plan—

(i) objects to the provision of such service on moral or religious grounds; and

(ii) in the manner and through the written instrumentalities such Medicare+Choice organization deems appropriate, makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization or plan adopts a change in policy regarding such a counseling or referral service.

(C) CONSTRUCTION.—Nothing in subparagraph (B) shall be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

(D) HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this paragraph, the term "health care professional" means a physician (as defined in section 1861(r)) or other health care professional if coverage for the professional's services is provided under the Medicare+Choice plan for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

(4) LIMITATIONS ON PHYSICIAN INCENTIVE PLANS.—

(A) IN GENERAL.—No Medicare+Choice organization may operate any physician incentive plan (as defined in subparagraph (B)) unless the organization provides assurances satisfactory to the Secretary that the following requirements are met:

(i) No specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the organization.

(ii) If the plan places a physician or physician group at substantial financial risk (as determined by the Secretary) for services not provided by the physician or physician group, the organization provides stop-loss protection for the physician or group that is adequate and appropriate, based on standards developed by the Secretary that take into account the number of physicians placed at such substantial financial risk in the group or under the plan and the number of individuals enrolled with the organization who receive services from the physician or group.

(B) PHYSICIAN INCENTIVE PLAN DEFINED.—In this paragraph, the term "physician incentive plan" means any compensation arrangement between a Medicare+Choice organization and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the organization under this part.

(5) LIMITATION ON PROVIDER INDEMNIFICATION.—A Medicare+Choice organization may not provide (directly or indirectly) for a health care professional, provider of services, or other entity providing health care services (or group of such professionals, providers, or entities) to indemnify the organization against any liability resulting from a civil action brought for any damage caused to an enrollee with a Medicare+Choice

plan of the organization under this part by the organization's denial of medically necessary care.

(6) SPECIAL RULES FOR MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLANS.—For purposes of applying this part (including subsection (k)(1)) and section 1866(a)(1)(O), a hospital (or other provider of services), a physician or other health care professional, or other entity furnishing health care services is treated as having an agreement or contract in effect with a Medicare+Choice organization (with respect to an individual enrolled in a Medicare+Choice private fee-for-service plan it offers), if—

(A) the provider, professional, or other entity furnishes services that are covered under the plan to such an enrollee; and

(B) before providing such services, the provider, professional, or other entity —

(i) has been informed of the individual's enrollment under the plan, and

(ii) either—

(I) has been informed of the terms and conditions of payment for such services under the plan, or

(II) is given a reasonable opportunity to obtain information concerning such terms and conditions, in a manner reasonably designed to effect informed agreement by a provider.

The previous sentence shall only apply in the absence of an explicit agreement between such a provider, professional, or other entity and the Medicare+Choice organization.

(7) PROMOTION OF E-PRESCRIBING BY MA PLANS.—

(A) IN GENERAL.—An MA–PD plan may provide for a separate payment or otherwise provide for a differential payment for a participating physician that prescribes covered part D drugs in accordance with an electronic prescription drug program that meets standards established under section 1860D–4(e).

(B) CONSIDERATIONS.—Such payment may take into consideration the costs of the physician in implementing such a program and may also be increased for those participating physicians who significantly increase—

(i) formulary compliance;

(ii) lower cost, therapeutically equivalent alternatives;

(iii) reductions in adverse drug interactions; and

(iv) efficiencies in filing prescriptions through reduced administrative costs.

(C) STRUCTURE.—Additional or increased payments under this subsection may be structured in the same manner as medication therapy management fees are structured under section 1860D–4(c)(2)(E).

(k) TREATMENT OF SERVICES FURNISHED BY CERTAIN PROVIDERS.—

(1) IN GENERAL.—Except as provided in paragraph (2), a physician or other entity (other than a provider of services) that does not have a contract establishing payment amounts for

services furnished to an individual enrolled under this part with a Medicare+Choice organization described in section 1851(a)(2)(A) or with an organization offering an MSA plan shall accept as payment in full for covered services under this title that are furnished to such an individual the amounts that the physician or other entity could collect if the individual were not so enrolled. Any penalty or other provision of law that applies to such a payment with respect to an individual entitled to benefits under this title (but not enrolled with a Medicare+Choice organization under this part) also applies with respect to an individual so enrolled.

(2) APPLICATION TO MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLANS.—

(A) BALANCE BILLING LIMITS UNDER MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLANS IN CASE OF CONTRACT PROVIDERS.—

(i) IN GENERAL.—In the case of an individual enrolled in a Medicare+Choice private fee-for-service plan under this part, a physician, provider of services, or other entity that has a contract (including through the operation of subsection (j)(6)) establishing a payment rate for services furnished to the enrollee shall accept as payment in full for covered services under this title that are furnished to such an individual an amount not to exceed (including any deductibles, coinsurance, copayments, or balance billing otherwise permitted under the plan) an amount equal to 115 percent of such payment rate.

(ii) PROCEDURES TO ENFORCE LIMITS.—The Medicare+Choice organization that offers such a plan shall establish procedures, similar to the procedures described in section 1848(g)(1)(A), in order to carry out the previous sentence.

(iii) ASSURING ENFORCEMENT.—If the Medicare+Choice organization fails to establish and enforce procedures required under clause (ii), the organization is subject to intermediate sanctions under section 1857(g).

(B) ENROLLEE LIABILITY FOR NONCONTRACT PROVIDERS.—For provision—

(i) establishing minimum payment rate in the case of noncontract providers under a Medicare+Choice private fee-for-service plan, see section 1852(a)(2); or

(ii) limiting enrollee liability in the case of covered services furnished by such providers, see paragraph (1) and section 1866(a)(1)(O).

(C) INFORMATION ON BENEFICIARY LIABILITY.—

(i) IN GENERAL.—Each Medicare+Choice organization that offers a Medicare+Choice private fee-for-service plan shall provide that enrollees under the plan who are furnished services for which payment is sought under the plan are provided an appropriate explanation of benefits (consistent with that provided under parts A and B and, if applicable, under medicare supplemental policies) that includes a clear state-

ment of the amount of the enrollee's liability (including any liability for balance billing consistent with this subsection) with respect to payments for such services.

(ii) ADVANCE NOTICE BEFORE RECEIPT OF INPATIENT HOSPITAL SERVICES AND CERTAIN OTHER SERVICES.—In addition, such organization shall, in its terms and conditions of payments to hospitals for inpatient hospital services and for other services identified by the Secretary for which the amount of the balance billing under subparagraph (A) could be substantial, require the hospital to provide to the enrollee, before furnishing such services and if the hospital imposes balance billing under subparagraph (A)—

(I) notice of the fact that balance billing is permitted under such subparagraph for such services, and

(II) a good faith estimate of the likely amount of such balance billing (if any), with respect to such services, based upon the presenting condition of the enrollee.

(l) RETURN TO HOME SKILLED NURSING FACILITIES FOR COVERED POST-HOSPITAL EXTENDED CARE SERVICES.—

(1) ENSURING RETURN TO HOME SNF.—

(A) IN GENERAL.—In providing coverage of post-hospital extended care services, a Medicare+Choice plan shall provide for such coverage through a home skilled nursing facility if the following conditions are met:

(i) ENROLLEE ELECTION.—The enrollee elects to receive such coverage through such facility.

(ii) SNF AGREEMENT.—The facility has a contract with the Medicare+Choice organization for the provision of such services, or the facility agrees to accept substantially similar payment under the same terms and conditions that apply to similarly situated skilled nursing facilities that are under contract with the Medicare+Choice organization for the provision of such services and through which the enrollee would otherwise receive such services.

(B) MANNER OF PAYMENT TO HOME SNF.—The organization shall provide payment to the home skilled nursing facility consistent with the contract or the agreement described in subparagraph (A)(ii), as the case may be.

(2) NO LESS FAVORABLE COVERAGE.—The coverage provided under paragraph (1) (including scope of services, cost-sharing, and other criteria of coverage) shall be no less favorable to the enrollee than the coverage that would be provided to the enrollee with respect to a skilled nursing facility the post-hospital extended care services of which are otherwise covered under the Medicare+Choice plan.

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to do the following:

(A) To require coverage through a skilled nursing facility that is not otherwise qualified to provide benefits under part A for medicare beneficiaries not enrolled in a Medicare+Choice plan.

(B) To prevent a skilled nursing facility from refusing to accept, or imposing conditions upon the acceptance of, an enrollee for the receipt of post-hospital extended care services.

(4) DEFINITIONS.—In this subsection:

(A) HOME SKILLED NURSING FACILITY.—The term "home skilled nursing facility" means, with respect to an enrollee who is entitled to receive post-hospital extended care services under a Medicare+Choice plan, any of the following skilled nursing facilities:

(i) SNF RESIDENCE AT TIME OF ADMISSION.—The skilled nursing facility in which the enrollee resided at the time of admission to the hospital preceding the receipt of such post-hospital extended care services.

(ii) SNF IN CONTINUING CARE RETIREMENT COMMUNITY.—A skilled nursing facility that is providing such services through a continuing care retirement community (as defined in subparagraph (B)) which provided residence to the enrollee at the time of such admission.

(iii) SNF RESIDENCE OF SPOUSE AT TIME OF DISCHARGE.—The skilled nursing facility in which the spouse of the enrollee is residing at the time of discharge from such hospital.

(B) CONTINUING CARE RETIREMENT COMMUNITY.—The term "continuing care retirement community" means, with respect to an enrollee in a Medicare+Choice plan, an arrangement under which housing and health-related services are provided (or arranged) through an organization for the enrollee under an agreement that is effective for the life of the enrollee or for a specified period.

(m) PROVISION OF ADDITIONAL TELEHEALTH BENEFITS.—

(1) MA PLAN OPTION.—For plan year 2020 and subsequent plan years, subject to the requirements of paragraph (3), an MA plan may provide additional telehealth benefits (as defined in paragraph (2)) to individuals enrolled under this part.

(2) ADDITIONAL TELEHEALTH BENEFITS DEFINED.—

(A) IN GENERAL.—For purposes of this subsection and section 1854:

(i) DEFINITION.—The term "additional telehealth benefits" means services—

(I) for which benefits are available under part B, including services for which payment is not made under section 1834(m) due to the conditions for payment under such section; and

(II) that are identified for such year as clinically appropriate to furnish using electronic information and telecommunications technology when a physician (as defined in section 1861(r)) or practitioner (described in section 1842(b)(18)(C)) providing the service is not at the same location as the plan enrollee.

(ii) EXCLUSION OF CAPITAL AND INFRASTRUCTURE COSTS AND INVESTMENTS.—The term "additional telehealth benefits" does not include capital and infra-

structure costs and investments relating to such benefits.

(B) PUBLIC COMMENT.—Not later than November 30, 2018, the Secretary shall solicit comments on—

(i) what types of items and services (including those provided through supplemental health care benefits, such as remote patient monitoring, secure messaging, store and forward technologies, and other non-face-to-face communication) should be considered to be additional telehealth benefits; and

(ii) the requirements for the provision or furnishing of such benefits (such as training and coordination requirements).

(3) REQUIREMENTS FOR ADDITIONAL TELEHEALTH BENEFITS.—The Secretary shall specify requirements for the provision or furnishing of additional telehealth benefits, including with respect to the following:

(A) Physician or practitioner qualifications (other than licensure) and other requirements such as specific training.

(B) Factors necessary for the coordination of such benefits with other items and services including those furnished in-person.

(C) Such other areas as determined by the Secretary.

(4) ENROLLEE CHOICE.—If an MA plan provides a service as an additional telehealth benefit (as defined in paragraph (2))—

(A) the MA plan shall also provide access to such benefit through an in-person visit (and not only as an additional telehealth benefit); and

(B) an individual enrollee shall have discretion as to whether to receive such service through the in-person visit or as an additional telehealth benefit.

(5) TREATMENT UNDER MA.—For purposes of this subsection and section 1854, if a plan provides additional telehealth benefits, such additional telehealth benefits shall be treated as if they were benefits under the original Medicare fee-for-service program option.

(6) CONSTRUCTION.—Nothing in this subsection shall be construed as affecting the requirement under subsection (a)(1) that MA plans provide enrollees with items and services (other than hospice care) for which benefits are available under parts A and B, including benefits available under section 1834(m).

(n) PROVISION OF INFORMATION RELATING TO THE SAFE DISPOSAL OF CERTAIN PRESCRIPTION DRUGS.—

(1) IN GENERAL.—In the case of an individual enrolled under an MA or MA–PD plan who is furnished an in-home health risk assessment on or after January 1, 2021, such plan shall ensure that such assessment includes information on the safe disposal of prescription drugs that are controlled substances that meets the criteria established under paragraph (2). Such information shall include information on drug takeback programs that meet such requirements determined appropriate by the Secretary and information on in-home disposal.

(2) CRITERIA.—The Secretary shall, through rulemaking, establish criteria the Secretary determines appropriate with re-

spect to information provided to an individual to ensure that such information sufficiently educates such individual on the safe disposal of prescription drugs that are controlled substances.

*(o) PRIOR AUTHORIZATION REQUIREMENTS.—*

*(1) IN GENERAL.—In the case of a Medicare Advantage plan that imposes any prior authorization requirement with respect to any applicable item or service (as defined in paragraph (5)) during a plan year, such plan shall—*

*(A) beginning with the third plan year beginning after the date of the enactment of this subsection—*

*(i) establish the electronic prior authorization program described in paragraph (2); and*

*(ii) meet the enrollee protection standards specified pursuant to paragraph (4); and*

*(B) beginning with the fourth plan year beginning after the date of the enactment of this subsection, meet the transparency requirements specified in paragraph (3).*

*(2) ELECTRONIC PRIOR AUTHORIZATION PROGRAM.—*

*(A) IN GENERAL.—For purposes of paragraph (1)(A), the electronic prior authorization program described in this paragraph is a program that provides for the secure electronic transmission of—*

*(i) a prior authorization request from a provider of services or supplier to a Medicare Advantage plan with respect to an applicable item or service to be furnished to an individual and a response, in accordance with this paragraph, from such plan to such provider or supplier; and*

*(ii) any attachment relating to such request or response.*

*(B) ELECTRONIC TRANSMISSION.—*

*(i) EXCLUSIONS.—For purposes of this paragraph, a facsimile, a proprietary payer portal that does not meet standards specified by the Secretary, or an electronic form shall not be treated as an electronic transmission described in subparagraph (A).*

*(ii) STANDARDS.—An electronic transmission described in subparagraph (A) shall comply with—*

*(I) applicable technical standards adopted by the Secretary pursuant to section 1173; and*

*(II) other requirements to promote the standardization and streamlining of electronic transactions under this part specified by the Secretary.*

*(iii) DEADLINE FOR SPECIFICATION OF ADDITIONAL REQUIREMENTS.—Not later than July 1, 2024, the Secretary shall finalize requirements described in clause (ii)(II).*

*(C) REAL-TIME DECISIONS.—*

*(i) IN GENERAL.—Subject to clause (iv), the program described in subparagraph (A) shall provide for real-time decisions (as defined by the Secretary in accordance with clause (v)) by a Medicare Advantage plan with respect to prior authorization requests for applicable items and services identified by the Secretary pur-*

*suant to clause (ii) if such requests are submitted with all medical or other documentation required by such plan.*

*(ii) IDENTIFICATION OF ITEMS AND SERVICES.—*

*(I) IN GENERAL.—For purposes of clause (i), the Secretary shall identify, not later than the date on which the initial announcement described in section 1853(b)(1)(B)(i) for the third plan year beginning after the date of the enactment of this subsection is required to be announced, applicable items and services for which prior authorization requests are routinely approved.*

*(II) UPDATES.—The Secretary shall consider updating the applicable items and services identified under subclause (I) based on the information described in paragraph (3)(A)(i) (if available and determined practicable to utilize by the Secretary) and any other information determined appropriate by the Secretary not less frequently than biennially. The Secretary shall announce any such update that is to apply with respect to a plan year not later than the date on which the initial announcement described in section 1853(b)(1)(B)(i) for such plan year is required to be announced.*

*(iii) REQUEST FOR INFORMATION.—The Secretary shall issue a request for information for purposes of initially identifying applicable items and services under clause (ii)(I).*

*(iv) EXCEPTION FOR EXTENUATING CIRCUMSTANCES.—In the case of a prior authorization request submitted to a Medicare Advantage plan for an individual enrolled in such plan during a plan year with respect to an item or service identified by the Secretary pursuant to clause (ii) for such plan year, such plan may, in lieu of providing a real-time decision with respect to such request in accordance with clause (i), delay such decision under extenuating circumstances (as specified by the Secretary), provided that such decision is provided no later than 72 hours after receipt of such request (or, in the case that the provider of services or supplier submitting such request has indicated that such delay may seriously jeopardize such individual's life, health, or ability to regain maximum function, no later than 24 hours after receipt of such request).*

*(v) DEFINITION OF REAL-TIME DECISION.—In establishing the definition of a real-time decision for purposes of clause (i), the Secretary shall take into account current medical practice, technology, health care industry standards, and other relevant information relating to how quickly a Medicare Advantage plan may provide responses with respect to prior authorization requests.*

*(vi) IMPLEMENTATION.—The Secretary shall use notice and comment rulemaking for each of the following:*

*(I) Establishing the definition of a "real-time decision" for purposes of clause (i).*

*(II) Updating such definition.*

*(III) Initially identifying applicable items or services pursuant to clause (ii)(I).*

*(IV) Updating applicable items and services so identified as described in clause (ii)(II).*

*(3) TRANSPARENCY REQUIREMENTS.—*

*(A) IN GENERAL.—For purposes of paragraph (1)(B), the transparency requirements specified in this paragraph are, with respect to a Medicare Advantage plan, the following:*

*(i) The plan, annually and in a manner specified by the Secretary, shall submit to the Secretary the following information:*

*(I) A list of all applicable items and services that were subject to a prior authorization requirement under the plan during the previous plan year.*

*(II) The percentage and number of specified requests (as defined in subparagraph (F)) approved during the previous plan year by the plan in an initial determination and the percentage and number of specified requests denied during such plan year by such plan in an initial determination (both in the aggregate and categorized by each item and service).*

*(III) The percentage and number of specified requests submitted during the previous plan year that were made with respect to an item or service identified by the Secretary pursuant to paragraph (2)(C)(ii) for such plan year, and the percentage and number of such requests that were subject to an exception under paragraph (2)(C)(iv) (categorized by each item and service).*

*(IV) The percentage and number of specified requests submitted during the previous plan year that were made with respect to an item or service identified by the Secretary pursuant to paragraph (2)(C)(ii) for such plan year that were approved (categorized by each item and service).*

*(V) The percentage and number of specified requests that were denied during the previous plan year by the plan in an initial determination and that were subsequently appealed.*

*(VI) The number of appeals of specified requests resolved during the preceding plan year, and the percentage and number of such resolved appeals that resulted in approval of the furnishing of the item or service that was the subject of such request, categorized by each applicable item and service and categorized by each level of appeal (including judicial review).*

*(VII) The percentage and number of specified requests that were denied, and the percentage and number of specified requests that were approved, by the plan during the previous plan year through*

*the utilization of decision support technology, artificial intelligence technology, machine-learning technology, clinical decision-making technology, or any other technology specified by the Secretary.*

*(VIII) The average and the median amount of time (in hours) that elapsed during the previous plan year between the submission of a specified request to the plan and a determination by the plan with respect to such request for each such item and service, excluding any such requests that were not submitted with the medical or other documentation required to be submitted by the plan.*

*(IX) The percentage and number of specified requests that were excluded from the calculation described in subclause (VIII) based on the plan's determination that such requests were not submitted with the medical or other documentation required to be submitted by the plan.*

*(X) Information on each occurrence during the previous plan year in which, during a surgical or medical procedure involving the furnishing of an applicable item or service with respect to which such plan had approved a prior authorization request, the provider of services or supplier furnishing such item or service determined that a different or additional item or service was medically necessary, including a specification of whether such plan subsequently approved the furnishing of such different or additional item or service.*

*(XI) A disclosure and description of any technology described in subclause (VII) that the plan utilized during the previous plan year in making determinations with respect to specified requests.*

*(XII) The number of grievances (as described in subsection (f)) received by such plan during the previous plan year that were related to a prior authorization requirement.*

*(XIII) Such other information as the Secretary determines appropriate.*

*(ii) The plan shall provide—*

*(I) to each provider or supplier who seeks to enter into a contract with such plan to furnish applicable items and services under such plan, the list described in clause (i)(I) and any policies or procedures used by the plan for making determinations with respect to prior authorization requests;*

*(II) to each such provider and supplier that enters into such a contract, access to the criteria used by the plan for making such determinations and an itemization of the medical or other documentation required to be submitted by a provider or supplier with respect to such a request; and*

*(III) to an enrollee of the plan, upon request, access to the criteria used by the plan for making de-*

*terminations with respect to prior authorization requests for an item or service.*

*(B) OPTION FOR PLAN TO PROVIDE CERTAIN ADDITIONAL INFORMATION.—As part of the information described in subparagraph (A)(i) provided to the Secretary during a plan year, a Medicare Advantage plan may elect to include information regarding the percentage and number of specified requests made with respect to an individual and an item or service that were denied by the plan during the preceding plan year in an initial determination based on such requests failing to demonstrate that such individuals met the clinical criteria established by such plan to receive such items or services.*

*(C) REGULATIONS.—The Secretary shall, through notice and comment rulemaking, establish requirements for Medicare Advantage plans regarding the provision of—*

*(i) access to criteria described in subparagraph (A)(ii)(II) to providers of services and suppliers in accordance with such subparagraph; and*

*(ii) access to such criteria to enrollees in accordance with subparagraph (A)(ii)(III).*

*(D) PUBLICATION OF INFORMATION.—The Secretary shall publish information described in subparagraph (A)(i) and subparagraph (B) on a public website of the Centers for Medicare & Medicaid Services. Such information shall be so published on an individual plan level and may in addition be aggregated in such manner as determined appropriate by the Secretary.*

*(E) MEDPAC REPORT.—Not later than 3 years after the date information is first submitted under subparagraph (A)(i), the Medicare Payment Advisory Commission shall submit to Congress a report on such information that includes a descriptive analysis of the use of prior authorization. As appropriate, the Commission should report on statistics including the frequency of appeals and overturned decisions. The Commission shall provide recommendations, as appropriate, on any improvement that should be made to the electronic prior authorization programs of Medicare Advantage plans.*

*(F) SPECIFIED REQUEST DEFINED.—For purposes of this paragraph, the term "specified request" means a prior authorization request made with respect to an applicable item or service.*

*(4) ENROLLEE PROTECTION STANDARDS.—For purposes of paragraph (1)(A)(ii), with respect to the use of prior authorization by Medicare Advantage plans for applicable items and services, the enrollee protection standards specified in this paragraph are—*

*(A) the adoption of transparent prior authorization programs developed in consultation with enrollees and with providers and suppliers with contracts in effect with such plans for furnishing such items and services under such plans;*

*(B) allowing for the waiver or modification of prior authorization requirements based on the performance of such*

*providers and suppliers in demonstrating compliance with such requirements, such as adherence to evidence-based medical guidelines and other quality criteria; and*

*(C) conducting annual reviews of such items and services for which prior authorization requirements are imposed under such plans through a process that takes into account input from enrollees and from providers and suppliers with such contracts in effect and is based on consideration of prior authorization data from previous plan years and analyses of current coverage criteria.*

*(5) APPLICABLE ITEM OR SERVICE DEFINED.—For purposes of this subsection, the term "applicable item or service" means, with respect to a Medicare Advantage plan, any item or service for which benefits are available under such plan, other than a covered part D drug.*

*(6) REPORTS TO CONGRESS.—*

*(A) GAO.—Not later than the end of the fourth plan year beginning on or after the date of the enactment of this subsection, the Comptroller General of the United States shall submit to Congress a report containing an evaluation of the implementation of the requirements of this subsection and an analysis of issues in implementing such requirements faced by Medicare Advantage plans.*

*(B) HHS.—Not later than the end of the fifth plan year beginning after the date of the enactment of this subsection, and biennially thereafter through the date that is 10 years after such date of enactment, the Secretary shall submit to Congress a report containing a description of the information submitted under paragraph (3)(A)(i) during—*

*(i) in the case of the first such report, the fourth plan year beginning after the date of the enactment of this subsection; and*

*(ii) in the case of a subsequent report, the 2 plan years preceding the year of the submission of such report.*

* * * * * * *

CONTRACTS WITH MEDICARE+CHOICE ORGANIZATIONS

SEC. 1857. (a) IN GENERAL.—The Secretary shall not permit the election under section 1851 of a Medicare+Choice plan offered by a Medicare+Choice organization under this part, and no payment shall be made under section 1853 to an organization, unless the Secretary has entered into a contract under this section with the organization with respect to the offering of such plan. Such a contract with an organization may cover more than 1 Medicare+Choice plan. Such contract shall provide that the organization agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

(b) MINIMUM ENROLLMENT REQUIREMENTS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary may not enter into a contract under this section with a Medicare+Choice organization unless the organization has—

(A) at least 5,000 individuals (or 1,500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the organization, or

(B) at least 1,500 individuals (or 500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the organization if the organization primarily serves individuals residing outside of urbanized areas.

(2) APPLICATION TO MSA PLANS.—In applying paragraph (1) in the case of a Medicare+Choice organization that is offering an MSA plan, paragraph (1) shall be applied by substituting covered lives for individuals.

(3) ALLOWING TRANSITION.—The Secretary may waive the requirement of paragraph (1) during the first 3 contract years with respect to an organization.

(c) CONTRACT PERIOD AND EFFECTIVENESS.—

(1) PERIOD.—Each contract under this section shall be for a term of at least 1 year, as determined by the Secretary, and may be made automatically renewable from term to term in the absence of notice by either party of intention to terminate at the end of the current term.

(2) TERMINATION AUTHORITY.—In accordance with procedures established under subsection (h), the Secretary may at any time terminate any such contract if the Secretary determines that the organization—

(A) has failed substantially to carry out the contract;

(B) is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part; or

(C) no longer substantially meets the applicable conditions of this part.

(3) EFFECTIVE DATE OF CONTRACTS.—The effective date of any contract executed pursuant to this section shall be specified in the contract, except that in no case shall a contract under this section which provides for coverage under an MSA plan be effective before January 1999 with respect to such coverage.

(4) PREVIOUS TERMINATIONS.—

(A) IN GENERAL.—The Secretary may not enter into a contract with a Medicare+Choice organization if a previous contract with that organization under this section was terminated at the request of the organization within the preceding 2-year period, except as provided in subparagraph (B) and except in such other circumstances which warrant special consideration, as determined by the Secretary.

(B) EARLIER RE-ENTRY PERMITTED WHERE CHANGE IN PAYMENT POLICY.—Subparagraph (A) shall not apply with respect to the offering by a Medicare+Choice organization of a Medicare+Choice plan in a Medicare+Choice payment area if during the 6-month period beginning on the date the organization notified the Secretary of the intention to terminate the most recent previous contract, there was a legislative change enacted (or a regulatory change adopted) that has the effect of increasing payment amounts

under section 1853 for that Medicare+Choice payment area.

(5) CONTRACTING AUTHORITY.—The authority vested in the Secretary by this part may be performed without regard to such provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose of this title.

(d) PROTECTIONS AGAINST FRAUD AND BENEFICIARY PROTECTIONS.—

(1) PERIODIC AUDITING.—The Secretary shall provide for the annual auditing of the financial records (including data relating to medicare utilization and costs, including allowable costs under section 1858(c)) of at least one-third of the Medicare+Choice organizations offering Medicare+Choice plans under this part. The Comptroller General shall monitor auditing activities conducted under this subsection.

(2) INSPECTION AND AUDIT.—Each contract under this section shall provide that the Secretary, or any person or organization designated by the Secretary—

(A) shall have the right to timely inspect or otherwise evaluate (i) the quality, appropriateness, and timeliness of services performed under the contract, and (ii) the facilities of the organization when there is reasonable evidence of some need for such inspection, and

(B) shall have the right to timely audit and inspect any books and records of the Medicare+Choice organization that pertain (i) to the ability of the organization to bear the risk of potential financial losses, or (ii) to services performed or determinations of amounts payable under the contract.

(3) ENROLLEE NOTICE AT TIME OF TERMINATION.—Each contract under this section shall require the organization to provide (and pay for) written notice in advance of the contract's termination, as well as a description of alternatives for obtaining benefits under this title, to each individual enrolled with the organization under this part.

(4) DISCLOSURE.—

(A) IN GENERAL.—Each Medicare+Choice organization shall, in accordance with regulations of the Secretary, report to the Secretary financial information which shall include the following:

(i) Such information as the Secretary may require demonstrating that the organization has a fiscally sound operation.

(ii) A copy of the report, if any, filed with the Secretary containing the information required to be reported under section 1124 by disclosing entities.

(iii) A description of transactions, as specified by the Secretary, between the organization and a party in interest. Such transactions shall include—

(I) any sale or exchange, or leasing of any property between the organization and a party in interest;

(II) any furnishing for consideration of goods, services (including management services), or facilities between the organization and a party in interest, but not including salaries paid to employees for services provided in the normal course of their employment and health services provided to members by hospitals and other providers and by staff, medical group (or groups), individual practice association (or associations), or any combination thereof; and

(III) any lending of money or other extension of credit between an organization and a party in interest.

The Secretary may require that information reported respecting an organization which controls, is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(B) PARTY IN INTEREST DEFINED.—For the purposes of this paragraph, the term "party in interest" means—

(i) any director, officer, partner, or employee responsible for management or administration of a Medicare+Choice organization, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the organization, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the organization, and, in the case of a Medicare+Choice organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law;

(ii) any entity in which a person described in clause (i)—

(I) is an officer or director;

(II) is a partner (if such entity is organized as a partnership);

(III) has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(IV) has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(iii) any person directly or indirectly controlling, controlled by, or under common control with an organization; and

(iv) any spouse, child, or parent of an individual described in clause (i).

(C) ACCESS TO INFORMATION.—Each Medicare+Choice organization shall make the information reported pursuant to subparagraph (A) available to its enrollees upon reasonable request.

(5) LOAN INFORMATION.—The contract shall require the organization to notify the Secretary of loans and other special financial arrangements which are made between the organization and subcontractors, affiliates, and related parties.

(6) REVIEW TO ENSURE COMPLIANCE WITH CARE MANAGEMENT REQUIREMENTS FOR SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS INDIVIDUALS.—In conjunction with the periodic audit of a specialized Medicare Advantage plan for special needs individuals under paragraph (1), the Secretary shall conduct a review to ensure that such organization offering the plan meets the requirements described in section 1859(f)(5).

(e) ADDITIONAL CONTRACT TERMS.—

(1) IN GENERAL.—The contract shall contain such other terms and conditions not inconsistent with this part (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate.

(2) COST-SHARING IN ENROLLMENT-RELATED COSTS.—

(A) IN GENERAL.—A Medicare+Choice organization and a PDP sponsor under part D shall pay the fee established by the Secretary under subparagraph (B).

(B) AUTHORIZATION.—The Secretary is authorized to charge a fee to each Medicare+Choice organization with a contract under this part and each PDP sponsor with a contract under part D that is equal to the organization' or sponsor's pro rata share (as determined by the Secretary) of the aggregate amount of fees which the Secretary is directed to collect in a fiscal year. Any amounts collected shall be available without further appropriation to the Secretary for the purpose of carrying out section 1851 (relating to enrollment and dissemination of information), section 1860D-1(c), and section 4360 of the Omnibus Budget Reconciliation Act of 1990 (relating to the health insurance counseling and assistance program).

(C) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for the purposes described in subparagraph (B) for each fiscal year beginning with fiscal year 2001 and ending with fiscal year 2005 an amount equal to $100,000,000, and for each fiscal year beginning with fiscal year 2006 an amount equal to $200,000,000, reduced by the amount of fees authorized to be collected under this paragraph and section 1860D–12(b)(3)(D) for the fiscal year.

(D) LIMITATION.—In any fiscal year the fees collected by the Secretary under subparagraph (B) shall not exceed the lesser of—

(i) the estimated costs to be incurred by the Secretary in the fiscal year in carrying out the activities described in section 1851 and section 1860D–1(c) and section 4360 of the Omnibus Budget Reconciliation Act of 1990; or

(ii)(I) $200,000,000 in fiscal year 1998;

(II) $150,000,000 in fiscal year 1999;

(III) $100,000,000 in fiscal year 2000;

(IV) the Medicare+Choice portion (as defined in subparagraph (E)) of $100,000,000 in fiscal year 2001 and each succeeding fiscal year before fiscal year 2006; and

(V) the applicable portion (as defined in subparagraph (F)) of $200,000,000 in fiscal year 2006 and each succeeding fiscal year.

(E) MEDICARE+CHOICE PORTION DEFINED.—In this paragraph, the term "Medicare+Choice portion" means, for a fiscal year, the ratio, as estimated by the Secretary, of—

(i) the average number of individuals enrolled in Medicare+Choice plans during the fiscal year, to

(ii) the average number of individuals entitled to benefits under part A, and enrolled under part B, during the fiscal year.

(F) APPLICABLE PORTION DEFINED.—In this paragraph, the term "applicable portion" means, for a fiscal year—

(i) with respect to MA organizations, the Secretary's estimate of the total proportion of expenditures under this title that are attributable to expenditures made under this part (including payments under part D that are made to such organizations); or

(ii) with respect to PDP sponsors, the Secretary's estimate of the total proportion of expenditures under this title that are attributable to expenditures made to such sponsors under part D.

(3) AGREEMENTS WITH FEDERALLY QUALIFIED HEALTH CENTERS.—

(A) PAYMENT LEVELS AND AMOUNTS.—A contract under this section with an MA organization shall require the organization to provide, in any written agreement described in section 1853(a)(4) between the organization and a federally qualified health center, for a level and amount of payment to the federally qualified health center for services provided by such health center that is not less than the level and amount of payment that the plan would make for such services if the services had been furnished by a entity providing similar services that was not a federally qualified health center.

(B) COST-SHARING.—Under the written agreement referred to in subparagraph (A), a federally qualified health center must accept the payment amount referred to in such subparagraph plus the Federal payment provided for in section 1833(a)(3)(B) as payment in full for services covered by the agreement, except that such a health center may collect any amount of cost-sharing permitted under the contract under this section, so long as the amounts of any deductible, coinsurance, or copayment comply with the requirements under section 1854(e).

(4) REQUIREMENT FOR MINIMUM MEDICAL LOSS RATIO.—If the Secretary determines for a contract year (beginning with 2014) that an MA plan has failed to have a medical loss ratio of at least .85—

(A) the MA plan shall remit to the Secretary an amount equal to the product of—

(i) the total revenue of the MA plan under this part for the contract year; and

(ii) the difference between .85 and the medical loss ratio;

(B) for 3 consecutive contract years, the Secretary shall not permit the enrollment of new enrollees under the plan for coverage during the second succeeding contract year; and

(C) the Secretary shall terminate the plan contract if the plan fails to have such a medical loss ratio for 5 consecutive contract years.

(5) COMMUNICATING PLAN CORRECTIVE ACTIONS AGAINST OPIOIDS OVER-PRESCRIBERS.—

(A) IN GENERAL.—Beginning with plan years beginning on or after January 1, 2021, a contract under this section with an MA organization shall require the organization to submit to the Secretary, through the process established under subparagraph (B), information on the investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier related to fraud, and other actions taken by such plans related to inappropriate prescribing of opioids.

(B) PROCESS.—Not later than January 1, 2021, the Secretary shall, in consultation with stakeholders, establish a process under which MA plans and prescription drug plans shall submit to the Secretary information described in subparagraph (A).

(C) REGULATIONS.—For purposes of this paragraph, including as applied under section 1860D–12(b)(3)(D), the Secretary shall, pursuant to rulemaking—

(i) specify a definition for the term "inappropriate prescribing" and a method for determining if a provider of services prescribes inappropriate prescribing; and

(ii) establish the process described in subparagraph (B) and the types of information that shall be submitted through such process.

*(6) REQUIRED DISCLOSURE OF CERTAIN INFORMATION RELATING TO HEALTH CARE PROVIDER OWNERSHIP.—*

*(A) IN GENERAL.—For plan year 2025 and for every third plan year thereafter, each MA organization offering an MA plan under this part during such plan year shall submit to the Secretary, at a time and in a manner specified by the Secretary—*

*(i) the taxpayer identification number for each health care provider that was a specified health care provider with respect to such organization during such year;*

*(ii) the total amount of incentive-based payments made to, and the total amount of shared losses recoupments collected from, such specified health care providers during such plan year; and*

*(iii) the total amount of incentive-based payments made to, and the total amount of shared losses recoupments collected from, providers of services and suppliers not described in clause (ii) during such plan year.*

*(B) DEFINITION.—For purposes of this paragraph, the term "specified health care provider" means, with respect to an MA organization and a plan year, a provider of services*

*or supplier with respect to which such organization (or any person with an ownership or control interest (as defined in section 1124(a)(3)) in such organization) is a person with an ownership or control interest (as so defined).*

(f) PROMPT PAYMENT BY MEDICARE+CHOICE ORGANIZATION.—

(1) REQUIREMENT.—A contract under this part shall require a Medicare+Choice organization to provide prompt payment (consistent with the provisions of sections 1816(c)(2) and 1842(c)(2)) of claims submitted for services and supplies furnished to enrollees pursuant to the contract, if the services or supplies are not furnished under a contract between the organization and the provider or supplier (or in the case of a Medicare+Choice private fee-for-service plan, if a claim is submitted to such organization by an enrollee).

(2) SECRETARY'S OPTION TO BYPASS NONCOMPLYING ORGANIZATION.—In the case of a Medicare+Choice eligible organization which the Secretary determines, after notice and opportunity for a hearing, has failed to make payments of amounts in compliance with paragraph (1), the Secretary may provide for direct payment of the amounts owed to providers and suppliers (or, in the case of a Medicare+Choice private fee-for-service plan, amounts owed to the enrollees) for covered services and supplies furnished to individuals enrolled under this part under the contract. If the Secretary provides for the direct payments, the Secretary shall provide for an appropriate reduction in the amount of payments otherwise made to the organization under this part to reflect the amount of the Secretary's payments (and the Secretary's costs in making the payments).

(3) INCORPORATION OF CERTAIN PRESCRIPTION DRUG PLAN CONTRACT REQUIREMENTS.—The following provisions shall apply to contracts with a Medicare Advantage organization offering an MA–PD plan in the same manner as they apply to contracts with a PDP sponsor offering a prescription drug plan under part D:

(A) PROMPT PAYMENT.—Section 1860D–12(b)(4).

(B) SUBMISSION OF CLAIMS BY PHARMACIES LOCATED IN OR CONTRACTING WITH LONG-TERM CARE FACILITIES.—Section 1860D–12(b)(5).

(C) REGULAR UPDATE OF PRESCRIPTION DRUG PRICING STANDARD.—Section 1860D–12(b)(6).

(D) SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD BY PHARMACIES.—Section 1860D–12(b)(7).

(E) PROVISION OF INFORMATION RELATED TO MAXIMUM FAIR PRICES.—Section 1860D–12(b)(8).

(g) INTERMEDIATE SANCTIONS.—

(1) IN GENERAL.—If the Secretary determines that a Medicare+Choice organization with a contract under this section—

(A) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(B) imposes premiums on individuals enrolled under this part in excess of the amount of the Medicare+Choice monthly basic and supplemental beneficiary premiums permitted under section 1854;

(C) acts to expel or to refuse to re-enroll an individual in violation of the provisions of this part;

(D) engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services;

(E) misrepresents or falsifies information that is furnished—

(i) to the Secretary under this part, or

(ii) to an individual or to any other entity under this part;

(F) fails to comply with the applicable requirements of section 1852(j)(3) or 1852(k)(2)(A)(ii);

(G) employs or contracts with any individual or entity that is excluded from participation under this title under section 1128 or 1128A for the provision of health care, utilization review, medical social work, or administrative services or employs or contracts with any entity for the provision (directly or indirectly) through such an excluded individual or entity of such services;

(H) except as provided under subparagraph (C) or (D) of section 1860D–1(b)(1), enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual;

(I) transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission;

(J) fails to comply with marketing restrictions described in subsections (h) and (j) of section 1851 or applicable implementing regulations or guidance; or

(K) employs or contracts with any individual or entity who engages in the conduct described in subparagraphs (A) through (J) of this paragraph;

the Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2). The Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2), if the Secretary determines that any employee or agent of such organization, or any provider or supplier who contracts with such organization, has engaged in any conduct described in subparagraphs (A) through (K) of this paragraph.

(2) REMEDIES.—The remedies described in this paragraph are—

(A) civil money penalties of not more than $25,000 for each determination under paragraph (1) or, with respect to a determination under subparagraph (D) or (E)(i) of such paragraph, of not more than $100,000 for each such deter-

mination, except with respect to a determination under subparagraph (E), an assessment of not more than the amount claimed by such plan or plan sponsor based upon the misrepresentation or falsified information involved, plus, with respect to a determination under paragraph (1)(B), double the excess amount charged in violation of such paragraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under paragraph (1)(D), $15,000 for each individual not enrolled as a result of the practice involved,

(B) suspension of enrollment of individuals under this part after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur, or

(C) suspension of payment to the organization under this part for individuals enrolled after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

(3) OTHER INTERMEDIATE SANCTIONS.—In the case of a Medicare+Choice organization for which the Secretary makes a determination under subsection (c)(2) the basis of which is not described in paragraph (1), the Secretary may apply the following intermediate sanctions:

(A) Civil money penalties of not more than $25,000 for each determination under subsection (c)(2) if the deficiency that is the basis of the determination has directly adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.

(B) Civil money penalties of not more than $10,000 for each week beginning after the initiation of civil money penalty procedures by the Secretary during which the deficiency that is the basis of a determination under subsection (c)(2) exists.

(C) Suspension of enrollment of individuals under this part after the date the Secretary notifies the organization of a determination under subsection (c)(2) and until the Secretary is satisfied that the deficiency that is the basis for the determination has been corrected and is not likely to recur.

(D) Civil monetary penalties of not more than $100,000, or such higher amount as the Secretary may establish by regulation, where the finding under subsection (c)(2)(A) is based on the organization's termination of its contract under this section other than at a time and in a manner provided for under subsection (a).

(4) CIVIL MONEY PENALTIES.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under paragraph (2) or (3) in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a).

(h) PROCEDURES FOR TERMINATION.—

(1) IN GENERAL.—The Secretary may terminate a contract with a Medicare+Choice organization under this section in accordance with formal investigation and compliance procedures established by the Secretary under which—

(A) the Secretary provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Secretary's determination under subsection (c)(2); and

(B) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before terminating the contract.

(2) EXCEPTION FOR IMMINENT AND SERIOUS RISK TO HEALTH.—Paragraph (1) shall not apply if the Secretary determines that a delay in termination, resulting from compliance with the procedures specified in such paragraph prior to termination, would pose an imminent and serious risk to the health of individuals enrolled under this part with the organization.

(3) DELAY IN CONTRACT TERMINATION AUTHORITY FOR PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATING.—During the period beginning on the date of the enactment of this paragraph and through the end of plan year 2018, the Secretary may not terminate a contract under this section with respect to the offering of an MA plan by a Medicare Advantage organization solely because the MA plan has failed to achieve a minimum quality rating under the 5-star rating system under section 1853(o)(4).

(i) MEDICARE+CHOICE PROGRAM COMPATIBILITY WITH EMPLOYER OR UNION GROUP HEALTH PLANS.—

(1) CONTRACTS WITH MA ORGANIZATIONS.—To facilitate the offering of Medicare+Choice plans under contracts between Medicare+Choice organizations and employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such Medicare+Choice plans.

(2) EMPLOYER SPONSORED MA PLANS.—To facilitate the offering of MA plans by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such MA plans. Notwithstanding section 1851(g), an MA plan described in the previous sentence may restrict the enrollment of individuals under this part to individuals who are beneficiaries and participants in such plan.

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PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

Subpart 1—Part D Eligible Individuals and Prescription Drug Benefits

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PRESCRIPTION DRUG BENEFITS

SEC. 1860D–2. (a) REQUIREMENTS.—

(1) IN GENERAL.—For purposes of this part and part C, the term "qualified prescription drug coverage" means either of the following:

(A) STANDARD PRESCRIPTION DRUG COVERAGE WITH ACCESS TO NEGOTIATED PRICES.—Standard prescription drug coverage (as defined in subsection (b)) and access to negotiated prices under subsection (d).

(B) ALTERNATIVE PRESCRIPTION DRUG COVERAGE WITH AT LEAST ACTUARIALLY EQUIVALENT BENEFITS AND ACCESS TO NEGOTIATED PRICES.—Coverage of covered part D drugs which meets the alternative prescription drug coverage requirements of subsection (c) and access to negotiated prices under subsection (d), but only if the benefit design of such coverage is approved by the Secretary, as provided under subsection (c).

(2) PERMITTING SUPPLEMENTAL PRESCRIPTION DRUG COVERAGE.—

(A) IN GENERAL.—Subject to subparagraph (B), qualified prescription drug coverage may include supplemental prescription drug coverage consisting of either or both of the following:

(i) CERTAIN REDUCTIONS IN COST-SHARING.—

(I) IN GENERAL.—A reduction in the annual deductible, a reduction in the coinsurance percentage or, for a year preceding 2025, an increase in the initial coverage limit with respect to covered part D drugs, or any combination thereof, insofar as such a reduction or increase increases the actuarial value of benefits above the actuarial value of basic prescription drug coverage.

(II) CONSTRUCTION.—Nothing in this paragraph shall be construed as affecting the application of subsection (c)(3).

(ii) OPTIONAL DRUGS.—Coverage of any product that would be a covered part D drug but for the application of subsection (e)(2)(A).

(B) REQUIREMENT.—A PDP sponsor may not offer a prescription drug plan that provides supplemental prescription drug coverage pursuant to subparagraph (A) in an area unless the sponsor also offers a prescription drug plan in the area that only provides basic prescription drug coverage.

(3) BASIC PRESCRIPTION DRUG COVERAGE.—For purposes of this part and part C, the term "basic prescription drug coverage" means either of the following:

(A) Coverage that meets the requirements of paragraph (1)(A).

(B) Coverage that meets the requirements of paragraph (1)(B) but does not have any supplemental prescription drug coverage described in paragraph (2)(A).

(4) APPLICATION OF SECONDARY PAYOR PROVISIONS.—The provisions of section 1852(a)(4) shall apply under this part in the same manner as they apply under part C.

(5) CONSTRUCTION.—Nothing in this subsection shall be construed as changing the computation of incurred costs under subsection (b)(4).

(b) STANDARD PRESCRIPTION DRUG COVERAGE.—For purposes of this part and part C, the term "standard prescription drug coverage" means coverage of covered part D drugs that meets the following requirements:

(1) DEDUCTIBLE.—

(A) IN GENERAL.—Subject to paragraphs (8) and (9), the coverage has an annual deductible—

(i) for 2006, that is equal to $250; or

(ii) for a subsequent year, that is equal to the amount specified under this paragraph for the previous year increased by the percentage specified in paragraph (6) for the year involved.

(B) ROUNDING.—Any amount determined under subparagraph (A)(ii) that is not a multiple of $5 shall be rounded to the nearest multiple of $5.

(2) BENEFIT STRUCTURE.—

(A) 25 PERCENT COINSURANCE.—Subject to subparagraphs (C), (D), and (E) and paragraphs [(8) and (9)] *(8), (9), and (10)*, the coverage has coinsurance (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3) for a year preceding 2025 and for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold specified in paragraph (4)(B) for 2025 and each subsequent year) that is—

(i) equal to 25 percent; or

(ii) actuarially equivalent (using processes and methods established under section 1860D–11(c)) to an average expected payment of 25 percent of such costs.

(B) USE OF TIERS.—Nothing in this part shall be construed as preventing a PDP sponsor or an MA organization from applying tiered copayments under a plan, so long as such tiered copayments are consistent with subparagraphs (A)(ii), (C), and (D).

(C) COVERAGE FOR GENERIC DRUGS IN COVERAGE GAP.—

(i) IN GENERAL.—Except as provided in paragraphs (4), (8), and (9), for a year preceding 2025, the coverage for an applicable beneficiary (as defined in section 1860D–14A(g)(1)) has coinsurance (for costs above the initial coverage limit under paragraph (3) and below the out-of-pocket threshold) for covered part D drugs that are not applicable drugs under section 1860D–14A(g)(2) that is—

(I) equal to the generic-gap coinsurance percentage (specified in clause (ii)) for the year; or

(II) actuarially equivalent (using processes and methods established under section 1860D–11(c)) to an average expected payment of such percentage of such costs for covered part D drugs that are not applicable drugs under section 1860D–14A(g)(2).

(ii) GENERIC-GAP COINSURANCE PERCENTAGE.—The generic-gap coinsurance percentage specified in this clause for—

(I) 2011 is 93 percent;

(II) 2012 and each succeeding year before 2020 is the generic-gap coinsurance percentage under this clause for the previous year decreased by 7 percentage points; and

(III) 2020 through 2024 is 25 percent.

(D) COVERAGE FOR APPLICABLE DRUGS IN COVERAGE GAP.—

(i) IN GENERAL.—Except as provided in paragraphs (4), (8), and (9), for a year preceding 2025, the coverage for an applicable beneficiary (as defined in section 1860D–14A(g)(1)) has coinsurance (for costs above the initial coverage limit under paragraph (3) and below the out-of-pocket threshold) for the negotiated price (as defined in section 1860D–14A(g)(6)) of covered part D drugs that are applicable drugs under section 1860D–14A(g)(2) that is—

(I) equal to the difference between—

(aa) the applicable gap percentage (specified in clause (ii) for the year); and

(bb) the discount percentage specified in section 1860D–14A(g)(4)(A) for such applicable drugs (or, in the case of each of years 2019 through 2024, 50 percent); or

(II) actuarially equivalent (using processes and methods established under section 1860D–11(c)) to an average expected payment of such percentage of such costs, for covered part D drugs that are applicable drugs under section 1860D–14A(g)(2).

(ii) APPLICABLE GAP PERCENTAGE.—The applicable gap percentage specified in this clause for—

(I) 2013 and 2014 is 97.5 percent;

(II) 2015 and 2016 is 95 percent;

(III) 2017 is 90 percent;

(IV) 2018 is 85 percent; and

(V) each of years 2019 through 2024 is 75 percent.

(E) MAXIMUM MONTHLY CAP ON COST-SHARING PAYMENTS.—

(i) IN GENERAL.—For plan years beginning on or after January 1, 2025, each PDP sponsor offering a prescription drug plan and each MA organization offering an MA–PD plan shall provide to any enrollee of such plan, including an enrollee who is a subsidy eligible individual (as defined in paragraph (3) of section

1860D–14(a)), the option to elect with respect to a plan year to pay cost-sharing under the plan in monthly amounts that are capped in accordance with this subparagraph.

(ii) DETERMINATION OF MAXIMUM MONTHLY CAP.—For each month in the plan year for which an enrollee in a prescription drug plan or an MA–PD plan has made an election pursuant to clause (i), the PDP sponsor or MA organization shall determine a maximum monthly cap (as defined in clause (iv)) for such enrollee.

(iii) BENEFICIARY MONTHLY PAYMENTS.—With respect to an enrollee who has made an election pursuant to clause (i), for each month described in clause (ii), the PDP sponsor or MA organization shall bill such enrollee an amount (not to exceed the maximum monthly cap) for the out-of-pocket costs of such enrollee in such month.

(iv) MAXIMUM MONTHLY CAP DEFINED.—In this subparagraph, the term "maximum monthly cap" means, with respect to an enrollee—

(I) for the first month for which the enrollee has made an election pursuant to clause (i), an amount determined by calculating—

(aa) the annual out-of-pocket threshold specified in paragraph (4)(B) minus the incurred costs of the enrollee as described in paragraph (4)(C); divided by

(bb) the number of months remaining in the plan year; and

(II) for a subsequent month, an amount determined by calculating—

(aa) the sum of any remaining out-of-pocket costs owed by the enrollee from a previous month that have not yet been billed to the enrollee and any additional out-of-pocket costs incurred by the enrollee; divided by

(bb) the number of months remaining in the plan year.

(v) ADDITIONAL REQUIREMENTS.—The following requirements shall apply with respect to the option to make an election pursuant to clause (i) under this subparagraph:

(I) SECRETARIAL RESPONSIBILITIES.—The Secretary shall provide information to part D eligible individuals on the option to make such election through educational materials, including through the notices provided under section 1804(a).

(II) TIMING OF ELECTION.—An enrollee in a prescription drug plan or an MA–PD plan may make such an election—

(aa) prior to the beginning of the plan year; or

(bb) in any month during the plan year.

(III) PDP SPONSOR AND MA ORGANIZATION RESPONSIBILITIES.—Each PDP sponsor offering a prescription drug plan or MA organization offering an MA–PD plan—

(aa) may not limit the option for an enrollee to make such an election to certain covered part D drugs;

(bb) shall, prior to the plan year, notify prospective enrollees of the option to make such an election in promotional materials;

(cc) shall include information on such option in enrollee educational materials;

(dd) shall have in place a mechanism to notify a pharmacy during the plan year when an enrollee incurs out-of-pocket costs with respect to covered part D drugs that make it likely the enrollee may benefit from making such an election;

(ee) shall provide that a pharmacy, after receiving a notification described in item (dd) with respect to an enrollee, informs the enrollee of such notification;

(ff) shall ensure that such an election by an enrollee has no effect on the amount paid to pharmacies (or the timing of such payments) with respect to covered part D drugs dispensed to the enrollee; and

(gg) shall have in place a financial reconciliation process to correct inaccuracies in payments made by an enrollee under this subparagraph with respect to covered part D drugs during the plan year.

(IV) FAILURE TO PAY AMOUNT BILLED.—If an enrollee fails to pay the amount billed for a month as required under this subparagraph—

(aa) the election of the enrollee pursuant to clause (i) shall be terminated and the enrollee shall pay the cost-sharing otherwise applicable for any covered part D drugs subsequently dispensed to the enrollee up to the annual out-of-pocket threshold specified in paragraph (4)(B); and

(bb) the PDP sponsor or MA organization may preclude the enrollee from making an election pursuant to clause (i) in a subsequent plan year.

(V) CLARIFICATION REGARDING PAST DUE AMOUNTS.—Nothing in this subparagraph shall be construed as prohibiting a PDP sponsor or an MA organization from billing an enrollee for an amount owed under this subparagraph.

(VI) TREATMENT OF UNSETTLED BALANCES.—Any unsettled balances with respect to amounts owed under this subparagraph shall be treated as plan losses and the Secretary shall not be liable for any

such balances outside of those assumed as losses estimated in plan bids.

(3) INITIAL COVERAGE LIMIT.—

(A) IN GENERAL.—Except as provided in paragraphs (2)(C), (2)(D), (4), (8), and (9), for a year preceding 2025, the coverage has an initial coverage limit on the maximum costs that may be recognized for payment purposes (including the annual deductible)—

(i) for 2006, that is equal to $2,250; or

(ii) for each of years 2007 through 2024, that is equal to the amount specified in this paragraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

(B) ROUNDING.—Any amount determined under subparagraph (A)(ii) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(4) PROTECTION AGAINST HIGH OUT-OF-POCKET EXPENDITURES.—

(A) IN GENERAL.—

(i) IN GENERAL.—Subject to paragraphs (8) and (9), the coverage provides benefits, after the part D eligible individual has incurred costs (as described in subparagraph (C)) for covered part D drugs in a year equal to the annual out-of-pocket threshold specified in subparagraph (B), with cost-sharing that is equal to—

(I) for a year preceding 2024, the greater of—

(aa) a copayment of $2 for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i)) and $5 for any other drug; or

(bb) coinsurance that is equal to 5 percent; and

(II) for 2024 and each succeeding year, $0.

(ii) ADJUSTMENT OF AMOUNT.—For a year after 2006, the dollar amounts specified in clause (i)(I)(aa) shall be equal to the dollar amounts specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved. Any amount established under this clause that is not a multiple of a 5 cents shall be rounded to the nearest multiple of 5 cents. The Secretary shall continue to calculate the dollar amounts specified in clause (i)(I)(aa), including with the adjustment under this clause, after 2023 for purposes of section 1860D–14(a)(1)(D)(iii).

(B) ANNUAL OUT-OF-POCKET THRESHOLD.—

(i) IN GENERAL.—For purposes of this part, the "annual out-of-pocket threshold" specified in this subparagraph—

(I) for 2006, is equal to $3,600;

(II) for each of years 2007 through 2013, is equal to the amount specified in this subparagraph for the previous year, increased by the an-

nual percentage increase described in paragraph (6) for the year involved;

(III) for 2014 and 2015, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved, minus 0.25 percentage point;

(IV) for each of years 2016 through 2019, is equal to the amount specified in this subparagraph for the previous year, increased by the lesser of—

(aa) the annual percentage increase described in paragraph (7) for the year involved, plus 2 percentage points; or

(bb) the annual percentage increase described in paragraph (6) for the year;

(V) for 2020, is equal to the amount that would have been applied under this subparagraph for 2020 if the amendments made by section 1101(d)(1) of the Health Care and Education Reconciliation Act of 2010 had not been enacted;

(VI) for each of years 2021 through 2024, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved;

(VII) for 2025, is equal to $2,000; or

(VIII) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

(ii) ROUNDING.—Any amount determined under clause (i) that is not a multiple of $50 shall be rounded to the nearest multiple of $50.

(C) APPLICATION.—Except as provided in subparagraph (E) or subparagraph (F), in applying subparagraph (A)—

(i) incurred costs shall only include costs incurred with respect to covered part D drugs for the annual deductible described in paragraph (1), for cost-sharing described in paragraph (2), and, for a year preceding 2025, for amounts for which benefits are not provided because of the application of the initial coverage limit described in paragraph (3), but does not include any costs incurred for covered part D drugs which are not included (or treated as being included) in the plan's formulary;

(ii) subject to clause (iii), such costs shall be treated as incurred only if they are paid by the part D eligible individual (or by another person, such as a family member, on behalf of the individual) and the part D eligible individual (or other person) is not reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement (other than

under such section or such a Program) for such costs; and

(iii) such costs shall be treated as incurred and shall not be considered to be reimbursed under clause (ii) if such costs—

(I) are borne or paid——

(aa) under section 1860D–14;

(bb) under a State Pharmaceutical Assistance Program;

(cc) by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act);

(dd) under an AIDS Drug Assistance Program under part B of title XXVI of the Public Health Service Act; or

(dd) under section 1860D–15(h); or

(II) for 2025 and subsequent years, are reimbursed through insurance, a group health plan, or certain other third party payment arrangements, but not including the coverage provided by a prescription drug plan or an MA–PD plan that is basic prescription drug coverage (as defined in subsection (a)(3)) or any payments by a manufacturer under the manufacturer discount program under section 1860D–14C.

(D) INFORMATION REGARDING THIRD-PARTY REIMBURSEMENT.—

(i) PROCEDURES FOR EXCHANGING INFORMATION.—In order to accurately apply the requirements of subparagraph (C)(ii), the Secretary is authorized to establish procedures, in coordination with the Secretary of the Treasury and the Secretary of Labor—

(I) for determining whether costs for part D eligible individuals are being reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement; and

(II) for alerting the PDP sponsors and MA organizations that offer the prescription drug plans and MA–PD plans in which such individuals are enrolled about such reimbursement arrangements.

(ii) AUTHORITY TO REQUEST INFORMATION FROM ENROLLEES.—A PDP sponsor or an MA organization may periodically ask part D eligible individuals enrolled in a prescription drug plan or an MA–PD plan offered by the sponsor or organization whether such individuals have or expect to receive such third-party reimbursement. A material misrepresentation of the information described in the preceding sentence by an individual (as defined in standards set by the Secretary and determined through a process established by the Secretary) shall constitute grounds for termination of enrollment in any plan under section 1851(g)(3)(B) (and as applied under this part under section 1860D–1(b)(1)(B)(v)) for a period specified by the Secretary.

(E) INCLUSION OF COSTS OF APPLICABLE DRUGS UNDER MEDICARE COVERAGE GAP DISCOUNT PROGRAM.—For each of years 2011 through 2024, in applying subparagraph (A), incurred costs shall include the negotiated price (as defined in paragraph (6) of section 1860D–14A(g)) of an applicable drug (as defined in paragraph (2) of such section) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1860D–14A, regardless of whether part of such costs were paid by a manufacturer under such program, except that incurred costs shall not include the portion of the negotiated price that represents the reduction in coinsurance resulting from the application of paragraph (2)(D).

(F) INCLUSION OF COSTS PAID UNDER MAXIMUM MONTHLY CAP OPTION.—In applying subparagraph (A), with respect to an enrollee who has made an election pursuant to clause (i) of paragraph (2)(E), costs shall be treated as incurred if such costs are paid by a PDP sponsor or an MA organization under the option provided under such paragraph.

(5) CONSTRUCTION.—Nothing in this part shall be construed as preventing a PDP sponsor or an MA organization offering an MA–PD plan from reducing to zero the cost-sharing otherwise applicable to preferred or generic drugs.

(6) ANNUAL PERCENTAGE INCREASE.—The annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered part D drugs in the United States for part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify.

(7) ADDITIONAL ANNUAL PERCENTAGE INCREASE.—The annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending in July of the previous year.

(8) TREATMENT OF COST-SHARING FOR ADULT VACCINES RECOMMENDED BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES CONSISTENT WITH TREATMENT OF VACCINES UNDER PART B.—

(A) IN GENERAL.—For plan years beginning on or after January 1, 2023, with respect to an adult vaccine recommended by the Advisory Committee on Immunization Practices (as defined in subparagraph (B))—

(i) the deductible under paragraph (1) shall not apply; and

(ii) there shall be no coinsurance or other cost-sharing under this part with respect to such vaccine.

(B) ADULT VACCINES RECOMMENDED BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.—For purposes of this paragraph, the term "adult vaccine recommended by the Advisory Committee on Immunization Practices" means a covered part D drug that is a vaccine licensed under section 351 of the Public Health Service Act for use

by adult populations and administered in accordance with recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention.

(9) TREATMENT OF COST-SHARING FOR COVERED INSULIN PRODUCTS.—

(A) NO APPLICATION OF DEDUCTIBLE.—For plan year 2023 and subsequent plan years, the deductible under paragraph (1) shall not apply with respect to any covered insulin product.

(B) APPLICATION OF COST-SHARING.—

(i) PLAN YEARS 2023 AND 2024.—For plan years 2023 and 2024, the coverage provides benefits for any covered insulin product, regardless of whether an individual has reached the initial coverage limit under paragraph (3) or the out-of-pocket threshold under paragraph (4), with cost-sharing for a month's supply that does not exceed the applicable copayment amount.

(ii) PLAN YEAR 2025 AND SUBSEQUENT PLAN YEARS.—[For a plan year] *Subject to paragraph (10), for a plan year* beginning on or after January 1, 2025, the coverage provides benefits for any covered insulin product, prior to an individual reaching the out-of-pocket threshold under paragraph (4), with cost-sharing for a month's supply that does not exceed the applicable copayment amount.

(C) COVERED INSULIN PRODUCT.—In this paragraph, the term "covered insulin product" means an insulin product that is a covered part D drug covered under the prescription drug plan or MA–PD plan that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act and marketed pursuant to such approval or licensure, including any covered insulin product that has been deemed to be licensed under section 351 of the Public Health Service Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and marketed pursuant to such section.

(D) APPLICABLE COPAYMENT AMOUNT.—In this paragraph, the term "applicable copayment amount" means, with respect to a covered insulin product under a prescription drug plan or an MA–PD plan dispensed—

(i) during plan years 2023, 2024, and 2025, $35; and

(ii) during plan year 2026 and each subsequent plan year, the lesser of—

(I) $35;

(II) an amount equal to 25 percent of the maximum fair price established for the covered insulin product in accordance with part E of title XI; or

(III) an amount equal to 25 percent of the negotiated price of the covered insulin product under the prescription drug plan or MA–PD plan.

(E) SPECIAL RULE FOR FIRST 3 MONTHS OF 2023.—With respect to a month's supply of a covered insulin product dis-

pensed during the period beginning on January 1, 2023, and ending on March 31, 2023, a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall reimburse an enrollee within 30 days for any cost-sharing paid by such enrollee that exceeds the cost-sharing applied by the prescription drug plan or MA–PD plan under subparagraph (B)(i) at the point-of-sale for such month's supply.

*(10) LIMITATION ON COST SHARING TO NET PRICE AMOUNT.—*

*(A) IN GENERAL.—For a plan year beginning on or after January 1, 2027, the coverage provides benefits for a supply of a covered part D drug dispensed by a pharmacy, for costs in excess of the deductible specified in paragraph (1) and prior to an individual reaching the out-of-pocket threshold under paragraph (4), with cost-sharing for a month's supply that does not exceed the average net price for such a supply of such drug during such plan year (or, if lower, the applicable cash price for such a supply of such drug so dispensed by such pharmacy).*

*(B) DEFINITIONS.—In this paragraph:*

*(i) APPLICABLE CASH PRICE.—The term "applicable cash price" means, with respect to a supply of a covered part D drug dispensed by a pharmacy, the price that such pharmacy would charge for such supply of such drug dispensed to an individual without benefits for such drug under any Federal health care program (as defined in section 1128B), a group health plan or group or individual health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act), or the program established under chapter 89 of title 5, United States Code.*

*(ii) AVERAGE NET PRICE.—The term "average net price" means, with respect to a supply of a covered part D drug, a prescription drug plan, and a plan year, the average amount paid under such plan (including any amounts paid by an individual enrolled under such plan as cost sharing for such drug) as payment for such a supply of such drug dispensed during such year, less any rebates or other forms of remuneration received under such plan with respect to such drug.*

(c) ALTERNATIVE PRESCRIPTION DRUG COVERAGE REQUIREMENTS.—A prescription drug plan or an MA–PD plan may provide a different prescription drug benefit design from standard prescription drug coverage so long as the Secretary determines (consistent with section 1860D–11(c)) that the following requirements are met and the plan applies for, and receives, the approval of the Secretary for such benefit design:

(1) ASSURING AT LEAST ACTUARIALLY EQUIVALENT COVERAGE.—

(A) ASSURING EQUIVALENT VALUE OF TOTAL COVERAGE.—The actuarial value of the total coverage is at least equal to the actuarial value of standard prescription drug coverage.

(B) ASSURING EQUIVALENT UNSUBSIDIZED VALUE OF COVERAGE.—The unsubsidized value of the coverage is at least

equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under section 1860D–15 with respect to such coverage.

(C) ASSURING STANDARD PAYMENT FOR COSTS.—The coverage is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under subsection (b)(3) for the year for a year preceding 2025 or the annual out-of-pocket threshold specified in subsection (b)(4)(B) for the year for 2025 and each subsequent year, of an amount equal to at least the product of—

(i) the amount by which the initial coverage limit described in subsection (b)(3) for the year for a year preceding 2025 or the annual out-of-pocket threshold specified in subsection (b)(4)(B) for the year for 2025 and each subsequent year exceeds the deductible described in subsection (b)(1) for the year; and

(ii) 100 percent minus the coinsurance percentage specified in subsection (b)(2)(A)(i).

(2) MAXIMUM REQUIRED DEDUCTIBLE.—The deductible under the coverage shall not exceed the deductible amount specified under subsection (b)(1) for the year.

(3) SAME PROTECTION AGAINST HIGH OUT-OF-POCKET EXPENDITURES.—The coverage provides the coverage required under subsection (b)(4).

(4) SAME MAXIMUM MONTHLY CAP ON COST-SHARING.—The maximum monthly cap on cost-sharing payments shall apply to coverage with respect to an enrollee who has made an election pursuant to clause (i) of subsection (b)(2)(E) under the option provided under such subsection.

(5) TREATMENT OF COST-SHARING FOR ADULT VACCINES RECOMMENDED BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.—The coverage is in accordance with subsection (b)(8).

(6) TREATMENT OF COST-SHARING FOR COVERED INSULIN PRODUCTS.—The coverage is provided in accordance with subsection (b)(9).

*(7) COST SHARING LIMITED TO NET PRICE.—The coverage is provided in accordance with subsection (b)(10).*

(d) ACCESS TO NEGOTIATED PRICES.—

(1) ACCESS.—

(A) IN GENERAL.—Under qualified prescription drug coverage offered by a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan, the sponsor or organization shall provide enrollees with access to negotiated prices used for payment for covered part D drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of a deductible or other cost-sharing or, for a year preceding 2025, an initial coverage limit (described in subsection (b)(3)).

(B) NEGOTIATED PRICES.—For purposes of this part, negotiated prices, subject to subparagraph (D), shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs.

(C) MEDICAID-RELATED PROVISIONS.—The prices negotiated by a prescription drug plan, by an MA–PD plan with respect to covered part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2)) with respect to such drugs on behalf of part D eligible individuals, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

(D) APPLICATION OF MAXIMUM FAIR PRICE FOR SELECTED DRUGS.—In applying this section, in the case of a covered part D drug that is a selected drug (as referred to in section 1192(c)), with respect to a price applicability period (as defined in section 1191(b)(2)), the negotiated prices used for payment (as described in this subsection) shall be no greater than the maximum fair price (as defined in section 1191(c)(3)) for such drug and for each year during such period plus any dispensing fees for such drug.

(2) DISCLOSURE.—A PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall disclose to the Secretary (in a manner specified by the Secretary) the aggregate negotiated price concessions described in paragraph (1)(B) made available to the sponsor or organization by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers. The provisions of section 1927(b)(3)(D) apply to information disclosed to the Secretary under this paragraph.

(3) AUDITS.—To protect against fraud and abuse and to ensure proper disclosures and accounting under this part and in accordance with section 1857(d)(2)(B) (as applied under section 1860D–12(b)(3)(C)), the Secretary may conduct periodic audits, directly or through contracts, of the financial statements and records of PDP sponsors with respect to prescription drug plans and MA organizations with respect to MA–PD plans.

(e) COVERED PART D DRUG DEFINED.—

(1) IN GENERAL.—Except as provided in this subsection, for purposes of this part, the term "covered part D drug" means—

(A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2);

(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary); or

(C) for the period beginning on the date of the enactment of this subparagraph and ending on December 31, 2024, an oral antiviral drug that may be dispensed only upon a prescription and is authorized under section 564 of

the Federal Food, Drug, and Cosmetic Act, on the basis of the declaration published in the Federal Register by the Secretary of Health and Human Services on April 1, 2020 (85 Fed. Reg. 18250 et seq.),

and such term includes a vaccine licensed under section 351 of the Public Health Service Act (and, for vaccines administered on or after January 1, 2008, its administration) and any use of a covered part D drug for a medically accepted indication (as defined in paragraph (4)).

(2) EXCLUSIONS.—

(A) IN GENERAL.—Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2), other than subparagraph (E) of such section (relating to smoking cessation agents), other than subparagraph (I) of such section (relating to barbiturates) if the barbiturate is used in the treatment of epilepsy, cancer, or a chronic mental health disorder, and other than subparagraph (J) of such section (relating to benzodiazepines), or under section 1927(d)(3), as such sections were in effect on the date of the enactment of this part. Such term also does not include a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration.

(B) MEDICARE COVERED DRUGS.—A drug prescribed for a part D eligible individual that would otherwise be a covered part D drug under this part shall not be so considered if payment for such drug as so prescribed and dispensed or administered with respect to that individual is available (or would be available but for the application of a deductible) under part A or B for that individual.

(3) APPLICATION OF GENERAL EXCLUSION PROVISIONS.—A prescription drug plan or an MA–PD plan may exclude from qualified prescription drug coverage any covered part D drug—

(A) for which payment would not be made if section 1862(a) applied to this part; or

(B) which is not prescribed in accordance with the plan or this part.

Such exclusions are determinations subject to reconsideration and appeal pursuant to subsections (g) and (h), respectively, of section 1860D–4.

(4) MEDICALLY ACCEPTED INDICATION DEFINED.—

(A) IN GENERAL.—For purposes of paragraph (1), the term "medically accepted indication" has the meaning given that term—

(i) in the case of a covered part D drug used in an anticancer chemotherapeutic regimen, in section 1861(t)(2)(B), except that in applying such section—

(I) "prescription drug plan or MA–PD plan" shall be substituted for "carrier" each place it appears; and

(II) subject to subparagraph (B), the compendia described in section 1927(g)(1)(B)(i)(III) shall be

included in the list of compendia described in clause (ii)(I) section 1861(t)(2)(B); and

(ii) in the case of any other covered part D drug, in section 1927(k)(6).

(B) CONFLICT OF INTEREST.—On and after January 1, 2010, subparagraph (A)(i)(II) shall not apply unless the compendia described in section 1927(g)(1)(B)(i)(III) meets the requirement in the third sentence of section 1861(t)(2)(B).

(C) UPDATE.—For purposes of applying subparagraph (A)(ii), the Secretary shall revise the list of compendia described in section 1927(g)(1)(B)(i) as is appropriate for identifying medically accepted indications for drugs. Any such revision shall be done in a manner consistent with the process for revising compendia under section 1861(t)(2)(B).

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Subpart 2—Prescription Drug Plans; PDP Sponsors; Financing

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REQUIREMENTS FOR AND CONTRACTS WITH PRESCRIPTION DRUG PLAN (PDP) SPONSORS

SEC. 1860D–12. (a) GENERAL REQUIREMENTS.—Each PDP sponsor of a prescription drug plan shall meet the following requirements:

(1) LICENSURE.—Subject to subsection (c), the sponsor is organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan.

(2) ASSUMPTION OF FINANCIAL RISK FOR UNSUBSIDIZED COVERAGE.—

(A) IN GENERAL.—Subject to subparagraph (B), to the extent that the entity is at risk the entity assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1860D–15(b).

(B) REINSURANCE PERMITTED.—The plan sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing such coverage.

(3) SOLVENCY FOR UNLICENSED SPONSORS.—In the case of a PDP sponsor that is not described in paragraph (1) and for which a waiver has been approved under subsection (c), such sponsor shall meet solvency standards established by the Secretary under subsection (d).

(b) CONTRACT REQUIREMENTS.—

(1) IN GENERAL.—The Secretary shall not permit the enrollment under section 1860D–1 in a prescription drug plan offered by a PDP sponsor under this part, and the sponsor shall not be eligible for payments under section 1860D–14 or 1860D–15, unless the Secretary has entered into a contract under this subsection with the sponsor with respect to the offering of such plan. Such a contract with a sponsor may cover

more than one prescription drug plan. Such contract shall provide that the sponsor agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

(2) LIMITATION ON ENTITIES OFFERING FALLBACK PRESCRIPTION DRUG PLANS.—The Secretary shall not enter into a contract with a PDP sponsor for the offering of a prescription drug plan (other than a fallback prescription drug plan) in a PDP region for a year if the sponsor—

(A) submitted a bid under section 1860D–11(g) for such year (as the first year of a contract period under such section) to offer a fallback prescription drug plan in any PDP region;

(B) offers a fallback prescription drug plan in any PDP region during the year; or

(C) offered a fallback prescription drug plan in that PDP region during the previous year.

For purposes of this paragraph, an entity shall be treated as submitting a bid with respect to a prescription drug plan or offering a fallback prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering such a plan. The previous sentence shall not apply to entities that are subcontractors of an MA organization except insofar as such organization is acting as a PDP sponsor with respect to a prescription drug plan.

(3) INCORPORATION OF CERTAIN MEDICARE ADVANTAGE CONTRACT REQUIREMENTS.—Except as otherwise provided, the following provisions of section 1857 shall apply to contracts under this section in the same manner as they apply to contracts under section 1857(a):

(A) MINIMUM ENROLLMENT.—Paragraphs (1) and (3) of section 1857(b), except that—

(i) the Secretary may increase the minimum number of enrollees required under such paragraph (1) as the Secretary determines appropriate; and

(ii) the requirement of such paragraph (1) shall be waived during the first contract year with respect to an organization in a region.

(B) CONTRACT PERIOD AND EFFECTIVENESS.—Section 1857(c), except that in applying paragraph (4)(B) of such section any reference to payment amounts under section 1853 shall be deemed payment amounts under section 1860D–15.

(C) PROTECTIONS AGAINST FRAUD AND BENEFICIARY PROTECTIONS.—Section 1857(d).

(D) ADDITIONAL CONTRACT TERMS.—Section 1857(e); except that section 1857(e)(2) shall apply as specified to PDP sponsors and payments under this part to an MA–PD plan shall be treated as expenditures made under part D. Notwithstanding any other provision of law, information provided to the Secretary under the application of section 1857(e)(1) to contracts under this section under the preceding sentence—

(i) may be used for the purposes of carrying out this part, improving public health through research on the

utilization, safety, effectiveness, quality, and efficiency of health care services (as the Secretary determines appropriate), or carrying out part E of title XI; and

(ii) shall be made available to Congressional support agencies (in accordance with their obligations to support Congress as set out in their authorizing statutes) for the purposes of conducting Congressional oversight, monitoring, making recommendations, and analysis of the program under this title.

(E) INTERMEDIATE SANCTIONS.—Section 1857(g) (other than paragraph (1)(F) of such section), except that in applying such section the reference in section 1857(g)(1)(B) to section 1854 is deemed a reference to this part.

(F) PROCEDURES FOR TERMINATION.—Section 1857(h).

(4) PROMPT PAYMENT OF CLEAN CLAIMS.—

(A) PROMPT PAYMENT.—

(i) IN GENERAL.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to all clean claims submitted by pharmacies (other than pharmacies that dispense drugs by mail order only or are located in, or contract with, a long-term care facility) under this part within the applicable number of calendar days after the date on which the claim is received.

(ii) CLEAN CLAIM DEFINED.—In this paragraph, the term "clean claim" means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part.

(iii) DATE OF RECEIPT OF CLAIM.—In this paragraph, a claim is considered to have been received—

(I) with respect to claims submitted electronically, on the date on which the claim is transferred; and

(II) with respect to claims submitted otherwise, on the 5th day after the postmark date of the claim or the date specified in the time stamp of the transmission.

(B) APPLICABLE NUMBER OF CALENDAR DAYS DEFINED.—In this paragraph, the term "applicable number of calendar days" means—

(i) with respect to claims submitted electronically, 14 days; and

(ii) with respect to claims submitted otherwise, 30 days.

(C) INTEREST PAYMENT.—

(i) IN GENERAL.—Subject to clause (ii), if payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in subparagraph (B)) after a clean claim is received, the PDP sponsor shall pay interest to the pharmacy that submitted the claim at a rate equal to the weighted

average of interest on 3-month marketable Treasury securities determined for such period, increased by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which payment is made (as determined under subparagraph (D)(iv)). Interest amounts paid under this subparagraph shall not be counted against the administrative costs of a prescription drug plan or treated as allowable risk corridor costs under section 1860D–15(e).

(ii) AUTHORITY NOT TO CHARGE INTEREST.—The Secretary may provide that a PDP sponsor is not charged interest under clause (i) in the case where there are exigent circumstances, including natural disasters and other unique and unexpected events, that prevent the timely processing of claims.

(D) PROCEDURES INVOLVING CLAIMS.—

(i) CLAIM DEEMED TO BE CLEAN.—A claim is deemed to be a clean claim if the PDP sponsor involved does not provide notice to the claimant of any deficiency in the claim—

(I) with respect to claims submitted electronically, within 10 days after the date on which the claim is received; and

(II) with respect to claims submitted otherwise, within 15 days after the date on which the claim is received.

(ii) CLAIM DETERMINED TO NOT BE A CLEAN CLAIM.—

(I) IN GENERAL.—If a PDP sponsor determines that a submitted claim is not a clean claim, the PDP sponsor shall, not later than the end of the period described in clause (i), notify the claimant of such determination. Such notification shall specify all defects or improprieties in the claim and shall list all additional information or documents necessary for the proper processing and payment of the claim.

(II) DETERMINATION AFTER SUBMISSION OF ADDITIONAL INFORMATION.—A claim is deemed to be a clean claim under this paragraph if the PDP sponsor involved does not provide notice to the claimant of any defect or impropriety in the claim within 10 days of the date on which additional information is received under subclause (I).

(iii) OBLIGATION TO PAY.—A claim submitted to a PDP sponsor that is not paid or contested by the sponsor within the applicable number of days (as defined in subparagraph (B)) after the date on which the claim is received shall be deemed to be a clean claim and shall be paid by the PDP sponsor in accordance with subparagraph (A).

(iv) DATE OF PAYMENT OF CLAIM.—Payment of a clean claim under such subparagraph is considered to have been made on the date on which—

(I) with respect to claims paid electronically, the payment is transferred; and

(II) with respect to claims paid otherwise, the payment is submitted to the United States Postal Service or common carrier for delivery.

(E) ELECTRONIC TRANSFER OF FUNDS.—A PDP sponsor shall pay all clean claims submitted electronically by electronic transfer of funds if the pharmacy so requests or has so requested previously. In the case where such payment is made electronically, remittance may be made by the PDP sponsor electronically as well.

(F) PROTECTING THE RIGHTS OF CLAIMANTS.—

(i) IN GENERAL.—Nothing in this paragraph shall be construed to prohibit or limit a claim or action not covered by the subject matter of this section that any individual or organization has against a provider or a PDP sponsor.

(ii) ANTI-RETALIATION.—Consistent with applicable Federal or State law, a PDP sponsor shall not retaliate against an individual or provider for exercising a right of action under this subparagraph.

(G) RULE OF CONSTRUCTION.—A determination under this paragraph that a claim submitted by a pharmacy is a clean claim shall not be construed as a positive determination regarding eligibility for payment under this title, nor is it an indication of government approval of, or acquiescence regarding, the claim submitted. The determination shall not relieve any party of civil or criminal liability with respect to the claim, nor does it offer a defense to any administrative, civil, or criminal action with respect to the claim.

(5) SUBMISSION OF CLAIMS BY PHARMACIES LOCATED IN OR CONTRACTING WITH LONG-TERM CARE FACILITIES.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that a pharmacy located in, or having a contract with, a long-term care facility shall have not less than 30 days (but not more than 90 days) to submit claims to the sponsor for reimbursement under the plan.

(6) REGULAR UPDATE OF PRESCRIPTION DRUG PRICING STANDARD.—If the PDP sponsor of a prescription drug plan uses a standard for reimbursement of pharmacies based on the cost of a drug, each contract entered into with such sponsor under this part with respect to the plan shall provide that the sponsor shall update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug.

(7) SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD BY PHARMACIES.—

(A) IN GENERAL.—Section 1862(o)(1) shall apply with respect to a PDP sponsor with a contract under this part, a pharmacy, and payments to such pharmacy under this part in the same manner as such section applies with respect to the Secretary, a provider of services or supplier,

and payments to such provider of services or supplier under this title. A PDP sponsor shall notify the Secretary regarding the imposition of any payment suspension pursuant to the previous sentence, such as through the secure internet website portal (or other successor technology) established under section 1859(i).

(B) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed as limiting the authority of a PDP sponsor to conduct postpayment review.

(8) PROVISION OF INFORMATION RELATED TO MAXIMUM FAIR PRICES.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall require the sponsor to provide information to the Secretary as requested by the Secretary for purposes of carrying out section 1194.

*(9) PROVISION OF INFORMATION RELATING TO PHARMACY OWNERSHIP.—*

*(A) IN GENERAL.—For plan year 2025 and for every third plan year thereafter, each PDP sponsor offering a prescription drug plan under this part during such plan year shall submit to the Secretary, at a time and in a manner specified by the Secretary, the taxpayer identification number and National Provider Identifier for each pharmacy that was a specified pharmacy with respect to such sponsor during such year.*

*(B) DEFINITION.—For purposes of this paragraph, the term "specified pharmacy" means, with respect to an PDP sponsor offering a prescription drug plan and a plan year, a pharmacy with respect to which—*

*(i) such sponsor (or any person with an ownership or control interest (as defined in section 1124(a)(3)) in such sponsor) is a person with an ownership or control interest (as so defined); or*

*(ii) a pharmacy benefit manager offering services under such plan (or any person with an ownership or control interest (as so defined) in such sponsor) is a person with an ownership or control interest (as so defined).*

(c) WAIVER OF CERTAIN REQUIREMENTS TO EXPAND CHOICE.—

(1) AUTHORIZING WAIVER.—

(A) IN GENERAL.—In the case of an entity that seeks to offer a prescription drug plan in a State, the Secretary shall waive the requirement of subsection (a)(1) that the entity be licensed in that State if the Secretary determines, based on the application and other evidence presented to the Secretary, that any of the grounds for approval of the application described in paragraph (2) have been met.

(B) APPLICATION OF REGIONAL PLAN WAIVER RULE.—In addition to the waiver available under subparagraph (A), the provisions of section 1858(d) shall apply to PDP sponsors under this part in a manner similar to the manner in which such provisions apply to MA organizations under part C, except that no application shall be required under

paragraph (1)(B) of such section in the case of a State that does not provide a licensing process for such a sponsor.

(2) GROUNDS FOR APPROVAL.—

(A) IN GENERAL.—The grounds for approval under this paragraph are—

(i) subject to subparagraph (B), the grounds for approval described in subparagraphs (B), (C), and (D) of section 1855(a)(2); and

(ii) the application by a State of any grounds other than those required under Federal law.

(B) SPECIAL RULES.—In applying subparagraph (A)(i)—

(i) the ground of approval described in section 1855(a)(2)(B) is deemed to have been met if the State does not have a licensing process in effect with respect to the PDP sponsor; and

(ii) for plan years beginning before January 1, 2008, if the State does have such a licensing process in effect, such ground for approval described in such section is deemed to have been met upon submission of an application described in such section.

(3) APPLICATION OF WAIVER PROCEDURES.—With respect to an application for a waiver (or a waiver granted) under paragraph (1)(A) of this subsection, the provisions of subparagraphs (E), (F), and (G) of section 1855(a)(2) shall apply, except that clauses (i) and (ii) of such subparagraph (E) shall not apply in the case of a State that does not have a licensing process described in paragraph (2)(B)(i) in effect.

(4) REFERENCES TO CERTAIN PROVISIONS.—In applying provisions of section 1855(a)(2) under paragraphs (2) and (3) of this subsection to prescription drug plans and PDP sponsors—

(A) any reference to a waiver application under section 1855 shall be treated as a reference to a waiver application under paragraph (1)(A) of this subsection; and

(B) any reference to solvency standards shall be treated as a reference to solvency standards established under subsection (d) of this section.

(d) SOLVENCY STANDARDS FOR NON-LICENSED ENTITIES.—

(1) ESTABLISHMENT AND PUBLICATION.—The Secretary, in consultation with the National Association of Insurance Commissioners, shall establish and publish, by not later than January 1, 2005, financial solvency and capital adequacy standards for entities described in paragraph (2).

(2) COMPLIANCE WITH STANDARDS.—A PDP sponsor that is not licensed by a State under subsection (a)(1) and for which a waiver application has been approved under subsection (c) shall meet solvency and capital adequacy standards established under paragraph (1). The Secretary shall establish certification procedures for such sponsors with respect to such solvency standards in the manner described in section 1855(c)(2).

(e) LICENSURE DOES NOT SUBSTITUTE FOR OR CONSTITUTE CERTIFICATION.—The fact that a PDP sponsor is licensed in accordance with subsection (a)(1) or has a waiver application approved under subsection (c) does not deem the sponsor to meet other requirements imposed under this part for a sponsor.

(f) PERIODIC REVIEW AND REVISION OF STANDARDS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary may periodically review the standards established under this section and, based on such review, may revise such standards if the Secretary determines such revision to be appropriate.

(2) PROHIBITION OF MIDYEAR IMPLEMENTATION OF SIGNIFICANT NEW REGULATORY REQUIREMENTS.—The Secretary may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

(g) PROHIBITION OF STATE IMPOSITION OF PREMIUM TAXES; RELATION TO STATE LAWS.—The provisions of sections 1854(g) and 1856(b)(3) shall apply with respect to PDP sponsors and prescription drug plans under this part in the same manner as such sections apply to MA organizations and MA plans under part C.

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PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

SEC. 1860D–14. (a) INCOME-RELATED SUBSIDIES FOR CERTAIN INDIVIDUALS.—

(1) INDIVIDUALS WITH CERTAIN LOW INCOMES.—In the case of a subsidy eligible individual (as defined in paragraph (3)) who is determined to have income that is below 135 percent (or, with respect to a plan year beginning on or after January 1, 2024, 150 percent) of the poverty line applicable to a family of the size involved and who meets the resources requirement described in paragraph (3)(D) (or, with respect to a plan year beginning on or after January 1, 2024, paragraph (3)(E)) or who is covered under this paragraph under paragraph (3)(B)(i), the individual is entitled under this section to the following:

(A) FULL PREMIUM SUBSIDY.—An income-related premium subsidy equal to 100 percent of the amount described in subsection (b)(1), but not to exceed the premium amount specified in subsection (b)(2)(B).

(B) ELIMINATION OF DEDUCTIBLE.—A reduction in the annual deductible applicable under section 1860D–2(b)(1) to $0.

(C) CONTINUATION OF COVERAGE ABOVE THE INITIAL COVERAGE LIMIT.—For a year preceding 2025, the continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D–2(b)) for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4) of such section, subject to the reduced cost-sharing described in subparagraph (D).

(D) REDUCTION IN COST-SHARING BELOW OUT-OF-POCKET THRESHOLD.—

(i) INSTITUTIONALIZED INDIVIDUALS.—In the case of an individual who is a full-benefit dual eligible individual and who is an institutionalized individual or couple (as defined in section 1902(q)(1)(B)) or, effective on a date specified by the Secretary (but in no case earlier than January 1, 2012), who would be such an institutionalized individual or couple, if the full-benefit

dual eligible individual were not receiving services under a home and community-based waiver authorized for a State under section 1115 or subsection (c) or (d) of section 1915 or under a State plan amendment under subsection (i) of such section or services provided through enrollment in a medicaid managed care organization with a contract under section 1903(m) or under section 1932, the elimination of any beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)).

(ii) LOWEST INCOME DUAL ELIGIBLE INDIVIDUALS.—Subject to paragraph (6), in the case of an individual not described in clause (i) who is a full-benefit dual eligible individual and whose income does not exceed 100 percent of the poverty line applicable to a family of the size involved, the substitution for the beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)) of a copayment amount that does not exceed $1 for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i)) and $3 for any other drug, or, if less, the copayment amount applicable to an individual under clause (iii).

(iii) OTHER INDIVIDUALS.—Subject to paragraph (6), in the case of an individual not described in clause (i) or (ii), the substitution for the beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)) of a copayment amount that does not exceed the copayment amount specified under section 1860D–2(b)(4)(A)(i)(I)(aa) for the drug and year involved. For plan year 2023 and subsequent plan years, the copayment amount applicable under the preceding sentence to a month's supply of a covered insulin product (as defined in section 1860D–2(b)(9)(C)) dispensed to the individual may not exceed the applicable copayment amount for the product under the prescription drug plan or MA–PD plan in which the individual is enrolled. *For plan year 2027 and subsequent plan years, the copayment amount applicable under this clause to a supply of a covered part D drug dispensed to the individual may not exceed the amount provided under section 1860D–2(b)(10).*

(E) ELIMINATION OF COST-SHARING ABOVE ANNUAL OUT-OF-POCKET THRESHOLD.—For a year preceding 2024, the elimination of any cost-sharing imposed under section 1860D–2(b)(4)(A). or under section 1860D–2(b)(9) in the case of a covered insulin product (as defined in subparagraph (C) of such section).

(2) OTHER LOW-INCOME INDIVIDUALS.—With respect to a plan year beginning before January 1, 2024, in the case of a subsidy eligible individual who is not described in paragraph (1), the individual is entitled under this section to the following:

(A) SLIDING SCALE PREMIUM SUBSIDY.—An income-related premium subsidy determined on a linear sliding scale ranging from 100 percent of the amount described in paragraph (1)(A) for individuals with incomes at or below 135 percent of such level to 0 percent of such amount for individuals with incomes at 150 percent of such level.

(B) REDUCTION OF DEDUCTIBLE.—Subject to paragraphs (8) and (9) of section1860D–2(b), a reduction in the annual deductible applicable under section 1860D–2(b)(1) to $50.

(C) CONTINUATION OF COVERAGE ABOVE THE INITIAL COVERAGE LIMIT.—The continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D–2(b)) for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4) of such section, subject to the reduced coinsurance described in subparagraph (D).

(D) REDUCTION IN COST-SHARING BELOW OUT-OF-POCKET THRESHOLD.—Subject to paragraph (6), the substitution for the beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts above the deductible under subparagraph (B) through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)) of coinsurance of "15 percent" instead of coinsurance of "25 percent" in section 1860D–2(b)(2). For plan year 2023, the amount of the coinsurance applicable under the preceding sentence to a month's supply of a covered insulin product (as defined in section 1860D–2(b)(9)(C)) dispensed to the individual may not exceed the applicable copayment amount for the product under the prescription drug plan or MA–PD plan in which the individual is enrolled.

(E) REDUCTION OF COST-SHARING ABOVE ANNUAL OUT-OF-POCKET THRESHOLD.—Subject to paragraph (6) of this subsection and subsection (c), the substitution for the cost-sharing imposed under section 1860D–2(b)(4)(A) of a copayment or coinsurance not to exceed the copayment or coinsurance amount specified under section 1860D–2(b)(4)(A)(i)(I)(aa) for the drug and year involved. For plan year 2023, the amount of the copayment or coinsurance applicable under the preceding sentence to a month's supply of a covered insulin product (as defined in section 1860D–2(b)(9)(C)) dispensed to the individual may not exceed the applicable copayment amount for the product under the prescription drug plan or MA–PD plan in which the individual is enrolled.

(3) DETERMINATION OF ELIGIBILITY.—

(A) SUBSIDY ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this part, subject to subparagraph (F), the term "subsidy eligible individual" means a part D eligible individual who—

(i) is enrolled in a prescription drug plan or MA–PD plan;

(ii) has income below 150 percent of the poverty line applicable to a family of the size involved; and

(iii) meets the resources requirement described in subparagraph (D) or (E).

(B) DETERMINATIONS.—

(i) IN GENERAL.—The determination of whether a part D eligible individual residing in a State is a subsidy eligible individual and whether the individual is described in paragraph (1) shall be determined under the State plan under title XIX for the State under section 1935(a) or by the Commissioner of Social Security. There are authorized to be appropriated to the Social Security Administration such sums as may be necessary for the determination of eligibility under this subparagraph.

(ii) EFFECTIVE PERIOD.—Determinations under this subparagraph shall be effective beginning with the month in which the individual applies for a determination that the individual is a subsidy eligible individual and shall remain in effect for a period specified by the Secretary, but not to exceed 1 year.

(iii) REDETERMINATIONS AND APPEALS THROUGH MEDICAID.—Redeterminations and appeals, with respect to eligibility determinations under clause (i) made under a State plan under title XIX, shall be made in accordance with the frequency of, and manner in which, redeterminations and appeals of eligibility are made under such plan for purposes of medical assistance under such title.

(iv) REDETERMINATIONS AND APPEALS THROUGH COMMISSIONER.—With respect to eligibility determinations under clause (i) made by the Commissioner of Social Security—

(I) redeterminations shall be made at such time or times as may be provided by the Commissioner;

(II) the Commissioner shall establish procedures for appeals of such determinations that are similar to the procedures described in the third sentence of section 1631(c)(1)(A); and

(III) judicial review of the final decision of the Commissioner made after a hearing shall be available to the same extent, and with the same limitations, as provided in subsections (g) and (h) of section 205.

(v) TREATMENT OF MEDICAID BENEFICIARIES.—Subject to subparagraph (F), the Secretary—

(I) shall provide that part D eligible individuals who are full-benefit dual eligible individuals (as defined in section 1935(c)(6)) or who are recipients of supplemental security income benefits under title XVI shall be treated as subsidy eligible individuals described in paragraph (1); and

(II) may provide that part D eligible individuals not described in subclause (I) who are determined for purposes of the State plan under title XIX to

be eligible for medical assistance under clause (i), (iii), or (iv) of section 1902(a)(10)(E) are treated as being determined to be subsidy eligible individuals described in paragraph (1).

Insofar as the Secretary determines that the eligibility requirements under the State plan for medical assistance referred to in subclause (II) are substantially the same as the requirements for being treated as a subsidy eligible individual described in paragraph (1), the Secretary shall provide for the treatment described in such subclause.

(vi) SPECIAL RULE FOR WIDOWS AND WIDOWERS.—Notwithstanding the preceding provisions of this subparagraph, in the case of an individual whose spouse dies during the effective period for a determination or redetermination that has been made under this subparagraph, such effective period shall be extended through the date that is 1 year after the date on which the determination or redetermination would (but for the application of this clause) otherwise cease to be effective.

(C) INCOME DETERMINATIONS.—For purposes of applying this section—

(i) in the case of a part D eligible individual who is not treated as a subsidy eligible individual under subparagraph (B)(v), income shall be determined in the manner described in section 1905(p)(1)(B), without regard to the application of section 1902(r)(2) and except that support and maintenance furnished in kind shall not be counted as income; and

(ii) the term "poverty line" has the meaning given such term in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)), including any revision required by such section.

Nothing in clause (i) shall be construed to affect the application of section 1902(r)(2) for the determination of eligibility for medical assistance under title XIX.

(D) RESOURCE STANDARD APPLIED TO FULL LOW-INCOME SUBSIDY TO BE BASED ON THREE TIMES SSI RESOURCE STANDARD.—The resources requirement of this subparagraph is that an individual's resources (as determined under section 1613 for purposes of the supplemental security income program subject to the life insurance policy exclusion provided under subparagraph (G)) do not exceed—

(i) for 2006 three times the maximum amount of resources that an individual may have and obtain benefits under that program; and

(ii) for a subsequent year the resource limitation established under this clause for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any resource limitation established under clause (ii) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(E) ALTERNATIVE RESOURCE STANDARD.—

(i) IN GENERAL.—The resources requirement of this subparagraph is that an individual's resources (as determined under section 1613 for purposes of the supplemental security income program subject to the life insurance policy exclusion provided under subparagraph (G)) do not exceed—

(I) for 2006, $10,000 (or $20,000 in the case of the combined value of the individual's assets or resources and the assets or resources of the individual's spouse); and

(II) for a subsequent year the dollar amounts specified in this subclause (or subclause (I)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any dollar amount established under subclause (II) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(ii) USE OF SIMPLIFIED APPLICATION FORM AND PROCESS.—The Secretary, jointly with the Commissioner of Social Security, shall—

(I) develop a model, simplified application form and process consistent with clause (iii) for the determination and verification of a part D eligible individual's assets or resources under this subparagraph; and

(II) provide such form to States.

(iii) DOCUMENTATION AND SAFEGUARDS.—Under such process—

(I) the application form shall consist of an attestation under penalty of perjury regarding the level of assets or resources (or combined assets and resources in the case of a married part D eligible individual) and valuations of general classes of assets or resources;

(II) such form shall be accompanied by copies of recent statements (if any) from financial institutions in support of the application; and

(III) matters attested to in the application shall be subject to appropriate methods of verification.

(iv) METHODOLOGY FLEXIBILITY.—The Secretary may permit a State in making eligibility determinations for premium and cost-sharing subsidies under this section to use the same asset or resource methodologies that are used with respect to eligibility for medical assistance for medicare cost-sharing described in section 1905(p) so long as the Secretary determines that the use of such methodologies will not result in any significant differences in the number of individuals determined to be subsidy eligible individuals.

(F) TREATMENT OF TERRITORIAL RESIDENTS.—In the case of a part D eligible individual who is not a resident of the 50 States or the District of Columbia, the individual is not

eligible to be a subsidy eligible individual under this section but may be eligible for financial assistance with prescription drug expenses under section 1935(e).

(G) LIFE INSURANCE POLICY EXCLUSION.—In determining the resources of an individual (and the eligible spouse of the individual, if any) under section 1613 for purposes of subparagraphs (D) and (E) no part of the value of any life insurance policy shall be taken into account.

(4) INDEXING DOLLAR AMOUNTS.—

(A) COPAYMENT FOR LOWEST INCOME DUAL ELIGIBLE INDIVIDUALS.—The dollar amounts applied under paragraph (1)(D)(ii)—

(i) for 2007 shall be the dollar amounts specified in such paragraph increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year; or

(ii) for a subsequent year shall be the dollar amounts specified in this clause (or clause (i)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any amount established under clause (i) or (ii), that is based on an increase of $1 or $3, that is not a multiple of 5 cents or 10 cents, respectively, shall be rounded to the nearest multiple of 5 cents or 10 cents, respectively.

(B) REDUCED DEDUCTIBLE.—The dollar amount applied under paragraph (2)(B)—

(i) for 2007 shall be the dollar amount specified in such paragraph increased by the annual percentage increase described in section 1860D–2(b)(6) for 2007; or

(ii) for a subsequent year shall be the dollar amount specified in this clause (or clause (i)) for the previous year increased by the annual percentage increase described in section 1860D–2(b)(6) for the year involved.

Any amount established under clause (i) or (ii) that is not a multiple of $1 shall be rounded to the nearest multiple of $1.

(5) WAIVER OF DE MINIMIS PREMIUMS.—The Secretary shall, under procedures established by the Secretary, permit a prescription drug plan or an MA–PD plan to waive the monthly beneficiary premium for a subsidy eligible individual if the amount of such premium is de minimis. If such premium is waived under the plan, the Secretary shall not reassign subsidy eligible individuals enrolled in the plan to other plans based on the fact that the monthly beneficiary premium under the plan was greater than the low-income benchmark premium amount.

(6) NO APPLICATION OF COST-SHARING OR DEDUCTIBLE FOR ADULT VACCINES RECOMMENDED BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.—For plan years beginning on or after January 1, 2023, with respect to an adult vaccine recommended by the Advisory Committee on Immunization Practices (as defined in section 1860D–2(b)(8)(B))—

(A) the deductible under section 1860D–2(b)(1) shall not apply; and

(B) there shall be no cost-sharing under this section with respect to such vaccine.

(b) PREMIUM SUBSIDY AMOUNT.—

(1) IN GENERAL.—The premium subsidy amount described in this subsection for a subsidy eligible individual residing in a PDP region and enrolled in a prescription drug plan or MA–PD plan is the low-income benchmark premium amount (as defined in paragraph (2)) for the PDP region in which the individual resides or, if greater, the amount specified in paragraph (3).

(2) LOW-INCOME BENCHMARK PREMIUM AMOUNT DEFINED.—

(A) IN GENERAL.—For purposes of this subsection, the term "low-income benchmark premium amount" means, with respect to a PDP region in which—

(i) all prescription drug plans are offered by the same PDP sponsor, the weighted average of the amounts described in subparagraph (B)(i) for such plans; or

(ii) there are prescription drug plans offered by more than one PDP sponsor, the weighted average of amounts described in subparagraph (B) for prescription drug plans and MA–PD plans described in section 1851(a)(2)(A)(i) offered in such region.

(B) PREMIUM AMOUNTS DESCRIBED.—The premium amounts described in this subparagraph are, in the case of—

(i) a prescription drug plan that is a basic prescription drug plan, the monthly beneficiary premium for such plan;

(ii) a prescription drug plan that provides alternative prescription drug coverage the actuarial value of which is greater than that of standard prescription drug coverage, the portion of the monthly beneficiary premium that is attributable to basic prescription drug coverage; and

(iii) an MA–PD plan, the portion of the MA monthly prescription drug beneficiary premium that is attributable to basic prescription drug benefits (described in section 1852(a)(6)(B)(ii)) and determined before the application of the monthly rebate computed under section 1854(b)(1)(C)(i) for that plan and year involved and, in the case of a qualifying plan, before the application of the increase under section 1853(o) for that plan and year involved.

The premium amounts described in this subparagraph do not include any amounts attributable to late enrollment penalties under section 1860D–13(b).

(3) ACCESS TO 0 PREMIUM PLAN.—In no case shall the premium subsidy amount under this subsection for a PDP region be less than the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the region.

(c) ADMINISTRATION OF SUBSIDY PROGRAM.—

(1) IN GENERAL.—The Secretary shall provide a process whereby, in the case of a part D eligible individual who is determined to be a subsidy eligible individual and who is enrolled in a prescription drug plan or is enrolled in an MA–PD plan—

(A) the Secretary provides for a notification of the PDP sponsor or the MA organization offering the plan involved that the individual is eligible for a subsidy and the amount of the subsidy under subsection (a);

(B) the sponsor or organization involved reduces the premiums or cost-sharing otherwise imposed by the amount of the applicable subsidy and submits to the Secretary information on the amount of such reduction;

(C) the Secretary periodically and on a timely basis reimburses the sponsor or organization for the amount of such reductions; and

(D) the Secretary ensures the confidentiality of individually identifiable information.

In applying subparagraph (C), the Secretary shall compute reductions based upon imposition under subsections (a)(1)(D) and (a)(2)(E) of unreduced copayment amounts applied under such subsections.

(2) USE OF CAPITATED FORM OF PAYMENT.—The reimbursement under this section with respect to cost-sharing subsidies may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved.

(d) FACILITATION OF REASSIGNMENTS.—Beginning not later than January 1, 2011, the Secretary shall, in the case of a subsidy eligible individual who is enrolled in one prescription drug plan and is subsequently reassigned by the Secretary to a new prescription drug plan, provide the individual, within 30 days of such reassignment, with—

(1) information on formulary differences between the individual's former plan and the plan to which the individual is reassigned with respect to the individual's drug regimens; and

(2) a description of the individual's right to request a coverage determination, exception, or reconsideration under section 1860D–4(g), bring an appeal under section 1860D–4(h), or resolve a grievance under section 1860D–4(f).

(e) LIMITED INCOME NEWLY ELIGIBLE TRANSITION PROGRAM.—

(1) IN GENERAL.—Beginning not later than January 1, 2024, the Secretary shall carry out a program to provide transitional coverage for covered part D drugs for LI NET eligible individuals in accordance with this subsection.

(2) LI NET ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this subsection, the term "LI NET eligible individual" means a part D eligible individual who—

(A) meets the requirements of clauses (ii) and (iii) of subsection (a)(3)(A); and

(B) has not yet enrolled in a prescription drug plan or an MA–PD plan, or, who has so enrolled, but with respect to whom coverage under such plan has not yet taken effect.

(3) TRANSITIONAL COVERAGE.—For purposes of this subsection, the term "transitional coverage" means with respect to an LI NET eligible individual—

(A) immediate access to covered part D drugs at the point of sale during the period that begins on the first day of the month such individual is determined to meet the requirements of clauses (ii) and (iii) of subsection (a)(3)(A) and ends on the date that coverage under a prescription drug plan or MA–PD plan takes effect with respect to such individual; and

(B) in the case of an LI NET eligible individual who is a full-benefit dual eligible individual (as defined in section 1935(c)(6)) or a recipient of supplemental security income benefits under title XVI, retroactive coverage (in the form of reimbursement of the amounts that would have been paid under this part had such individual been enrolled in a prescription drug plan or MA–PD plan) of covered part D drugs purchased by such individual during the period that begins on the date that is the later of—

(i) the date that such individual was first eligible for a low-income subsidy under this part; or

(ii) the date that is 36 months prior to the date such individual enrolls in a prescription drug plan or MA–PD plan,

and ends on the date that coverage under such plan takes effect.

(4) PROGRAM ADMINISTRATION.—

(A) POINT OF CONTACT.—The Secretary shall, as determined appropriate by the Secretary, administer the program under this subsection through a contract with a single program administrator.

(B) BENEFIT DESIGN.—The Secretary shall ensure that the transitional coverage provided to LI NET eligible individuals under this subsection—

(i) provides access to all covered part D drugs under an open formulary;

(ii) permits all pharmacies determined by the Secretary to be in good standing to process claims under the program;

(iii) is consistent with such requirements as the Secretary considers necessary to improve patient safety and ensure appropriate dispensing of medication; and

(iv) meets such other requirements as the Secretary may establish.

(5) RELATIONSHIP TO OTHER PROVISIONS OF THIS TITLE; WAIVER AUTHORITY.—

(A) IN GENERAL.—The following provisions shall not apply with respect to the program under this subsection:

(i) Paragraphs (1) and (3)(B) of section 1860D–4(a) (relating to dissemination of general information; availability of information on changes in formulary through the internet).

(ii) Subparagraphs (A) and (B) of section 1860D–4(b)(3) (relating to requirements on development and application of formularies; formulary development).

(iii) Paragraphs (1)(C) and (2) of section 1860D–4(c) (relating to medication therapy management program).

(B) WAIVER AUTHORITY.—The Secretary may waive such other requirements of title XI and this title as may be necessary to carry out the purposes of the program established under this subsection.

(6) CONTRACTING AUTHORITY.—The authority vested in the Secretary by this subsection may be performed without regard to such provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose of this title.

(f) RELATION TO MEDICAID PROGRAM.—For special provisions under the medicaid program relating to medicare prescription drug benefits, see section 1935.

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## PART E—MISCELLANEOUS PROVISIONS

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### PAYMENT TO HOSPITALS FOR INPATIENT HOSPITAL SERVICES

SEC. 1886. (a)(1)(A)(i) The Secretary, in determining the amount of the payments that may be made under this title with respect to operating costs of inpatient hospital services (as defined in paragraph (4)) shall not recognize as reasonable (in the efficient delivery of health services) costs for the provision of such services by a hospital for a cost reporting period to the extent such costs exceed the applicable percentage (as determined under clause (ii)) of the average of such costs for all hospitals in the same grouping as such hospital for comparable time periods.

(ii) For purposes of clause (i), the applicable percentage for hospital cost reporting periods beginning—

(I) on or after October 1, 1982, and before October 1, 1983, is 120 percent;

(II) on or after October 1, 1983, and before October 1, 1984, is 115 percent; and

(III) on or after October 1, 1984, is 110 percent.

(B)(i) For purposes of subparagraph (A) the Secretary shall establish case mix indexes for all short- term hospitals, and shall set limits for each hospital based upon the general mix of types of medical cases with respect to which such hospital provides services for which payment may be made under this title.

(ii) The Secretary shall set such limits for a cost reporting period of a hospital—

(I) by updating available data for a previous period to the immediate preceding cost reporting period by the estimated average rate of change of hospital costs industry-wide, and

(II) by projecting for the cost reporting period by the applicable percentage increase (as defined in subsection (b)(3)(B)).

(C) The limitation established under subparagraph (A) for any hospital shall in no event be lower than the allowable operating costs of inpatient hospital services (as defined in paragraph (4)) recognized under this title for such hospital for such hospital's last

cost reporting period prior to the hospital's first cost reporting period for which this section is in effect.

(D) Subparagraph (A) shall not apply to cost reporting periods beginning on or after October 1, 1983.

(2) The Secretary shall provide for such exemptions from, and exceptions and adjustments to, the limitation established under paragraph (1)(A) as he deems appropriate, including those which he deems necessary to take into account—

(A) the special needs of sole community hospitals, of new hospitals, of risk based health maintenance organizations, and of hospitals which provide atypical services or essential community services, and to take into account extraordinary circumstances beyond the hospital's control, medical and paramedical education costs, significantly fluctuating population in the service area of the hospital, and unusual labor costs,

(B) the special needs of psychiatric hospitals and of public or other hospitals that serve a significantly disproportionate number of patients who have low income or are entitled to benefits under part A of this title, and

(C) a decrease in the inpatient hospital services that a hospital provides and that are customarily provided directly by similar hospitals which results in a significant distortion in the operating costs of inpatient hospital services.

(3) The limitation established under paragraph (1)(A) shall not apply with respect to any hospital which—

(A) is located outside of a standard metropolitan statistical area, and

(B)(i) has less than 50 beds, and

(ii) was in operation and had less than 50 beds on the date of the enactment of this section.

(4) For purposes of this section, the term "operating costs of inpatient hospital services" includes all routine operating costs, ancillary service operating costs, and special care unit operating costs with respect to inpatient hospital services as such costs are determined on an average per admission or per discharge basis (as determined by the Secretary), and includes the costs of all services for which payment may be made under this title that are provided by the hospital (or by an entity wholly owned or operated by the hospital) to the patient during the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) immediately preceding the date of the patient's admission if such services are diagnostic services (including clinical diagnostic laboratory tests) or are other services related to the admission (as defined by the Secretary). Such term does not include costs of approved educational activities, a return on equity capital, other capital-related costs (as defined by the Secretary for periods before October 1, 1987), for cost reporting periods beginning on or after October 1, 2020, costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant (as described in subsection (d)(5)(M)), or costs with respect to administering blood clotting factors to individuals with hemophilia. In applying the first sentence of this paragraph, the term "other services related to the admission" includes all services that are not diagnostic services (other than ambulance and maintenance renal dialysis services) for which payment may be made under this title that

are provided by a hospital (or an entity wholly owned or operated by the hospital) to a patient—

(A) on the date of the patient's inpatient admission; or

(B) during the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) immediately preceding the date of such admission unless the hospital demonstrates (in a form and manner, and at a time, specified by the Secretary) that such services are not related (as determined by the Secretary) to such admission.

(b)(1) Notwithstanding section 1814(b) but subject to the provisions of section 1813, if the operating costs of inpatient hospital services (as defined in subsection (a)(4)) of a hospital (other than a subsection (d) hospital, as defined in subsection (d)(1)(B) and other than a rehabilitation facility described in subsection (j)(1)) for a cost reporting period subject to this paragraph—

(A) are less than or equal to the target amount (as defined in paragraph (3)) for that hospital for that period, the amount of the payment with respect to such operating costs payable under part A on a per discharge or per admission basis (as the case may be) shall be equal to the amount of such operating costs, plus—

(i) 15 percent of the amount by which the target amount exceeds the amount of the operating costs, or

(ii) 2 percent of the target amount,

whichever is less;

(B) are greater than the target amount but do not exceed 110 percent of the target amount, the amount of the payment with respect to those operating costs payable under part A on a per discharge basis shall equal the target amount; or

(C) are greater than 110 percent of the target amount, the amount of the payment with respect to such operating costs payable under part A on a per discharge or per admission basis (as the case may be) shall be equal to (i) the target amount, plus (ii) in the case of cost reporting periods beginning on or after October 1, 1991, an additional amount equal to 50 percent of the amount by which the operating costs exceed 110 percent of the target amount (except that such additional amount may not exceed 10 percent of the target amount) after any exceptions or adjustments are made to such target amount for the cost reporting period;

plus the amount, if any, provided under paragraph (2), except that in no case may the amount payable under this title (other than on the basis of a DRG prospective payment rate determined under subsection (d)) with respect to operating costs of inpatient hospital services exceed the maximum amount payable with respect to such costs pursuant to subsection (a).

(2)(A) Except as provided in subparagraph (E), in addition to the payment computed under paragraph (1), in the case of an eligible hospital (described in subparagraph (B)) for a cost reporting period beginning on or after October 1, 1997, the amount of payment on a per discharge basis under paragraph (1) shall be increased by the lesser of—

(i) 50 percent of the amount by which the operating costs are less than the expected costs (as defined in subparagraph (D)) for the period; or

(ii) 1 percent of the target amount for the period.

(B) For purposes of this paragraph, an "eligible hospital" means with respect to a cost reporting period, a hospital—

(i) that has received payments under this subsection for at least 3 full cost reporting periods before that cost reporting period, and

(ii) whose operating costs for the period are less than the least of its target amount, its trended costs (as defined in subparagraph (C)), or its expected costs (as defined in subparagraph (D)) for the period.

(C) For purposes of subparagraph (B)(ii), the term "trended costs" means for a hospital cost reporting period ending in a fiscal year—

(i) in the case of a hospital for which its cost reporting period ending in fiscal year 1996 was its third or subsequent full cost reporting period for which it receives payments under this subsection, the lesser of the operating costs or target amount for that hospital for its cost reporting period ending in fiscal year 1996, or

(ii) in the case of any other hospital, the operating costs for that hospital for its third full cost reporting period for which it receives payments under this subsection,

increased (in a compounded manner) for each succeeding fiscal year (through the fiscal year involved) by the market basket percentage increase for the fiscal year.

(D) For purposes of this paragraph, the term "expected costs", with respect to the cost reporting period ending in a fiscal year, means the lesser of the operating costs of inpatient hospital services or target amount per discharge for the previous cost reporting period updated by the market basket percentage increase (as defined in paragraph (3)(B)(iii)) for the fiscal year.

(E)(i) In the case of an eligible hospital that is a hospital or unit that is within a class of hospital described in clause (ii) with a 12-month cost reporting period beginning before the enactment of this subparagraph, in determining the amount of the increase under subparagraph (A), the Secretary shall substitute for the percentage of the target amount applicable under subparagraph (A)(ii)—

(I) for a cost reporting period beginning on or after October 1, 2000, and before September 30, 2001, 1.5 percent; and

(II) for a cost reporting period beginning on or after October 1, 2001, and before September 30, 2002, 2 percent.

(ii) For purposes of clause (i), each of the following shall be treated as a separate class of hospital:

(I) Hospitals described in clause (i) of subsection (d)(1)(B) and psychiatric units described in the matter following clause (v) of such subsection.

(II) Hospitals described in clause (iv) of such subsection.

(3)(A) Except as provided in subparagraph (C) and succeeding subparagraphs and in paragraph (7)(A)(ii), for purposes of this subsection, the term "target amount" means, with respect to a hospital for a particular 12-month cost reporting period—

(i) in the case of the first such reporting period for which this subsection is in effect, the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this title for such hospital for the preceding 12-month cost reporting period, and

(ii) in the case of a later reporting period, the target amount for the preceding 12-month cost reporting period,

increased by the applicable percentage increase under subparagraph (B) for that particular cost reporting period.

(B)(i) For purposes of subsection (d) and subsection (j) for discharges occurring during a fiscal year, the "applicable percentage increase" shall be—

(I) for fiscal year 1986, ½ percent,

(II) for fiscal year 1987, 1.15 percent,

(III) for fiscal year 1988, 3.0 percent for hospitals located in a rural area, 1.5 percent for hospitals located in a large urban area (as defined in subsection (d)(2)(D)), and 1.0 percent for hospitals located in other urban areas,

(IV) for fiscal year 1989, the market basket percentage increase minus 1.5 percentage points for hospitals located in a rural area, the market basket percentage increase minus 2.0 percentage points for hospitals located in a large urban area, and the market basket percentage increase minus 2.5 percentage points for hospitals located in other urban areas,

(V) for fiscal year 1990, the market basket percentage increase plus 4.22 percentage points for hospitals located in a rural area, the market basket percentage increase plus 0.12 percentage points for hospitals located in a large urban area, and the market basket percentage increase minus 0.53 percentage points for hospitals located in other urban areas,

(VI) for fiscal year 1991, the market basket percentage increase minus 2.0 percentage points for hospitals in a large urban or other urban area, and the market basket percentage increase minus 0.7 percentage point for hospitals located in a rural area,

(VII) for fiscal year 1992, the market basket percentage increase minus 1.6 percentage points for hospitals in a large urban or other urban area, and the market basket percentage increase minus 0.6 percentage point for hospitals located in a rural area,

(VIII) for fiscal year 1993, the market basket percentage increase minus 1.55 percentage point for hospitals in a large urban or other urban area, and the market basket percentage increase minus 0.55 for hospitals located in a rural area,

(IX) for fiscal year 1994, the market basket percentage increase minus 2.5 percentage points for hospitals located in a large urban or other urban area, and the market basket percentage increase minus 1.0 percentage point for hospitals located in a rural area,

(X) for fiscal year 1995, the market basket percentage increase minus 2.5 percentage points for hospitals located in a large urban or other urban area, and such percentage increase for hospitals located in a rural area as will provide for the average standardized amount determined under subsection (d)(3)(A) for hospitals located in a rural area being equal to such average standardized amount for hospitals located in an urban area (other than a large urban area),

(XI) for fiscal year 1996, the market basket percentage increase minus 2.0 percentage points for hospitals in all areas,

(XII) for fiscal year 1997, the market basket percentage increase minus 0.5 percentage point for hospitals in all areas,

(XIII) for fiscal year 1998, 0 percent,

(XIV) for fiscal year 1999, the market basket percentage increase minus 1.9 percentage points for hospitals in all areas,

(XV) for fiscal year 2000, the market basket percentage increase minus 1.8 percentage points for hospitals in all areas,

(XVI) for fiscal year 2001, the market basket percentage increase for hospitals in all areas,

(XVII) for fiscal year 2002, the market basket percentage increase minus 0.55 percentage points for hospitals in all areas,

(XVIII) for fiscal year 2003, the market basket percentage increase minus 0.55 percentage points for hospitals in all areas,

(XIX) for each of fiscal years 2004 through 2006, subject to clause (vii), the market basket percentage increase for hospitals in all areas; and

(XX) for each subsequent fiscal year, subject to clauses (viii), (ix), (xi), and (xii), the market basket percentage increase for hospitals in all areas.

(ii) For purposes of subparagraphs (A) and (E), the "applicable percentage increase" for 12-month cost reporting periods beginning during—

(I) fiscal year 1986, is 0.5 percent,

(II) fiscal year 1987, is 1.15 percent,

(III) fiscal year 1988, is the market basket percentage increase minus 2.0 percentage points,

(IV) a subsequent fiscal year ending on or before September 30, 1993, is the market basket percentage increase,

(V) fiscal years 1994 through 1997, is the market basket percentage increase minus the applicable reduction (as defined in clause (v)(II)), or in the case of a hospital for a fiscal year for which the hospital's update adjustment percentage (as defined in clause (v)(I)) is at least 10 percent, the market basket percentage increase,

(VI) for fiscal year 1998, is 0 percent,

(VII) for fiscal years 1999 through 2002, is the applicable update factor specified under clause (vi) for the fiscal year, and

(VIII) subsequent fiscal years is the market basket percentage increase.

(iii) For purposes of this subparagraph, the term "market basket percentage increase" means, with respect to cost reporting periods and discharges occurring in a fiscal year, the percentage, estimated by the Secretary before the beginning of the period or fiscal year, by which the cost of the mix of goods and services (including personnel costs but excluding nonoperating costs) comprising routine, ancillary, and special care unit inpatient hospital services, based on an index of appropriately weighted indicators of changes in wages and prices which are representative of the mix of goods and services included in such inpatient hospital services, for the period or fiscal year will exceed the cost of such mix of goods and services for the preceding 12-month cost reporting period or fiscal year.

(iv) For purposes of subparagraphs (C) and (D), the "applicable percentage increase" is—

(I) for 12-month cost reporting periods beginning during fiscal years 1986 through 1993, the applicable percentage increase specified in clause (ii),

(II) for fiscal year 1994, the market basket percentage increase minus 2.3 percentage points (adjusted to exclude any portion of a cost reporting period beginning during fiscal year 1993 for which the applicable percentage increase is determined under subparagraph (I)),

(III) for fiscal year 1995, the market basket percentage increase minus 2.2 percentage points, and

(IV) for fiscal year 1996 and each subsequent fiscal year, the applicable percentage increase under clause (i).

(v) For purposes of clause (ii)(V)—

(I) a hospital's "update adjustment percentage" for a fiscal year is the percentage by which the hospital's allowable operating costs of inpatient hospital services recognized under this title for the cost reporting period beginning in fiscal year 1990 exceeds the hospital's target amount (as determined under subparagraph (A)) for such cost reporting period, increased for each fiscal year (beginning with fiscal year 1994) by the sum of any of the hospital's applicable reductions under subclause (V) for previous fiscal years; and

(II) the "applicable reduction" with respect to a hospital for a fiscal year is the lesser of 1 percentage point or the percentage point difference between 10 percent and the hospital's update adjustment percentage for the fiscal year.

(vi) For purposes of clause (ii)(VII) for a fiscal year, if a hospital's allowable operating costs of inpatient hospital services recognized under this title for the most recent cost reporting period for which information is available—

(I) is equal to, or exceeds, 110 percent of the hospital's target amount (as determined under subparagraph (A)) for such cost reporting period, the applicable update factor specified under this clause is the market basket percentage;

(II) exceeds 100 percent, but is less than 110 percent, of such target amount for the hospital, the applicable update factor specified under this clause is 0 percent or, if greater, the market basket percentage minus 0.25 percentage points for each percentage point by which such allowable operating costs (expressed as a percentage of such target amount) is less than 110 percent of such target amount;

(III) is equal to, or less than 100 percent, but exceeds ⅔ of such target amount for the hospital, the applicable update factor specified under this clause is 0 percent or, if greater, the market basket percentage minus 2.5 percentage points; or

(IV) does not exceed ⅔ of such target amount for the hospital, the applicable update factor specified under this clause is 0 percent.

(vii)(I) For purposes of clause (i)(XIX) for fiscal years 2005 and 2006, in a case of a subsection (d) hospital that does not submit data to the Secretary in accordance with subclause (II) with respect to such a fiscal year, the applicable percentage increase under such clause for such fiscal year shall be reduced by 0.4 percentage points. Such reduction shall apply only with respect to the fiscal year involved, and the Secretary shall not take into account such

reduction in computing the applicable percentage increase under clause (i)(XIX) for a subsequent fiscal year.

(II) For fiscal years 2005 and 2006, each subsection (d) hospital shall submit to the Secretary quality data (for a set of 10 indicators established by the Secretary as of November 1, 2003) that relate to the quality of care furnished by the hospital in inpatient settings in a form and manner, and at a time, specified by the Secretary for purposes of this clause, but with respect to fiscal year 2005, the Secretary shall provide for a 30-day grace period for the submission of data by a hospital.

(viii)(I) For purposes of clause (i) for fiscal year 2007 and each subsequent fiscal year, in the case of a subsection (d) hospital that does not submit, to the Secretary in accordance with this clause, data required to be submitted on measures selected under this clause with respect to such a fiscal year, the applicable percentage increase under clause (i) for such fiscal year shall be reduced by 2.0 percentage points (or, beginning with fiscal year 2015, by one-quarter of such applicable percentage increase (determined without regard to clause (ix), (xi), or (xii))). Such reduction shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i) for a subsequent fiscal year, and the Secretary and the Medicare Payment Advisory Commission shall carry out the requirements under section 5001(b) of the Deficit Reduction Act of 2005.

(II) Each subsection (d) hospital shall submit data on measures selected under this clause to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this clause. The Secretary may require hospitals to submit data on measures that are not used for the determination of value-based incentive payments under subsection (o).

(III) The Secretary shall expand, beyond the measures specified under clause (vii)(II) and consistent with the succeeding subclauses, the set of measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in inpatient settings.

(IV) Effective for payments beginning with fiscal year 2007, in expanding the number of measures under subclause (III), the Secretary shall begin to adopt the baseline set of performance measures as set forth in the November 2005 report by the Institute of Medicine of the National Academy of Sciences under section 238(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(V) Effective for payments for fiscal years 2008 through 2012, the Secretary shall add other measures that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

(VI) For purposes of this clause and clause (vii), the Secretary may replace any measures or indicators in appropriate cases, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice.

(VII) The Secretary shall establish procedures for making information regarding measures submitted under this clause available

to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in inpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(VIII) Effective for payments beginning with fiscal year 2013, with respect to quality measures for outcomes of care, the Secretary shall provide for such risk adjustment as the Secretary determines to be appropriate to maintain incentives for hospitals to treat patients with severe illnesses or conditions.

(IX)(aa) Subject to item (bb), effective for payments beginning with fiscal year 2013, each measure specified by the Secretary under this clause shall be endorsed by the entity with a contract under section 1890(a).

(bb) In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(X) To the extent practicable, the Secretary shall, with input from consensus organizations and other stakeholders, take steps to ensure that the measures specified by the Secretary under this clause are coordinated and aligned with quality measures applicable to—

(aa) physicians under section 1848(k); and

(bb) other providers of services and suppliers under this title.

(XI) The Secretary shall establish a process to validate measures specified under this clause as appropriate. Such process shall include the auditing of a number of randomly selected hospitals sufficient to ensure validity of the reporting program under this clause as a whole and shall provide a hospital with an opportunity to appeal the validation of measures reported by such hospital.

(XII)(aa) With respect to a Hospital Consumer Assessment of Healthcare Providers and Systems survey (or a successor survey) conducted on or after January 1, 2020, such survey may not include questions about communication by hospital staff with an individual about such individual's pain unless such questions take into account, as applicable, whether an individual experiencing pain was informed about risks associated with the use of opioids and about non-opioid alternatives for the treatment of pain.

(bb) The Secretary shall not include on the Hospital Compare internet website any measures based on the questions appearing on the Hospital Consumer Assessment of Healthcare Providers and Systems survey in 2018 or 2019 about communication by hospital staff with an individual about such individual's pain.

(ix)(I) For purposes of clause (i) for fiscal year 2015 and each subsequent fiscal year, in the case of an eligible hospital (as defined in subsection (n)(6)(B)) that is not a meaningful EHR user (as defined in subsection (n)(3)) for an EHR reporting period for such fiscal year, three-quarters of the applicable percentage increase otherwise applicable under clause (i) (determined without regard to

clause (viii), (xi), or (xii)) for such fiscal year shall be reduced by 33⅓ percent for fiscal year 2015, 66⅔ percent for fiscal year 2016, and 100 percent for fiscal year 2017 and each subsequent fiscal year. Such reduction shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i) for a subsequent fiscal year.

(II) The Secretary may, on a case-by-case basis (and, with respect to the application of subclause (I) for fiscal year 2017, for categories of subsection (d) hospitals, as established by the Secretary and posted on the Internet website of the Centers for Medicare & Medicaid Services prior to December 15, 2015, an application for which must be submitted to the Secretary by not later than April 1, 2016), exempt an eligible hospital from the application of subclause (I) with respect to a fiscal year if the Secretary determines, subject to annual renewal, that requiring such hospital to be a meaningful EHR user during such fiscal year would result in a significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access. The Secretary shall exempt an eligible hospital from the application of the payment adjustment under subclause (I) with respect to a fiscal year, subject to annual renewal, if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by such hospital is decertified under a program kept or recognized pursuant to section 3001(c)(5) of the Public Health Service Act. In no case may a hospital be granted an exemption under this subclause for more than 5 years.

(III) For fiscal year 2015 and each subsequent fiscal year, a State in which hospitals are paid for services under section 1814(b)(3) shall adjust the payments to each subsection (d) hospital in the State that is not a meaningful EHR user (as defined in subsection (n)(3)) in a manner that is designed to result in an aggregate reduction in payments to hospitals in the State that is equivalent to the aggregate reduction that would have occurred if payments had been reduced to each subsection (d) hospital in the State in a manner comparable to the reduction under the previous provisions of this clause. The State shall report to the Secretary the methodology it will use to make the payment adjustment under the previous sentence.

(IV) For purposes of this clause, the term "EHR reporting period" means, with respect to a fiscal year, any period (or periods) as specified by the Secretary.

(x)(I) The Secretary shall develop standard Internet website reports tailored to meet the needs of various stakeholders such as hospitals, patients, researchers, and policymakers. The Secretary shall seek input from such stakeholders in determining the type of information that is useful and the formats that best facilitate the use of the information.

(II) The Secretary shall modify the Hospital Compare Internet website to make the use and navigation of that website readily available to individuals accessing it.

(xi)(I) For 2012 and each subsequent fiscal year, after determining the applicable percentage increase described in clause (i) and after application of clauses (viii) and (ix), such percentage in-

crease shall be reduced by the productivity adjustment described in subclause (II).

(II) The productivity adjustment described in this subclause, with respect to a percentage, factor, or update for a fiscal year, year, cost reporting period, or other annual period, is a productivity adjustment equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period).

(III) The application of subclause (I) may result in the applicable percentage increase described in clause (i) being less than 0.0 for a fiscal year, and may result in payment rates under this section for a fiscal year being less than such payment rates for the preceding fiscal year.

(xii) After determining the applicable percentage increase described in clause (i), and after application of clauses (viii), (ix), and (xi), the Secretary shall reduce such applicable percentage increase—

(I) for each of fiscal years 2010 and 2011, by 0.25 percentage point;

(II) for each of fiscal years 2012 and 2013, by 0.1 percentage point;

(III) for fiscal year 2014, by 0.3 percentage point;

(IV) for each of fiscal years 2015 and 2016, by 0.2 percentage point; and

(V) for each of fiscal years 2017, 2018, and 2019, by 0.75 percentage point.

The application of this clause may result in the applicable percentage increase described in clause (i) being less than 0.0 for a fiscal year, and may result in payment rates under this section for a fiscal year being less than such payment rates for the preceding fiscal year.

(C) In the case of a hospital that is a sole community hospital (as defined in subsection (d)(5)(D)(iii)), subject to subparagraphs (I) and (L), the term "target amount" means—

(i) with respect to the first 12-month cost reporting period in which this subparagraph is applied to the hospital—

(I) the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this title for the hospital for the 12-month cost reporting period (in this subparagraph referred to as the "base cost reporting period") preceding the first cost reporting period for which this subsection was in effect with respect to such hospital, increased (in a compounded manner) by—

(II) the applicable percentage increases applied to such hospital under this paragraph for cost reporting periods after the base cost reporting period and up to and including such first 12-month cost reporting period,

(ii) with respect to a later cost reporting period beginning before fiscal year 1994, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(iv) for discharges occurring in the fiscal year in which that later cost reporting period begins,

(iii) with respect to discharges occurring in fiscal year 1994, the target amount for the cost reporting period beginning in fiscal year 1993 increased by the applicable percentage increase under subparagraph (B)(iv), or

(iv) with respect to discharges occurring in fiscal year 1995 and each subsequent fiscal year, the target amount for the preceding year increased by the applicable percentage increase under subparagraph (B)(iv).

There shall be substituted for the base cost reporting period described in clause (i) a hospital's cost reporting period (if any) beginning during fiscal year 1987 if such substitution results in an increase in the target amount for the hospital.

(D) For cost reporting periods ending on or before September 30, 1994, and for cost reporting periods occurring on or after October 1, 1997, and before October 1, 2024, in the case of a hospital that is a medicare-dependent, small rural hospital (as defined in subsection (d)(5)(G)), subject to subparagraph (K), the term "target amount" means—

(i) with respect to the first 12-month cost reporting period in which this subparagraph is applied to the hospital—

(I) the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this title for the hospital for the 12-month cost reporting period (in this subparagraph referred to as the "base cost reporting period") preceding the first cost reporting period for which this subsection was in effect with respect to such hospital, increased (in a compounded manner) by—

(II) the applicable percentage increases applied to such hospital under this paragraph for cost reporting periods after the base cost reporting period and up to and including such first 12-month cost reporting period, or

(ii) with respect to a later cost reporting period beginning before fiscal year 1994, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(iv) for discharges occurring in the fiscal year in which that later cost reporting period begins,

(iii) with respect to discharges occurring in fiscal year 1994, the target amount for the cost reporting period beginning in fiscal year 1993 increased by the applicable percentage increase under subparagraph (B)(iv), and

(iv) with respect to discharges occurring during fiscal year 1998 through fiscal year 2024 the target amount for the preceding year increased by the applicable percentage increase under subparagraph (B)(iv).

There shall be substituted for the base cost reporting period described in clause (i) a hospital's cost reporting period (if any) beginning during fiscal year 1987 if such substitution results in an increase in the target amount for the hospital.

(E) In the case of a hospital described in clause (v) of subsection (d)(1)(B), the term "target amount" means—

(i) with respect to the first 12-month cost reporting period in which this subparagraph is applied to the hospital—

(I) the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under

this title for the hospital for the 12-month cost reporting period (in this subparagraph referred to as the "base cost reporting period") preceding the first cost reporting period for which this subsection was in effect with respect to such hospital, increased (in a compounded manner) by—

(II) the sum of the applicable percentage increases applied to such hospital under this paragraph for cost reporting periods after the base cost reporting period and up to and including such first 12-month cost reporting period, or

(ii) with respect to a later cost reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(ii) for that later cost reporting period.

There shall be substituted for the base cost reporting period described in clause (i) a hospital's cost reporting period (if any) beginning during fiscal year 1987 if such substitution results in an increase in the target amount for the hospital.

(F)(i) In the case of a hospital (or unit described in the matter following clause (v) of subsection (d)(1)(B)) that received payment under this subsection for inpatient hospital services furnished during cost reporting periods beginning before October 1, 1990, that is within a class of hospital described in clause (iii), and that elects (in a form and manner determined by the Secretary) this subparagraph to apply to the hospital, the target amount for the hospital's 12-month cost reporting period beginning during fiscal year 1998 is equal to the average described in clause (ii).

(ii) The average described in this clause for a hospital or unit shall be determined by the Secretary as follows:

(I) The Secretary shall determine the allowable operating costs for inpatient hospital services for the hospital or unit for each of the 5 cost reporting periods for which the Secretary has the most recent settled cost reports as of the date of the enactment of this subparagraph.

(II) The Secretary shall increase the amount determined under subclause (I) for each cost reporting period by the applicable percentage increase under subparagraph (B)(ii) for each subsequent cost reporting period up to the cost reporting period described in clause (i).

(III) The Secretary shall identify among such 5 cost reporting periods the cost reporting periods for which the amount determined under subclause (II) is the highest, and the lowest.

(IV) The Secretary shall compute the averages of the amounts determined under subclause (II) for the 3 cost reporting periods not identified under subclause (III).

(iii) For purposes of this subparagraph, each of the following shall be treated as a separate class of hospital:

(I) Hospitals described in clause (i) of subsection (d)(1)(B) and psychiatric units described in the matter following clause (v) of such subsection.

(II) Hospitals described in clause (ii) of such subsection and rehabilitation units described in the matter following clause (v) of such subsection.

(III) Hospitals described in clause (iii) of such subsection.

(IV) Hospitals described in clause (iv) of such subsection.

(V) Hospitals described in clause (v) of such subsection.

(G)(i) In the case of a qualified long-term care hospital (as defined in clause (ii)) that elects (in a form and manner determined by the Secretary) this subparagraph to apply to the hospital, the target amount for the hospital's 12-month cost reporting period beginning during fiscal year 1998 is equal to the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this title for the hospital for the 12-month cost reporting period beginning during fiscal year 1996, increased by the applicable percentage increase for the cost reporting period beginning during fiscal year 1997.

(ii) In clause (i), a "qualified long-term care hospital" means, with respect to a cost reporting period, a hospital described in clause (iv) of subsection (d)(1)(B) during each of the 2 cost reporting periods for which the Secretary has the most recent settled cost reports as of the date of the enactment of this subparagraph for each of which—

(I) the hospital's allowable operating costs of inpatient hospital services recognized under this title exceeded 115 percent of the hospital's target amount, and

(II) the hospital would have a disproportionate patient percentage of at least 70 percent (as determined by the Secretary under subsection (d)(5)(F)(vi)) if the hospital were a subsection (d) hospital.

(H)(i) In the case of a hospital or unit that is within a class of hospital described in clause (iv), for a cost reporting period beginning during fiscal years 1998 through 2002, the target amount for such a hospital or unit may not exceed the amount as updated up to or for such cost reporting period under clause (ii).

(ii)(I) In the case of a hospital or unit that is within a class of hospital described in clause (iv), the Secretary shall estimate the 75th percentile of the target amounts for such hospitals within such class for cost reporting periods ending during fiscal year 1996, as adjusted under clause (iii).

(II) The Secretary shall update the amount determined under subclause (I), for each cost reporting period after the cost reporting period described in such subclause and up to the first cost reporting period beginning on or after October 1, 1997, by a factor equal to the market basket percentage increase.

(III) For cost reporting periods beginning during each of fiscal years 1999 through 2002, subject to subparagraph (J), the Secretary shall update such amount by a factor equal to the market basket percentage increase.

(iii) In applying clause (ii)(I) in the case of a hospital or unit, the Secretary shall provide for an appropriate adjustment to the labor-related portion of the amount determined under such subparagraph to take into account differences between average wage-related costs in the area of the hospital and the national average of such costs within the same class of hospital.

(iv) For purposes of this subparagraph, each of the following shall be treated as a separate class of hospital:

(I) Hospitals described in clause (i) of subsection (d)(1)(B) and psychiatric units described in the matter following clause (v) of such subsection.

(II) Hospitals described in clause (ii) of such subsection and rehabilitation units described in the matter following clause (v) of such subsection.

(III) Hospitals described in clause (iv) of such subsection.

(I)(i) Subject to subparagraph (L), for cost reporting periods beginning on or after October 1, 2000, in the case of a sole community hospital there shall be substituted for the amount otherwise determined under subsection (d)(5)(D)(i), if such substitution results in a greater amount of payment under this section for the hospital—

(I) with respect to discharges occurring in fiscal year 2001, 75 percent of the amount otherwise applicable to the hospital under subsection (d)(5)(D)(i) (referred to in this clause as the "subsection (d)(5)(D)(i) amount") and 25 percent of the rebased target amount (as defined in clause (ii));

(II) with respect to discharges occurring in fiscal year 2002, 50 percent of the subsection (d)(5)(D)(i) amount and 50 percent of the rebased target amount;

(III) with respect to discharges occurring in fiscal year 2003, 25 percent of the subsection (d)(5)(D)(i) amount and 75 percent of the rebased target amount; and

(IV) with respect to discharges occurring after fiscal year 2003, 100 percent of the rebased target amount.

(ii) For purposes of this subparagraph, the "rebased target amount" has the meaning given the term "target amount" in subparagraph (C) except that—

(I) there shall be substituted for the base cost reporting period the 12-month cost reporting period beginning during fiscal year 1996;

(II) any reference in subparagraph (C)(i) to the "first cost reporting period" described in such subparagraph is deemed a reference to the first cost reporting period beginning on or after October 1, 2000; and

(III) applicable increase percentage shall only be applied under subparagraph (C)(iv) for discharges occurring in fiscal years beginning with fiscal year 2002.

(iii) In no case shall a hospital be denied treatment as a sole community hospital or payment (on the basis of a target rate as such as a hospital) because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data for at least one applicable base cost reporting period is available.

(J) For cost reporting periods beginning during fiscal year 2001, for a hospital described in subsection (d)(1)(B)(iv)—

(i) the limiting or cap amount otherwise determined under subparagraph (H) shall be increased by 2 percent; and

(ii) the target amount otherwise determined under subparagraph (A) shall be increased by 25 percent (subject to the limiting or cap amount determined under subparagraph (H), as increased by clause (i)).

(K)(i) With respect to discharges occurring on or after October 1, 2006, in the case of a medicare-dependent, small rural hospital, for purposes of applying subparagraph (D)—

(I) there shall be substituted for the base cost reporting period described in subparagraph (D)(i) the 12-month cost reporting period beginning during fiscal year 2002; and

(II) any reference in such subparagraph to the "first cost reporting period" described in such subparagraph is deemed a reference to the first cost reporting period beginning on or after October 1, 2006.

(ii) This subparagraph shall only apply to a hospital if the substitution described in clause (i)(I) results in an increase in the target amount under subparagraph (D) for the hospital.

(L)(i) For cost reporting periods beginning on or after January 1, 2009, in the case of a sole community hospital there shall be substituted for the amount otherwise determined under subsection (d)(5)(D)(i) of this section, if such substitution results in a greater amount of payment under this section for the hospital, the subparagraph (L) rebased target amount.

(ii) For purposes of this subparagraph, the term "subparagraph (L) rebased target amount" has the meaning given the term "target amount" in subparagraph (C), except that—

(I) there shall be substituted for the base cost reporting period the 12-month cost reporting period beginning during fiscal year 2006;

(II) any reference in subparagraph (C)(i) to the "first cost reporting period" described in such subparagraph is deemed a reference to the first cost reporting period beginning on or after January 1, 2009; and

(III) the applicable percentage increase shall only be applied under subparagraph (C)(iv) for discharges occurring on or after January 1, 2009.

(4)(A)(i) The Secretary shall provide for an exception and adjustment to (and in the case of a hospital described in subsection (d)(1)(B)(iii), may provide an exemption from) the method under this subsection for determining the amount of payment to a hospital where events beyond the hospital's control or extraordinary circumstances, including changes in the case mix of such hospital, create a distortion in the increase in costs for a cost reporting period (including any distortion in the costs for the base period against which such increase is measured). The Secretary may provide for such other exemptions from, and exceptions and adjustments to, such method as the Secretary deems appropriate, including the assignment of a new base period which is more representative, as determined by the Secretary, of the reasonable and necessary cost of inpatient services and including those which he deems necessary to take into account a decrease in the inpatient hospital services that a hospital provides and that are customarily provided directly by similar hospitals which results in a significant distortion in the operating costs of inpatient hospital services. The Secretary shall announce a decision on any request for an exemption, exception, or adjustment under this paragraph not later than 180 days after receiving a completed application from the intermediary for such exemption, exception, or adjustment, and shall include in such decision a detailed explanation of the grounds on which such request was approved or denied.

(ii) The payment reductions under paragraph (3)(B)(ii)(V) shall not be considered by the Secretary in making adjustments pursuant to clause (i). In making such reductions, the Secretary shall treat the applicable update factor described in paragraph (3)(B)(vi)

for a fiscal year as being equal to the market basket percentage for that year.

(B) In determining under subparagraph (A) whether to assign a new base period which is more representative of the reasonable and necessary cost to a hospital of providing inpatient services, the Secretary shall take into consideration—

(i) changes in applicable technologies and medical practices, or differences in the severity of illness among patients, that increase the hospital's costs;

(ii) whether increases in wages and wage-related costs for hospitals located in the geographic area in which the hospital is located exceed the average of the increases in such costs paid by hospitals in the United States; and

(iii) such other factors as the Secretary considers appropriate in determining increases in the hospital's costs of providing inpatient services.

(C) Paragraph (1) shall not apply to payment of hospitals which is otherwise determined under paragraph (3) of section 1814(b).

(5) In the case of any hospital having any cost reporting period of other than a 12-month period, the Secretary shall determine the 12-month period which shall be used for purposes of this section.

(6) In the case of any hospital which becomes subject to the taxes under section 3111 of the Internal Revenue Code of 1954, with respect to any or all of its employees, for part or all of a cost reporting period, and was not subject to such taxes with respect to any or all of its employees for all or part of the 12-month base cost reporting period referred to in subsection (b)(3)(A)(i), the Secretary shall provide for an adjustment by increasing the base period amount described in such subsection for such hospital by an amount equal to the amount of such taxes which would have been paid or accrued by such hospital for such base period if such hospital had been subject to such taxes for all of such base period with respect to all its employees, minus the amount of any such taxes actually paid or accrued for such base period.

(7)(A) Notwithstanding paragraph (1), in the case of a hospital or unit that is within a class of hospital described in subparagraph (B) which first receives payments under this section on or after October 1, 1997—

(i) for each of the first 2 cost reporting periods for which the hospital has a settled cost report, the amount of the payment with respect to operating costs described in paragraph (1) under part A on a per discharge or per admission basis (as the case may be) is equal to the lesser of—

(I) the amount of operating costs for such respective period, or

(II) 110 percent of the national median (as estimated by the Secretary) of the target amount for hospitals in the same class as the hospital for cost reporting periods ending during fiscal year 1996, updated by the hospital market basket increase percentage to the fiscal year in which the hospital first received payments under this section, as adjusted under subparagraph (C); and

(ii) for purposes of computing the target amount for the subsequent cost reporting period, the target amount for the pre-

ceding cost reporting period is equal to the amount determined under clause (i) for such preceding period.

(B) For purposes of this paragraph, each of the following shall be treated as a separate class of hospital:

(i) Hospitals described in clause (i) of subsection (d)(1)(B) and psychiatric units described in the matter following clause (v) of such subsection.

(ii) Hospitals described in clause (ii) of such subsection and rehabilitation units described in the matter following clause (v) of such subsection.

(iii) Hospitals described in clause (iv) of such subsection.

(C) In applying subparagraph (A)(i)(II) in the case of a hospital or unit, the Secretary shall provide for an appropriate adjustment to the labor-related portion of the amount determined under such subparagraph to take into account differences between average wage-related costs in the area of the hospital and the national average of such costs within the same class of hospital.

(c)(1) The Secretary may provide, in his discretion, that payment with respect to services provided by a hospital in a State may be made in accordance with a hospital reimbursement control system in a State, rather than in accordance with the other provisions of this title, if the chief executive officer of the State requests such treatment and if—

(A) the Secretary determines that the system, if approved under this subsection, will apply (i) to substantially all non-Federal acute care hospitals (as defined by the Secretary) in the State and (ii) to the review of at least 75 percent of all revenues or expenses in the State for inpatient hospital services and of revenues or expenses for inpatient hospital services provided under the State's plan approved under title XIX;

(B) the Secretary has been provided satisfactory assurances as to the equitable treatment under the system of all entities (including Federal and State programs) that pay hospitals for inpatient hospital services, of hospital employees, and of hospital patients;

(C) the Secretary has been provided satisfactory assurances that under the system, over 36-month periods (the first such period beginning with the first month in which this subsection applies to that system in the State), the amount of payments made under this title under such system will not exceed the amount of payments which would otherwise have been made under this title not using such system;

(D) the Secretary determines that the system will not preclude an eligible organization (as defined in section 1876(b)) from negotiating directly with hospitals with respect to the organization's rate of payment for inpatient hospital services; and

(E) the Secretary determines that the system requires hospitals to meet the requirement of section 1866(a)(1)(G) and the system provides for the exclusion of certain costs in accordance with section 1862(a)(14) (except for such waivers thereof as the Secretary provides by regulation).

The Secretary cannot deny the application of a State under this subsection on the ground that the State's hospital reimbursement control system is based on a payment methodology other than on

the basis of a diagnosis-related group or on the ground that the amount of payments made under this title under such system must be less than the amount of payments which would otherwise have been made under this title not using such system. If the Secretary determines that the conditions described in subparagraph (C) are based on maintaining payment amounts at no more than a specified percentage increase above the payment amounts in a base period, the State has the option of applying such test (for inpatient hospital services under part A) on an aggregate payment basis or on the basis of the amount of payment per inpatient discharge or admission. If the Secretary determines that the conditions described in subparagraph (C) are based on maintaining aggregate payment amounts below a national average percentage increase in total payments under part A for inpatient hospital services, the Secretary cannot deny the application of a State under this subsection on the ground that the State's rate of increase in such payments for such services must be less than such national average rate of increase.

(2) In determining under paragraph (1)(C) the amount of payment which would otherwise have been made under this title for a State, the Secretary may provide for appropriate adjustment of such amount to take into account previous reductions effected in the amount of payments made under this title in the State due to the operation of the hospital reimbursement control system in the State if the system has resulted in an aggregate rate of increase in operating costs of inpatient hospital services (as defined in subsection (a)(4)) under this title for hospitals in the State which is less than the aggregate rate of increase in such costs under this title for hospitals in the United States.

(3) The Secretary shall discontinue payments under a system described in paragraph (1) if the Secretary—

(A) determines that the system no longer meets the requirements of subparagraphs (A), (D), and (E) of paragraph (1) and, if applicable, the requirements of paragraph (5), or

(B) has reason to believe that the assurances described in subparagraph (B) or (C) of paragraph (1) (or, if applicable, in paragraph (5)) are not being (or will not be) met.

(4) The Secretary shall approve the request of a State under paragraph (1) with respect to a hospital reimbursement control system if—

(A) the requirements of subparagraphs (A), (B), (C), (D), and (E) of paragraph (1) have been met with respect to the system, and

(B) with respect to that system a waiver of certain requirements of title XVIII of the Social Security Act has been approved on or before (and which is in effect as of) the date of the enactment of the Social Security Amendments of 1983, pursuant to section 402(a) of the Social Security Amendments of 1967 or section 222(a) of the Social Security Amendments of 1972.

With respect to a State system described in this paragraph, the Secretary shall judge the effectiveness of such system on the basis of its rate of increase or inflation in inpatient hospital payments for individuals under this title, as compared to the national rate of increase or inflation for such payments, with the State retaining

the option to have the test applied on the basis of the aggregate payments under the State system as compared to aggregate payments which would have been made under the national system since October 1, 1984, to the most recent date for which annual data are available.

(5) The Secretary shall approve the request of a State under paragraph (1) with respect to a hospital reimbursement control system if—

(A) the requirements of subparagraphs (A), (B), (C), (D), and (E) of paragraph (1) have been met with respect to the system;

(B) the Secretary determines that the system—

(i) is operated directly by the State or by an entity designated pursuant to State law,

(ii) provides for payment of hospitals covered under the system under a methodology (which sets forth exceptions and adjustments, as well as any method for changes in the methodology) by which rates or amounts to be paid for hospital services during a specified period are established under the system prior to the defined rate period, and

(iii) hospitals covered under the system will make such reports (in lieu of cost and other reports, identified by the Secretary, otherwise required under this title) as the Secretary may require in order to properly monitor assurances provided under this subsection;

(C) the State has provided the Secretary with satisfactory assurances that operation of the system will not result in any change in hospital admission practices which result in—

(i) a significant reduction in the proportion of patients (receiving hospital services covered under the system) who have no third-party coverage and who are unable to pay for hospital services,

(ii) a significant reduction in the proportion of individuals admitted to hospitals for inpatient hospital services for which payment is (or is likely to be) less than the anticipated charges for or costs of such services,

(iii) the refusal to admit patients who would be expected to require unusually costly or prolonged treatment for reasons other than those related to the appropriateness of the care available at the hospital, or

(iv) the refusal to provide emergency services to any person who is in need of emergency services if the hospital provides such services;

(D) any change by the State in the system which has the effect of materially reducing payments to hospitals can only take effect upon 60 days notice to the Secretary and to the hospitals the payment to which is likely to be materially affected by the change; and

(E) the State has provided the Secretary with satisfactory assurances that in the development of the system the State has consulted with local governmental officials concerning the impact of the system on public hospitals.

The Secretary shall respond to requests of States under this paragraph within 60 days of the date the request is submitted to the Secretary.

(6) If the Secretary determines that the assurances described in paragraph (1)(C) have not been met with respect to any 36-month period, the Secretary may reduce payments under this title to hospitals under the system in an amount equal to the amount by which the payment under this title under such system for such period exceeded the amount of payments which would otherwise have been made under this title not using such system.

(7) In the case of a State which made a request under paragraph (5) before December 31, 1984, for the approval of a State hospital reimbursement control system and which request was approved—

(A) in applying paragraphs (1)(C) and (6), a reference to a "36-month period" is deemed a reference to a "48-month period", and

(B) in order to allow the State the opportunity to provide the assurances described in paragraph (1)(C) for a 48-month period, the Secretary may not discontinue payments under the system, under the authority of paragraph (3)(A) because the Secretary has reason to believe that such assurances are not being (or will not be) met, before July 1, 1986.

(d)(1)(A) Notwithstanding section 1814(b) but subject to the provisions of section 1813, the amount of the payment with respect to the operating costs of inpatient hospital services (as defined in subsection (a)(4)) of a subsection (d) hospital (as defined in subparagraph (B)) for inpatient hospital discharges in a cost reporting period or in a fiscal year—

(i) beginning on or after October 1, 1983, and before October 1, 1984, is equal to the sum of—

(I) the target percentage (as defined in subparagraph (C)) of the hospital's target amount for the cost reporting period (as defined in subsection (b)(3)(A), but determined without the application of subsection (a)), and

(II) the DRG percentage (as defined in subparagraph (C)) of the regional adjusted DRG prospective payment rate determined under paragraph (2) for such discharges;

(ii) beginning on or after October 1, 1984, and before October 1, 1987, is equal to the sum of—

(I) the target percentage (as defined in subparagraph (C)) of the hospital's target amount for the cost reporting period (as defined in subsection (b)(3)(A), but determined without the application of subsection (a)), and

(II) the DRG percentage (as defined in subparagraph (C)) of the applicable combined adjusted DRG prospective payment rate determined under subparagraph (D) for such discharges; or

(iii) beginning on or after April 1, 1988, is equal to

(I) the national adjusted DRG prospective payment rate determined under paragraph (3) for such discharges, or

(II) for discharges occurring during a fiscal year ending on or before September 30, 1996, the sum of 85 percent of the national adjusted DRG prospective payment rate determined under paragraph (3) for such discharges and 15 percent of the regional adjusted DRG prospective payment rate determined under such paragraph, but only if the average standardized amount (described in clause (i)(I) or clause (ii)(I) of paragraph (3)(D)) for hospitals within the

region of, and in the same large urban or other area (or, for discharges occurring during a fiscal year ending on or before September 30, 1994, the same rural, large urban, or other urban area) as, the hospital is greater than the average standardized amount (described in the respective clause) for hospitals within the United States in that type of area for discharges occurring during such fiscal year.

(B) As used in this section, the term "subsection (d) hospital" means a hospital located in one of the fifty States or the District of Columbia other than—

(i) a psychiatric hospital (as defined in section 1861(f)),

(ii) a rehabilitation hospital (as defined by the Secretary),

(iii) a hospital whose inpatients are predominantly individuals under 18 years of age,

(iv) a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days,

(v)(I) a hospital that the Secretary has classified, at any time on or before December 31, 1990, (or, in the case of a hospital that, as of the date of the enactment of this clause, is located in a State operating a demonstration project under section 1814(b), on or before December 31, 1991) for purposes of applying exceptions and adjustments to payment amounts under this subsection, as a hospital involved extensively in treatment for or research on cancer,

(II) a hospital that was recognized as a comprehensive cancer center or clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of April 20, 1983, that is located in a State which, as of December 19, 1989, was not operating a demonstration project under section 1814(b), that applied and was denied, on or before December 31, 1990, for classification as a hospital involved extensively in treatment for or research on cancer under this clause (as in effect on the day before the date of the enactment of this subclause), that as of the date of the enactment of this subclause, is licensed for less than 50 acute care beds, and that demonstrates for the 4–year period ending on December 31, 1996, that at least 50 percent of its total discharges have a principal finding of neoplastic disease, as defined in subparagraph (E), or

(III) a hospital that was recognized as a clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of February 18, 1998, that has never been reimbursed for inpatient hospital services pursuant to a reimbursement system under a demonstration project under section 1814(b), that is a freestanding facility organized primarily for treatment of and research on cancer and is not a unit of another hospital, that as of the date of the enactment of this subclause, is licensed for 162 acute care beds, and that demonstrates for the 4-year period ending on June 30, 1999, that at least 50 percent of its total discharges have a principal finding of neoplastic disease, as defined in subparagraph (E), or

(vi) a hospital that first received payment under this subsection in 1986 which has an average inpatient length of stay (as determined by the Secretary) of greater than 20 days and

that has 80 percent or more of its annual medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in fiscal year 1997;

and, in accordance with regulations of the Secretary, does not include a psychiatric or rehabilitation unit of the hospital which is a distinct part of the hospital (as defined by the Secretary). A hospital that was classified by the Secretary on or before September 30, 1995, as a hospital described in clause (iv) (as in effect as of such date) shall continue to be so classified (or, in the case of a hospital described in clause (iv)(II), as so in effect, shall be classified under clause (vi) on and after the effective date of such clause (vi) and for cost reporting periods beginning on or after January 1, 2015, shall not be subject to subsection (m) as of the date of such classification) notwithstanding that it is located in the same building as, or on the same campus as, another hospital.

(C) For purposes of this subsection, for cost reporting periods beginning—

(i) on or after October 1, 1983, and before October 1, 1984, the "target percentage" is 75 percent and the "DRG percentage" is 25 percent;

(ii) on or after October 1, 1984, and before October 1, 1985, the "target percentage" is 50 percent and the "DRG percentage" is 50 percent;

(iii) on or after October 1, 1985, and before October 1, 1986, the "target percentage" is 45 percent and the "DRG percentage" is 55 percent; and

(iv) on or after October 1, 1986, and before October 1, 1987, the "target percentage" is 25 percent and the "DRG percentage" is 75 percent.

(D) For purposes of subparagraph (A)(ii)(II), the "applicable combined adjusted DRG prospective payment rate" for discharges occurring—

(i) on or after October 1, 1984, and before October 1, 1986, is a combined rate consisting of 25 percent of the national adjusted DRG prospective payment rate, and 75 percent of the regional adjusted DRG prospective payment rate, determined under paragraph (3) for such discharges; and

(ii) on or after October 1, 1986, and before October 1, 1987, is a combined rate consisting of 50 percent of the national adjusted DRG prospective payment rate, and 50 percent of the regional adjusted DRG prospective payment rate, determined under paragraph (3) for such discharges.

(E) For purposes of subclauses (II) and (III) of subparagraph (B)(v) only, the term "principal finding of neoplastic disease" means the condition established after study to be chiefly responsible for occasioning the admission of a patient to a hospital, except that only discharges with ICD–9–CM principal diagnosis codes of 140 through 239, V58.0, V58.1, V66.1, V66.2, or 990 will be considered to reflect such a principal diagnosis.

(2) The Secretary shall determine a national adjusted DRG prospective payment rate, for each inpatient hospital discharge in fiscal year 1984 involving inpatient hospital services of a subsection (d) hospital in the United States, and shall determine a regional adjusted DRG prospective payment rate for such discharges in each

region, for which payment may be made under part A of this title. Each such rate shall be determined for hospitals located in urban or rural areas within the United States or within each such region, respectively, as follows:

(A) DETERMINING ALLOWABLE INDIVIDUAL HOSPITAL COSTS FOR BASE PERIOD.—The Secretary shall determine the allowable operating costs per discharge of inpatient hospital services for the hospital for the most recent cost reporting period for which data are available.

(B) UPDATING FOR FISCAL YEAR 1984.—The Secretary shall update each amount determined under subparagraph (A) for fiscal year 1984 by—

(i) updating for fiscal year 1983 by the estimated average rate of change of hospital costs industry-wide between the cost reporting period used under such subparagraph and fiscal year 1983 and the most recent case-mix data available, and

(ii) projecting for fiscal year 1984 by the applicable percentage increase (as defined in subsection (b)(3)(B)) for fiscal year 1984.

(C) STANDARDIZING AMOUNTS.—The Secretary shall standardize the amount updated under subparagraph (B) for each hospital by—

(i) excluding an estimate of indirect medical education costs (taking into account, for discharges occurring after September 30, 1986, the amendments made by section 9104(a) of the Medicare and Medicaid Budget Reconciliation Amendments of 1985), except that the Secretary shall not take into account any reduction in the amount of additional payments under paragraph (5)(B)(ii) resulting from the amendment made by section 4621(a)(1) of the Balanced Budget Act of 1997 or any additional payments under such paragraph resulting from the application of section 111 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, of section 302 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, or the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,

(ii) adjusting for variations among hospitals by area in the average hospital wage level,

(iii) adjusting for variations in case mix among hospitals, and

(iv) for discharges occurring on or after October 1, 1986, excluding an estimate of the additional payments to certain hospitals to be made under paragraph (5)(F), except that the Secretary shall not exclude additional payments under such paragraph made as a result of the enactment of section 6003(c) of the Omnibus Budget Reconciliation Act of 1989, the enactment of section 4002(b) of the Omnibus Budget Reconciliation Act of 1990, the enactment of section 303 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, or the enactment of section 402(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(D) COMPUTING URBAN AND RURAL AVERAGES.—The Secretary shall compute an average of the standardized amounts determined under subparagraph (C) for the United States and for each region—

(i) for all subsection (d) hospitals located in an urban area within the United States or that region, respectively, and

(ii) for all subsection (d) hospitals located in a rural area within the United States or that region, respectively.

For purposes of this subsection, the term "region" means one of the nine census divisions, comprising the fifty States and the District of Columbia, established by the Bureau of the Census for statistical and reporting purposes; the term "urban area" means an area within a Metropolitan Statistical Area (as defined by the Office of Management and Budget) or within such similar area as the Secretary has recognized under subsection (a) by regulation; the term "large urban area" means, with respect to a fiscal year, such an urban area which the Secretary determines (in the publications described in subsection (e)(5) before the fiscal year) has a population of more than 1,000,000 (as determined by the Secretary based on the most recent available population data published by the Bureau of the Census); and the term "rural area" means any area outside such an area or similar area. A hospital located in a Metropolitan Statistical Area shall be deemed to be located in the region in which the largest number of the hospitals in the same Metropolitan Statistical Area are located, or, at the option of the Secretary, the region in which the majority of the inpatient discharges (with respect to which payments are made under this title) from hospitals in the same Metropolitan Statistical Area are made.

(E) REDUCING FOR VALUE OF OUTLIER PAYMENTS.—The Secretary shall reduce each of the average standardized amounts determined under subparagraph (D) by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this subsection based on DRG prospective payment rates which are additional payments described in paragraph (5)(A) (relating to outlier payments).

(F) MAINTAINING BUDGET NEUTRALITY.—The Secretary shall adjust each of such average standardized amounts as may be required under subsection (e)(1)(B) for that fiscal year.

(G) COMPUTING DRG-SPECIFIC RATES FOR URBAN AND RURAL HOSPITALS IN THE UNITED STATES AND IN EACH REGION.—For each discharge classified within a diagnosis-related group, the Secretary shall establish a national DRG prospective payment rate and shall establish a regional DRG prospective payment rate for each region, each of which is equal—

(i) for hospitals located in an urban area in the United States or that region (respectively), to the product of—

(I) the average standardized amount (computed under subparagraph (D), reduced under subparagraph (E), and adjusted under subparagraph (F)) for hospitals located in an urban area in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group; and

(ii) for hospitals located in a rural area in the United States or that region (respectively), to the product of—

(I) the average standardized amount (computed under subparagraph (D), reduced under subparagraph (E), and adjusted under subparagraph (F)) for hospitals located in a rural area in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(H) ADJUSTING FOR DIFFERENT AREA WAGE LEVELS.—The Secretary shall adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the national and regional DRG prospective payment rates computed under subparagraph (G) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.

(3) The Secretary shall determine a national adjusted DRG prospective payment rate, for each inpatient hospital discharge in a fiscal year after fiscal year 1984 involving inpatient hospital services of a subsection (d) hospital in the United States, and shall determine, for fiscal years before fiscal year 1997, a regional adjusted DRG prospective payment rate for such discharges in each region for which payment may be made under part A of this title. Each such rate shall be determined for hospitals located in large urban, other urban, or rural areas within the United States and within each such region, respectively, as follows:

(A) UPDATING PREVIOUS STANDARDIZED AMOUNTS.—(i) For discharges occurring in a fiscal year beginning before October 1, 1987, the Secretary shall compute an average standardized amount for hospitals located in an urban area and for hospitals located in a rural area within the United States and for hospitals located in an urban area and for hospitals located in a rural area within each region, equal to the respective average standardized amount computed for the previous fiscal year under paragraph (2)(D) or under this subparagraph, increased for the fiscal year involved by the applicable percentage increase under subsection (b)(3)(B). With respect to discharges occurring on or after October 1, 1987, the Secretary shall compute urban and rural averages on the basis of discharge weighting rather than hospital weighting, making appropriate adjustments to ensure that computation on such basis does not result in total payments under this section that are greater or less than the total payments that would have been made under this section but for this sentence, and making appropriate changes in the manner of determining the reductions under subparagraph (C)(ii).

(ii) For discharges occurring in a fiscal year beginning on or after October 1, 1987, and ending on or before September 30, 1994, the Secretary shall compute an average standardized amount for hospitals located in a large urban area, for hospitals located in a rural area, and for hospitals located in other

urban areas, within the United States and within each region, equal to the respective average standardized amount computed for the previous fiscal year under this subparagraph increased by the applicable percentage increase under subsection (b)(3)(B)(i) with respect to hospitals located in the respective areas for the fiscal year involved.

(iii) For discharges occurring in the fiscal year beginning on October 1, 1994, the average standardized amount for hospitals located in a rural area shall be equal to the average standardized amount for hospitals located in an urban area. For discharges occurring on or after October 1, 1994, the Secretary shall adjust the ratio of the labor portion to non-labor portion of each average standardized amount to equal such ratio for the national average of all standardized amounts.

(iv)(I) Subject to subclause (II), for discharges occurring in a fiscal year beginning on or after October 1, 1995, the Secretary shall compute an average standardized amount for hospitals located in a large urban area and for hospitals located in other areas within the United States and within each region equal to the respective average standardized amount computed for the previous fiscal year under this subparagraph increased by the applicable percentage increase under subsection (b)(3)(B)(i) with respect to hospitals located in the respective areas for the fiscal year involved.

(II) For discharges occurring in a fiscal year (beginning with fiscal year 2004), the Secretary shall compute a standardized amount for hospitals located in any area within the United States and within each region equal to the standardized amount computed for the previous fiscal year under this subparagraph for hospitals located in a large urban area (or, beginning with fiscal year 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B)(i) for the fiscal year involved.

(v) Average standardized amounts computed under this paragraph shall be adjusted to reflect the most recent case-mix data available.

(vi) Insofar as the Secretary determines that the adjustments under paragraph (4)(C)(i) for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under this subsection during the fiscal year that are a result of changes in the coding or classification of discharges that do not reflect real changes in case mix, the Secretary may adjust the average standardized amounts computed under this paragraph for subsequent fiscal years so as to eliminate the effect of such coding or classification changes.

(B) REDUCING FOR VALUE OF OUTLIER PAYMENTS.—The Secretary shall reduce each of the average standardized amounts determined under subparagraph (A) by a factor equal to the proportion of payments under this subsection (as estimated by the Secretary) based on DRG prospective payment amounts which are additional payments described in paragraph (5)(A) (relating to outlier payments).

(C)(i) MAINTAINING BUDGET NEUTRALITY FOR FISCAL YEAR 1985.—For discharges occurring in fiscal year 1985, the Sec-

retary shall adjust each of such average standardized amounts as may be required under subsection (e)(1)(B) for that fiscal year.

(ii) REDUCING FOR SAVINGS FROM AMENDMENT TO INDIRECT TEACHING ADJUSTMENT FOR DISCHARGES AFTER SEPTEMBER 30, 1986.—For discharges occurring after September 30, 1986, the Secretary shall further reduce each of the average standardized amounts (in a proportion which takes into account the differing effects of the standardization effected under paragraph (2)(C)(i)) so as to provide for a reduction in the total of the payments (attributable to this paragraph) made for discharges occurring on or after October 1, 1986, of an amount equal to the estimated reduction in the payment amounts under paragraph (5)(B) that would have resulted from the enactment of the amendments made by section 9104 of the Medicare and Medicaid Budget Reconciliation Amendments of 1985 and by section 4003(a)(1) of the Omnibus Budget Reconciliation Act of 1987 if the factor described in clause (ii)(II) of paragraph (5)(B) (determined without regard to amendments made by the Omnibus Budget Reconciliation Act of 1990) were applied for discharges occurring on or after such date instead of the factor described in clause (ii) of that paragraph.

(D) COMPUTING DRG-SPECIFIC RATES FOR HOSPITALS.—For each discharge classified within a diagnosis-related group, the Secretary shall establish for the fiscal year a national DRG prospective payment rate and shall establish, for fiscal years before fiscal year 1997, a regional DRG prospective payment rate for each region which is equal—

(i) for fiscal years before fiscal year 2004, for hospitals located in a large urban area in the United States or that region (respectively), to the product of—

(I) the average standardized amount (computed under subparagraph (A), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C)) for the fiscal year for hospitals located in such a large urban area in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group;

(ii) for fiscal years before fiscal year 2004, for hospitals located in other areas in the United States or that region (respectively), to the product of—

(I) the average standardized amount (computed under subparagraph (A), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C)) for the fiscal year for hospitals located in other areas in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group; and

(iii) for a fiscal year beginning after fiscal year 2003, for hospitals located in all areas, to the product of—

(I) the applicable standardized amount (computed under subparagraph (A)), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C) for the fiscal year; and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(E) ADJUSTING FOR DIFFERENT AREA WAGE LEVELS.—

(i) IN GENERAL.—Except as provided in clause (ii), (iii), or (iv), the Secretary shall adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the DRG prospective payment rates computed under subparagraph (D) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. Not later than October 1, 1990, and October 1, 1993 (and at least every 12 months thereafter), the Secretary shall update the factor under the preceding sentence on the basis of a survey conducted by the Secretary (and updated as appropriate) of the wages and wage-related costs of subsection (d) hospitals in the United States. Not less often than once every 3 years the Secretary (through such survey or otherwise) shall measure the earnings and paid hours of employment by occupational category and shall exclude data with respect to the wages and wage-related costs incurred in furnishing skilled nursing facility services. Any adjustments or updates made under this subparagraph for a fiscal year (beginning with fiscal year 1991) shall be made in a manner that assures that the aggregate payments under this subsection in the fiscal year are not greater or less than those that would have been made in the year without such adjustment. The Secretary shall apply the previous sentence for any period as if the amendments made by section 403(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the amendments made by section 10324(a)(1) of the Patient Protection and Affordable Care Act, and the amendments made by section 9831(a) of the American Rescue Plan Act of 2021 had not been enacted.

(ii) ALTERNATIVE PROPORTION TO BE ADJUSTED BEGINNING IN FISCAL YEAR 2005.—For discharges occurring on or after October 1, 2004, the Secretary shall substitute "62 percent" for the proportion described in the first sentence of clause (i), unless the application of this clause would result in lower payments to a hospital than would otherwise be made.

(iii) FLOOR ON AREA WAGE INDEX FOR HOSPITALS IN FRONTIER STATES.—

(I) IN GENERAL.—Subject to subclause (IV), for discharges occurring on or after October 1, 2010, the area wage index applicable under this subparagraph to any hospital which is located in a frontier State (as defined in subclause (II)) may not be less than 1.00.

(II) FRONTIER STATE DEFINED.—In this clause, the term "frontier State" means a State in which at least 50 percent of the counties in the State are frontier counties.

(III) FRONTIER COUNTY DEFINED.—In this clause, the term "frontier county" means a county in which the population per square mile is less than 6.

(IV) LIMITATION.—This clause shall not apply to any hospital located in a State that receives a non-labor related share adjustment under paragraph (5)(H).

(iv) FLOOR ON AREA WAGE INDEX FOR HOSPITALS IN ALL-URBAN STATES.—

(I) IN GENERAL.—For discharges occurring on or after October 1, 2021, the area wage index applicable under this subparagraph to any hospital in an all-urban State (as defined in subclause (IV)) may not be less than the minimum area wage index for the fiscal year for hospitals in that State, as established under subclause (II).

(II) MINIMUM AREA WAGE INDEX.—For purposes of subclause (I), the Secretary shall establish a minimum area wage index for a fiscal year for hospitals in each all-urban State using the methodology described in section 412.64(h)(4)(vi) of title 42, Code of Federal Regulations, as in effect for fiscal year 2018.

(III) WAIVING BUDGET NEUTRALITY.—Pursuant to the fifth sentence of clause (i), this clause shall not be applied in a budget neutral manner.

(IV) ALL-URBAN STATE DEFINED.—In this clause, the term "all-urban State" means a State in which there are no rural areas (as defined in paragraph (2)(D)) or a State in which there are no hospitals classified as rural under this section.

(4)(A) The Secretary shall establish a classification of inpatient hospital discharges by diagnosis-related groups and a methodology for classifying specific hospital discharges within these groups.

(B) For each such diagnosis-related group the Secretary shall assign an appropriate weighting factor which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups.

(C)(i) The Secretary shall adjust the classifications and weighting factors established under subparagraphs (A) and (B), for discharges in fiscal year 1988 and at least annually thereafter, to reflect changes in treatment patterns, technology (including a new medical service or technology under paragraph (5)(K)), and other factors which may change the relative use of hospital resources.

(ii) For discharges in fiscal year 1990, the Secretary shall reduce the weighting factor for each diagnosis-related group by 1.22 percent.

(iii) Any such adjustment under clause (i) for discharges in a fiscal year (beginning with fiscal year 1991) or payments under paragraph (5)(M) (beginning with fiscal year 2021) shall be made in a manner that assures that the aggregate payments under this subsection for discharges in the fiscal year are not greater or less than those that would have been made for discharges in the year without such adjustment or payments under paragraph (5)(M).

(iv)(I) For discharges occurring during the emergency period described in section 1135(g)(1)(B), in the case of a discharge of an individual diagnosed with COVID–19, the Secretary shall increase

the weighting factor that would otherwise apply to the diagnosis-related group to which the discharge is assigned by 20 percent. The Secretary shall identify a discharge of such an individual through the use of diagnosis codes, condition codes, or other such means as may be necessary.

(II) Any adjustment under subclause (I) shall not be taken into account in applying budget neutrality under clause (iii)

(III) In the case of a State for which the Secretary has waived all or part of this section under the authority of section 1115A, nothing in this section shall preclude such State from implementing an adjustment similar to the adjustment under subclause (I).

(D)(i) For discharges occurring on or after October 1, 2008, the diagnosis-related group to be assigned under this paragraph for a discharge described in clause (ii) shall be a diagnosis-related group that does not result in higher payment based on the presence of a secondary diagnosis code described in clause (iv).

(ii) A discharge described in this clause is a discharge which meets the following requirements:

(I) The discharge includes a condition identified by a diagnosis code selected under clause (iv) as a secondary diagnosis.

(II) But for clause (i), the discharge would have been classified to a diagnosis-related group that results in a higher payment based on the presence of a secondary diagnosis code selected under clause (iv).

(III) At the time of admission, no code selected under clause (iv) was present.

(iii) As part of the information required to be reported by a hospital with respect to a discharge of an individual in order for payment to be made under this subsection, for discharges occurring on or after October 1, 2007, the information shall include the secondary diagnosis of the individual at admission.

(iv) By not later than October 1, 2007, the Secretary shall select diagnosis codes associated with at least two conditions, each of which codes meets all of the following requirements (as determined by the Secretary):

(I) Cases described by such code have a high cost or high volume, or both, under this title.

(II) The code results in the assignment of a case to a diagnosis-related group that has a higher payment when the code is present as a secondary diagnosis.

(III) The code describes such conditions that could reasonably have been prevented through the application of evidence-based guidelines.

The Secretary may from time to time revise (through addition or deletion of codes) the diagnosis codes selected under this clause so long as there are diagnosis codes associated with at least two conditions selected for discharges occurring during any fiscal year.

(v) In selecting and revising diagnosis codes under clause (iv), the Secretary shall consult with the Centers for Disease Control and Prevention and other appropriate entities.

(vi) Any change resulting from the application of this subparagraph shall not be taken into account in adjusting the weighting factors under subparagraph (C)(i) or in applying budget neutrality under subparagraph (C)(iii).

(5)(A)(i) For discharges occurring during fiscal years ending on or before September 30, 1997, the Secretary shall provide for an additional payment for a subsection (d) hospital for any discharge in a diagnosis-related group, the length of stay of which exceeds the mean length of stay for discharges within that group by a fixed number of days, or exceeds such mean length of stay by some fixed number of standard deviations, whichever is the fewer number of days.

(ii) For cases which are not included in clause (i), a subsection (d) hospital may request additional payments in any case where charges, adjusted to cost, exceed a fixed multiple of the applicable DRG prospective payment rate, or exceed such other fixed dollar amount, whichever is greater, or for discharges in fiscal years beginning on or after October 1, 1994, exceed the sum of the applicable DRG prospective payment rate plus any amounts payable under subparagraphs (B) and (F) plus a fixed dollar amount determined by the Secretary.

(iii) The amount of such additional payment under clauses (i) and (ii) shall be determined by the Secretary and shall (except as payments under clause (i) are required to be reduced to take into account the requirements of clause (v)) approximate the marginal cost of care beyond the cutoff point applicable under clause (i) or (ii).

(iv) The total amount of the additional payments made under this subparagraph for discharges in a fiscal year may not be less than 5 percent nor more than 6 percent of the total payments projected or estimated to be made based on DRG prospective payment rates for discharges in that year.

(v) The Secretary shall provide that—

(I) the day outlier percentage for fiscal year 1995 shall be 75 percent of the day outlier percentage for fiscal year 1994;

(II) the day outlier percentage for fiscal year 1996 shall be 50 percent of the day outlier percentage for fiscal year 1994; and

(III) the day outlier percentage for fiscal year 1997 shall be 25 percent of the day outlier percentage for fiscal year 1994.

(vi) For purposes of this subparagraph the term "day outlier percentage" means, for a fiscal year, the percentage of the total additional payments made by the Secretary under this subparagraph for discharges in that fiscal year which are additional payments under clause (i).

(B) The Secretary shall provide for an additional payment amount for subsection (d) hospitals with indirect costs of medical education, in an amount computed in the same manner as the adjustment for such costs under regulations (in effect as of January 1, 1983) under subsection (a)(2), except as follows:

(i) The amount of such additional payment shall be determined by multiplying (I) the sum of the amount determined under paragraph (1)(A)(ii)(II) (or, if applicable, the amount determined under paragraph (1)(A)(iii)) and, for cases qualifying for additional payment under subparagraph (A)(i), the amount paid to the hospital under subparagraph (A), by (II) the indirect teaching adjustment factor described in clause (ii).

(ii) For purposes of clause (i)(II), the indirect teaching adjustment factor is equal to c $\times$ (((1+r) to the nth power) $-$ 1),

where "r" is the ratio of the hospital's full-time equivalent interns and residents to beds and "n" equals .405. Subject to clause (ix), for discharges occurring—

(I) on or after October 1, 1988, and before October 1, 1997, "c" is equal to 1.89;

(II) during fiscal year 1998, "c" is equal to 1.72;

(III) during fiscal year 1999, "c" is equal to 1.6;

(IV) during fiscal year 2000, "c" is equal to 1.47;

(V) during fiscal year 2001, "c" is equal to 1.54;

(VI) during fiscal year 2002, "c" is equal to 1.6;

(VII) on or after October 1, 2002, and before April 1, 2004, "c" is equal to 1.35;

(VIII) on or after April 1, 2004, and before October 1, 2004, "c" is equal to 1.47;

(IX) during fiscal year 2005, "c" is equal to 1.42;

(X) during fiscal year 2006, "c" is equal to 1.37;

(XI) during fiscal year 2007, "c" is equal to 1.32; and

(XII) on or after October 1, 2007, "c" is equal to 1.35.

(iii) In determining such adjustment the Secretary shall not distinguish between those interns and residents who are employees of a hospital and those interns and residents who furnish services to a hospital but are not employees of such hospital.

(iv)(I) Effective for discharges occurring on or after October 1, 1997, and before July 1, 2010, all the time spent by an intern or resident in patient care activities under an approved medical residency training program at an entity in a nonhospital setting shall be counted towards the determination of full-time equivalency if the hospital incurs all, or substantially all, of the costs for the training program in that setting.

(II) Effective for discharges occurring on or after July 1, 2010, all the time spent by an intern or resident in patient care activities in a nonprovider setting shall be counted towards the determination of full-time equivalency if a hospital incurs the costs of the stipends and fringe benefits of the intern or resident during the time the intern or resident spends in that setting. If more than one hospital incurs these costs, either directly or through a third party, such hospitals shall count a proportional share of the time, as determined by written agreement between the hospitals, that a resident spends training in that setting.

(v) In determining the adjustment with respect to a hospital for discharges occurring on or after October 1, 1997, the total number of full-time equivalent interns and residents in the fields of allopathic and osteopathic medicine in either a hospital or nonhospital setting may not exceed the number (or, 130 percent of such number in the case of a hospital located in a rural area) of such full-time equivalent interns and residents in the hospital with respect to the hospital's most recent cost reporting period ending on or before December 31, 1996. Rules similar to the rules of subsection (h)(4)(F)(ii) shall apply for purposes of this clause. The provisions of subsections (h)(4)(H)(vi), (h)(7), (h)(8), (h)(9), and (h)(10) shall apply with respect to the first sentence of this clause in the same manner as they apply with respect to subsection (h)(4)(F)(i).

(vi) For purposes of clause (ii)—

(I) "r" may not exceed the ratio of the number of interns and residents, subject to the limit under clause (v), with respect to the hospital for its most recent cost reporting period to the hospital's available beds (as defined by the Secretary) during that cost reporting period, and

(II) for the hospital's cost reporting periods beginning on or after October 1, 1997, subject to the limits described in clauses (iv) and (v), the total number of full-time equivalent residents for payment purposes shall equal the average of the actual full-time equivalent resident count for the cost reporting period and the preceding two cost reporting periods.

In the case of the first cost reporting period beginning on or after October 1, 1997, subclause (II) shall be applied by using the average for such period and the preceding cost reporting period.

(vii) If any cost reporting period beginning on or after October 1, 1997, is not equal to twelve months, the Secretary shall make appropriate modifications to ensure that the average full-time equivalent residency count pursuant to subclause (II) of clause (vi) is based on the equivalent of full twelve-month cost reporting periods.

(viii) Rules similar to the rules of paragraphs (2)(F)(iv) and (4)(H) of subsection (h) shall apply for purposes of clauses (v) and (vi).

(ix) For discharges occurring on or after July 1, 2005, insofar as an additional payment amount under this subparagraph is attributable to resident positions redistributed to a hospital under subsection (h)(7)(B), in computing the indirect teaching adjustment factor under clause (ii) the adjustment shall be computed in a manner as if "c" were equal to 0.66 with respect to such resident positions.

(x) For discharges occurring on or after July 1, 2011, insofar as an additional payment amount under this subparagraph is attributable to resident positions distributed to a hospital under subsection (h)(8)(B), the indirect teaching adjustment factor shall be computed in the same manner as provided under clause (ii) with respect to such resident positions.

(xi)(I) The provisions of subparagraph (K) of subsection (h)(4) shall apply under this subparagraph in the same manner as they apply under such subsection.

(II) In determining the hospital's number of full-time equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in non-patient care activities, such as didactic conferences and seminars, as such time and activities are defined by the Secretary, that occurs in the hospital shall be counted toward the determination of full-time equivalency if the hospital—

(aa) is recognized as a subsection (d) hospital;

(bb) is recognized as a subsection (d) Puerto Rico hospital;

(cc) is reimbursed under a reimbursement system authorized under section 1814(b)(3); or

(dd) is a provider-based hospital outpatient department.

(III) In determining the hospital's number of full-time equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in research activities that are not associated with the treatment or diagnosis of a particular patient, as such time and activities are defined by the Secretary, shall not be counted toward the determination of full-time equivalency.

(xii) For discharges occurring on or after July 1, 2023, insofar as an additional payment amount under this subparagraph is attributable to resident positions distributed to a hospital under subsection (h)(9), the indirect teaching adjustment factor shall be computed in the same manner as provided under clause (ii) with respect to such resident positions.

(xiii) For discharges occurring on or after July 1, 2026, insofar as an additional payment amount under this subparagraph is attributable to resident positions distributed to a hospital under subsection (h)(10), the indirect teaching adjustment factor shall be computed in the same manner as provided under clause (ii) with respect to such resident positions.

(C)(i) The Secretary shall provide for such exceptions and adjustments to the payment amounts established under this subsection (other than under paragraph (9)) as the Secretary deems appropriate to take into account the special needs of regional and national referral centers (including those hospitals of 275 or more beds located in rural areas). A hospital which is classified as a rural hospital may appeal to the Secretary to be classified as a rural referral center under this clause on the basis of criteria (established by the Secretary) which shall allow the hospital to demonstrate that it should be so reclassified by reason of certain of its operating characteristics being similar to those of a typical urban hospital located in the same census region and which shall not require a rural osteopathic hospital to have more than 3,000 discharges in a year in order to be classified as a rural referral center. Such characteristics may include wages, scope of services, service area, and the mix of medical specialties. The Secretary shall publish the criteria not later than August 17, 1984, for implementation by October 1, 1984. An appeal allowed under this clause must be submitted to the Secretary (in such form and manner as the Secretary may prescribe) during the quarter before the first quarter of the hospital's cost reporting period (or, in the case of a cost reporting period beginning during October 1984, during the first quarter of that period), and the Secretary must make a final determination with respect to such appeal within 60 days after the date the appeal was submitted. Any payment adjustments necessitated by a reclassification based upon the appeal shall be effective at the beginning of such cost reporting period.

(ii) The Secretary shall provide, under clause (i), for the classification of a rural hospital as a regional referral center if the hospital has a case mix index equal to or greater than the median case mix index for hospitals (other than hospitals with approved teaching programs) located in an urban area in the same region (as defined in paragraph (2)(D)), has at least 5,000 discharges a year or, if less, the median number of discharges in urban hospitals in the

region in which the hospital is located (or, in the case of a rural osteopathic hospital, meets the criterion established by the Secretary under clause (i) with respect to the annual number of discharges for such hospitals), and meets any other criteria established by the Secretary under clause (i).

(D)(i) For any cost reporting period beginning on or after April 1, 1990, with respect to a subsection (d) hospital which is a sole community hospital, payment under paragraph (1)(A) shall be—

(I) an amount based on 100 percent of the hospital's target amount for the cost reporting period, as defined in subsection (b)(3)(C), or

(II) the amount determined under paragraph (1)(A)(iii),

whichever results in greater payment to the hospital.

(ii) In the case of a sole community hospital that experiences, in a cost reporting period compared to the previous cost reporting period, a decrease of more than 5 percent in its total number of inpatient cases due to circumstances beyond its control, the Secretary shall provide for such adjustment to the payment amounts under this subsection (other than under paragraph (9)) as may be necessary to fully compensate the hospital for the fixed costs it incurs in the period in providing inpatient hospital services, including the reasonable cost of maintaining necessary core staff and services.

(iii) For purposes of this title, the term "sole community hospital" means any hospital—

(I) that the Secretary determines is located more than 35 road miles from another hospital,

(II) that, by reason of factors such as the time required for an individual to travel to the nearest alternative source of appropriate inpatient care (in accordance with standards promulgated by the Secretary), location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of inpatient hospital services reasonably available to individuals in a geographic area who are entitled to benefits under part A, or

(III) that is located in a rural area and designated by the Secretary as an essential access community hospital under section 1820(i)(1) as in effect on September 30, 1997.

(iv) The Secretary shall promulgate a standard for determining whether a hospital meets the criteria for classification as a sole community hospital under clause (iii)(II) because of the time required for an individual to travel to the nearest alternative source of appropriate inpatient care.

(v) If the Secretary determines that, in the case of a hospital located in a rural area and designated by the Secretary as an essential access community hospital under section 1820(i)(1) as in effect on September 30, 1997, the hospital has incurred increases in reasonable costs during a cost reporting period as a result of becoming a member of a rural health network (as defined in section 1820(d)) in the State in which it is located, and in incurring such increases, the hospital will increase its costs for subsequent cost reporting periods, the Secretary shall increase the hospital's target amount under subsection (b)(3)(C) to account for such incurred increases.

(E)(i) The Secretary shall estimate the amount of reimbursement made for services described in section 1862(a)(14) with respect to which payment was made under part B in the base reporting peri-

ods referred to in paragraph (2)(A) and with respect to which payment is no longer being made.

(ii) The Secretary shall provide for an adjustment to the payment for subsection (d) hospitals in each fiscal year so as appropriately to reflect the net amount described in clause (i).

(F)(i) Subject to subsection (r), for discharges occurring on or after May 1, 1986, the Secretary shall provide, in accordance with this subparagraph, for an additional payment amount for each subsection (d) hospital which—

(I) serves a significantly disproportionate number of low-income patients (as defined in clause (v)), or

(II) is located in an urban area, has 100 or more beds, and can demonstrate that its net inpatient care revenues (excluding any of such revenues attributable to this title or State plans approved under title XIX), during the cost reporting period in which the discharges occur, for indigent care from State and local government sources exceed 30 percent of its total of such net inpatient care revenues during the period.

(ii) Subject to clause (ix), the amount of such payment for each discharge shall be determined by multiplying (I) the sum of the amount determined under paragraph (1)(A)(ii)(II) (or, if applicable, the amount determined under paragraph (1)(A)(iii)) and, for cases qualifying for additional payment under subparagraph (A)(i), the amount paid to the hospital under subparagraph (A) for that discharge, by (II) the disproportionate share adjustment percentage established under clause (iii) or (iv) for the cost reporting period in which the discharge occurs.

(iii) The disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (i)(II) is equal to 35 percent.

(iv) The disproportionate share adjustment percentage for a cost reporting period for a hospital that is not described in clause (i)(II) and that—

(I) is located in an urban area and has 100 or more beds or is described in the second sentence of clause (v), is equal to the percent determined in accordance with the applicable formula described in clause (vii);

(II) is located in an urban area and has less than 100 beds, is equal to 5 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xiii);

(III) is located in a rural area and is not described in subclause (IV) or (V) or in the second sentence of clause (v), is equal to 4 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xii);

(IV) is located in a rural area, is classified as a rural referral center under subparagraph (C), and is classified as a sole community hospital under subparagraph (D), is equal to 10 percent or, if greater, the percent determined in accordance with the applicable formula described in clause (viii) or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, the greater of the percentages determined under clause (x) or (xi);

(V) is located in a rural area, is classified as a rural referral center under subparagraph (C), and is not classified as a sole community hospital under subparagraph (D), is equal to the percent determined in accordance with the applicable formula described in clause (viii) or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xi); or

(VI) is located in a rural area, is classified as a sole community hospital under subparagraph (D), and is not classified as a rural referral center under subparagraph (C), is 10 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (x).

(v) In this subparagraph, a hospital "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals, or exceeds—

(I) 15 percent, if the hospital is located in an urban area and has 100 or more beds,

(II) 30 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and has more than 100 beds, or is located in a rural area and is classified as a sole community hospital under subparagraph (D),

(III) 40 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in an urban area and has less than 100 beds, or

(IV) 45 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and is not described in subclause (II).

A hospital located in a rural area and with 500 or more beds also "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals or exceeds a percentage specified by the Secretary.

(vi) In this subparagraph, the term "disproportionate patient percentage" means, with respect to a cost reporting period of a hospital, the sum of—

(I) the fraction (expressed as a percentage), the numerator of which is the number of such hospital's patient days for such period which were made up of patients who (for such days) were entitled to benefits under part A of this title and were entitled to supplementary security income benefits (excluding any State supplementation) under title XVI of this Act, and the denominator of which is the number of such hospital's patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under part A of this title, and

(II) the fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under title XIX, but who were not entitled to benefits under part A of this title, and the denominator of which is the total number of the hospital's patient days for such period.

In determining under subclause (II) the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under title XIX, the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under title XI.

(vii) The formula used to determine the disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (iv)(I) is—

(I) in the case of such a hospital with a disproportionate patient percentage (as defined in clause (vi)) greater than 20.2—

(a) for discharges occurring on or after April 1, 1990, and on or before December 31, 1990, (P–20.2)(.65) + 5.62,

(b) for discharges occurring on or after January 1, 1991, and on or before September 30, 1993, (P–20.2)(.7) + 5.62,

(c) for discharges occurring on or after October 1, 1993, and on or before September 30, 1994, (P–20.2)(.8) + 5.88, and

(d) for discharges occurring on or after October 1, 1994, (P–20.2)(.825) + 5.88; or

(II) in the case of any other such hospital—

(a) for discharges occurring on or after April 1, 1990, and on or before December 31, 1990, (P–15)(.6) + 2.5,

(b) for discharges occurring on or after January 1, 1991, and on or before September 30, 1993, (P–15)(.6) + 2.5,

(c) for discharges occurring on or after October 1, 1993, (P–15)(.65) + 2.5,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(viii) Subject to clause (xiv), the formula used to determine the disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (iv)(IV) or (iv)(V) is the percentage determined in accordance with the following formula:(P–30)(.6) + 4.0, where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(ix) In the case of discharges occurring—

(I) during fiscal year 1998, the additional payment amount otherwise determined under clause (ii) shall be reduced by 1 percent;

(II) during fiscal year 1999, such additional payment amount shall be reduced by 2 percent;

(III) during fiscal years 2000 and 2001, such additional payment amount shall be reduced by 3 percent and 2 percent, respectively;

(IV) during fiscal year 2002, such additional payment amount shall be reduced by 3 percent; and

(V) during fiscal year 2003 and each subsequent fiscal year, such additional payment amount shall be reduced by 0 percent.

(x) Subject to clause (xiv), for purposes of clause (iv)(VI) (relating to sole community hospitals), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P–15)(.65) + 2.5;

(II) is equal to or exceeds 19.3, but is less than 30.0, such adjustment percentage is equal to 5.25 percent; or

(III) is equal to or exceeds 30, such adjustment percentage is equal to 10 percent,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xi) Subject to clause (xiv), for purposes of clause (iv)(V) (relating to rural referral centers), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P–15)(.65) + 2.5;

(II) is equal to or exceeds 19.3, but is less than 30.0, such adjustment percentage is equal to 5.25 percent; or

(III) is equal to or exceeds 30, such adjustment percentage is determined in accordance with the following formula: (P–30)(.6) + 5.25,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xii) Subject to clause (xiv), for purposes of clause (iv)(III) (relating to small rural hospitals generally), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P–15)(.65) + 2.5; or

(II) is equal to or exceeds 19.3, such adjustment percentage is equal to 5.25 percent,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xiii) Subject to clause (xiv), for purposes of clause (iv)(II) (relating to urban hospitals with less than 100 beds), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P–15)(.65) + 2.5; or

(II) is equal to or exceeds 19.3, such adjustment percentage is equal to 5.25 percent,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xiv)(I) In the case of discharges occurring on or after April 1, 2004, subject to subclause (II), there shall be substituted for the disproportionate share adjustment percentage otherwise determined under clause (iv) (other than subclause (I)) or under clause (viii), (x), (xi), (xii), or (xiii), the disproportionate share adjustment percentage determined under clause (vii) (relating to large, urban hospitals).

(II) Under subclause (I), the disproportionate share adjustment percentage shall not exceed 12 percent for a hospital that is not classified as a rural referral center under subparagraph (C) or, in

the case of discharges occurring on or after October 1, 2006, as a medicare-dependent, small rural hospital under subparagraph (G)(iv).

(G)(i) For any cost reporting period beginning on or after April 1, 1990, and before October 1, 1994, or discharges occurring on or after October 1, 1997, and before October 1, 2024, in the case of a subsection (d) hospital which is a medicare-dependent, small rural hospital, payment under paragraph (1)(A) shall be equal to the sum of the amount determined under clause (ii) and the amount determined under paragraph (1)(A)(iii).

(ii) The amount determined under this clause is—

(I) for discharges occurring during the 36-month period beginning with the first day of the cost reporting period that begins on or after April 1, 1990, the amount by which the hospital's target amount for the cost reporting period (as defined in subsection (b)(3)(D)) exceeds the amount determined under paragraph (1)(A)(iii); and

(II) for discharges occurring during any subsequent cost reporting period (or portion thereof) and before October 1, 1994, or discharges occurring on or after October 1, 1997, and before October 1, 2024, 50 percent (or 75 percent in the case of discharges occurring on or after October 1, 2006) of the amount by which the hospital's target amount for the cost reporting period or for discharges in the fiscal year (as defined in subsection (b)(3)(D)) exceeds the amount determined under paragraph (1)(A)(iii).

(iii) In the case of a medicare dependent, small rural hospital that experiences, in a cost reporting period compared to the previous cost reporting period, a decrease of more than 5 percent in its total number of inpatient cases due to circumstances beyond its control, the Secretary shall provide for such adjustment to the payment amounts under this subsection (other than under paragraph (9)) as may be necessary to fully compensate the hospital for the fixed costs it incurs in the period in providing inpatient hospital services, including the reasonable cost of maintaining necessary core staff and services.

(iv) The term "medicare-dependent, small rural hospital" means, with respect to any cost reporting period to which clause (i) applies, any hospital—

(I) that is located in—

(aa) a rural area; or

(bb) a State with no rural area (as defined in paragraph (2)(D)) and satisfies any of the criteria in subclause (I), (II), or (III) of paragraph (8)(E)(ii),

(II) that has not more than 100 beds,

(III) that is not classified as a sole community hospital under subparagraph (D), and

(IV) for which not less than 60 percent of its inpatient days or discharges during the cost reporting period beginning in fiscal year 1987, or two of the three most recently audited cost reporting periods for which the Secretary has a settled cost report, were attributable to inpatients entitled to benefits under part A.

Subclause (I)(bb) shall apply for purposes of payment under clause (ii) only for discharges of a hospital occurring on or after the effec-

tive date of a determination of medicare-dependent small rural hospital status made by the Secretary with respect to the hospital after the date of the enactment of this sentence. For purposes of applying subclause (II) of paragraph (8)(E)(ii) under subclause (I)(bb), such subclause (II) shall be applied by inserting "as of January 1, 2018," after "such State" each place it appears.

(H) The Secretary may provide for such adjustments to the payment amounts under this subsection as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii.

(I)(i) The Secretary shall provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate.

(ii) In making adjustments under clause (i) for transfer cases (as defined by the Secretary) in a fiscal year, not taking in account the effect of subparagraph (J), the Secretary may make adjustments to each of the average standardized amounts determined under paragraph (3) to assure that the aggregate payments made under this subsection for such fiscal year are not greater or lesser than those that would have otherwise been made in such fiscal year.

(J)(i) The Secretary shall treat the term "transfer case" (as defined in subparagraph (I)(ii)) as including the case of a qualified discharge (as defined in clause (ii)), which is classified within a diagnosis-related group described in clause (iii), and which occurs on or after October 1, 1998. In the case of a qualified discharge for which a substantial portion of the costs of care are incurred in the early days of the inpatient stay (as defined by the Secretary), in no case may the payment amount otherwise provided under this subsection exceed an amount equal to the sum of—

(I) 50 percent of the amount of payment under this subsection for transfer cases (as established under subparagraph (I)(i)), and

(II) 50 percent of the amount of payment which would have been made under this subsection with respect to the qualified discharge if no transfer were involved.

(ii) For purposes of clause (i), subject to clause (iii), the term "qualified discharge" means a discharge classified with a diagnosis-related group (described in clause (iii)) of an individual from a subsection (d) hospital, if upon such discharge the individual—

(I) is admitted as an inpatient to a hospital or hospital unit that is not a subsection (d) hospital for the provision of inpatient hospital services;

(II) is admitted to a skilled nursing facility;

(III) is provided home health services from a home health agency, if such services relate to the condition or diagnosis for which such individual received inpatient hospital services from the subsection (d) hospital, and if such services are provided within an appropriate period (as determined by the Secretary);

(IV) for discharges occurring on or after October 1, 2018, is provided hospice care by a hospice program; or

(V) for discharges occurring on or after October 1, 2000, the individual receives post discharge services described in clause (iv)(I).

(iii) Subject to clause (iv), a diagnosis-related group described in this clause is—

(I) 1 of 10 diagnosis-related groups selected by the Secretary based upon a high volume of discharges classified within such groups and a disproportionate use of post discharge services described in clause (ii); and

(II) a diagnosis-related group specified by the Secretary under clause (iv)(II).

(iv) The Secretary shall include in the proposed rule published under subsection (e)(5)(A) for fiscal year 2001, a description of the effect of this subparagraph. The Secretary shall include in the proposed rule published for fiscal year 2019, a description of the effect of clause (ii)(IV). The Secretary may include in the proposed rule (and in the final rule published under paragraph (6)) for fiscal year 2001 or a subsequent fiscal year, a description of—

(I) post-discharge services not described in subclauses (I), (II), (III), and, in the case of proposed and final rules for fiscal year 2019 and subsequent fiscal years, (IV) of clause (ii), the receipt of which results in a qualified discharge; and

(II) diagnosis-related groups described in clause (iii)(I) in addition to the 10 selected under such clause.

(K)(i) Effective for discharges beginning on or after October 1, 2001, the Secretary shall establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under this subsection. Such mechanism shall be established after notice and opportunity for public comment (in the publications required by subsection (e)(5) for a fiscal year or otherwise). Such mechanism shall be modified to meet the requirements of clause (viii).

(ii) The mechanism established pursuant to clause (i) shall—

(I) apply to a new medical service or technology if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate (applying a threshold specified by the Secretary that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation for the diagnosis-related group involved);

(II) provide for the collection of data with respect to the costs of a new medical service or technology described in subclause (I) for a period of not less than two years and not more than three years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology;

(III) provide for additional payment to be made under this subsection with respect to discharges involving a new medical service or technology described in subclause (I) that occur during the period described in subclause (II) in an amount that adequately reflects the estimated average cost of such service or technology; and

(IV) provide that discharges involving such a service or technology that occur after the close of the period described in subclause (II) will be classified within a new or existing diagnosis-related group with a weighting factor under paragraph (4)(B) that is derived from cost data collected with respect to discharges occurring during such period.

(iii) For purposes of clause (ii)(II), the term "inpatient hospital code" means any code that is used with respect to inpatient hospital services for which payment may be made under this subsection and includes an alphanumeric code issued under the International Classification of Diseases, 9th Revision, Clinical Modification ("ICD–9–CM") and its subsequent revisions.

(iv) For purposes of clause (ii)(III), the term "additional payment" means, with respect to a discharge for a new medical service or technology described in clause (ii)(I), an amount that exceeds the prospective payment rate otherwise applicable under this subsection to discharges involving such service or technology that would be made but for this subparagraph.

(v) The requirement under clause (ii)(III) for an additional payment may be satisfied by means of a new-technology group (described in subparagraph (L)), an add-on payment, a payment adjustment, or any other similar mechanism for increasing the amount otherwise payable with respect to a discharge under this subsection. The Secretary may not establish a separate fee schedule for such additional payment for such services and technologies, by utilizing a methodology established under subsection (a) or (h) of section 1834 to determine the amount of such additional payment, or by other similar mechanisms or methodologies.

(vi) For purposes of this subparagraph and subparagraph (L), a medical service or technology will be considered a "new medical service or technology" if the service or technology meets criteria established by the Secretary after notice and an opportunity for public comment.

(vii) Under the mechanism under this subparagraph, the Secretary shall provide for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) under this subsection until the fiscal year that begins after such date.

(viii) The mechanism established pursuant to clause (i) shall be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of individuals entitled to benefits under part A as follows:

(I) The Secretary shall make public and periodically update a list of all the services and technologies for which an application for additional payment under this subparagraph is pending.

(II) The Secretary shall accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.

(III) The Secretary shall provide for a meeting at which organizations representing hospitals, physicians, such individuals, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of the Centers for Medicare & Medicaid Services before publication of a notice of proposed rulemaking regarding whether service or technology represents a substantial improvement.

(ix) Before establishing any add-on payment under this subparagraph with respect to a new technology, the Secretary shall seek

to identify one or more diagnosis-related groups associated with such technology, based on similar clinical or anatomical characteristics and the cost of the technology. Within such groups the Secretary shall assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. No add-on payment under this subparagraph shall be made with respect to such new technology and this clause shall not affect the application of paragraph (4)(C)(iii).

(L)(i) In establishing the mechanism under subparagraph (K), the Secretary may establish new-technology groups into which a new medical service or technology will be classified if, based on the estimated average costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate.

(ii) Such groups—

(I) shall not be based on the costs associated with a specific new medical service or technology; but

(II) shall, in combination with the applicable standardized amounts and the weighting factors assigned to such groups under paragraph (4)(B), reflect such cost cohorts as the Secretary determines are appropriate for all new medical services and technologies that are likely to be provided as inpatient hospital services in a fiscal year.

(iii) The methodology for classifying specific hospital discharges within a diagnosis-related group under paragraph (4)(A) or a new-technology group shall provide that a specific hospital discharge may not be classified within both a diagnosis-related group and a new-technology group.

(M)(i) For cost reporting periods beginning on or after October 1, 2020, in the case of a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant to an individual during such a period, payment to such hospital for hematopoietic stem cell acquisition shall be made on a reasonable cost basis. The items included in such hematopoietic stem cell acquisition shall be specified by the Secretary through rulemaking.

(ii) For purposes of this subparagraph, the term "allogeneic hematopoietic stem cell transplant" means, with respect to an individual, the intravenous infusion of hematopoietic cells derived from bone marrow, peripheral blood stem cells, or cord blood, but not including embryonic stem cells, of a donor to an individual that are or may be used to restore hematopoietic function in such individual having an inherited or acquired deficiency or defect.

(6) The Secretary shall provide for publication in the Federal Register, on or before the August 1 before each fiscal year (beginning with fiscal year 1984), of a description of the methodology and data used in computing the adjusted DRG prospective payment rates under this subsection, including any adjustments required under subsection (e)(1)(B).

(7) There shall be no administrative or judicial review under section 1878 or otherwise of—

(A) the determination of the requirement, or the proportional amount, of any adjustment effected pursuant to subsection

(e)(1) or the determination of the applicable percentage increase under paragraph (12)(A)(ii),

(B) the establishment of diagnosis-related groups, of the methodology for the classification of discharges within such groups, and of the appropriate weighting factors thereof under paragraph (4), including the selection and revision of codes under paragraph (4)(D), and

(C) the determination of whether services provided prior to a patient's inpatient admission are related to the admission (as described in subsection (a)(4)).

(8)(A) In the case of any hospital which is located in an area which is, at any time after April 20, 1983, reclassified from an urban to a rural area, payments to such hospital for the first two cost reporting periods for which such reclassification is effective shall be made as follows:

(i) For the first such cost reporting period, payment shall be equal to the amount payable to such hospital for such reporting period on the basis of the rural classification, plus an amount equal to two-thirds of the amount (if any) by which—

(I) the amount which would have been payable to such hospital for such reporting period on the basis of an urban classification, exceeds

(II) the amount payable to such hospital for such reporting period on the basis of the rural classification.

(ii) For the second such cost reporting period, payment shall be equal to the amount payable to such hospital for such reporting period on the basis of the rural classification, plus an amount equal to one-third of the amount (if any) by which—

(I) the amount which would have been payable to such hospital for such reporting period on the basis of an urban classification, exceeds

(II) the amount payable to such hospital for such reporting period on the basis of the rural classification.

(B)(i) For purposes of this subsection, the Secretary shall treat a hospital located in a rural county adjacent to one or more urban areas as being located in the urban metropolitan statistical area to which the greatest number of workers in the county commute, if the rural county would otherwise be considered part of an urban area, under the standards for designating Metropolitan Statistical Areas (and for designating New England County Metropolitan Areas) described in clause (ii), if the commuting rates used in determining outlying counties (or, for New England, similar recognized areas) were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of all contiguous Metropolitan Statistical Areas (or New England County Metropolitan Areas).

(ii) The standards described in this clause for cost reporting periods beginning in a fiscal year—

(I) before fiscal year 2003, are the standards published in the Federal Register on January 3, 1980, or, at the election of the hospital with respect to fiscal years 2001 and 2002, standards so published on March 30, 1990; and

(II) after fiscal year 2002, are the standards published in the Federal Register by the Director of the Office of Management

and Budget based on the most recent available decennial population data.

Subparagraphs (C) and (D) shall not apply with respect to the application of subclause (I).

(C)(i) If the application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10), by treating hospitals located in a rural county or counties as being located in an urban area, or by treating hospitals located in one urban area as being located in another urban area—

(I) reduces the wage index for that urban area (as applied under this subsection) by 1 percentage point or less, the Secretary, in calculating such wage index under this subsection, shall exclude those hospitals so treated, or

(II) reduces the wage index for that urban area by more than 1 percentage point (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection separately to hospitals located in such urban area (excluding all the hospitals so treated) and to the hospitals so treated (as if such hospitals were located in such urban area).

(ii) If the application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10), by treating hospitals located in a rural county or counties as not being located in the rural area in a State, reduces the wage index for that rural area (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection as if the hospitals so treated had not been excluded from calculation of the wage index for that rural area.

(iii) The application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10) may not result in the reduction of any county's wage index to a level below the wage index for rural areas in the State in which the county is located.

(iv) The application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or of the Secretary under paragraph (10) may not result in a reduction in an urban area's wage index if—

(I) the urban area has a wage index below the wage index for rural areas in the State in which it is located; or

(II) the urban area is located in a State that is composed of a single urban area.

(v) This subparagraph shall apply with respect to discharges occurring in a fiscal year only if the Secretary uses a method for making adjustments to the DRG prospective payment rate for area differences in hospital wage levels under paragraph (3)(E) for the fiscal year that is based on the use of Metropolitan Statistical Area classifications.

(D) The Secretary shall make a proportional adjustment in the standardized amounts determined under paragraph (3) to assure that the provisions of subparagraphs (B) and (C) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10) do not result in aggregate payments under this section that are greater or less than those that would otherwise be made.

(E)(i) For purposes of this subsection, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital described in clause (ii), the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located.

(ii) For purposes of clause (i), a subsection (d) hospital described in this clause is a subsection (d) hospital that is located in an urban area (as defined in paragraph (2)(D)) and satisfies any of the following criteria:

(I) The hospital is located in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)).

(II) The hospital is located in an area designated by any law or regulation of such State as a rural area (or is designated by such State as a rural hospital).

(III) The hospital would qualify as a rural, regional, or national referral center under paragraph (5)(C) or as a sole community hospital under paragraph (5)(D) if the hospital were located in a rural area.

(IV) The hospital meets such other criteria as the Secretary may specify.

(9)(A) Notwithstanding section 1814(b) but subject to the provisions of section 1813, the amount of the payment with respect to the operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges is equal to the sum of—

(i) the applicable Puerto Rico percentage (specified in subparagraph (E)) of the Puerto Rico adjusted DRG prospective payment rate (determined under subparagraph (B) or (C)) for such discharges,

(ii) the applicable Federal percentage (specified in subparagraph (E)) of—

(I) for discharges beginning in a fiscal year beginning on or after October 1, 1997, and before October 1, 2003, the discharge-weighted average of—

(aa) the national adjusted DRG prospective payment rate (determined under paragraph (3)(D)) for hospitals located in a large urban area,

(bb) such rate for hospitals located in other urban areas, and

(cc) such rate for hospitals located in a rural area, for such discharges, adjusted in the manner provided in paragraph (3)(E) for different area wage levels; and

(II) for discharges in a fiscal year beginning on or after October 1, 2003, the national DRG prospective payment rate determined under paragraph (3)(D)(iii) for hospitals located in any area for such discharges, adjusted in the manner provided in paragraph (3)(E) for different area wage levels.

As used in this section, the term "subsection (d) Puerto Rico hospital" means a hospital that is located in Puerto Rico and that

would be a subsection (d) hospital (as defined in paragraph (1)(B)) if it were located in one of the 50 States.

(B) The Secretary shall determine a Puerto Rico adjusted DRG prospective payment rate, for each inpatient hospital discharge in fiscal year 1988 involving inpatient hospital services of a subsection (d) Puerto Rico hospital for which payment may be made under part A of this title. Such rate shall be determined for such hospitals located in urban or rural areas within Puerto Rico, as follows:

(i) The Secretary shall determine the target amount (as defined in subsection (b)(3)(A)) for the hospital for the cost reporting period beginning in fiscal year 1987 and increase such amount by prorating the applicable percentage increase (as defined in subsection (b)(3)(B)) to update the amount to the midpoint in fiscal year 1988.

(ii) The Secretary shall standardize the amount determined under clause (i) for each hospital by—

(I) excluding an estimate of indirect medical education costs,

(II) adjusting for variations among hospitals by area in the average hospital wage level,

(III) adjusting for variations in case mix among hospitals, and

(IV) excluding an estimate of the additional payments to certain subsection (d) Puerto Rico hospitals to be made under subparagraph (D)(iii) (relating to disproportionate share payments).

(iii) The Secretary shall compute a discharge weighted average of the standardized amounts determined under clause (ii) for all hospitals located in an urban area and for all hospitals located in a rural area (as such terms are defined in paragraph (2)(D)).

(iv) The Secretary shall reduce the average standardized amount by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this paragraph which are additional payments described in subparagraph (D)(i) (relating to outlier payments).

(v) For each discharge classified within a diagnosis-related group for hospitals located in an urban or rural area, respectively, the Secretary shall establish a Puerto Rico DRG prospective payment rate equal to the product of—

(I) the average standardized amount (computed under clause (iii) and reduced under clause (iv)) for hospitals located in an urban or rural area, respectively, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(vi) The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the Puerto Rico DRG prospective payment rate computed under clause (v) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the Puerto Rican average hospital wage level.

(C) The Secretary shall determine a Puerto Rico adjusted DRG prospective payment rate, for each inpatient hospital discharge after fiscal year 1988 involving inpatient hospital services of a subsection (d) Puerto Rico hospital for which payment may be made under part A of this title. Such rate shall be determined for hospitals located in urban or rural areas within Puerto Rico as follows:

(i)(I) For discharges in a fiscal year after fiscal year 1988 and before fiscal year 2004, the Secretary shall compute an average standardized amount for hospitals located in an urban area and for hospitals located in a rural area equal to the respective average standardized amount computed for the previous fiscal year under subparagraph (B)(iii) or under this clause, increased for fiscal year 1989 by the applicable percentage increase under subsection (b)(3)(B), and adjusted for subsequent fiscal years in accordance with the final determination of the Secretary under subsection (e)(4), and adjusted to reflect the most recent case-mix data available.

(II) For discharges occurring in a fiscal year (beginning with fiscal year 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year 2003 for hospitals in a large urban area (or, beginning with fiscal year 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved.

(ii) The Secretary shall reduce each of the average standardized amounts (or for fiscal year 2004 and thereafter, the average standardized amount) by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this paragraph which are additional payments described in subparagraph (D)(i) (relating to outlier payments).

(iii) For each discharge classified within a diagnosis-related group for hospitals located in an urban or rural area, respectively, the Secretary shall establish a Puerto Rico DRG prospective payment rate equal to the product of—

(I) the average standardized amount (computed under clause (i) and reduced under clause (ii)), and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(iv)(I) The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the Puerto Rico DRG prospective payment rate computed under clause (iii) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the Puerto Rico average hospital wage level. The second and third sentences of paragraph (3)(E)(i) shall apply to subsection (d) Puerto Rico hospitals under this clause in the same manner as they apply to subsection (d) hospitals under such paragraph and, for purposes of this clause, any reference in such paragraph to a subsection (d) hospital is deemed a reference to a subsection (d) Puerto Rico hospital.

(II) For discharges occurring on or after October 1, 2004, the Secretary shall substitute "62 percent" for the proportion described in the first sentence of clause (i), unless the application of this subclause would result in lower payments to a hospital than would otherwise be made.

(D) The following provisions of paragraph (5) shall apply to subsection (d) Puerto Rico hospitals receiving payment under this paragraph in the same manner and to the extent as they apply to subsection (d) hospitals receiving payment under this subsection:

(i) Subparagraph (A) (relating to outlier payments).

(ii) Subparagraph (B) (relating to payments for indirect medical education costs), except that for this purpose the sum of the amount determined under subparagraph (A) of this paragraph and the amount paid to the hospital under clause (i) of this subparagraph shall be substituted for the sum referred to in paragraph (5)(B)(i)(I).

(iii) Subparagraph (F) (relating to disproportionate share payments), except that for this purpose the sum described in clause (ii) of this subparagraph shall be substituted for the sum referred to in paragraph (5)(F)(ii)(I).

(iv) Subparagraph (H) (relating to exceptions and adjustments).

(E) For purposes of subparagraph (A), for discharges occurring—

(i) on or after October 1, 1987, and before October 1, 1997, the applicable Puerto Rico percentage is 75 percent and the applicable Federal percentage is 25 percent;

(ii) on or after October 1, 1997, and before April 1, 2004, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent;

(iii) on or after April 1, 2004, and before October 1, 2004, the applicable Puerto Rico percentage is 37.5 percent and the applicable Federal percentage is 62.5 percent;

(iv) on or after October 1, 2004, and before January 1, 2016, the applicable Puerto Rico percentage is 25 percent and the applicable Federal percentage is 75 percent; and

(v) on or after January 1, 2016, the applicable Puerto Rico percentage is 0 percent and the applicable Federal percentage is 100 percent.

(10)(A) There is hereby established the Medicare Geographic Classification Review Board (hereinafter in this paragraph referred to as the "Board").

(B)(i) The Board shall be composed of 5 members appointed by the Secretary without regard to the provisions of title 5, United States Code, governing appointments in the competitive service. Two of such members shall be representative of subsection (d) hospitals located in a rural area under paragraph (2)(D). At least 1 member shall be knowledgeable in the field of analyzing costs with respect to the provision of inpatient hospital services.

(ii) The Secretary shall make initial appointments to the Board as provided in this paragraph within 180 days after the date of the enactment of this paragraph.

(C)(i) The Board shall consider the application of any subsection (d) hospital requesting that the Secretary change the hospital's geographic classification for purposes of determining for a fiscal year—

(I) the hospital's average standardized amount under paragraph (2)(D), or

(II) the factor used to adjust the DRG prospective payment rate for area differences in hospital wage levels that applies to such hospital under paragraph (3)(E).

(ii) A hospital requesting a change in geographic classification under clause (i) for a fiscal year shall submit its application to the Board not later than the first day of the 13-month period ending on September 30 of the preceding fiscal year.

(iii)(I) The Board shall render a decision on an application submitted under clause (i) not later than 180 days after the deadline referred to in clause (ii).

(II) Appeal of decisions of the Board shall be subject to the provisions of section 557b of title 5, United States Code. The Secretary shall issue a decision on such an appeal not later than 90 days after the date on which the appeal is filed. The decision of the Secretary shall be final and shall not be subject to judicial review.

(D)(i) The Secretary shall publish guidelines to be utilized by the Board in rendering decisions on applications submitted under this paragraph, and shall include in such guidelines the following:

(I) Guidelines for comparing wages, taking into account (to the extent the Secretary determines appropriate) occupational mix, in the area in which the hospital is classified and the area in which the hospital is applying to be classified.

(II) Guidelines for determining whether the county in which the hospital is located should be treated as being a part of a particular Metropolitan Statistical Area.

(III) Guidelines for considering information provided by an applicant with respect to the effects of the hospital's geographic classification on access to inpatient hospital services by medicare beneficiaries.

(IV) Guidelines for considering the appropriateness of the criteria used to define New England County Metropolitan Areas.

(ii) Notwithstanding clause (i), if the Secretary uses a method for making adjustments to the DRG prospective payment rate for area differences in hospital wage levels under paragraph (3)(E) that is not based on the use of Metropolitan Statistical Area classifications, the Secretary may revise the guidelines published under clause (i) to the extent such guidelines are used to determine the appropriateness of the geographic area in which the hospital is determined to be located for purposes of making such adjustments.

(iii) Under the guidelines published by the Secretary under clause (i), in the case of a hospital which has ever been classified by the Secretary as a rural referral center under paragraph (5)(C), the Board may not reject the application of the hospital under this paragraph on the basis of any comparison between the average hourly wage of the hospital and the average hourly wage of hospitals in the area in which it is located.

(iv) The Secretary shall publish the guidelines described in clause (i) by July 1, 1990.

(v) Any decision of the Board to reclassify a subsection (d) hospital for purposes of the adjustment factor described in subparagraph (C)(i)(II) for fiscal year 2001 or any fiscal year thereafter shall be effective for a period of 3 fiscal years, except that the Sec-

retary shall establish procedures under which a subsection (d) hospital may elect to terminate such reclassification before the end of such period.

(vi) Such guidelines shall provide that, in making decisions on applications for reclassification for the purposes described in clause (v) for fiscal year 2003 and any succeeding fiscal year, the Board shall base any comparison of the average hourly wage for the hospital with the average hourly wage for hospitals in an area on—

(I) an average of the average hourly wage amount for the hospital from the most recently published hospital wage survey data of the Secretary (as of the date on which the hospital applies for reclassification) and such amount from each of the two immediately preceding surveys; and

(II) an average of the average hourly wage amount for hospitals in such area from the most recently published hospital wage survey data of the Secretary (as of the date on which the hospital applies for reclassification) and such amount from each of the two immediately preceding surveys.

(E)(i) The Board shall have full power and authority to make rules and establish procedures, not inconsistent with the provisions of this title or regulations of the Secretary, which are necessary or appropriate to carry out the provisions of this paragraph. In the course of any hearing the Board may administer oaths and affirmations. The provisions of subsections (d) and (e) of section 205 with respect to subpenas shall apply to the Board to the same extent as such provisions apply to the Secretary with respect to title II.

(ii) The Board is authorized to engage such technical assistance and to receive such information as may be required to carry out its functions, and the Secretary shall, in addition, make available to the Board such secretarial, clerical, and other assistance as the Board may require to carry out its functions.

(F)(i) Each member of the Board who is not an officer or employee of the Federal Government shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for grade GS–18 of the General Schedule under section 5332 of title 5, United States Code, for each day (including travel time) during which such member is engaged in the performance of the duties of the Board. Each member of the Board who is an officer or employee of the United States shall serve without compensation in addition to that received for service as an officer or employee of the United States.

(ii) Members of the Board shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Board.

(11) ADDITIONAL PAYMENTS FOR MANAGED CARE ENROLLEES.—

(A) IN GENERAL.—For portions of cost reporting periods occurring on or after January 1, 1998, the Secretary shall provide for an additional payment amount for each applicable discharge of any subsection (d) hospital that has an approved medical residency training program.

(B) APPLICABLE DISCHARGE.—For purposes of this paragraph, the term "applicable discharge" means the dis-

charge of any individual who is enrolled under a risk-sharing contract with an eligible organization under section 1876 and who is entitled to benefits under part A or any individual who is enrolled with a Medicare+Choice organization under part C.

(C) DETERMINATION OF AMOUNT.—The amount of the payment under this paragraph with respect to any applicable discharge shall be equal to the applicable percentage (as defined in subsection (h)(3)(D)(ii)) of the estimated average per discharge amount that would otherwise have been paid under paragraph (5)(B) if the individuals had not been enrolled as described in subparagraph (B).

(D) SPECIAL RULE FOR HOSPITALS UNDER REIMBURSEMENT SYSTEM.—The Secretary shall establish rules for the application of this paragraph to a hospital reimbursed under a reimbursement system authorized under section 1814(b)(3) in the same manner as it would apply to the hospital if it were not reimbursed under such section.

(12) PAYMENT ADJUSTMENT FOR LOW-VOLUME HOSPITALS.—

(A) IN GENERAL.—In addition to any payments calculated under this section for a subsection (d) hospital, for discharges occurring during a fiscal year (beginning with fiscal year 2005), the Secretary shall provide for an additional payment amount to each low-volume hospital (as defined in subparagraph (C)(i)) for discharges occurring during that fiscal year that is equal to the applicable percentage increase (determined under subparagraph (B) or (D) for the hospital involved) in the amount paid to such hospital under this section for such discharges (determined without regard to this paragraph).

(B) APPLICABLE PERCENTAGE INCREASE.—For discharges occurring in fiscal years 2005 through 2010 and for discharges occurring in fiscal year 2025 and subsequent fiscal years, the Secretary shall determine an applicable percentage increase for purposes of subparagraph (A) as follows:

(i) The Secretary shall determine the empirical relationship for subsection (d) hospitals between the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges.

(ii) The applicable percentage increase shall be determined based upon such relationship in a manner that reflects, based upon the number of such discharges for a subsection (d) hospital, such additional incremental costs.

(iii) In no case shall the applicable percentage increase exceed 25 percent.

(C) DEFINITIONS.—

(i) LOW-VOLUME HOSPITAL.—For purposes of this paragraph, the term "low-volume hospital" means, for a fiscal year, a subsection (d) hospital (as defined in paragraph (1)(B)) that the Secretary determines is located more than 25 road miles (or, with respect to fis-

cal years 2011 through 2024, 15 road miles) from another subsection (d) hospital and has—

(I) with respect to each of fiscal years 2005 through 2010, less than 800 discharges during the fiscal year;

(II) with respect to each of fiscal years 2011 through 2018, less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under part A during the fiscal year or portion of fiscal year;

(III) with respect to each of fiscal years 2019 through 2024, less than 3,800 discharges during the fiscal year; and

(IV) with respect to fiscal year 2025 and each subsequent fiscal year, less than 800 discharges during the fiscal year.

(ii) DISCHARGE.—For purposes of subparagraphs (B) and (D) and clause (i), the term "discharge" means an inpatient acute care discharge of an individual regardless (except as provided in clause (i)(II) and subparagraph (D)(i)) of whether the individual is entitled to benefits under part A.

(iii) TREATMENT OF INDIAN HEALTH SERVICE AND NON-INDIAN HEALTH SERVICE FACILITIES.—For purposes of determining whether—

(I) a subsection (d) hospital of the Indian Health Service (whether operated by such Service or by an Indian tribe or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act)), or

(II) a subsection (d) hospital other than a hospital of the Indian Health Service meets the mileage criterion under clause (i) with respect to fiscal year 2011 or a succeeding fiscal year, the Secretary shall apply the policy described in the regulation at part 412.101(e) of title 42, Code of Federal Regulations (as in effect on the date of enactment of this clause).

(D) TEMPORARY APPLICABLE PERCENTAGE INCREASE.—For discharges occurring in fiscal years 2011 through 2024, the Secretary shall determine an applicable percentage increase for purposes of subparagraph (A) using a continuous linear sliding scale ranging from 25 percent for low-volume hospitals—

(i) with respect to each of fiscal years 2011 through 2018, with 200 or fewer discharges of individuals entitled to, or enrolled for, benefits under part A in the fiscal year or the portion of fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal yearor portion of fiscal year; and

(ii) with respect to each of fiscal years 2019 through 2024, with 500 or fewer discharges in the fiscal year to 0 percent for low-volume hospitals with greater than 3,800 discharges in the fiscal year.

(13)(A) In order to recognize commuting patterns among geographic areas, the Secretary shall establish a process through application or otherwise for an increase of the wage index applied under paragraph (3)(E) for subsection (d) hospitals located in a qualifying county described in subparagraph (B) in the amount computed under subparagraph (D) based on out-migration of hospital employees who reside in that county to any higher wage index area.

(B) The Secretary shall establish criteria for a qualifying county under this subparagraph based on the out-migration referred to in subparagraph (A) and differences in the area wage indices. Under such criteria the Secretary shall, utilizing such data as the Secretary determines to be appropriate, establish—

(i) a threshold percentage, established by the Secretary, of the weighted average of the area wage index or indices for the higher wage index areas involved;

(ii) a threshold (of not less than 10 percent) for minimum out-migration to a higher wage index area or areas; and

(iii) a requirement that the average hourly wage of the hospitals in the qualifying county equals or exceeds the average hourly wage of all the hospitals in the area in which the qualifying county is located.

(C) For purposes of this paragraph, the term "higher wage index area" means, with respect to a county, an area with a wage index that exceeds that of the county.

(D) The increase in the wage index under subparagraph (A) for a qualifying county shall be equal to the percentage of the hospital employees residing in the qualifying county who are employed in any higher wage index area multiplied by the sum of the products, for each higher wage index area of—

(i) the difference between—

(I) the wage index for such higher wage index area, and

(II) the wage index of the qualifying county; and

(ii) the number of hospital employees residing in the qualifying county who are employed in such higher wage index area divided by the total number of hospital employees residing in the qualifying county who are employed in any higher wage index area.

(E) The process under this paragraph may be based upon the process used by the Medicare Geographic Classification Review Board under paragraph (10). As the Secretary determines to be appropriate to carry out such process, the Secretary may require hospitals (including subsection (d) hospitals and other hospitals) and critical access hospitals, as required under section 1866(a)(1)(T), to submit data regarding the location of residence, or the Secretary may use data from other sources.

(F) A wage index increase under this paragraph shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to waive the application of such wage index increase.

(G) A hospital in a county that has a wage index increase under this paragraph for a period and that has not waived the application of such an increase under subparagraph (F) is not eligible for reclassification under paragraph (8) or (10) during that period.

(H) Any increase in a wage index under this paragraph for a county shall not be taken into account for purposes of—

(i) computing the wage index for portions of the wage index area (not including the county) in which the county is located; or

(ii) applying any budget neutrality adjustment with respect to such index under paragraph (8)(D).

(I) The thresholds described in subparagraph (B), data on hospital employees used under this paragraph, and any determination of the Secretary under the process described in subparagraph (E) shall be final and shall not be subject to judicial review.

(e)(1)(A) For cost reporting periods of hospitals beginning in fiscal year 1984 or fiscal year 1985, the Secretary shall provide for such proportional adjustment in the applicable percentage increase (otherwise applicable to the periods under subsection (b)(3)(B)) as may be necessary to assure that—

(i) the aggregate payment amounts otherwise provided under subsection (d)(1)(A)(i)(I) for that fiscal year for operating costs of inpatient hospital services of hospitals (excluding payments made under section 1866(a)(1)(F)),

are not greater or less than—

(ii) the target percentage (as defined in subsection (d)(1)(C)) of the payment amounts which would have been payable for such services for those same hospitals for that fiscal year under this section under the law as in effect before the date of the enactment of the Social Security Amendments of 1983 (excluding payments made under section 1866(a)(1)(F));

except that the adjustment made under this subparagraph shall apply only to subsection (d) hospitals and shall not apply for purposes of making computations under subsection (d)(2)(B)(ii) or subsection (d)(3)(A).

(B) For discharges occurring in fiscal year 1984 or fiscal year 1985, the Secretary shall provide under subsections (d)(2)(F) and (d)(3)(C) for such equal proportional adjustment in each of the average standardized amounts otherwise computed for that fiscal year as may be necessary to assure that—

(i) the aggregate payment amounts otherwise provided under subsection (d)(1)(A)(i)(II) and (d)(5) for that fiscal year for operating costs of inpatient hospital services of hospitals (excluding payments made under section 1866(a)(1)(F)),

are not greater or less than—

(ii) the DRG percentage (as defined in subsection (d)(1)(C)) of the payment amounts which would have been payable for such services for those same hospitals for that fiscal year under this section under the law as in effect before the date of the enactment of the Social Security Amendments of 1983 (excluding payments made under section 1866(a)(1)(F)).

(C) For discharges occurring in fiscal year 1988, the Secretary shall provide for such equal proportional adjustment in each of the average standardized amounts otherwise computed under subsection (d)(3) for that fiscal year as may be necessary to assure that—

(i) the aggregate payment amounts otherwise provided under subsections (d)(1)(A)(iii), (d)(5), and (d)(9) for that fiscal year

for operating costs of inpatient hospital services of subsection (d) hospitals and subsection (d) Puerto Rico hospitals,

are not greater or less than—

(ii) the payment amounts that would have been payable for such services for those same hospitals for that fiscal year but for the enactment of the amendments made by section 9304 of the Omnibus Budget Reconciliation Act of 1986.

(4)(A) Taking into consideration the recommendations of the Commission, the Secretary shall recommend for each fiscal year (beginning with fiscal year 1988) an appropriate change factor for inpatient hospital services for discharges in that fiscal year which will take into account amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. The appropriate change factor may be different for all large urban subsection (d) hospitals, other urban subsection (d) hospitals, urban subsection (d) Puerto Rico hospitals, rural subsection (d) hospitals, and rural subsection (d) Puerto Rico hospitals, and all other hospitals and units not paid under subsection (d), and may vary among such other hospitals and units.

(B) In addition to the recommendation made under subparagraph (A), the Secretary shall, taking into consideration the recommendations of the Commission under paragraph (2)(B), recommend for each fiscal year (beginning with fiscal year 1992) other appropriate changes in each existing reimbursement policy under this title under which payments to an institution are based upon prospectively determined rates.

(5) The Secretary shall cause to have published in the Federal Register, not later than—

(A) the April 1 before each fiscal year (beginning with fiscal year 1986), the Secretary's proposed recommendations under paragraph (4) for that fiscal year for public comment, and

(B) the August 1 before such fiscal year after such consideration of public comment on the proposal as is feasible in the time available, the Secretary's final recommendations under such paragraph for that year.

The Secretary shall include in the publication referred to in subparagraph (A) for a fiscal year the report of the Commission's recommendations submitted under paragraph (3) for that fiscal year. To the extent that the Secretary's recommendations under paragraph (4) differ from the Commission's recommendations for that fiscal year, the Secretary shall include in the publication referred to in subparagraph (A) an explanation of the Secretary's grounds for not following the Commission's recommendations.

(f)(1)(A) The Secretary shall maintain a system for the reporting of costs of hospitals receiving payments computed under subsection (d).

(B)(i) Subject to clause (ii), the Secretary shall place into effect a standardized electronic cost reporting format for hospitals under this title.

(ii) The Secretary may delay or waive the implementation of such format in particular instances where such implementation would result in financial hardship (in particular with respect to hospitals with a small percentage of inpatients entitled to benefits under this title).

(2) If the Secretary determines, based upon information supplied by a quality improvement organization under part B of title XI, that a hospital, in order to circumvent the payment method established under subsection (b) or (d) of this section, has taken an action that results in the admission of individuals entitled to benefits under part A unnecessarily, unnecessary multiple admissions of the same such individuals, or other inappropriate medical or other practices with respect to such individuals, the Secretary may—

(A) deny payment (in whole or in part) under part A with respect to inpatient hospital services provided with respect to such an unnecessary admission (or subsequent admission of the same individual), or

(B) require the hospital to take other corrective action necessary to prevent or correct the inappropriate practice.

(3) The provisions of subsections (c) through (g) of section 1128 shall apply to determinations made under paragraph (2) in the same manner as they apply to exclusions effected under section 1128(b)(13).

(g)(1)(A) Notwithstanding section 1861(v), instead of any amounts that are otherwise payable under this title with respect to the reasonable costs of subsection (d) hospitals and subsection (d) Puerto Rico hospitals for capital-related costs of inpatient hospital services, the Secretary shall, for hospital cost reporting periods beginning on or after October 1, 1991, provide for payments for such costs in accordance with a prospective payment system established by the Secretary. Aggregate payments made under subsection (d) and this subsection during fiscal years 1992 through 1995 shall be reduced in a manner that results in a reduction (as estimated by the Secretary) in the amount of such payments equal to a 10 percent reduction in the amount of payments attributable to capital-related costs that would otherwise have been made during such fiscal year had the amount of such payments been based on reasonable costs (as defined in section 1861(v)). For discharges occurring after September 30, 1993, the Secretary shall reduce by 7.4 percent the unadjusted standard Federal capital payment rate (as described in 42 CFR 412.308(c), as in effect on the date of the enactment of the Omnibus Budget Reconciliation Act of 1993) and shall (for hospital cost reporting periods beginning on or after October 1, 1993) redetermine which payment methodology is applied to the hospital under such system to take into account such reduction. In addition to the reduction described in the preceding sentence, for discharges occurring on or after October 1, 1997, the Secretary shall apply the budget neutrality adjustment factor used to determine the Federal capital payment rate in effect on September 30, 1995 (as described in section 412.352 of title 42 of the Code of Federal Regulations), to (i) the unadjusted standard Federal capital payment rate (as described in section 412.308(c) of that title, as in effect on September 30, 1997), and (ii) the unadjusted hospital-specific rate (as described in section 412.328(e)(1) of that title, as in effect on September 30, 1997), and, for discharges occurring on or after October 1, 1997, and before October 1, 2002, reduce the rates described in clauses (i) and (ii) by 2.1 percent.

(B) Such system—

(i) shall provide for (I) a payment on a per discharge basis, and (II) an appropriate weighting of such payment amount as relates to the classification of the discharge;

(ii) may provide for an adjustment to take into account variations in the relative costs of capital and construction for the different types of facilities or areas in which they are located;

(iii) may provide for such exceptions (including appropriate exceptions to reflect capital obligations) as the Secretary determines to be appropriate, and

(iv) may provide for suitable adjustment to reflect hospital occupancy rate.

(C) In this paragraph, the term "capital-related costs" has the meaning given such term by the Secretary under subsection (a)(4) as of September 30, 1987, and does not include a return on equity capital.

(2)(A) The Secretary shall provide that the amount which is allowable, with respect to reasonable costs of inpatient hospital services for which payment may be made under this title, for a return on equity capital for hospitals shall, for cost reporting periods beginning on or after the date of the enactment of this subsection, be equal to amounts otherwise allowable under regulations in effect on March 1, 1983, except that the rate of return to be recognized shall be equal to the applicable percentage (described in subparagraph (B)) of the average of the rates of interest, for each of the months any part of which is included in the reporting period, on obligations issued for purchase by the Federal Hospital Insurance Trust Fund.

(B) In this paragraph, the "applicable percentage" is—

(i) 75 percent, for cost reporting periods beginning during fiscal year 1987,

(ii) 50 percent, for cost reporting periods beginning during fiscal year 1988,

(iii) 25 percent, for cost reporting periods beginning during fiscal year 1989, and

(iv) 0 percent, for cost reporting periods beginning on or after October 1, 1989.

(3)(A) Except as provided in subparagraph (B), in determining the amount of the payments that may be made under this title with respect to all the capital-related costs of inpatient hospital services of a subsection (d) hospital and a subsection (d) Puerto Rico hospital, the Secretary shall reduce the amounts of such payments otherwise established under this title by—

(i) 3.5 percent for payments attributable to portions of cost reporting periods occurring during fiscal year 1987,

(ii) 7 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during fiscal year 1988 on or after October 1, 1987, and before January 1, 1988,

(iii) 12 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) in fiscal year 1988, occurring on or after January 1, 1988,

(iv) 15 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during fiscal year 1989, and

(v) 15 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during the period beginning January 1, 1990, and ending September 30, 1991.

(B) Subparagraph (A) shall not apply to payments with respect to the capital-related costs of any hospital that is a sole community hospital (as defined in subsection (d)(5)(D)(iii)) or a critical access hospital (as defined in section 1861(mm)(1)).

(4) In determining the amount of the payments that are attributable to portions of cost reporting periods occurring during fiscal years 1998 through 2002 and that may be made under this title with respect to capital-related costs of inpatient hospital services of a hospital which is described in clause (i), (ii), or (iv) of subsection (d)(1)(B) or a unit described in the matter after clause (v) of such subsection, the Secretary shall reduce the amounts of such payments otherwise determined under this title by 15 percent.

(h) PAYMENTS FOR DIRECT GRADUATE MEDICAL EDUCATION COSTS.—

(1) SUBSTITUTION OF SPECIAL PAYMENT RULES.—Notwithstanding section 1861(v), instead of any amounts that are otherwise payable under this title with respect to the reasonable costs of hospitals for direct graduate medical education costs, the Secretary shall provide for payments for such costs in accordance with paragraph (3) of this subsection. In providing for such payments, the Secretary shall provide for an allocation of such payments between part A and part B (and the trust funds established under the respective parts) as reasonably reflects the proportion of direct graduate medical education costs of hospitals associated with the provision of services under each respective part.

(2) DETERMINATION OF HOSPITAL-SPECIFIC APPROVED FTE RESIDENT AMOUNTS.—The Secretary shall determine, for each hospital with an approved medical residency training program, an approved FTE resident amount for each cost reporting period beginning on or after July 1, 1985, as follows:

(A) DETERMINING ALLOWABLE AVERAGE COST PER FTE RESIDENT IN A HOSPITAL'S BASE PERIOD.—The Secretary shall determine, for the hospital's cost reporting period that began during fiscal year 1984, the average amount recognized as reasonable under this title for direct graduate medical education costs of the hospital for each full-time-equivalent resident.

(B) UPDATING TO THE FIRST COST REPORTING PERIOD.—

(i) IN GENERAL.—The Secretary shall update each average amount determined under subparagraph (A) by the percentage increase in the consumer price index during the 12-month cost reporting period described in such subparagraph.

(ii) EXCEPTION.—The Secretary shall not perform an update under clause (i) in the case of a hospital if the hospital's reporting period, described in subparagraph (A), began on or after July 1, 1984, and before October 1, 1984.

(C) AMOUNT FOR FIRST COST REPORTING PERIOD.—For the first cost reporting period of the hospital beginning on or

after July 1, 1985, the approved FTE resident amount for the hospital is equal to the amount determined under subparagraph (B) increased by 1 percent.

(D) AMOUNT FOR SUBSEQUENT COST REPORTING PERIODS.—

(i) IN GENERAL.—Except as provided in a subsequent clause, for each subsequent cost reporting period, the approved FTE resident amount for the hospital is equal to the approved FTE resident amount determined under this paragraph for the previous cost reporting period updated, through the midpoint of the period, by projecting the estimated percentage change in the consumer price index during the 12-month period ending at that midpoint, with appropriate adjustments to reflect previous under-or over-estimations under this subparagraph in the projected percentage change in the consumer price index.

(ii) FREEZE IN UPDATE FOR FISCAL YEARS 1994 AND 1995.—For cost reporting periods beginning during fiscal year 1994 or fiscal year 1995, the approved FTE resident amount for a hospital shall not be updated under clause (i) for a resident who is not a primary care resident (as defined in paragraph (5)(H)) or a resident enrolled in an approved medical residency training program in obstetrics and gynecology.

(iii) FLOOR FOR LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—The approved FTE resident amount for a hospital for the cost reporting period beginning during fiscal year 2001 shall not be less than 70 percent, and for the cost reporting period beginning during fiscal year 2002 shall not be less than 85 percent, of the locality adjusted national average per resident amount computed under subparagraph (E) for the hospital and period.

(iv) ADJUSTMENT IN RATE OF INCREASE FOR HOSPITALS WITH FTE APPROVED AMOUNT ABOVE 140 PERCENT OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—

(I) FREEZE FOR FISCAL YEARS 2001 AND 2002 AND 2004 THROUGH 2013.—For a cost reporting period beginning during fiscal year 2001 or fiscal year 2002 or during the period beginning with fiscal year 2004 and ending with fiscal year 2013, if the approved FTE resident amount for a hospital for the preceding cost reporting period exceeds 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital and period, subject to subclause (III), the approved FTE resident amount for the period involved shall be the same as the approved FTE resident amount for the hospital for such preceding cost reporting period.

(II) 2 PERCENT DECREASE IN UPDATE FOR FISCAL YEARS 2003, 2004, AND 2005.—For the cost reporting period beginning during fiscal year 2003, if the

approved FTE resident amount for a hospital for the preceding cost reporting period exceeds 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital and preceding period, the approved FTE resident amount for the period involved shall be updated in the manner described in subparagraph (D)(i) except that, subject to subclause (III), the consumer price index applied for a 12-month period shall be reduced (but not below zero) by 2 percentage points.

(III) NO ADJUSTMENT BELOW 140 PERCENT.—In no case shall subclause (I) or (II) reduce an approved FTE resident amount for a hospital for a cost reporting period below 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for such hospital and period.

(E) DETERMINATION OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—The Secretary shall determine a locality adjusted national average per resident amount with respect to a cost reporting period of a hospital beginning during a fiscal year as follows:

(i) DETERMINING HOSPITAL SINGLE PER RESIDENT AMOUNT.—The Secretary shall compute for each hospital operating an approved graduate medical education program a single per resident amount equal to the average (weighted by number of full-time equivalent residents, as determined under paragraph (4)) of the primary care per resident amount and the non-primary care per resident amount computed under paragraph (2) for cost reporting periods ending during fiscal year 1997.

(ii) STANDARDIZING PER RESIDENT AMOUNTS.—The Secretary shall compute a standardized per resident amount for each such hospital by dividing the single per resident amount computed under clause (i) by an average of the 3 geographic index values (weighted by the national average weight for each of the work, practice expense, and malpractice components) as applied under section 1848(e) for 1999 for the fee schedule area in which the hospital is located.

(iii) COMPUTING OF WEIGHTED AVERAGE.—The Secretary shall compute the average of the standardized per resident amounts computed under clause (ii) for such hospitals, with the amount for each hospital weighted by the average number of full-time equivalent residents at such hospital (as determined under paragraph (4)).

(iv) COMPUTING NATIONAL AVERAGE PER RESIDENT AMOUNT.—The Secretary shall compute the national average per resident amount, for a hospital's cost reporting period that begins during fiscal year 2001, equal to the weighted average computed under clause (iii) increased by the estimated percentage increase in

the consumer price index for all urban consumers during the period beginning with the month that represents the midpoint of the cost reporting periods described in clause (i) and ending with the midpoint of the hospital's cost reporting period that begins during fiscal year 2001.

(v) ADJUSTING FOR LOCALITY.—The Secretary shall compute the product of—

(I) the national average per resident amount computed under clause (iv) for the hospital, and

(II) the geographic index value average (described and applied under clause (ii)) for the fee schedule area in which the hospital is located.

(vi) COMPUTING LOCALITY ADJUSTED AMOUNT.—The locality adjusted national per resident amount for a hospital for—

(I) the cost reporting period beginning during fiscal year 2001 is the product computed under clause (v); or

(II) each subsequent cost reporting period is equal to the locality adjusted national per resident amount for the hospital for the previous cost reporting period (as determined under this clause) updated, through the midpoint of the period, by projecting the estimated percentage change in the consumer price index for all urban consumers during the 12-month period ending at that midpoint.

(F) TREATMENT OF CERTAIN HOSPITALS.—(i) In the case of a hospital that did not have an approved medical residency training program or was not participating in the program under this title for a cost reporting period beginning during fiscal year 1984, the Secretary shall, for the first such period for which it has such a residency training program and is participating under this title, provide for such approved FTE resident amount as the Secretary determines to be appropriate, based on approved FTE resident amounts for comparable programs.

(ii) In applying this subparagraph in the case of a hospital that trains residents and has not entered into a GME affiliation agreement (as defined by the Secretary for purposes of paragraph (4)(H)(ii)), on or after the date of the enactment of this clause, the Secretary shall not establish an FTE resident amount until such time as the Secretary determines that the hospital has trained at least 1.0 full-time-equivalent resident in an approved medical residency training program in a cost reporting period.

(iii) In applying this subparagraph for cost reporting periods beginning on or after the date of enactment of this clause, in the case of a hospital that, as of such date of enactment, has an approved FTE resident amount based on the training in an approved medical residency program or programs of—

(I) less than 1.0 full-time-equivalent resident in any cost reporting period beginning before October 1, 1997, as determined by the Secretary; or

(II) no more than 3.0 full-time-equivalent residents in any cost reporting period beginning on or after October 1, 1997, and before the date of the enactment of this clause, as determined by the Secretary,

in lieu of such FTE resident amount the Secretary shall, in accordance with the methodology described in section 413.77(e) of title 42 of the Code of Federal Regulations (or any successor regulation), establish a new FTE resident amount if the hospital trains at least 1.0 full-time-equivalent resident (in the case of a hospital described in subclause (I)) or more than 3.0 full-time-equivalent residents (in the case of a hospital described in subclause (II)) in a cost reporting period beginning on or after such date of enactment and before the date that is 5 years after such date of enactment.

(iv) For purposes of carrying out this subparagraph for cost reporting periods beginning on or after the date of the enactment of this clause, a hospital shall report full-time-equivalent residents on its cost report for a cost reporting period if the hospital trains at least 1.0 full-time-equivalent residents in an approved medical residency training program or programs in such period.

(v) As appropriate, the Secretary may consider information from any cost reporting period necessary to establish a new FTE resident amount as described in clause (iii).

(3) HOSPITAL PAYMENT AMOUNT PER RESIDENT.—

(A) IN GENERAL.—The payment amount, for a hospital cost reporting period beginning on or after July 1, 1985, is equal to the product of—

(i) the aggregate approved amount (as defined in subparagraph (B)) for that period, and

(ii) the hospital's medicare patient load (as defined in subparagraph (C)) for that period.

(B) AGGREGATE APPROVED AMOUNT.—As used in subparagraph (A), the term "aggregate approved amount" means, for a hospital cost reporting period, the product of—

(i) the hospital's approved FTE resident amount (determined under paragraph (2)) for that period, and

(ii) the weighted average number of full-time-equivalent residents (as determined under paragraph (4)) in the hospital's approved medical residency training programs in that period.

The Secretary shall reduce the aggregate approved amount to the extent payment is made under subsection (k) for residents included in the hospital's count of full-time equivalent residents.

(C) MEDICARE PATIENT LOAD.—As used in subparagraph (A), the term "medicare patient load" means, with respect to a hospital's cost reporting period, the fraction of the total number of inpatient-bed-days (as established by the Secretary) during the period which are attributable to patients with respect to whom payment may be made under part A.

(D) PAYMENT FOR MANAGED CARE ENROLLEES.—

(i) IN GENERAL.—For portions of cost reporting periods occurring on or after January 1, 1998, the Secretary shall provide for an additional payment amount under this subsection for services furnished to individuals who are enrolled under a risk-sharing contract with an eligible organization under section 1876 and who are entitled to part A or with a Medicare+Choice organization under part C. The amount of such a payment shall equal, subject to clause (iii), the applicable percentage of the product of—

(I) the aggregate approved amount (as defined in subparagraph (B)) for that period; and

(II) the fraction of the total number of inpatient-bed days (as established by the Secretary) during the period which are attributable to such enrolled individuals.

(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the applicable percentage is—

(I) 20 percent in 1998,

(II) 40 percent in 1999,

(III) 60 percent in 2000,

(IV) 80 percent in 2001, and

(V) 100 percent in 2002 and subsequent years.

(iii) PROPORTIONAL REDUCTION FOR NURSING AND ALLIED HEALTH EDUCATION.—The Secretary shall estimate a proportional adjustment in payments to all hospitals determined under clauses (i) and (ii) for portions of cost reporting periods beginning in a year (beginning with 2000) such that the proportional adjustment reduces payments in an amount for such year equal to the total additional payment amounts for nursing and allied health education determined under subsection (l) for portions of cost reporting periods occurring in that year. In applying the preceding sentence for each of 2010 through 2019, the Secretary shall not take into account any increase in the total amount of such additional payment amounts for such nursing and allied health education for portions of cost reporting periods occurring in the year pursuant to the application of paragraph (2)(B)(ii) of such subsection.

(iv) SPECIAL RULE FOR HOSPITALS UNDER REIMBURSEMENT SYSTEM.—The Secretary shall establish rules for the application of this subparagraph to a hospital reimbursed under a reimbursement system authorized under section 1814(b)(3) in the same manner as it would apply to the hospital if it were not reimbursed under such section.

(4) DETERMINATION OF FULL-TIME-EQUIVALENT RESIDENTS.—

(A) RULES.—The Secretary shall establish rules consistent with this paragraph for the computation of the number of full-time- equivalent residents in an approved medical residency training program.

(B) ADJUSTMENT FOR PART-YEAR OR PART-TIME RESIDENTS.—Such rules shall take into account individuals

who serve as residents for only a portion of a period with a hospital or simultaneously with more than one hospital.

(C) WEIGHTING FACTORS FOR CERTAIN RESIDENTS.—Subject to subparagraph (D), such rules shall provide, in calculating the number of full-time-equivalent residents in an approved residency program—

(i) before July 1, 1986, for each resident the weighting factor is 1.00,

(ii) on or after July 1, 1986, for a resident who is in the resident's initial residency period (as defined in paragraph (5)(F)), the weighting factor is 1.00,

(iii) on or after July 1, 1986, and before July 1, 1987, for a resident who is not in the resident's initial residency period (as defined in paragraph (5)(F)), the weighting factor is .75, and

(iv) on or after July 1, 1987, for a resident who is not in the resident's initial residency period (as defined in paragraph (5)(F)), the weighting factor is .50.

(D) FOREIGN MEDICAL GRADUATES REQUIRED TO PASS FMGEMS EXAMINATION.—

(i) IN GENERAL.—Except as provided in clause (ii), such rules shall provide that, in the case of an individual who is a foreign medical graduate (as defined in paragraph (5)(D)), the individual shall not be counted as a resident on or after July 1, 1986, unless—

(I) the individual has passed the FMGEMS examination (as defined in paragraph (5)(E)), or

(II) the individual has previously received certification from, or has previously passed the examination of, the Educational Commission for Foreign Medical Graduates.

(ii) TRANSITION FOR CURRENT FMGS.—On or after July 1, 1986, but before July 1, 1987, in the case of a foreign medical graduate who—

(I) has served as a resident before July 1, 1986, and is serving as a resident after that date, but

(II) has not passed the FMGEMS examination or a previous examination of the Educational Commission for Foreign Medical Graduates before July 1, 1986,

the individual shall be counted as a resident at a rate equal to one-half of the rate at which the individual would otherwise be counted.

(E) COUNTING TIME SPENT IN OUTPATIENT SETTINGS.—Subject to subparagraphs (J) and (K), such rules shall provide that only time spent in activities relating to patient care shall be counted and that—

(i) effective for cost reporting periods beginning before July 1, 2010, all the time;

(ii) effective for cost reporting periods beginning on or after July 1, 2010, all the time so spent by a resident shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if a hospital incurs the costs of the stipends and fringe benefits of the

resident during the time the resident spends in that setting. If more than one hospital incurs these costs, either directly or through a third party, such hospitals shall count a proportional share of the time, as determined by written agreement between the hospitals, that a resident spends training in that setting.

so spent by a resident under an approved medical residency training program shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs all, or substantially all, of the costs for the training program in that setting.

Any hospital claiming under this subparagraph for time spent in a nonprovider setting shall maintain and make available to the Secretary records regarding the amount of such time and such amount in comparison with amounts of such time in such base year as the Secretary shall specify.

(F) LIMITATION ON NUMBER OF RESIDENTS IN ALLOPATHIC AND OSTEOPATHIC MEDICINE.—

(i) IN GENERAL.—Such rules shall provide that for purposes of a cost reporting period beginning on or after October 1, 1997, subject to paragraphs (7), (8), (9), and (10), the total number of full-time equivalent residents before application of weighting factors (as determined under this paragraph) with respect to a hospital's approved medical residency training program in the fields of allopathic medicine and osteopathic medicine may not exceed the number (or, 130 percent of such number in the case of a hospital located in a rural area) of such full-time equivalent residents for the hospital's most recent cost reporting period ending on or before December 31, 1996.

(ii) COUNTING PRIMARY CARE RESIDENTS ON CERTAIN APPROVED LEAVES OF ABSENCE IN BASE YEAR FTE COUNT.—

(I) IN GENERAL.—In determining the number of such full-time equivalent residents for a hospital's most recent cost reporting period ending on or before December 31, 1996, for purposes of clause (i), the Secretary shall count an individual to the extent that the individual would have been counted as a primary care resident for such period but for the fact that the individual, as determined by the Secretary, was on maternity or disability leave or a similar approved leave of absence.

(II) LIMITATION TO 3 FTE RESIDENTS FOR ANY HOSPITAL.—The total number of individuals counted under subclause (I) for a hospital may not exceed 3 full-time equivalent residents.

(G) COUNTING INTERNS AND RESIDENTS FOR FY 1998 AND SUBSEQUENT YEARS.—

(i) IN GENERAL.—For cost reporting periods beginning during fiscal years beginning on or after October 1, 1997, subject to the limit described in subparagraph

(F), the total number of full-time equivalent residents for determining a hospital's graduate medical education payment shall equal the average of the actual full-time equivalent resident counts for the cost reporting period and the preceding two cost reporting periods.

(ii) ADJUSTMENT FOR SHORT PERIODS.—If any cost reporting period beginning on or after October 1, 1997, is not equal to twelve months, the Secretary shall make appropriate modifications to ensure that the average full-time equivalent resident counts pursuant to clause (i) are based on the equivalent of full twelve-month cost reporting periods.

(iii) TRANSITION RULE FOR 1998.—In the case of a hospital's first cost reporting period beginning on or after October 1, 1997, clause (i) shall be applied by using the average for such period and the preceding cost reporting period.

(H) SPECIAL RULES FOR APPLICATION OF SUBPARAGRAPHS (F) AND (G).—

(i) NEW FACILITIES.—(I) The Secretary shall, consistent with the principles of subparagraphs (F) and (G) and subject to paragraphs (7), (8), (9), and (10), prescribe rules for the application of such subparagraphs in the case of medical residency training programs established on or after January 1, 1995. In promulgating such rules for purposes of subparagraph (F), the Secretary shall give special consideration to facilities that meet the needs of underserved rural areas.

(II) In applying this clause in the case of a hospital that, on or after the date of the enactment of this subclause, begins training residents in a new approved medical residency training program or programs (as defined by the Secretary), the Secretary shall not determine a limitation applicable to the hospital under subparagraph (F) until such time as the Secretary determines that the hospital has trained at least 1.0 full-time-equivalent resident in such new approved medical residency training program or programs in a cost reporting period.

(III) In applying this clause in the case of a hospital that, as of the date of the enactment of this subclause, has a limitation under subparagraph (F), based on a cost reporting period beginning before October 1, 1997, of less than 1.0 full-time-equivalent resident, the Secretary shall adjust the limitation in the manner applicable to a new approved medical residency training program if the Secretary determines the hospital begins training at least 1.0 full-time-equivalent residents in a program year beginning on or after such date of enactment and before the date that is 5 years after such date of enactment.

(IV) In applying this clause in the case of a hospital that, as of the date of the enactment of this subclause,

has a limitation under subparagraph (F), based on a cost reporting period beginning on or after October 1, 1997, and before such date of enactment, of no more than 3.0 full-time-equivalent residents, the Secretary shall adjust the limitation in the manner applicable to a new approved medical residency training program if the Secretary determines the hospital begins training more than 3.0 full-time-equivalent residents in a program year beginning on or after such date of enactment and before the date that is 5 years after such date of enactment.

(V) An adjustment to the limitation applicable to a hospital made pursuant to subclause (III) or (IV) shall be made in a manner consistent with the methodology, as appropriate, in section 413.79(e) of title 42, Code of Federal Regulations (or any successor regulation). As appropriate, the Secretary may consider information from any cost reporting periods necessary to make such an adjustment to the limitation.

(ii) AGGREGATION.—The Secretary may prescribe rules which allow institutions which are members of the same affiliated group (as defined by the Secretary) to elect to apply the limitation of subparagraph (F) on an aggregate basis.

(iii) DATA COLLECTION.—The Secretary may require any entity that operates a medical residency training program and to which subparagraphs (F) and (G) apply to submit to the Secretary such additional information as the Secretary considers necessary to carry out such subparagraphs.

(iv) TRAINING PROGRAMS IN RURAL AREAS.—

(I) COST REPORTING PERIODS BEGINNING BEFORE OCTOBER 1, 2022.—For cost reporting periods beginning before October 1, 2022, in the case of a hospital that is not located in a rural area but establishes separately accredited approved medical residency training programs (or rural tracks) in a rural area or has an accredited training program with an integrated rural track, the Secretary shall adjust the limitation under subparagraph (F) in an appropriate manner insofar as it applies to such programs in such rural areas in order to encourage the training of physicians in rural areas.

(II) COST REPORTING PERIODS BEGINNING ON OR AFTER OCTOBER 1, 2022.—For cost reporting periods beginning on or after October 1, 2022, in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area or establishes an accredited program where greater than 50 percent of the program occurs in a rural area, the Secretary shall consistent with the principles of subparagraphs (F) and (G) and subject to paragraphs (7) and (8), prescribe rules for the application of such subparagraphs with respect to

such a program and, in accordance with such rules, adjust in an appropriate manner the limitation under subparagraph (F) for such hospital and each such hospital located in a rural area that participates in such a training.

(v) SPECIAL PROVIDER AGREEMENT.—If an entity enters into a provider agreement pursuant to section 1866(a) to provide hospital services on the same physical site previously used by Medicare Provider No. 05–0578—

(I) the limitation on the number of total full time equivalent residents under subparagraph (F) and clauses (v) and (vi)(I) of subsection (d)(5)(B) applicable to such provider shall be equal to the limitation applicable under such provisions to Provider No. 05–0578 for its cost reporting period ending on June 30, 2006; and

(II) the provisions of subparagraph (G) and subsection (d)(5)(B)(vi)(II) shall not be applicable to such provider for the first three cost reporting years in which such provider trains residents under any approved medical residency training program.

(vi) REDISTRIBUTION OF RESIDENCY SLOTS AFTER A HOSPITAL CLOSES.—

(I) IN GENERAL.—Subject to the succeeding provisions of this clause, the Secretary shall, by regulation, establish a process under which, in the case where a hospital (other than a hospital described in clause (v)) with an approved medical residency program closes on or after a date that is 2 years before the date of enactment of this clause, the Secretary shall increase the otherwise applicable resident limit under this paragraph for other hospitals in accordance with this clause.

(II) PRIORITY FOR HOSPITALS IN CERTAIN AREAS.—Subject to the succeeding provisions of this clause, in determining for which hospitals the increase in the otherwise applicable resident limit is provided under such process, the Secretary shall distribute the increase to hospitals in the following priority order (with preference given within each category to hospitals that are members of the same affiliated group (as defined by the Secretary under clause (ii)) as the closed hospital):

(aa) First, to hospitals located in the same core-based statistical area as, or a core-based statistical area contiguous to, the hospital that closed.

(bb) Second, to hospitals located in the same State as the hospital that closed.

(cc) Third, to hospitals located in the same region of the country as the hospital that closed.

(dd) Fourth, only if the Secretary is not able to distribute the increase to hospitals described in item (cc), to qualifying hospitals in accordance with the provisions of paragraph (8).

(III) REQUIREMENT HOSPITAL LIKELY TO FILL POSITION WITHIN CERTAIN TIME PERIOD.—The Secretary may only increase the otherwise applicable resident limit of a hospital under such process if the Secretary determines the hospital has demonstrated a likelihood of filling the positions made available under this clause within 3 years.

(IV) LIMITATION.—The aggregate number of increases in the otherwise applicable resident limits for hospitals under this clause shall be equal to the number of resident positions in the approved medical residency programs that closed on or after the date described in subclause (I).

(V) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the implementation of this clause.

(J) TREATMENT OF CERTAIN NONPROVIDER AND DIDACTIC ACTIVITIES.—Such rules shall provide that all time spent by an intern or resident in an approved medical residency training program in a nonprovider setting that is primarily engaged in furnishing patient care (as defined in paragraph (5)(K)) in non-patient care activities, such as didactic conferences and seminars, but not including research not associated with the treatment or diagnosis of a particular patient, as such time and activities are defined by the Secretary, shall be counted toward the determination of full-time equivalency.

(K) TREATMENT OF CERTAIN OTHER ACTIVITIES.—In determining the hospital's number of full-time equivalent residents for purposes of this subsection, all the time that is spent by an intern or resident in an approved medical residency training program on vacation, sick leave, or other approved leave, as such time is defined by the Secretary, and that does not prolong the total time the resident is participating in the approved program beyond the normal duration of the program shall be counted toward the determination of full-time equivalency.

(5) DEFINITIONS AND SPECIAL RULES.—As used in this subsection:

(A) APPROVED MEDICAL RESIDENCY TRAINING PROGRAM.—The term "approved medical residency training program" means a residency or other postgraduate medical training program participation in which may be counted toward certification in a specialty or subspecialty and includes formal postgraduate training programs in geriatric medicine approved by the Secretary.

(B) CONSUMER PRICE INDEX.—The term "consumer price index" refers to the Consumer Price Index for All Urban Consumers (United States city average), as published by the Secretary of Commerce.

(C) DIRECT GRADUATE MEDICAL EDUCATION COSTS.—The term "direct graduate medical education costs" means direct costs of approved educational activities for approved medical residency training programs.

(D) FOREIGN MEDICAL GRADUATE.—The term "foreign medical graduate" means a resident who is not a graduate of—

(i) a school of medicine accredited by the Liaison Committee on Medical Education of the American Medical Association and the Association of American Medical Colleges (or approved by such Committee as meeting the standards necessary for such accreditation),

(ii) a school of osteopathy accredited by the American Osteopathic Association, or approved by such Association as meeting the standards necessary for such accreditation, or

(iii) a school of dentistry or podiatry which is accredited (or meets the standards for accreditation) by an organization recognized by the Secretary for such purpose.

(E) FMGEMS EXAMINATION.—The term "FMGEMS examination" means parts I and II of the Foreign Medical Graduate Examination in the Medical Sciences or any successor examination recognized by the Secretary for this purpose.

(F) INITIAL RESIDENCY PERIOD.—The term "initial residency period" means the period of board eligibility, except that—

(i) except as provided in clause (ii), in no case shall the initial period of residency exceed an aggregate period of formal training of more than five years for any individual, and

(ii) a period, of not more than two years, during which an individual is in a geriatric residency or fellowship program or a preventive medicine residency or fellowship program which meets such criteria as the Secretary may establish, shall be treated as part of the initial residency period, but shall not be counted against any limitation on the initial residency period.

Subject to subparagraph (G)(v), the initial residency period shall be determined, with respect to a resident, as of the time the resident enters the residency training program.

(G) PERIOD OF BOARD ELIGIBILITY.—

(i) GENERAL RULE.—Subject to clauses (ii), (iii), (iv), and (v), the term "period of board eligibility" means, for a resident, the minimum number of years of formal training necessary to satisfy the requirements for initial board eligibility in the particular specialty for which the resident is training.

(ii) APPLICATION OF 1985–1986 DIRECTORY.—Except as provided in clause (iii), the period of board eligibility shall be such period specified in the 1985–1986 Directory of Residency Training Programs published by the Accreditation Council on Graduate Medical Education.

(iii) CHANGES IN PERIOD OF BOARD ELIGIBILITY.—On or after July 1, 1989, if the Accreditation Council on Graduate Medical Education, in its Directory of Residency Training Programs—

(I) increases the minimum number of years of formal training necessary to satisfy the requirements for a specialty, above the period specified in its 1985–1986 Directory, the Secretary may increase the period of board eligibility for that specialty, but not to exceed the period of board eligibility specified in that later Directory, or

(II) decreases the minimum number of years of formal training necessary to satisfy the requirements for a specialty, below the period specified in its 1985–1986 Directory, the Secretary may decrease the period of board eligibility for that specialty, but not below the period of board eligibility specified in that later Directory.

(iv) SPECIAL RULE FOR CERTAIN PRIMARY CARE COMBINED RESIDENCY PROGRAMS.—(I) In the case of a resident enrolled in a combined medical residency training program in which all of the individual programs (that are combined) are for training a primary care resident (as defined in subparagraph (H)), the period of board eligibility shall be the minimum number of years of formal training required to satisfy the requirements for initial board eligibility in the longest of the individual programs plus one additional year.

(II) A resident enrolled in a combined medical residency training program that includes an obstetrics and gynecology program shall qualify for the period of board eligibility under subclause (I) if the other programs such resident combines with such obstetrics and gynecology program are for training a primary care resident.

(v) CHILD NEUROLOGY TRAINING PROGRAMS.—In the case of a resident enrolled in a child neurology residency training program, the period of board eligibility and the initial residency period shall be the period of board eligibility for pediatrics plus 2 years.

(H) PRIMARY CARE RESIDENT.—The term "primary care resident" means a resident enrolled in an approved medical residency training program in family medicine, general internal medicine, general pediatrics, preventive medicine, geriatric medicine, or osteopathic general practice.

(I) RESIDENT.—The term "resident" includes an intern or other participant in an approved medical residency training program.

(J) ADJUSTMENTS FOR CERTAIN FAMILY PRACTICE RESIDENCY PROGRAMS.—

(i) IN GENERAL.—In the case of an approved medical residency training program (meeting the requirements of clause (ii)) of a hospital which received funds from the United States, a State, or a political subdivision of a State or an instrumentality of such a State or polit-

ical subdivision (other than payments under this title or a State plan under title XIX) for the program during the cost reporting period that began during fiscal year 1984, the Secretary shall—

(I) provide for an average amount under paragraph (2)(A) that takes into account the Secretary's estimate of the amount that would have been recognized as reasonable under this title if the hospital had not received such funds, and

(II) reduce the payment amount otherwise provided under this subsection in an amount equal to the proportion of such program funds received during the cost reporting period involved that is allocable to this title.

(ii) ADDITIONAL REQUIREMENTS.—A hospital's approved medical residency program meets the requirements of this clause if—

(I) the program is limited to training for family and community medicine;

(II) the program is the only approved medical residency program of the hospital; and

(III) the average amount determined under paragraph (2)(A) for the hospital (as determined without regard to the increase in such amount described in clause (i)(I)) does not exceed $10,000.

(K) NONPROVIDER SETTING THAT IS PRIMARILY ENGAGED IN FURNISHING PATIENT CARE.—The term "nonprovider setting that is primarily engaged in furnishing patient care" means a nonprovider setting in which the primary activity is the care and treatment of patients, as defined by the Secretary.

(6) INCENTIVE PAYMENT UNDER PLANS FOR VOLUNTARY REDUCTION IN NUMBER OF RESIDENTS.—

(A) IN GENERAL.—In the case of a voluntary residency reduction plan for which an application is approved under subparagraph (B), subject to subparagraph (F), each hospital which is part of the qualifying entity submitting the plan shall be paid an applicable hold harmless percentage (as specified in subparagraph (E)) of the sum of—

(i) the amount (if any) by which—

(I) the amount of payment which would have been made under this subsection if there had been a 5-percent reduction in the number of full-time equivalent residents in the approved medical education training programs of the hospital as of June 30, 1997, exceeds

(II) the amount of payment which is made under this subsection, taking into account the reduction in such number effected under the reduction plan; and

(ii) the amount of the reduction in payment under subsection (d)(5)(B) for the hospital that is attributable to the reduction in number of residents effected under the plan below 95 percent of the number of full-

time equivalent residents in such programs of the hospital as of June 30, 1997.

The determination of the amounts under clauses (i) and (ii) for any year shall be made on the basis of the provisions of this title in effect on the application deadline date for the first calendar year to which the reduction plan applies.

(B) APPROVAL OF PLAN APPLICATIONS.—The Secretary may not approve the application of an qualifying entity unless—

(i) the application is submitted in a form and manner specified by the Secretary and by not later than November 1, 1999,

(ii) the application provides for the operation of a plan for the reduction in the number of full-time equivalent residents in the approved medical residency training programs of the entity consistent with the requirements of subparagraph (D);

(iii) the entity elects in the application the period of residency training years (not greater than 5) over which the reduction will occur;

(iv) the entity will not reduce the proportion of its residents in primary care (to the total number of residents) below such proportion as in effect as of the applicable time described in subparagraph (D)(v); and

(v) the Secretary determines that the application and the entity and such plan meet such other requirements as the Secretary specifies in regulations.

(C) QUALIFYING ENTITY.—For purposes of this paragraph, any of the following may be a qualifying entity:

(i) Individual hospitals operating one or more approved medical residency training programs.

(ii) Two or more hospitals that operate such programs and apply for treatment under this paragraph as a single qualifying entity.

(iii) A qualifying consortium (as described in section 4628 of the Balanced Budget Act of 1997).

(D) RESIDENCY REDUCTION REQUIREMENTS.—

(i) INDIVIDUAL HOSPITAL APPLICANTS.—In the case of a qualifying entity described in subparagraph (C)(i), the number of full-time equivalent residents in all the approved medical residency training programs operated by or through the entity shall be reduced as follows:

(I) If the base number of residents exceeds 750 residents, by a number equal to at least 20 percent of such base number.

(II) Subject to subclause (IV), if the base number of residents exceeds 600 but is less than 750 residents, by 150 residents.

(III) Subject to subclause (IV), if the base number of residents does not exceed 600 residents, by a number equal to at least 25 percent of such base number.

(IV) In the case of a qualifying entity which is described in clause (v) and which elects treatment

under this subclause, by a number equal to at least 20 percent of the base number.

(ii) JOINT APPLICANTS.—In the case of a qualifying entity described in subparagraph (C)(ii), the number of full-time equivalent residents in the aggregate for all the approved medical residency training programs operated by or through the entity shall be reduced as follows:

(I) Subject to subclause (II), by a number equal to at least 25 percent of the base number.

(II) In the case of such a qualifying entity which is described in clause (v) and which elects treatment under this subclause, by a number equal to at least 20 percent of the base number.

(iii) CONSORTIA.—In the case of a qualifying entity described in subparagraph (C)(iii), the number of full-time equivalent residents in the aggregate for all the approved medical residency training programs operated by or through the entity shall be reduced by a number equal to at least 20 percent of the base number.

(iv) MANNER OF REDUCTION.—The reductions specified under the preceding provisions of this subparagraph for a qualifying entity shall be below the base number of residents for that entity and shall be fully effective not later than the 5th residency training year in which the application under subparagraph (B) is effective.

(v) ENTITIES PROVIDING ASSURANCE OF INCREASE IN PRIMARY CARE RESIDENTS.—An entity is described in this clause if—

(I) the base number of residents for the entity is less than 750 or the entity is described in subparagraph (C)(ii); and

(II) the entity represents in its application under subparagraph (B) that it will increase the number of full-time equivalent residents in primary care by at least 20 percent (from such number included in the base number of residents) by not later than the 5th residency training year in which the application under subparagraph (B) is effective.

If a qualifying entity fails to comply with the representation described in subclause (II) by the end of such 5th residency training year, the entity shall be subject to repayment of all amounts paid under this paragraph, in accordance with procedures established to carry out subparagraph (F).

(vi) BASE NUMBER OF RESIDENTS DEFINED.—For purposes of this paragraph, the term "base number of residents" means, with respect to a qualifying entity (or its participating hospitals) operating approved medical residency training programs, the number of full-time equivalent residents in such programs (before application of weighting factors) of the entity as of the

most recent residency training year ending before June 30, 1997, or, if less, for any subsequent residency training year that ends before the date the entity makes application under this paragraph.

(E) APPLICABLE HOLD HARMLESS PERCENTAGE.—For purposes of subparagraph (A), the "applicable hold harmless percentage" for the—

(i) first and second residency training years in which the reduction plan is in effect, 100 percent,

(ii) third such year, 75 percent,

(iii) fourth such year, 50 percent, and

(iv) fifth such year, 25 percent.

(F) PENALTY FOR NONCOMPLIANCE.—

(i) IN GENERAL.—No payment may be made under this paragraph to a hospital for a residency training year if the hospital has failed to reduce the number of full-time equivalent residents (in the manner required under subparagraph (D)) to the number agreed to by the Secretary and the qualifying entity in approving the application under this paragraph with respect to such year.

(ii) INCREASE IN NUMBER OF RESIDENTS IN SUBSEQUENT YEARS.—If payments are made under this paragraph to a hospital, and if the hospital increases the number of full-time equivalent residents above the number of such residents permitted under the reduction plan as of the completion of the plan, then, as specified by the Secretary, the entity is liable for repayment to the Secretary of the total amounts paid under this paragraph to the entity.

(G) TREATMENT OF ROTATING RESIDENTS.—In applying this paragraph, the Secretary shall establish rules regarding the counting of residents who are assigned to institutions the medical residency training programs in which are not covered under approved applications under this paragraph.

(7) REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.—

(A) REDUCTION IN LIMIT BASED ON UNUSED POSITIONS.—

(i) PROGRAMS SUBJECT TO REDUCTION.—

(I) IN GENERAL.—Except as provided in subclause (II), if a hospital's reference resident level (specified in clause (ii)) is less than the otherwise applicable resident limit (as defined in subparagraph (C)(ii)), effective for portions of cost reporting periods occurring on or after July 1, 2005, the otherwise applicable resident limit shall be reduced by 75 percent of the difference between such otherwise applicable resident limit and such reference resident level.

(II) EXCEPTION FOR SMALL RURAL HOSPITALS.—This subparagraph shall not apply to a hospital located in a rural area (as defined in subsection (d)(2)(D)(ii)) with fewer than 250 acute care inpatient beds.

(ii) REFERENCE RESIDENT LEVEL.—

(I) IN GENERAL.—Except as otherwise provided in subclauses (II) and (III), the reference resident level specified in this clause for a hospital is the resident level for the most recent cost reporting period of the hospital ending on or before September 30, 2002, for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

(II) USE OF MOST RECENT ACCOUNTING PERIOD TO RECOGNIZE EXPANSION OF EXISTING PROGRAMS.—If a hospital submits a timely request to increase its resident level due to an expansion of an existing residency training program that is not reflected on the most recent settled cost report, after audit and subject to the discretion of the Secretary, the reference resident level for such hospital is the resident level for the cost reporting period that includes July 1, 2003, as determined by the Secretary.

(III) EXPANSIONS UNDER NEWLY APPROVED PROGRAMS.—Upon the timely request of a hospital, the Secretary shall adjust the reference resident level specified under subclause (I) or (II) to include the number of medical residents that were approved in an application for a medical residency training program that was approved by an appropriate accrediting organization (as determined by the Secretary) before January 1, 2002, but which was not in operation during the cost reporting period used under subclause (I) or (II), as the case may be, as determined by the Secretary.

(iii) AFFILIATION.—The provisions of clause (i) shall be applied to hospitals which are members of the same affiliated group (as defined by the Secretary under paragraph (4)(H)(ii)) as of July 1, 2003.

(B) REDISTRIBUTION.—

(i) IN GENERAL.—The Secretary is authorized to increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application under this subparagraph by such number as the Secretary may approve for portions of cost reporting periods occurring on or after July 1, 2005. The aggregate number of increases in the otherwise applicable resident limits under this subparagraph may not exceed the Secretary's estimate of the aggregate reduction in such limits attributable to subparagraph (A).

(ii) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under clause (i), the Secretary shall take into account the demonstrated likelihood of the hospital filling the positions within the first 3 cost reporting periods beginning on or after July 1, 2005, made available under this subparagraph, as determined by the Secretary.

(iii) PRIORITY FOR RURAL AND SMALL URBAN AREAS.—In determining for which hospitals and residency training programs an increase in the otherwise applicable resident limit is provided under clause (i), the Secretary shall distribute the increase to programs of hospitals located in the following priority order:

(I) First, to hospitals located in rural areas (as defined in subsection (d)(2)(D)(ii)).

(II) Second, to hospitals located in urban areas that are not large urban areas (as defined for purposes of subsection (d)).

(III) Third, to other hospitals in a State if the residency training program involved is in a specialty for which there are not other residency training programs in the State.

Increases of residency limits within the same priority category under this clause shall be determined by the Secretary.

(iv) LIMITATION.—In no case shall more than 25 full-time equivalent additional residency positions be made available under this subparagraph with respect to any hospital.

(v) APPLICATION OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—With respect to additional residency positions in a hospital attributable to the increase provided under this subparagraph, notwithstanding any other provision of this subsection, the approved FTE resident amount is deemed to be equal to the locality adjusted national average per resident amount computed under paragraph (4)(E) for that hospital.

(vi) CONSTRUCTION.—Nothing in this subparagraph shall be construed as permitting the redistribution of reductions in residency positions attributable to voluntary reduction programs under paragraph (6), under a demonstration project approved as of October 31, 2003, under the authority of section 402 of Public Law 90–248, or as affecting the ability of a hospital to establish new medical residency training programs under paragraph (4)(H).

(C) RESIDENT LEVEL AND LIMIT DEFINED.—In this paragraph:

(i) RESIDENT LEVEL.—The term "resident level" means, with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under paragraph (4)), in the fields of allopathic and osteopathic medicine for the hospital.

(ii) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term "otherwise applicable resident limit" means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph.

(D) ADJUSTMENT BASED ON SETTLED COST REPORT.—In the case of a hospital with a dual accredited osteopathic and allopathic family practice program for which—

(i) the otherwise applicable resident limit was reduced under subparagraph (A)(i)(I); and

(ii) such reduction was based on a reference resident level that was determined using a cost report and where a revised or corrected notice of program reimbursement was issued for such cost report between September 1, 2006 and September 15, 2006, whether as a result of an appeal or otherwise, and the reference resident level under such settled cost report is higher than the level used for the reduction under subparagraph (A)(i)(I);

the Secretary shall apply subparagraph (A)(i)(I) using the higher resident reference level and make any necessary adjustments to such reduction. Any such necessary adjustments shall be effective for portions of cost reporting periods occurring on or after July 1, 2005.

(E) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, with respect to determinations made under this paragraph, paragraph (8), paragraph (10), clause (i), (ii), (iii), or (v) of paragraph (2)(F), or clause (i) or (vi) of paragraph (4)(H).

(8) DISTRIBUTION OF ADDITIONAL RESIDENCY POSITIONS.—

(A) REDUCTIONS IN LIMIT BASED ON UNUSED POSITIONS.—

(i) IN GENERAL.—Except as provided in clause (ii), if a hospital's reference resident level (as defined in subparagraph (H)(i)) is less than the otherwise applicable resident limit (as defined in subparagraph (H)(iii)), effective for portions of cost reporting periods occurring on or after July 1, 2011, the otherwise applicable resident limit shall be reduced by 65 percent of the difference between such otherwise applicable resident limit and such reference resident level.

(ii) EXCEPTIONS.—This subparagraph shall not apply to—

(I) a hospital located in a rural area (as defined in subsection (d)(2)(D)(ii)) with fewer than 250 acute care inpatient beds;

(II) a hospital that was part of a qualifying entity which had a voluntary residency reduction plan approved under paragraph (6)(B) or under the authority of section 402 of Public Law 90–248, if the hospital demonstrates to the Secretary that it has a specified plan in place for filling the unused positions by not later than 2 years after the date of enactment of this paragraph; or

(III) a hospital described in paragraph (4)(H)(v).

(B) DISTRIBUTION.—

(i) IN GENERAL.—The Secretary shall increase the otherwise applicable resident limit for each qualifying hospital that submits an application under this subparagraph by such number as the Secretary may ap-

prove for portions of cost reporting periods occurring on or after July 1, 2011. The aggregate number of increases in the otherwise applicable resident limit under this subparagraph shall be equal to the aggregate reduction in such limits attributable to subparagraph (A) (as estimated by the Secretary).

(ii) REQUIREMENTS.—Subject to clause (iii), a hospital that receives an increase in the otherwise applicable resident limit under this subparagraph shall ensure, during the 5-year period beginning on the date of such increase, that—

(I) the number of full-time equivalent primary care residents, as defined in paragraph (5)(H) (as determined by the Secretary), excluding any additional positions under subclause (II), is not less than the average number of full-time equivalent primary care residents (as so determined) during the 3 most recent cost reporting periods ending prior to the date of enactment of this paragraph; and

(II) not less than 75 percent of the positions attributable to such increase are in a primary care or general surgery residency (as determined by the Secretary).

The Secretary may determine whether a hospital has met the requirements under this clause during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period.

(iii) REDISTRIBUTION OF POSITIONS IF HOSPITAL NO LONGER MEETS CERTAIN REQUIREMENTS.—In the case where the Secretary determines that a hospital described in clause (ii) does not meet either of the requirements under subclause (I) or (II) of such clause, the Secretary shall—

(I) reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased under this paragraph; and

(II) provide for the distribution of positions attributable to such reduction in accordance with the requirements of this paragraph.

(C) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subparagraph (B), the Secretary shall take into account—

(i) the demonstration likelihood of the hospital filling the positions made available under this paragraph within the first 3 cost reporting periods beginning on or after July 1, 2011, as determined by the Secretary; and

(ii) whether the hospital has an accredited rural training track (as described in paragraph (4)(H)(iv)).

(D) PRIORITY FOR CERTAIN AREAS.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subparagraph (B), subject

to subparagraph (E), the Secretary shall distribute the increase to hospitals based on the following factors:

(i) Whether the hospital is located in a State with a resident-to-population ratio in the lowest quartile (as determined by the Secretary).

(ii) Whether the hospital is located in a State, a territory of the United States, or the District of Columbia that is among the top 10 States, territories, or Districts in terms of the ratio of—

(I) the total population of the State, territory, or District living in an area designated (under such section 332(a)(1)(A)) as a health professional shortage area (as of the date of enactment of this paragraph); to

(II) the total population of the State, territory, or District (as determined by the Secretary based on the most recent available population data published by the Bureau of the Census).

(iii) Whether the hospital is located in a rural area (as defined in subsection (d)(2)(D)(ii)).

(E) RESERVATION OF POSITIONS FOR CERTAIN HOSPITALS.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary shall reserve the positions available for distribution under this paragraph as follows:

(I) 70 percent of such positions for distribution to hospitals described in clause (i) of subparagraph (D).

(II) 30 percent of such positions for distribution to hospitals described in clause (ii) and (iii) of such subparagraph.

(ii) EXCEPTION IF POSITIONS NOT REDISTRIBUTED BY JULY 1, 2011.—In the case where the Secretary does not distribute positions to hospitals in accordance with clause (i) by July 1, 2011, the Secretary shall distribute such positions to other hospitals in accordance with the considerations described in subparagraph (C) and the priority described in subparagraph (D).

(F) LIMITATION.—A hospital may not receive more than 75 full-time equivalent additional residency positions under this paragraph.

(G) APPLICATION OF PER RESIDENT AMOUNTS FOR PRIMARY CARE AND NONPRIMARY CARE.—With respect to additional residency positions in a hospital attributable to the increase provided under this paragraph, the approved FTE per resident amounts are deemed to be equal to the hospital per resident amounts for primary care and nonprimary care computed under paragraph (2)(D) for that hospital.

(H) DEFINITIONS.—In this paragraph:

(i) REFERENCE RESIDENT LEVEL.—The term "reference resident level" means, with respect to a hospital, the highest resident level for any of the 3 most recent cost reporting periods (ending before the date of the enactment of this paragraph) of the hospital for

which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

(ii) RESIDENT LEVEL.—The term "resident level" has the meaning given such term in paragraph (7)(C)(i).

(iii) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term "otherwise applicable resident limit" means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph but taking into account paragraph (7)(A).

(I) AFFILIATION.—The provisions of this paragraph shall be applied to hospitals which are members of the same affiliated group (as defined by the Secretary under paragraph (4)(H)(ii)) and the reference resident level for each such hospital shall be the reference resident level with respect to the cost reporting period that results in the smallest difference between the reference resident level and the otherwise applicable resident limit.

(9) DISTRIBUTION OF ADDITIONAL RESIDENCY POSITIONS.—

(A) ADDITIONAL RESIDENCY POSITIONS.—

(i) IN GENERAL.—For fiscal year 2023, and for each succeeding fiscal year until the aggregate number of full-time equivalent residency positions distributed under this paragraph is equal to the aggregate number of such positions made available (as specified in clause (ii)(I)), the Secretary shall, subject to the succeeding provisions of this paragraph, increase the otherwise applicable resident limit for each qualifying hospital (as defined in subparagraph (F)) that submits a timely application under this subparagraph by such number as the Secretary may approve effective beginning July 1 of the fiscal year of the increase.

(ii) NUMBER AVAILABLE FOR DISTRIBUTION.—

(I) TOTAL NUMBER AVAILABLE.—The aggregate number of such positions made available under this paragraph shall be equal to 1,000.

(II) ANNUAL LIMIT.—The aggregate number of such positions so made available shall not exceed 200 for a fiscal year.

(iii) PROCESS FOR DISTRIBUTING POSITIONS.—

(I) ROUNDS OF APPLICATIONS.—The Secretary shall initiate a separate round of applications for an increase under clause (i) for each fiscal year for which such an increase is to be provided.

(II) TIMING.—The Secretary shall notify hospitals of the number of positions distributed to the hospital under this paragraph as a result of an increase in the otherwise applicable resident limit by January 31 of the fiscal year of the increase. Such increase shall be effective beginning July 1 of such fiscal year.

(B) DISTRIBUTION.—For purposes of providing an increase in the otherwise applicable resident limit under subparagraph (A), the following shall apply:

(i) CONSIDERATIONS IN DISTRIBUTION.—In determining for which qualifying hospitals such an increase is provided under subparagraph (A), the Secretary shall take into account the demonstrated likelihood of the hospital filling the positions made available under this paragraph within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary.

(ii) MINIMUM DISTRIBUTION FOR CERTAIN CATEGORIES OF HOSPITALS.—With respect to the aggregate number of such positions available for distribution under this paragraph, the Secretary shall distribute not less than 10 percent of such aggregate number to each of the following categories of hospitals:

(I) Hospitals that are located in a rural area (as defined in section 1886(d)(2)(D)) or are treated as being located in a rural area pursuant to section 1886(d)(8)(E).

(II) Hospitals in which the reference resident level of the hospital (as specified in subparagraph (F)(iii)) is greater than the otherwise applicable resident limit.

(III) Hospitals in States with—

(aa) new medical schools that received "Candidate School" status from the Liaison Committee on Medical Education or that received "Pre-Accreditation" status from the American Osteopathic Association Commission on Osteopathic College Accreditation on or after January 1, 2000, and that have achieved or continue to progress toward "Full Accreditation" status (as such term is defined by the Liaison Committee on Medical Education) or toward "Accreditation" status (as such term is defined by the American Osteopathic Association Commission on Osteopathic College Accreditation); or

(bb) additional locations and branch campuses established on or after January 1, 2000, by medical schools with "Full Accreditation" status (as such term is defined by the Liaison Committee on Medical Education) or "Accreditation" status (as such term is defined by the American Osteopathic Association Commission on Osteopathic College Accreditation).

(IV) Hospitals that serve areas designated as health professional shortage areas under section 332(a)(1)(A) of the Public Health Service Act, as determined by the Secretary.

(C) LIMITATIONS.—

(i) IN GENERAL.—A hospital may not receive more than 25 additional full-time equivalent residency positions under this paragraph.

(ii) PROHIBITION ON DISTRIBUTION TO HOSPITALS WITHOUT AN INCREASE AGREEMENT.—No increase in the otherwise applicable resident limit of a hospital may be made under this paragraph unless such hospital agrees to increase the total number of full-time equivalent residency positions under the approved medical residency training program of such hospital by the number of such positions made available by such increase under this paragraph.

(D) APPLICATION OF PER RESIDENT AMOUNTS FOR PRIMARY CARE AND NONPRIMARY CARE.—With respect to additional residency positions in a hospital attributable to the increase provided under this paragraph, the approved FTE per resident amounts are deemed to be equal to the hospital per resident amounts for primary care and nonprimary care computed under paragraph (2)(D) for that hospital.

(E) PERMITTING FACILITIES TO APPLY AGGREGATION RULES.—The Secretary shall permit hospitals receiving additional residency positions attributable to the increase provided under this paragraph to, beginning in the fifth year after the effective date of such increase, apply such positions to the limitation amount under paragraph (4)(F) that may be aggregated pursuant to paragraph (4)(H) among members of the same affiliated group.

(F) DEFINITIONS.—In this paragraph:

(i) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term "otherwise applicable resident limit" means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph but taking into account paragraphs (7)(A), (7)(B), (8)(A), and (8)(B).

(ii) QUALIFYING HOSPITAL.—The term "qualifying hospital" means a hospital described in any of subclauses (I) through (IV) of subparagraph (B)(ii).

(iii) REFERENCE RESIDENT LEVEL.—The term "reference resident level" means, with respect to a hospital, the resident level for the most recent cost reporting period of the hospital ending on or before the date of enactment of this paragraph, for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

(iv) RESIDENT LEVEL.—The term "resident level" has the meaning given such term in paragraph (7)(C)(i).

(10) DISTRIBUTION OF ADDITIONAL RESIDENCY POSITIONS IN PSYCHIATRY AND PSYCHIATRY SUBSPECIALTIES.—

(A) ADDITIONAL RESIDENCY POSITIONS.—

(i) IN GENERAL.—For fiscal year 2026, the Secretary shall, subject to the succeeding provisions of this paragraph, increase the otherwise applicable resident limit for each qualifying hospital (as defined in subpara-

graph (F)) that submits a timely application under this subparagraph by such number as the Secretary may approve effective beginning July 1 of the fiscal year of the increase.

(ii) NUMBER AVAILABLE FOR DISTRIBUTION.—The aggregate number of such positions made available under this paragraph shall be equal to 200.

(iii) DISTRIBUTION FOR PSYCHIATRY OR PSYCHIATRY SUBSPECIALTY RESIDENCIES.—At least 100 of the positions made available under this paragraph shall be distributed for a psychiatry or psychiatry subspecialty residency (as defined in subparagraph (F)).

(iv) TIMING.—The Secretary shall notify hospitals of the number of positions distributed to the hospital under this paragraph as a result of an increase in the otherwise applicable resident limit by January 31 of the fiscal year of the increase. Such increase shall be effective beginning July 1 of such fiscal year.

(B) DISTRIBUTION.—For purposes of providing an increase in the otherwise applicable resident limit under subparagraph (A), the following shall apply:

(i) CONSIDERATIONS IN DISTRIBUTION.—In determining for which qualifying hospitals such an increase is provided under subparagraph (A), the Secretary shall take into account the demonstrated likelihood of the hospital filling the positions made available under this paragraph within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary.

(ii) MINIMUM DISTRIBUTION FOR CERTAIN CATEGORIES OF HOSPITALS.—With respect to the aggregate number of such positions available for distribution under this paragraph, the Secretary shall distribute not less than 10 percent of such aggregate number to each of the following categories of hospitals:

(I) Hospitals that are located in a rural area (as defined in section 1886(d)(2)(D)) or are treated as being located in a rural area pursuant to section 1886(d)(8)(E).

(II) Hospitals in which the reference resident level of the hospital (as specified in subparagraph (F)(iii)) is greater than the otherwise applicable resident limit.

(III) Hospitals in States with—

(aa) new medical schools that received "Candidate School" status from the Liaison Committee on Medical Education or that received "Pre-Accreditation" status from the American Osteopathic Association Commission on Osteopathic College Accreditation on or after January 1, 2000, and that have achieved or continue to progress toward "Full Accreditation" status (as such term is defined by the Liaison Committee on Medical Education) or toward "Accreditation" status (as

such term is defined by the American Osteopathic Association Commission on Osteopathic College Accreditation); or

(bb) additional locations and branch campuses established on or after January 1, 2000, by medical schools with "Full Accreditation" status (as such term is defined by the Liaison Committee on Medical Education) or "Accreditation" status (as such term is defined by the American Osteopathic Association Commission on Osteopathic College Accreditation).

(IV) Hospitals that serve areas designated as health professional shortage areas under section 332(a)(1)(A) of the Public Health Service Act, as determined by the Secretary.

(iii) PRO RATA APPLICATION.—The Secretary shall ensure that each qualifying hospital that submits a timely application under subparagraph (A) receives at least 1 (or a fraction of 1) of the positions made available under this paragraph before any qualifying hospital receives more than 1 of such positions.

(C) REQUIREMENTS.—

(i) LIMITATION.—A hospital may not receive more than 10 additional full-time equivalent residency positions under this paragraph.

(ii) PROHIBITION ON DISTRIBUTION TO HOSPITALS WITHOUT AN INCREASE AGREEMENT.—No increase in the otherwise applicable resident limit of a hospital may be made under this paragraph unless such hospital agrees to increase the total number of full-time equivalent residency positions under the approved medical residency training program of such hospital by the number of such positions made available by such increase under this paragraph.

(iii) REQUIREMENT FOR HOSPITALS TO EXPAND PROGRAMS.—If a hospital that receives an increase in the otherwise applicable resident limit under this paragraph would be eligible for an adjustment to the otherwise applicable resident limit for participation in a new medical residency training program under section 413.79(e)(3) of title 42, Code of Federal Regulations (or any successor regulation), the hospital shall ensure that any positions made available under this paragraph are used to expand an existing program of the hospital, and not for participation in a new medical residency training program.

(D) APPLICATION OF PER RESIDENT AMOUNTS FOR NONPRIMARY CARE.—With respect to additional residency positions in a hospital attributable to the increase provided under this paragraph, the approved FTE per resident amounts are deemed to be equal to the hospital per resident amounts for nonprimary care computed under paragraph (2)(D) for that hospital.

(E) PERMITTING FACILITIES TO APPLY AGGREGATION RULES.—The Secretary shall permit hospitals receiving ad-

ditional residency positions attributable to the increase provided under this paragraph to, beginning in the fifth year after the effective date of such increase, apply such positions to the limitation amount under paragraph (4)(F) that may be aggregated pursuant to paragraph (4)(H) among members of the same affiliated group.

(F) DEFINITIONS.—In this paragraph:

(i) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term "otherwise applicable resident limit" means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph but taking into account paragraphs (7)(A), (7)(B), (8)(A), (8)(B), and (9)(A).

(ii) PSYCHIATRY OR PSYCHIATRY SUBSPECIALTY RESIDENCY.—The term "psychiatry or psychiatry subspecialty residency" means a residency in psychiatry as accredited by the Accreditation Council for Graduate Medical Education for the purpose of preventing, diagnosing, and treating mental health disorders.

(iii) QUALIFYING HOSPITAL.—The term "qualifying hospital" means a hospital described in any of subclauses (I) through (IV) of subparagraph (B)(ii).

(iv) REFERENCE RESIDENT LEVEL.—The term "reference resident level" means, with respect to a hospital, the resident level for the most recent cost reporting period of the hospital ending on or before the date of enactment of this paragraph, for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

(v) RESIDENT LEVEL.—The term "resident level" has the meaning given such term in paragraph (7)(C)(i).

(i) AVOIDING DUPLICATIVE PAYMENTS TO HOSPITALS PARTICIPATING IN RURAL DEMONSTRATION PROGRAMS.—The Secretary shall reduce any payment amounts otherwise determined under this section to the extent necessary to avoid duplication of any payment made under section 4005(e) of the Omnibus Budget Reconciliation Act of 1987.

(j) PROSPECTIVE PAYMENT FOR INPATIENT REHABILITATION SERVICES.—

(1) PAYMENT DURING TRANSITION PERIOD.—

(A) IN GENERAL.—Notwithstanding section 1814(b), but subject to the provisions of section 1813, the amount of the payment with respect to the operating and capital costs of inpatient hospital services of a rehabilitation hospital or a rehabilitation unit (in this subsection referred to as a "rehabilitation facility"), other than a facility making an election under subparagraph (F) in a cost reporting period beginning on or after October 1, 2000, and before October 1, 2002, is equal to the sum of—

(i) the TEFRA percentage (as defined in subparagraph (C)) of the amount that would have been paid under part A with respect to such costs if this subsection did not apply, and

(ii) the prospective payment percentage (as defined in subparagraph (C)) of the product of (I) the per unit payment rate established under this subsection for the fiscal year in which the payment unit of service occurs, and (II) the number of such payment units occurring in the cost reporting period.

(B) FULLY IMPLEMENTED SYSTEM.—Notwithstanding section 1814(b), but subject to the provisions of section 1813, the amount of the payment with respect to the operating and capital costs of inpatient hospital services of a rehabilitation facility for a payment unit in a cost reporting period beginning on or after October 1, 2002, or, in the case of a facility making an election under subparagraph (F), for any cost reporting period described in such subparagraph, is equal to the per unit payment rate established under this subsection for the fiscal year in which the payment unit of service occurs.

(C) TEFRA AND PROSPECTIVE PAYMENT PERCENTAGES SPECIFIED.—For purposes of subparagraph (A), for a cost reporting period beginning—

(i) on or after October 1, 2000, and before October 1, 2001, the "TEFRA percentage" is 66⅔ percent and the "prospective payment percentage" is 33⅓ percent; and

(ii) on or after October 1, 2001, and before October 1, 2002, the "TEFRA percentage" is 33⅓ percent and the "prospective payment percentage" is 66⅔ percent.

(D) PAYMENT UNIT.—For purposes of this subsection, the term "payment unit" means a discharge.

(E) CONSTRUCTION RELATING TO TRANSFER AUTHORITY.—Nothing in this subsection shall be construed as preventing the Secretary from providing for an adjustment to payments to take into account the early transfer of a patient from a rehabilitation facility to another site of care.

(F) ELECTION TO APPLY FULL PROSPECTIVE PAYMENT SYSTEM.—A rehabilitation facility may elect, not later than 30 days before its first cost reporting period for which the payment methodology under this subsection applies to the facility, to have payment made to the facility under this subsection under the provisions of subparagraph (B) (rather than subparagraph (A)) for each cost reporting period to which such payment methodology applies.

(2) PATIENT CASE MIX GROUPS.—

(A) ESTABLISHMENT.—The Secretary shall establish—

(i) classes of patient discharges of rehabilitation facilities by functional-related groups (each in this subsection referred to as a "case mix group"), based on impairment, age, comorbidities, and functional capability of the patient and such other factors as the Secretary deems appropriate to improve the explanatory power of functional independence measure-function related groups; and

(ii) a method of classifying specific patients in rehabilitation facilities within these groups.

(B) WEIGHTING FACTORS.—For each case mix group the Secretary shall assign an appropriate weighting which reflects the relative facility resources used with respect to patients classified within that group compared to patients classified within other groups.

(C) ADJUSTMENTS FOR CASE MIX.—

(i) IN GENERAL.—The Secretary shall from time to time adjust the classifications and weighting factors established under this paragraph as appropriate to reflect changes in treatment patterns, technology, case mix, number of payment units for which payment is made under this title, and other factors which may affect the relative use of resources. Such adjustments shall be made in a manner so that changes in aggregate payments under the classification system are a result of real changes and are not a result of changes in coding that are unrelated to real changes in case mix.

(ii) ADJUSTMENT.—Insofar as the Secretary determines that such adjustments for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under the classification system during the fiscal year that are a result of changes in the coding or classification of patients that do not reflect real changes in case mix, the Secretary shall adjust the per payment unit payment rate for subsequent years so as to eliminate the effect of such coding or classification changes.

(D) DATA COLLECTION.—The Secretary is authorized to require rehabilitation facilities that provide inpatient hospital services to submit such data as the Secretary deems necessary to establish and administer the prospective payment system under this subsection.

(3) PAYMENT RATE.—

(A) IN GENERAL.—The Secretary shall determine a prospective payment rate for each payment unit for which such rehabilitation facility is entitled to receive payment under this title. Subject to subparagraph (B), such rate for payment units occurring during a fiscal year shall be based on the average payment per payment unit under this title for inpatient operating and capital costs of rehabilitation facilities using the most recent data available (as estimated by the Secretary as of the date of establishment of the system) adjusted—

(i) by updating such per-payment-unit amount to the fiscal year involved by the weighted average of the applicable percentage increases provided under subsection (b)(3)(B)(ii) (for cost reporting periods beginning during the fiscal year) covering the period from the midpoint of the period for such data through the midpoint of fiscal year 2000 and by an increase factor (described in subparagraph (C)) specified by the Secretary for subsequent fiscal years up to the fiscal year involved;

(ii) by reducing such rates by a factor equal to the proportion of payments under this subsection (as estimated by the Secretary) based on prospective payment amounts which are additional payments described in paragraph (4) (relating to outlier and related payments);

(iii) for variations among rehabilitation facilities by area under paragraph (6);

(iv) by the weighting factors established under paragraph (2)(B); and

(v) by such other factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities.

(B) BUDGET NEUTRAL RATES.—The Secretary shall establish the prospective payment amounts under this subsection for payment units during fiscal years 2001 and 2002 at levels such that, in the Secretary's estimation, the amount of total payments under this subsection for such fiscal years (including any payment adjustments pursuant to paragraphs (4) and (6) but not taking into account any payment adjustment resulting from an election permitted under paragraph (1)(F)) shall be equal to 98 percent for fiscal year 2001 and 100 percent for fiscal year 2002 of the amount of payments that would have been made under this title during the fiscal years for operating and capital costs of rehabilitation facilities had this subsection not been enacted. In establishing such payment amounts, the Secretary shall consider the effects of the prospective payment system established under this subsection on the total number of payment units from rehabilitation facilities and other factors described in subparagraph (A).

(C) INCREASE FACTOR.—

(i) IN GENERAL.—For purposes of this subsection for payment units in each fiscal year (beginning with fiscal year 2001), the Secretary shall establish an increase factor subject to clauses (ii) and (iii). Such factor shall be based on an appropriate percentage increase in a market basket of goods and services comprising services for which payment is made under this subsection, which may be the market basket percentage increase described in subsection (b)(3)(B)(iii). The increase factor to be applied under this subparagraph for each of fiscal years 2008 and 2009 shall be 0 percent.

(ii) PRODUCTIVITY AND OTHER ADJUSTMENT.—Subject to clause (iii), after establishing the increase factor described in clause (i) for a fiscal year, the Secretary shall reduce such increase factor—

(I) for fiscal year 2012 and each subsequent fiscal year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(II) for each of fiscal years 2010 through 2019, by the other adjustment described in subparagraph (D).

The application of this clause may result in the increase factor under this subparagraph being less than 0.0 for a fiscal year, and may result in payment rates under this subsection for a fiscal year being less than such payment rates for the preceding fiscal year.

(iii) SPECIAL RULE FOR FISCAL YEAR 2018.—The increase factor to be applied under this subparagraph for fiscal year 2018, after the application of clause (ii), shall be 1 percent.

(D) OTHER ADJUSTMENT.—For purposes of subparagraph (C)(ii)(II), the other adjustment described in this subparagraph is—

(i) for each of fiscal years 2010 and 2011, 0.25 percentage point;

(ii) for each of fiscal years 2012 and 2013, 0.1 percentage point;

(iii) for fiscal year 2014, 0.3 percentage point;

(iv) for each of fiscal years 2015 and 2016, 0.2 percentage point; and

(v) for each of fiscal years 2017, 2018, and 2019, 0.75 percentage point.

(4) OUTLIER AND SPECIAL PAYMENTS.—

(A) OUTLIERS.—

(i) IN GENERAL.—The Secretary may provide for an additional payment to a rehabilitation facility for patients in a case mix group, based upon the patient being classified as an outlier based on an unusual length of stay, costs, or other factors specified by the Secretary.

(ii) PAYMENT BASED ON MARGINAL COST OF CARE.—The amount of such additional payment under clause (i) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the cutoff point applicable under clause (i).

(iii) TOTAL PAYMENTS.—The total amount of the additional payments made under this subparagraph for payment units in a fiscal year may not exceed 5 percent of the total payments projected or estimated to be made based on prospective payment rates for payment units in that year.

(B) ADJUSTMENT.—The Secretary may provide for such adjustments to the payment amounts under this subsection as the Secretary deems appropriate to take into account the unique circumstances of rehabilitation facilities located in Alaska and Hawaii.

(5) PUBLICATION.—The Secretary shall provide for publication in the Federal Register, on or before August 1 before each fiscal year (beginning with fiscal year 2001), of the classification and weighting factors for case mix groups under paragraph (2) for such fiscal year and a description of the methodology and data used in computing the prospective payment rates under this subsection for that fiscal year.

(6) AREA WAGE ADJUSTMENT.—The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of rehabilitation facilities' costs which are attributable to

wages and wage-related costs, of the prospective payment rates computed under paragraph (3) for area differences in wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for such facilities. Not later than October 1, 2001 (and at least every 36 months thereafter), the Secretary shall update the factor under the preceding sentence on the basis of information available to the Secretary (and updated as appropriate) of the wages and wage-related costs incurred in furnishing rehabilitation services. Any adjustments or updates made under this paragraph for a fiscal year shall be made in a manner that assures that the aggregated payments under this subsection in the fiscal year are not greater or less than those that would have been made in the year without such adjustment.

(7) QUALITY REPORTING.—

(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

(i) IN GENERAL.—For purposes of fiscal year 2014 and each subsequent fiscal year, in the case of a rehabilitation facility that does not submit data to the Secretary in accordance with subparagraphs (C) and (F) with respect to such a fiscal year, after determining the increase factor described in paragraph (3)(C), and after application of subparagraphs (C)(iii) and (D) of paragraph (3), the Secretary shall reduce such increase factor for payments for discharges occurring during such fiscal year by 2 percentage points.

(ii) SPECIAL RULE.—The application of this subparagraph may result in the increase factor described in paragraph (3)(C) being less than 0.0 for a fiscal year, and may result in payment rates under this subsection for a fiscal year being less than such payment rates for the preceding fiscal year.

(B) NONCUMULATIVE APPLICATION.—Any reduction under subparagraph (A) shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the payment amount under this subsection for a subsequent fiscal year.

(C) SUBMISSION OF QUALITY DATA.—Subject to subparagraph (G), for fiscal year 2014 and each subsequent fiscal year, each rehabilitation facility shall submit to the Secretary data on quality measures specified under subparagraph (D). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(D) QUALITY MEASURES.—

(i) IN GENERAL.—Subject to clause (ii), any measure specified by the Secretary under this subparagraph must have been endorsed by the entity with a contract under section 1890(a).

(ii) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that

is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(iii) TIME FRAME.—Not later than October 1, 2012, the Secretary shall publish the measures selected under this subparagraph that will be applicable with respect to fiscal year 2014.

(E) PUBLIC AVAILABILITY OF DATA SUBMITTED.—.—

(i) IN GENERAL.—The Secretary shall establish procedures for making data submitted under subparagraph (C) and subparagraph (F)(i) available to the public. Such procedures shall ensure that a rehabilitation facility has the opportunity to review the data that is to be made public with respect to the facility prior to such data being made public. The Secretary shall report quality measures that relate to services furnished in inpatient settings in rehabilitation facilities on the Internet website of the Centers for Medicare & Medicaid Services.

(ii) PUBLIC RECOGNITION OF REHABILITATION INNOVATION CENTERS.—Beginning not later than 18 months after the date of the enactment of this clause, the Secretary shall make publicly available on such Internet website, in addition to the information required to be reported on such website under clause (i), a list of all rehabilitation innovation centers, and shall update such list on such website not less frequently than biennially.

(iii) REHABILITATION INNOVATION CENTERS DEFINED.—For purposes of clause (ii), the term "rehabilitation innovation centers" means a rehabilitation facility that, as of the applicable date (as defined in clause (v)), is a rehabilitation facility described in clause (iv).

(iv) REHABILITATION FACILITY DESCRIBED.—

(I) IN GENERAL.—Subject to subclause (II), a rehabilitation facility described in this clause is a rehabilitation facility that—

(aa) is classified as a rehabilitation facility under the IRF Rate Setting File for the Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2019 (83 Fed. Reg. 38514), or any successor regulations that contain such information;

(bb) holds at least one Federal rehabilitation research and training designation for research projects on traumatic brain injury or spinal cord injury from the National Institute on Disability, Independent Living, and Rehabilitation Research at the Department of Health and Human Services, based on such data submitted to the Secretary by a facility, in a form, manner, and time frame specified by the Secretary;

(cc) submits to the Secretary a description of the clinical research enterprise of the facility and a summary of research activities of the facility that are supported by Federal agencies;

(dd) has a minimum Medicare estimated average weight per discharge of 1.20 for the most recent fiscal year for which such information is available according to the IRF Rate Setting File described in item (aa), or any successor regulations that contain such information; and

(ee) has a minimum teaching status of 0.075 for the most recent fiscal year for which such information is available according to the IRF Rate Setting File described in item (aa), or any successor regulations that contain such information.

(II) WAIVER.—The Secretary may, as determined appropriate, waive any of the requirements under items (aa) through (ee) of subclause (I).

(v) APPLICABLE DATE DEFINED.—For purposes of clauses (iii) and (iv), the term "applicable date" means—

(I) with respect to the initial publication of a list under clause (ii), the date of the enactment of such clause; and

(II) with respect to the publication of an updated list under clause (ii), a date specified by the Secretary that is not more than one year prior to the date of such publication.

(vi) IMPLEMENTATION.—Notwithstanding any other provision of law the Secretary may implement clauses (ii) through (v) by program instruction or otherwise.

(vii) NONAPPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to data collected under clauses (ii) through (v).

(F) SUBMISSION OF ADDITIONAL DATA.—

(i) IN GENERAL.—For the fiscal year beginning on the specified application date (as defined in subsection (a)(2)(E) of section 1899B), as applicable with respect to inpatient rehabilitation facilities and quality measures under subsection (c)(1) of such section and measures under subsection (d)(1) of such section, and each subsequent fiscal year, in addition to such data on the quality measures described in subparagraph (C), each rehabilitation facility shall submit to the Secretary data on the quality measures under such subsection (c)(1) and any necessary data specified by the Secretary under such subsection (d)(1).

(ii) STANDARDIZED PATIENT ASSESSMENT DATA.—For fiscal year 2019 and each subsequent fiscal year, in addition to such data described in clause (i), each rehabilitation facility shall submit to the Secretary

standardized patient assessment data required under subsection (b)(1) of section 1899B.

(iii) SUBMISSION.—Such data shall be submitted in the form and manner, and at the time, specified by the Secretary for purposes of this subparagraph.

(G) NON-DUPLICATION.—To the extent data submitted under subparagraph (F) duplicates other data required to be submitted under subparagraph (C), the submission of such data under subparagraph (F) shall be in lieu of the submission of such data under subparagraph (C). The previous sentence shall not apply insofar as the Secretary determines it is necessary to avoid a delay in the implementation of section 1899B, taking into account the different specified application dates under subsection (a)(2)(E) of such section.

(8) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise of the establishment of—

(A) case mix groups, of the methodology for the classification of patients within such groups, and of the appropriate weighting factors thereof under paragraph (2),

(B) the prospective payment rates under paragraph (3),

(C) outlier and special payments under paragraph (4), and

(D) area wage adjustments under paragraph (6).

(k) PAYMENT TO NONHOSPITAL PROVIDERS.—

(1) IN GENERAL.—For cost reporting periods beginning on or after October 1, 1997, the Secretary may establish rules for payment to qualified nonhospital providers for their direct costs of medical education, if those costs are incurred in the operation of an approved medical residency training program described in subsection (h). Such rules shall specify the amounts, form, and manner in which such payments will be made and the portion of such payments that will be made from each of the trust funds under this title.

(2) QUALIFIED NONHOSPITAL PROVIDERS.—For purposes of this subsection, the term "qualified nonhospital providers" means—

(A) a Federally qualified health center, as defined in section 1861(aa)(4);

(B) a rural health clinic, as defined in section 1861(aa)(2);

(C) Medicare+Choice organizations; and

(D) such other providers (other than hospitals) as the Secretary determines to be appropriate.

(l) PAYMENT FOR NURSING AND ALLIED HEALTH EDUCATION FOR MANAGED CARE ENROLLEES.—

(1) IN GENERAL.—For portions of cost reporting periods occurring in a year (beginning with 2000), the Secretary shall provide for an additional payment amount for any hospital that receives payments for the costs of approved educational activities for nurse and allied health professional training under section 1861(v)(1).

(2) PAYMENT AMOUNT.—The additional payment amount under this subsection for each hospital for portions of cost re-

porting periods occurring in a year shall be an amount specified by the Secretary in a manner consistent with the following:

(A) DETERMINATION OF MANAGED CARE ENROLLEE PAYMENT RATIO FOR GRADUATE MEDICAL EDUCATION PAYMENTS.—The Secretary shall estimate the ratio of payments for all hospitals for portions of cost reporting periods occurring in the year under subsection (h)(3)(D) to total direct graduate medical education payments estimated for such portions of periods under subsection (h)(3).

(B) APPLICATION TO FEE-FOR-SERVICE NURSING AND ALLIED HEALTH EDUCATION PAYMENTS.—

(i) IN GENERAL.—Subject to clause (ii), such ratio shall be applied to the Secretary's estimate of total payments for nursing and allied health education determined under section 1861(v) for portions of cost reporting periods occurring in the year to determine a total amount of additional payments for nursing and allied health education to be distributed to hospitals under this subsection for portions of cost reporting periods occurring in the year; except that in no case shall such total amount exceed $60,000,000 in any year.

(ii) EXCEPTION TO ANNUAL LIMITATION FOR EACH OF 2010 THROUGH 2019.—For each of 2010 through 2019, the limitation under clause (i) on the total amount of additional payments for nursing and allied health education to be distributed to hospitals under this subsection for portions of cost reporting periods occurring in the year shall not apply to such payments made in such year to those hospitals that, as of the date of the enactment of this clause, are operating a school of nursing, a school of allied health, or a school of nursing and allied health.

(C) APPLICATION TO HOSPITAL.—The amount of payment under this subsection to a hospital for portions of cost reporting periods occurring in a year is equal to the total amount of payments determined under subparagraph (B) for the year multiplied by the ratio of—

(i) the product of (I) the Secretary's estimate of the ratio of the amount of payments made under section 1861(v) to the hospital for nursing and allied health education activities for the hospital's cost reporting period ending in the second preceding fiscal year, to the hospital's total inpatient days for such period, and (II) the total number of inpatient days (as established by the Secretary) for such period which are attributable to services furnished to individuals who are enrolled under a risk sharing contract with an eligible organization under section 1876 and who are entitled to benefits under part A or who are enrolled with a Medicare+Choice organization under part C; to

(ii) the sum of the products determined under clause (i) for such cost reporting periods.

(m) PROSPECTIVE PAYMENT FOR LONG-TERM CARE HOSPITALS.—

(1) REFERENCE TO ESTABLISHMENT AND IMPLEMENTATION OF SYSTEM.—For provisions related to the establishment and implementation of a prospective payment system for payments under this title for inpatient hospital services furnished by a long-term care hospital described in subsection (d)(1)(B)(iv), see section 123 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000.

(2) UPDATE FOR RATE YEAR 2008.—In implementing the system described in paragraph (1) for discharges occurring during the rate year ending in 2008 for a hospital, the base rate for such discharges for the hospital shall be the same as the base rate for discharges for the hospital occurring during the rate year ending in 2007.

(3) IMPLEMENTATION FOR RATE YEAR 2010 AND SUBSEQUENT YEARS.—

(A) IN GENERAL.—Subject to subparagraph (C), in implementing the system described in paragraph (1) for rate year 2010 and each subsequent rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, shall be reduced—

(i) for rate year 2012 and each subsequent rate year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(ii) for each of rate years 2010 through 2019, by the other adjustment described in paragraph (4).

(B) SPECIAL RULE.—The application of this paragraph may result in such annual update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(C) ADDITIONAL SPECIAL RULE.—For fiscal year 2018, the annual update under subparagraph (A) for the fiscal year, after application of clauses (i) and (ii) of subparagraph (A), shall be 1 percent.

(4) OTHER ADJUSTMENT.—For purposes of paragraph (3)(A)(ii), the other adjustment described in this paragraph is—

(A) for rate year 2010, 0.25 percentage point;

(B) for rate year 2011, 0.50 percentage point;

(C) for each of the rate years beginning in 2012 and 2013, 0.1 percentage point;

(D) for rate year 2014, 0.3 percentage point;

(E) for each of rate years 2015 and 2016, 0.2 percentage point; and

(F) for each of rate years 2017, 2018, and 2019, 0.75 percentage point.

(5) QUALITY REPORTING.—

(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

(i) IN GENERAL.—Under the system described in paragraph (1), for rate year 2014 and each subsequent rate year, in the case of a long-term care hospital that does not submit data to the Secretary in accordance with subparagraphs (C) and (F) with respect to such a rate year, any annual update to a standard Federal

rate for discharges for the hospital during the rate year, and after application of paragraph (3), shall be reduced by 2 percentage points.

(ii) SPECIAL RULE.—The application of this subparagraph may result in such annual update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(B) NONCUMULATIVE APPLICATION.—Any reduction under subparagraph (A) shall apply only with respect to the rate year involved and the Secretary shall not take into account such reduction in computing the payment amount under the system described in paragraph (1) for a subsequent rate year.

(C) SUBMISSION OF QUALITY DATA.—Subject to subparagraph (G), for rate year 2014 and each subsequent rate year, each long-term care hospital shall submit to the Secretary data on quality measures specified under subparagraph (D). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(D) QUALITY MEASURES.—

(i) IN GENERAL.—Subject to clause (ii), any measure specified by the Secretary under this subparagraph must have been endorsed by the entity with a contract under section 1890(a).

(ii) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(iii) TIME FRAME.—Not later than October 1, 2012, the Secretary shall publish the measures selected under this subparagraph that will be applicable with respect to rate year 2014.

(iv) ADDITIONAL QUALITY MEASURES.—Not later than October 1, 2015, the Secretary shall establish a functional status quality measure for change in mobility among inpatients requiring ventilator support.

(E) PUBLIC AVAILABILITY OF DATA SUBMITTED.—The Secretary shall establish procedures for making data submitted under subparagraph (C) and subparagraph (F)(i) available to the public. Such procedures shall ensure that a long-term care hospital has the opportunity to review the data that is to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures that relate to services furnished in inpatient settings in long-term care hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(F) SUBMISSION OF ADDITIONAL DATA.—

(i) IN GENERAL.—For the rate year beginning on the specified application date (as defined in subsection (a)(2)(E) of section 1899B), as applicable with respect to long-term care hospitals and quality measures under subsection (c)(1) of such section and measures under subsection (d)(1) of such section, and each subsequent rate year, in addition to the data on the quality measures described in subparagraph (C), each long-term care hospital (other than a hospital classified under subsection (d)(1)(B)(vi)) shall submit to the Secretary data on the quality measures under such subsection (c)(1) and any necessary data specified by the Secretary under such subsection (d)(1).

(ii) STANDARDIZED PATIENT ASSESSMENT DATA.—For rate year 2019 and each subsequent rate year, in addition to such data described in clause (i), each long-term care hospital (other than a hospital classified under subsection (d)(1)(B)(vi)) shall submit to the Secretary standardized patient assessment data required under subsection (b)(1) of section 1899B.

(iii) SUBMISSION.—Such data shall be submitted in the form and manner, and at the time, specified by the Secretary for purposes of this subparagraph.

(G) NON-DUPLICATION.—To the extent data submitted under subparagraph (F) duplicates other data required to be submitted under subparagraph (C), the submission of such data under subparagraph (F) shall be in lieu of the submission of such data under subparagraph (C). The previous sentence shall not apply insofar as the Secretary determines it is necessary to avoid a delay in the implementation of section 1899B, taking into account the different specified application dates under subsection (a)(2)(E) of such section.

(6) APPLICATION OF SITE NEUTRAL IPPS PAYMENT RATE IN CERTAIN CASES.—

(A) GENERAL APPLICATION OF SITE NEUTRAL IPPS PAYMENT AMOUNT FOR DISCHARGES FAILING TO MEET APPLICABLE CRITERIA.—

(i) IN GENERAL.—For a discharge in cost reporting periods beginning on or after October 1, 2015, except as provided in clause (ii) and subparagraphs (C), (E), (F), and (G), payment under this title to a long-term care hospital for inpatient hospital services shall be made at the applicable site neutral payment rate (as defined in subparagraph (B)).

(ii) EXCEPTION FOR CERTAIN DISCHARGES MEETING CRITERIA.—Clause (i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) for a discharge if—

(I) the discharge meets the ICU criterion under clause (iii) or the ventilator criterion under clause (iv); and

(II) the discharge does not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation.

(iii) INTENSIVE CARE UNIT (ICU) CRITERION.—

(I) IN GENERAL.—The criterion specified in this clause (in this paragraph referred to as the "ICU criterion"), for a discharge from a long-term care hospital, is that the stay in the long-term care hospital ending with such discharge was immediately preceded by a discharge from a stay in a subsection (d) hospital that included at least 3 days in an intensive care unit (ICU), as determined by the Secretary.

(II) DETERMINING ICU DAYS.—In determining intensive care unit days under subclause (I), the Secretary shall use data from revenue center codes 020x or 021x (or such successor codes as the Secretary may establish).

(iv) VENTILATOR CRITERION.—The criterion specified in this clause (in this paragraph referred to as the "ventilator criterion"), for a discharge from a long-term care hospital, is that—

(I) the stay in the long-term care hospital ending with such discharge was immediately preceded by a discharge from a stay in a subsection (d) hospital; and

(II) the individual discharged was assigned to a Medicare-Severity-Long-Term-Care-Diagnosis-Related-Group (MS–LTC–DRG) based on the receipt of ventilator services of at least 96 hours.

(B) APPLICABLE SITE NEUTRAL PAYMENT RATE DEFINED.—

(i) IN GENERAL.—In this paragraph, the term "applicable site neutral payment rate" means—

(I) for discharges in cost reporting periods beginning during fiscal years 2016 through 2019, the blended payment rate specified in clause (iii); and

(II) for discharges in cost reporting periods beginning during fiscal year 2020 or a subsequent fiscal year, the site neutral payment rate (as defined in clause (ii)).

(ii) SITE NEUTRAL PAYMENT RATE DEFINED.—Subject to clause (iv), in this paragraph, the term "site neutral payment rate" means the lower of—

(I) the IPPS comparable per diem amount determined under paragraph (d)(4) of section 412.529 of title 42, Code of Federal Regulations, including any applicable outlier payments under section 412.525 of such title; or

(II) 100 percent of the estimated cost for the services involved.

(iii) BLENDED PAYMENT RATE.—The blended payment rate specified in this clause, for a long-term care hospital for inpatient hospital services for a discharge, is comprised of—

(I) half of the site neutral payment rate (as defined in clause (ii)) for the discharge; and

(II) half of the payment rate that would otherwise be applicable to such discharge without regard to this paragraph, as determined by the Secretary.

(iv) ADJUSTMENT.—For each of fiscal years 2018 through 2026, the amount that would otherwise apply under clause (ii)(I) for the year (determined without regard to this clause) shall be reduced by 4.6 percent.

(C) LIMITING PAYMENT FOR ALL HOSPITAL DISCHARGES TO SITE NEUTRAL PAYMENT RATE FOR HOSPITALS FAILING TO MEET APPLICABLE LTCH DISCHARGE THRESHOLDS.—

(i) NOTICE OF LTCH DISCHARGE PAYMENT PERCENTAGE.—For cost reporting periods beginning during or after fiscal year 2016, the Secretary shall inform each long-term care hospital of its LTCH discharge payment percentage (as defined in clause (iv)) for such period.

(ii) LIMITATION.—For cost reporting periods beginning during or after fiscal year 2020, if the Secretary determines for a long-term care hospital that its LTCH discharge payment percentage for the period is not at least 50 percent—

(I) the Secretary shall inform the hospital of such fact; and

(II) subject to clause (iii), for all discharges in the hospital in each succeeding cost reporting period, the payment amount under this subsection shall be the payment amount that would apply under subsection (d) for the discharge if the hospital were a subsection (d) hospital.

(iii) PROCESS FOR REINSTATEMENT.—The Secretary shall establish a process whereby a long-term care hospital may seek to and have the provisions of subclause (II) of clause (ii) discontinued with respect to that hospital.

(iv) LTCH DISCHARGE PAYMENT PERCENTAGE.—In this subparagraph, the term "LTCH discharge payment percentage" means, with respect to a long-term care hospital for a cost reporting period beginning during or after fiscal year 2020, the ratio (expressed as a percentage) of—

(I) the number of Medicare fee-for-service discharges for such hospital and period for which payment is not made at the site neutral payment rate, to

(II) the total number of Medicare fee-for-service discharges for such hospital and period.

(D) INCLUSION OF SUBSECTION (d) PUERTO RICO HOSPITALS.—In this paragraph, any reference in this paragraph to a subsection (d) hospital shall be deemed to include a reference to a subsection (d) Puerto Rico hospital.

(E) TEMPORARY EXCEPTION FOR CERTAIN SEVERE WOUND DISCHARGES FROM CERTAIN LONG-TERM CARE HOSPITALS.—

(i) IN GENERAL.—In the case of a discharge occurring prior to January 1, 2017, subparagraph (A)(i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) if such discharge—

(I) is from a long-term care hospital that is—

(aa) identified by the last sentence of subsection (d)(1)(B); and

(bb) located in a rural area (as defined in subsection (d)(2)(D)) or treated as being so located pursuant to subsection (d)(8)(E); and

(II) the individual discharged has a severe wound.

(ii) SEVERE WOUND DEFINED.—In this subparagraph, the term "severe wound" means a stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, infected wound, fistula, osteomyelitis, or wound with morbid obesity, as identified in the claim from the long-term care hospital.

(F) TEMPORARY EXCEPTION FOR CERTAIN SPINAL CORD SPECIALTY HOSPITALS.—For discharges in cost reporting periods beginning during fiscal years 2018 and 2019, subparagraph (A)(i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) if such discharge is from a long-term care hospital that meets each of the following requirements:

(i) NOT-FOR-PROFIT.—The long-term care hospital was a not-for-profit long-term care hospital on June 1, 2014, as determined by cost report data.

(ii) PRIMARILY PROVIDING TREATMENT FOR CATASTROPHIC SPINAL CORD OR ACQUIRED BRAIN INJURIES OR OTHER PARALYZING NEUROMUSCULAR CONDITIONS.—Of the discharges in calendar year 2013 from the long-term care hospital for which payment was made under this section, at least 50 percent were classified under MS–LTCH–DRGs 28, 29, 52, 57, 551, 573, and 963.

(iii) SIGNIFICANT OUT-OF-STATE ADMISSIONS.—

(I) IN GENERAL.—The long-term care hospital discharged inpatients (including both individuals entitled to, or enrolled for, benefits under this title and individuals not so entitled or enrolled) during fiscal year 2014 who had been admitted from at least 20 of the 50 States, determined by the States of residency of such inpatients and based on such data submitted by the hospital to the Secretary as the Secretary may require.

(II) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement subclause (I) by program instruction or otherwise.

(III) NON-APPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to data collected under this clause.

(G) ADDITIONAL TEMPORARY EXCEPTION FOR CERTAIN SEVERE WOUND DISCHARGES FROM CERTAIN LONG-TERM CARE HOSPITALS.—

(i) IN GENERAL.—For a discharge occurring in a cost reporting period beginning during fiscal year 2018, subparagraph (A)(i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) if such discharge—

(I) is from a long-term care hospital identified by the last sentence of subsection (d)(1)(B);

(II) is classified under MS–LTCH–DRG 602, 603, 539, or 540; and

(III) is with respect to an individual treated by a long-term care hospital for a severe wound.

(ii) SEVERE WOUND DEFINED.—In this subparagraph, the term "severe wound" means a wound which is a stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, or fistula as identified in the claim from the long-term care hospital.

(iii) WOUND DEFINED.—In this subparagraph, the term "wound" means an injury involving division of tissue or rupture of the integument or mucous membrane with exposure to the external environment.

(7) TREATMENT OF HIGH COST OUTLIER PAYMENTS.—

(A) ADJUSTMENT TO THE STANDARD FEDERAL PAYMENT RATE FOR ESTIMATED HIGH COST OUTLIER PAYMENTS.—Under the system described in paragraph (1), for fiscal years beginning on or after October 1, 2017, the Secretary shall reduce the standard Federal payment rate as if the estimated aggregate amount of high cost outlier payments for standard Federal payment rate discharges for each such fiscal year would be equal to 8 percent of estimated aggregate payments for standard Federal payment rate discharges for each such fiscal year.

(B) LIMITATION ON HIGH COST OUTLIER PAYMENT AMOUNTS.—Notwithstanding subparagraph (A), the Secretary shall set the fixed loss amount for high cost outlier payments such that the estimated aggregate amount of high cost outlier payments made for standard Federal payment rate discharges for fiscal years beginning on or after October 1, 2017, shall be equal to 99.6875 percent of 8 percent of estimated aggregate payments for standard Federal payment rate discharges for each such fiscal year.

(C) WAIVER OF BUDGET NEUTRALITY.—Any reduction in payments resulting from the application of subparagraph (B) shall not be taken into account in applying any budget neutrality provision under such system.

(D) NO EFFECT ON SITE NEUTRAL HIGH COST OUTLIER PAYMENT RATE.—This paragraph shall not apply with respect to the computation of the applicable site neutral payment rate under paragraph (6).

(n) INCENTIVES FOR ADOPTION AND MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—

(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, with respect to inpatient hospital services fur-

nished by an eligible hospital during a payment year (as defined in paragraph (2)(G)), if the eligible hospital is a meaningful EHR user (as determined under paragraph (3)) for the EHR reporting period with respect to such year, in addition to the amount otherwise paid under this section, there also shall be paid to the eligible hospital, from the Federal Hospital Insurance Trust Fund established under section 1817, an amount equal to the applicable amount specified in paragraph (2)(A) for the hospital for such payment year.

(2) PAYMENT AMOUNT.—

(A) IN GENERAL.—Subject to the succeeding subparagraphs of this paragraph, the applicable amount specified in this subparagraph for an eligible hospital for a payment year is equal to the product of the following:

(i) INITIAL AMOUNT.—The sum of—

(I) the base amount specified in subparagraph (B); plus

(II) the discharge related amount specified in subparagraph (C) for a 12-month period selected by the Secretary with respect to such payment year.

(ii) MEDICARE SHARE.—The Medicare share as specified in subparagraph (D) for the eligible hospital for a period selected by the Secretary with respect to such payment year.

(iii) TRANSITION FACTOR.—The transition factor specified in subparagraph (E) for the eligible hospital for the payment year.

(B) BASE AMOUNT.—The base amount specified in this subparagraph is $2,000,000.

(C) DISCHARGE RELATED AMOUNT.—The discharge related amount specified in this subparagraph for a 12-month period selected by the Secretary shall be determined as the sum of the amount, estimated based upon total discharges for the eligible hospital (regardless of any source of payment) for the period, for each discharge up to the 23,000th discharge as follows:

(i) For the first through 1,149th discharge, $0.

(ii) For the 1,150th through the 23,000th discharge, $200.

(iii) For any discharge greater than the 23,000th, $0.

(D) MEDICARE SHARE.—The Medicare share specified under this subparagraph for an eligible hospital for a period selected by the Secretary for a payment year is equal to the fraction—

(i) the numerator of which is the sum (for such period and with respect to the eligible hospital) of—

(I) the estimated number of inpatient-bed-days (as established by the Secretary) which are attributable to individuals with respect to whom payment may be made under part A; and

(II) the estimated number of inpatient-bed-days (as so established) which are attributable to individuals who are enrolled with a Medicare Advantage organization under part C; and

(ii) the denominator of which is the product of—

(I) the estimated total number of inpatient-bed-days with respect to the eligible hospital during such period; and

(II) the estimated total amount of the eligible hospital's charges during such period, not including any charges that are attributable to charity care (as such term is used for purposes of hospital cost reporting under this title), divided by the estimated total amount of the hospital's charges during such period.

Insofar as the Secretary determines that data are not available on charity care necessary to calculate the portion of the formula specified in clause (ii)(II), the Secretary shall use data on uncompensated care and may adjust such data so as to be an appropriate proxy for charity care including a downward adjustment to eliminate bad debt data from uncompensated care data. In the absence of the data necessary, with respect to a hospital, for the Secretary to compute the amount described in clause (ii)(II), the amount under such clause shall be deemed to be 1. In the absence of data, with respect to a hospital, necessary to compute the amount described in clause (i)(II), the amount under such clause shall be deemed to be 0.

(E) TRANSITION FACTOR SPECIFIED.—

(i) IN GENERAL.—Subject to clause (ii), the transition factor specified in this subparagraph for an eligible hospital for a payment year is as follows:

(I) For the first payment year for such hospital, 1.

(II) For the second payment year for such hospital, ¾.

(III) For the third payment year for such hospital, ½.

(IV) For the fourth payment year for such hospital, ¼.

(V) For any succeeding payment year for such hospital, 0.

(ii) PHASE DOWN FOR ELIGIBLE HOSPITALS FIRST ADOPTING EHR AFTER 2013.—If the first payment year for an eligible hospital is after 2013, then the transition factor specified in this subparagraph for a payment year for such hospital is the same as the amount specified in clause (i) for such payment year for an eligible hospital for which the first payment year is 2013. If the first payment year for an eligible hospital is after 2015 then the transition factor specified in this subparagraph for such hospital and for such year and any subsequent year shall be 0.

(F) FORM OF PAYMENT.—The payment under this subsection for a payment year may be in the form of a single consolidated payment or in the form of such periodic installments as the Secretary may specify.

(G) PAYMENT YEAR DEFINED.—

(i) IN GENERAL.—For purposes of this subsection, the term "payment year" means a fiscal year beginning with fiscal year 2011.

(ii) FIRST, SECOND, ETC. PAYMENT YEAR.—The term "first payment year" means, with respect to inpatient hospital services furnished by an eligible hospital, the first fiscal year for which an incentive payment is made for such services under this subsection. The terms "second payment year", "third payment year", and "fourth payment year" mean, with respect to an eligible hospital, each successive year immediately following the first payment year for that hospital.

(3) MEANINGFUL EHR USER.—

(A) IN GENERAL.—For purposes of paragraph (1), an eligible hospital shall be treated as a meaningful EHR user for an EHR reporting period for a payment year (or, for purposes of subsection (b)(3)(B)(ix), for an EHR reporting period under such subsection for a fiscal year) if each of the following requirements are met:

(i) MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—The eligible hospital demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period the hospital is using certified EHR technology in a meaningful manner.

(ii) INFORMATION EXCHANGE.—The eligible hospital demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period such certified EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination, and the hospital demonstrates (through a process specified by the Secretary, such as the use of an attestation) that the hospital has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the certified EHR technology.

(iii) REPORTING ON MEASURES USING EHR.—Subject to subparagraph (B)(ii) and using such certified EHR technology, the eligible hospital submits information for such period, in a form and manner specified by the Secretary, on such clinical quality measures and such other measures as selected by the Secretary under subparagraph (B)(i).

The Secretary shall seek to improve the use of electronic health records and health care quality over time.

(B) REPORTING ON MEASURES.—

(i) SELECTION.—The Secretary shall select measures for purposes of subparagraph (A)(iii) but only consistent with the following:

(I) The Secretary shall provide preference to clinical quality measures that have been selected for purposes of applying subsection (b)(3)(B)(viii)

or that have been endorsed by the entity with a contract with the Secretary under section 1890(a).

(II) Prior to any measure (other than a clinical quality measure that has been selected for purposes of applying subsection (b)(3)(B)(viii)) being selected under this subparagraph, the Secretary shall publish in the Federal Register such measure and provide for a period of public comment on such measure.

(ii) LIMITATIONS.—The Secretary may not require the electronic reporting of information on clinical quality measures under subparagraph (A)(iii) unless the Secretary has the capacity to accept the information electronically, which may be on a pilot basis.

(iii) COORDINATION OF REPORTING OF INFORMATION.—In selecting such measures, and in establishing the form and manner for reporting measures under subparagraph (A)(iii), the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under subsection (b)(3)(B)(viii).

(C) DEMONSTRATION OF MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY AND INFORMATION EXCHANGE.—

(i) IN GENERAL.—An eligible hospital may satisfy the demonstration requirement of clauses (i) and (ii) of subparagraph (A) through means specified by the Secretary, which may include—

(I) an attestation;

(II) the submission of claims with appropriate coding (such as a code indicating that inpatient care was documented using certified EHR technology);

(III) a survey response;

(IV) reporting under subparagraph (A)(iii); and

(V) other means specified by the Secretary.

(ii) USE OF PART D DATA.—Notwithstanding sections 1860D–15(d)(2)(B) and 1860D–15(f)(2), the Secretary may use data regarding drug claims submitted for purposes of section 1860D–15 that are necessary for purposes of subparagraph (A).

(4) APPLICATION.—

(A) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

(i) the methodology and standards for determining payment amounts under this subsection and payment adjustments under subsection (b)(3)(B)(ix), including selection of periods under paragraph (2) for determining, and making estimates or using proxies of, discharges under paragraph (2)(C) and inpatient-bed-days, hospital charges, charity charges, and Medicare share under paragraph (2)(D);

(ii) the methodology and standards for determining a meaningful EHR user under paragraph (3), including selection of measures under paragraph (3)(B),

specification of the means of demonstrating meaningful EHR use under paragraph (3)(C), and the hardship exception under subsection (b)(3)(B)(ix)(II); and

(iii) the specification of EHR reporting periods under paragraph (6)(B) and the selection of the form of payment under paragraph (2)(F).

(B) POSTING ON WEBSITE.—The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format, a list of the names of the eligible hospitals that are meaningful EHR users under this subsection or subsection (b)(3)(B)(ix) (and a list of the names of critical access hospitals to which paragraph (3) or (4) of section 1814(l) applies), and other relevant data as determined appropriate by the Secretary. The Secretary shall ensure that an eligible hospital (or critical access hospital) has the opportunity to review the other relevant data that are to be made public with respect to the hospital (or critical access hospital) prior to such data being made public.

(5) CERTIFIED EHR TECHNOLOGY DEFINED.—The term "certified EHR technology" has the meaning given such term in section 1848(o)(4).

(6) DEFINITIONS.—For purposes of this subsection:

(A) EHR REPORTING PERIOD.—The term "EHR reporting period" means, with respect to a payment year, any period (or periods) as specified by the Secretary.

(B) ELIGIBLE HOSPITAL.—The term "eligible hospital" means a hospital that is a subsection (d) hospital or a subsection (d) Puerto Rico hospital.

(o) HOSPITAL VALUE-BASED PURCHASING PROGRAM.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, the Secretary shall establish a hospital value-based purchasing program (in this subsection referred to as the "Program") under which value-based incentive payments are made in a fiscal year to hospitals that meet the performance standards under paragraph (3) for the performance period for such fiscal year (as established under paragraph (4)).

(B) PROGRAM TO BEGIN IN FISCAL YEAR 2013.—The Program shall apply to payments for discharges occurring on or after October 1, 2012.

(C) APPLICABILITY OF PROGRAM TO HOSPITALS.—

(i) IN GENERAL.—For purposes of this subsection, subject to clause (ii), the term "hospital" means a subsection (d) hospital (as defined in subsection (d)(1)(B)).

(ii) EXCLUSIONS.—The term "hospital" shall not include, with respect to a fiscal year, a hospital—

(I) that is subject to the payment reduction under subsection (b)(3)(B)(viii)(I) for such fiscal year;

(II) for which, during the performance period for such fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients;

(III) for which there are not a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for such fiscal year; or

(IV) for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for such fiscal year.

(iii) INDEPENDENT ANALYSIS.—For purposes of determining the minimum numbers under subclauses (III) and (IV) of clause (ii), the Secretary shall have conducted an independent analysis of what numbers are appropriate.

(iv) EXEMPTION.—In the case of a hospital that is paid under section 1814(b)(3), the Secretary may exempt such hospital from the application of this subsection if the State which is paid under such section submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under this subsection.

(2) MEASURES.—

(A) IN GENERAL.—The Secretary shall select measures, other than measures of readmissions, for purposes of the Program. Such measures shall be selected from the measures specified under subsection (b)(3)(B)(viii).

(B) REQUIREMENTS.—

(i) FOR FISCAL YEAR 2013.—For value-based incentive payments made with respect to discharges occurring during fiscal year 2013, the Secretary shall ensure the following:

(I) CONDITIONS OR PROCEDURES.—Measures are selected under subparagraph (A) that cover at least the following 5 specific conditions or procedures:

(aa) Acute myocardial infarction (AMI).

(bb) Heart failure.

(cc) Pneumonia.

(dd) Surgeries, as measured by the Surgical Care Improvement Project (formerly referred to as "Surgical Infection Prevention" for discharges occurring before July 2006).

(ee) Healthcare-associated infections, as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent Healthcare-Associated Infections (or any successor plan) of the Department of Health and Human Services.

(II) HCAHPS.—Measures selected under subparagraph (A) shall be related to the Hospital Consumer Assessment of Healthcare Providers and Systems survey (HCAHPS).

(ii) INCLUSION OF EFFICIENCY MEASURES.—For value-based incentive payments made with respect to dis-

charges occurring during fiscal year 2014 or a subsequent fiscal year, the Secretary shall ensure that measures selected under subparagraph (A) include efficiency measures, including measures of "Medicare spending per beneficiary". Such measures shall be adjusted for factors such as age, sex, race, severity of illness, and other factors that the Secretary determines appropriate.

(iii) HCAHPS PAIN QUESTIONS.—The Secretary may not include under subparagraph (A) a measure that is based on the questions appearing on the Hospital Consumer Assessment of Healthcare Providers and Systems survey in 2018 or 2019 about communication by hospital staff with an individual about the individual's pain.

(C) LIMITATIONS.—

(i) TIME REQUIREMENT FOR PRIOR REPORTING AND NOTICE.—The Secretary may not select a measure under subparagraph (A) for use under the Program with respect to a performance period for a fiscal year (as established under paragraph (4)) unless such measure has been specified under subsection (b)(3)(B)(viii) and included on the Hospital Compare Internet website for at least 1 year prior to the beginning of such performance period.

(ii) MEASURE NOT APPLICABLE UNLESS HOSPITAL FURNISHES SERVICES APPROPRIATE TO THE MEASURE.—A measure selected under subparagraph (A) shall not apply to a hospital if such hospital does not furnish services appropriate to such measure.

(D) REPLACING MEASURES.—Subclause (VI) of subsection (b)(3)(B)(viii) shall apply to measures selected under subparagraph (A) in the same manner as such subclause applies to measures selected under such subsection.

(3) PERFORMANCE STANDARDS.—

(A) ESTABLISHMENT.—The Secretary shall establish performance standards with respect to measures selected under paragraph (2) for a performance period for a fiscal year (as established under paragraph (4)).

(B) ACHIEVEMENT AND IMPROVEMENT.—The performance standards established under subparagraph (A) shall include levels of achievement and improvement.

(C) TIMING.—The Secretary shall establish and announce the performance standards under subparagraph (A) not later than 60 days prior to the beginning of the performance period for the fiscal year involved.

(D) CONSIDERATIONS IN ESTABLISHING STANDARDS.—In establishing performance standards with respect to measures under this paragraph, the Secretary shall take into account appropriate factors, such as—

(i) practical experience with the measures involved, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods;

(ii) historical performance standards;

(iii) improvement rates; and

(iv) the opportunity for continued improvement.

(4) PERFORMANCE PERIOD.—For purposes of the Program, the Secretary shall establish the performance period for a fiscal year. Such performance period shall begin and end prior to the beginning of such fiscal year.

(5) HOSPITAL PERFORMANCE SCORE.—

(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall develop a methodology for assessing the total performance of each hospital based on performance standards with respect to the measures selected under paragraph (2) for a performance period (as established under paragraph (4)). Using such methodology, the Secretary shall provide for an assessment (in this subsection referred to as the "hospital performance score") for each hospital for each performance period.

(B) APPLICATION.—

(i) APPROPRIATE DISTRIBUTION.—The Secretary shall ensure that the application of the methodology developed under subparagraph (A) results in an appropriate distribution of value-based incentive payments under paragraph (6) among hospitals achieving different levels of hospital performance scores, with hospitals achieving the highest hospital performance scores receiving the largest value-based incentive payments.

(ii) HIGHER OF ACHIEVEMENT OR IMPROVEMENT.—The methodology developed under subparagraph (A) shall provide that the hospital performance score is determined using the higher of its achievement or improvement score for each measure.

(iii) WEIGHTS.—The methodology developed under subparagraph (A) shall provide for the assignment of weights for categories of measures as the Secretary determines appropriate.

(iv) NO MINIMUM PERFORMANCE STANDARD.—The Secretary shall not set a minimum performance standard in determining the hospital performance score for any hospital.

(v) REFLECTION OF MEASURES APPLICABLE TO THE HOSPITAL.—The hospital performance score for a hospital shall reflect the measures that apply to the hospital.

(6) CALCULATION OF VALUE-BASED INCENTIVE PAYMENTS.—

(A) IN GENERAL.—In the case of a hospital that the Secretary determines meets (or exceeds) the performance standards under paragraph (3) for the performance period for a fiscal year (as established under paragraph (4)), the Secretary shall increase the base operating DRG payment amount (as defined in paragraph (7)(D)), as determined after application of paragraph (7)(B)(i), for a hospital for each discharge occurring in such fiscal year by the value-based incentive payment amount.

(B) VALUE-BASED INCENTIVE PAYMENT AMOUNT.—The value-based incentive payment amount for each discharge

of a hospital in a fiscal year shall be equal to the product of—

(i) the base operating DRG payment amount (as defined in paragraph (7)(D)) for the discharge for the hospital for such fiscal year; and

(ii) the value-based incentive payment percentage specified under subparagraph (C) for the hospital for such fiscal year.

(C) VALUE-BASED INCENTIVE PAYMENT PERCENTAGE.—

(i) IN GENERAL.—The Secretary shall specify a value-based incentive payment percentage for a hospital for a fiscal year.

(ii) REQUIREMENTS.—In specifying the value-based incentive payment percentage for each hospital for a fiscal year under clause (i), the Secretary shall ensure that—

(I) such percentage is based on the hospital performance score of the hospital under paragraph (5); and

(II) the total amount of value-based incentive payments under this paragraph to all hospitals in such fiscal year is equal to the total amount available for value-based incentive payments for such fiscal year under paragraph (7)(A), as estimated by the Secretary.

(7) FUNDING FOR VALUE-BASED INCENTIVE PAYMENTS.—

(A) AMOUNT.—The total amount available for value-based incentive payments under paragraph (6) for all hospitals for a fiscal year shall be equal to the total amount of reduced payments for all hospitals under subparagraph (B) for such fiscal year, as estimated by the Secretary.

(B) ADJUSTMENT TO PAYMENTS.—

(i) IN GENERAL.—The Secretary shall reduce the base operating DRG payment amount (as defined in subparagraph (D)) for a hospital for each discharge in a fiscal year (beginning with fiscal year 2013) by an amount equal to the applicable percent (as defined in subparagraph (C)) of the base operating DRG payment amount for the discharge for the hospital for such fiscal year. The Secretary shall make such reductions for all hospitals in the fiscal year involved, regardless of whether or not the hospital has been determined by the Secretary to have earned a value-based incentive payment under paragraph (6) for such fiscal year.

(ii) NO EFFECT ON OTHER PAYMENTS.—Payments described in items (aa) and (bb) of subparagraph (D)(i)(II) for a hospital shall be determined as if this subsection had not been enacted.

(C) APPLICABLE PERCENT DEFINED.—For purposes of subparagraph (B), the term "applicable percent" means—

(i) with respect to fiscal year 2013, 1.0 percent;

(ii) with respect to fiscal year 2014, 1.25 percent;

(iii) with respect to fiscal year 2015, 1.5 percent;

(iv) with respect to fiscal year 2016, 1.75 percent; and

(v) with respect to fiscal year 2017 and succeeding fiscal years, 2 percent.

(D) BASE OPERATING DRG PAYMENT AMOUNT DEFINED.—

(i) IN GENERAL.—Except as provided in clause (ii), in this subsection, the term "base operating DRG payment amount" means, with respect to a hospital for a fiscal year—

(I) the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (q)) for a discharge if this subsection did not apply; reduced by

(II) any portion of such payment amount that is attributable to—

(aa) payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d); and

(bb) such other payments under subsection (d) determined appropriate by the Secretary.

(ii) SPECIAL RULES FOR CERTAIN HOSPITALS.—

(I) SOLE COMMUNITY HOSPITALS AND MEDICARE-DEPENDENT, SMALL RURAL HOSPITALS.—In the case of a medicare-dependent, small rural hospital (with respect to discharges occurring during fiscal year 2012 and 2013) or a sole community hospital, in applying subparagraph (A)(i), the payment amount that would otherwise be made under subsection (d) shall be determined without regard to subparagraphs (I) and (L) of subsection (b)(3) and subparagraphs (D) and (G) of subsection (d)(5).

(II) HOSPITALS PAID UNDER SECTION 1814.—In the case of a hospital that is paid under section 1814(b)(3), the term "base operating DRG payment amount" means the payment amount under such section.

(8) ANNOUNCEMENT OF NET RESULT OF ADJUSTMENTS.—Under the Program, the Secretary shall, not later than 60 days prior to the fiscal year involved, inform each hospital of the adjustments to payments to the hospital for discharges occurring in such fiscal year under paragraphs (6) and (7)(B)(i).

(9) NO EFFECT IN SUBSEQUENT FISCAL YEARS.—The value-based incentive payment under paragraph (6) and the payment reduction under paragraph (7)(B)(i) shall each apply only with respect to the fiscal year involved, and the Secretary shall not take into account such value-based incentive payment or payment reduction in making payments to a hospital under this section in a subsequent fiscal year.

(10) PUBLIC REPORTING.—

(A) HOSPITAL SPECIFIC INFORMATION.—

(i) IN GENERAL.—The Secretary shall make information available to the public regarding the performance of individual hospitals under the Program, including—

(I) the performance of the hospital with respect to each measure that applies to the hospital;

(II) the performance of the hospital with respect to each condition or procedure; and

(III) the hospital performance score assessing the total performance of the hospital.

(ii) OPPORTUNITY TO REVIEW AND SUBMIT CORRECTIONS.—The Secretary shall ensure that a hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to the hospital under clause (i) prior to such information being made public.

(iii) WEBSITE.—Such information shall be posted on the Hospital Compare Internet website in an easily understandable format.

(B) AGGREGATE INFORMATION.—The Secretary shall periodically post on the Hospital Compare Internet website aggregate information on the Program, including—

(i) the number of hospitals receiving value-based incentive payments under paragraph (6) and the range and total amount of such value-based incentive payments; and

(ii) the number of hospitals receiving less than the maximum value-based incentive payment available to the hospital for the fiscal year involved and the range and amount of such payments.

(11) IMPLEMENTATION.—

(A) APPEALS.—The Secretary shall establish a process by which hospitals may appeal the calculation of a hospital's performance assessment with respect to the performance standards established under paragraph (3)(A) and the hospital performance score under paragraph (5). The Secretary shall ensure that such process provides for resolution of such appeals in a timely manner.

(B) LIMITATION ON REVIEW.—Except as provided in subparagraph (A), there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(i) The methodology used to determine the amount of the value-based incentive payment under paragraph (6) and the determination of such amount.

(ii) The determination of the amount of funding available for such value-based incentive payments under paragraph (7)(A) and the payment reduction under paragraph (7)(B)(i).

(iii) The establishment of the performance standards under paragraph (3) and the performance period under paragraph (4).

(iv) The measures specified under subsection (b)(3)(B)(viii) and the measures selected under paragraph (2).

(v) The methodology developed under paragraph (5) that is used to calculate hospital performance scores and the calculation of such scores.

(vi) The validation methodology specified in subsection (b)(3)(B)(viii)(XI).

(C) CONSULTATION WITH SMALL HOSPITALS.—The Secretary shall consult with small rural and urban hospitals on the application of the Program to such hospitals.

(12) PROMULGATION OF REGULATIONS.—The Secretary shall promulgate regulations to carry out the Program, including the selection of measures under paragraph (2), the methodology developed under paragraph (5) that is used to calculate hospital performance scores, and the methodology used to determine the amount of value-based incentive payments under paragraph (6).

(p) ADJUSTMENT TO HOSPITAL PAYMENTS FOR HOSPITAL ACQUIRED CONDITIONS.—

(1) IN GENERAL.—In order to provide an incentive for applicable hospitals to reduce hospital acquired conditions under this title, with respect to discharges from an applicable hospital occurring during fiscal year 2015 or a subsequent fiscal year, the amount of payment under this section or section 1814(b)(3), as applicable, for such discharges during the fiscal year shall be equal to 99 percent of the amount of payment that would otherwise apply to such discharges under this section or section 1814(b)(3) (determined after the application of subsections (o) and (q) and section 1814(l)(4) but without regard to this subsection).

(2) APPLICABLE HOSPITALS.—

(A) IN GENERAL.—For purposes of this subsection, the term "applicable hospital" means a subsection (d) hospital that meets the criteria described in subparagraph (B).

(B) CRITERIA DESCRIBED.—

(i) IN GENERAL.—The criteria described in this subparagraph, with respect to a subsection (d) hospital, is that the subsection (d) hospital is in the top quartile of all subsection (d) hospitals, relative to the national average, of hospital acquired conditions during the applicable period, as determined by the Secretary.

(ii) RISK ADJUSTMENT.—In carrying out clause (i), the Secretary shall establish and apply an appropriate risk adjustment methodology.

(C) EXEMPTION.—In the case of a hospital that is paid under section 1814(b)(3), the Secretary may exempt such hospital from the application of this subsection if the State which is paid under such section submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under this subsection.

(3) HOSPITAL ACQUIRED CONDITIONS.—For purposes of this subsection, the term "hospital acquired condition" means a condition identified for purposes of subsection (d)(4)(D)(iv) and any other condition determined appropriate by the Secretary that an individual acquires during a stay in an applicable hospital, as determined by the Secretary.

(4) APPLICABLE PERIOD.—In this subsection, the term "applicable period" means, with respect to a fiscal year, a period specified by the Secretary.

(5) REPORTING TO HOSPITALS.—Prior to fiscal year 2015 and each subsequent fiscal year, the Secretary shall provide confidential reports to applicable hospitals with respect to hospital

acquired conditions of the applicable hospital during the applicable period.

(6) REPORTING HOSPITAL SPECIFIC INFORMATION.—

(A) IN GENERAL.—The Secretary shall make information available to the public regarding hospital acquired conditions of each applicable hospital.

(B) OPPORTUNITY TO REVIEW AND SUBMIT CORRECTIONS.—The Secretary shall ensure that an applicable hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to the hospital under subparagraph (A) prior to such information being made public.

(C) WEBSITE.—Such information shall be posted on the Hospital Compare Internet website in an easily understandable format.

(7) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(A) The criteria described in paragraph (2)(A).

(B) The specification of hospital acquired conditions under paragraph (3).

(C) The specification of the applicable period under paragraph (4).

(D) The provision of reports to applicable hospitals under paragraph (5) and the information made available to the public under paragraph (6).

(q) HOSPITAL READMISSIONS REDUCTION PROGRAM.—

(1) IN GENERAL.—With respect to payment for discharges from an applicable hospital (as defined in paragraph (5)(C)) occurring during a fiscal year beginning on or after October 1, 2012, in order to account for excess readmissions in the hospital, the Secretary shall make payments (in addition to the payments described in paragraph (2)(A)(ii)) for such a discharge to such hospital under subsection (d) (or section 1814(b)(3), as the case may be) in an amount equal to the product of—

(A) the base operating DRG payment amount (as defined in paragraph (2)) for the discharge; and

(B) the adjustment factor (described in paragraph (3)(A)) for the hospital for the fiscal year.

(2) BASE OPERATING DRG PAYMENT AMOUNT DEFINED.—

(A) IN GENERAL.—Except as provided in subparagraph (B), in this subsection, the term "base operating DRG payment amount" means, with respect to a hospital for a fiscal year—

(i) the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (o)) for a discharge if this subsection did not apply; reduced by

(ii) any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d).

(B) SPECIAL RULES FOR CERTAIN HOSPITALS.—

(i) SOLE COMMUNITY HOSPITALS AND MEDICARE-DEPENDENT, SMALL RURAL HOSPITALS.—In the case of a

medicare-dependent, small rural hospital (with respect to discharges occurring during fiscal years 2012 and 2013) or a sole community hospital, in applying subparagraph (A)(i), the payment amount that would otherwise be made under subsection (d) shall be determined without regard to subparagraphs (I) and (L) of subsection (b)(3) and subparagraphs (D) and (G) of subsection (d)(5).

(ii) HOSPITALS PAID UNDER SECTION 1814.—In the case of a hospital that is paid under section 1814(b)(3), the Secretary may exempt such hospitals provided that States paid under such section submit an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established herein with respect to this section.

(3) ADJUSTMENT FACTOR.—

(A) IN GENERAL.—For purposes of paragraph (1), subject to subparagraph (D), the adjustment factor under this paragraph for an applicable hospital for a fiscal year is equal to the greater of—

(i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or

(ii) the floor adjustment factor specified in subparagraph (C).

(B) RATIO.—The ratio described in this subparagraph for a hospital for an applicable period is equal to 1 minus the ratio of—

(i) the aggregate payments for excess readmissions (as defined in paragraph (4)(A)) with respect to an applicable hospital for the applicable period; and

(ii) the aggregate payments for all discharges (as defined in paragraph (4)(B)) with respect to such applicable hospital for such applicable period.

(C) FLOOR ADJUSTMENT FACTOR.—For purposes of subparagraph (A), the floor adjustment factor specified in this subparagraph for—

(i) fiscal year 2013 is 0.99;

(ii) fiscal year 2014 is 0.98; or

(iii) fiscal year 2015 and subsequent fiscal years is 0.97.

(D) TRANSITIONAL ADJUSTMENT FOR DUAL ELIGIBLES.—

(i) IN GENERAL.—In determining a hospital's adjustment factor under this paragraph for purposes of making payments for discharges occurring during and after fiscal year 2019, and before the application of clause (i) of subparagraph (E), the Secretary shall assign hospitals to groups (as defined by the Secretary under clause (ii)) and apply the applicable provisions of this subsection using a methodology in a manner that allows for separate comparison of hospitals within each such group, as determined by the Secretary.

(ii) DEFINING GROUPS.—For purposes of this subparagraph, the Secretary shall define groups of hospitals, based on their overall proportion, of the inpatients who are entitled to, or enrolled for, benefits under part A, and who are full-benefit dual eligible individuals (as defined in section 1935(c)(6)). In defining groups, the Secretary shall consult the Medicare Payment Advisory Commission and may consider the analysis done by such Commission in preparing the portion of its report submitted to Congress in June 2013 relating to readmissions.

(iii) MINIMIZING REPORTING BURDEN ON HOSPITALS.—In carrying out this subparagraph, the Secretary shall not impose any additional reporting requirements on hospitals.

(iv) BUDGET NEUTRAL DESIGN METHODOLOGY.—The Secretary shall design the methodology to implement this subparagraph so that the estimated total amount of reductions in payments under this subsection equals the estimated total amount of reductions in payments that would otherwise occur under this subsection if this subparagraph did not apply.

(E) CHANGES IN RISK ADJUSTMENT.—

(i) CONSIDERATION OF RECOMMENDATIONS IN IMPACT REPORTS.—The Secretary may take into account the studies conducted and the recommendations made by the Secretary under section 2(d)(1) of the IMPACT Act of 2014 (Public Law 113–185; 42 U.S.C. 1395lll note) with respect to the application under this subsection of risk adjustment methodologies. Nothing in this clause shall be construed as precluding consideration of the use of groupings of hospitals.

(ii) CONSIDERATION OF EXCLUSION OF PATIENT CASES BASED ON V OR OTHER APPROPRIATE CODES.—In promulgating regulations to carry out this subsection with respect to discharges occurring after fiscal year 2018, the Secretary may consider the use of V or other ICD-related codes for removal of a readmission. The Secretary may consider modifying measures under this subsection to incorporate V or other ICD-related codes at the same time as other changes are being made under this subparagraph.

(iii) REMOVAL OF CERTAIN READMISSIONS.—In promulgating regulations to carry out this subsection, with respect to discharges occurring after fiscal year 2018, the Secretary may consider removal as a readmission of an admission that is classified within one or more of the following: transplants, end-stage renal disease, burns, trauma, psychosis, or substance abuse. The Secretary may consider modifying measures under this subsection to remove readmissions at the same time as other changes are being made under this subparagraph.

(4) AGGREGATE PAYMENTS, EXCESS READMISSION RATIO DEFINED.—For purposes of this subsection:

(A) AGGREGATE PAYMENTS FOR EXCESS READMISSIONS.—The term "aggregate payments for excess readmissions" means, for a hospital for an applicable period, the sum, for applicable conditions (as defined in paragraph (5)(A)), of the product, for each applicable condition, of—

(i) the base operating DRG payment amount for such hospital for such applicable period for such condition;

(ii) the number of admissions for such condition for such hospital for such applicable period; and

(iii) the excess readmissions ratio (as defined in subparagraph (C)) for such hospital for such applicable period minus 1.

(B) AGGREGATE PAYMENTS FOR ALL DISCHARGES.—The term "aggregate payments for all discharges" means, for a hospital for an applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period.

(C) EXCESS READMISSION RATIO.—

(i) IN GENERAL.—Subject to clause (ii), the term "excess readmissions ratio" means, with respect to an applicable condition for a hospital for an applicable period, the ratio (but not less than 1.0) of—

(I) the risk adjusted readmissions based on actual readmissions, as determined consistent with a readmission measure methodology that has been endorsed under paragraph (5)(A)(ii)(I), for an applicable hospital for such condition with respect to such applicable period; to

(II) the risk adjusted expected readmissions (as determined consistent with such a methodology) for such hospital for such condition with respect to such applicable period.

(ii) EXCLUSION OF CERTAIN READMISSIONS.—For purposes of clause (i), with respect to a hospital, excess readmissions shall not include readmissions for an applicable condition for which there are fewer than a minimum number (as determined by the Secretary) of discharges for such applicable condition for the applicable period and such hospital.

(5) DEFINITIONS.—For purposes of this subsection:

(A) APPLICABLE CONDITION.—The term "applicable condition" means, subject to subparagraph (B), a condition or procedure selected by the Secretary among conditions and procedures for which—

(i) readmissions (as defined in subparagraph (E)) that represent conditions or procedures that are high volume or high expenditures under this title (or other criteria specified by the Secretary); and

(ii) measures of such readmissions—

(I) have been endorsed by the entity with a contract under section 1890(a); and

(II) such endorsed measures have exclusions for readmissions that are unrelated to the prior dis-

charge (such as a planned readmission or transfer to another applicable hospital).

(B) EXPANSION OF APPLICABLE CONDITIONS.—Beginning with fiscal year 2015, the Secretary shall, to the extent practicable, expand the applicable conditions beyond the 3 conditions for which measures have been endorsed as described in subparagraph (A)(ii)(I) as of the date of the enactment of this subsection to the additional 4 conditions that have been identified by the Medicare Payment Advisory Commission in its report to Congress in June 2007 and to other conditions and procedures as determined appropriate by the Secretary. In expanding such applicable conditions, the Secretary shall seek the endorsement described in subparagraph (A)(ii)(I) but may apply such measures without such an endorsement in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(C) APPLICABLE HOSPITAL.—The term "applicable hospital" means a subsection (d) hospital or a hospital that is paid under section 1814(b)(3), as the case may be.

(D) APPLICABLE PERIOD.—The term "applicable period" means, with respect to a fiscal year, such period as the Secretary shall specify.

(E) READMISSION.—The term "readmission" means, in the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period specified by the Secretary from the date of such discharge. Insofar as the discharge relates to an applicable condition for which there is an endorsed measure described in subparagraph (A)(ii)(I), such time period (such as 30 days) shall be consistent with the time period specified for such measure.

(6) REPORTING HOSPITAL SPECIFIC INFORMATION.—

(A) IN GENERAL.—The Secretary shall make information available to the public regarding readmission rates of each subsection (d) hospital under the program.

(B) OPPORTUNITY TO REVIEW AND SUBMIT CORRECTIONS.—The Secretary shall ensure that a subsection (d) hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to the hospital under subparagraph (A) prior to such information being made public.

(C) WEBSITE.—Such information shall be posted on the Hospital Compare Internet website in an easily understandable format.

(7) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(A) The determination of base operating DRG payment amounts.

(B) The methodology for determining the adjustment factor under paragraph (3), including excess readmissions ratio under paragraph (4)(C), aggregate payments for excess readmissions under paragraph (4)(A), and aggregate payments for all discharges under paragraph (4)(B), and applicable periods and applicable conditions under paragraph (5).

(C) The measures of readmissions as described in paragraph (5)(A)(ii).

(8) READMISSION RATES FOR ALL PATIENTS.—

(A) CALCULATION OF READMISSION.—The Secretary shall calculate readmission rates for all patients (as defined in subparagraph (D)) for a specified hospital (as defined in subparagraph (D)(ii)) for an applicable condition (as defined in paragraph (5)(B)) and other conditions deemed appropriate by the Secretary for an applicable period (as defined in paragraph (5)(D)) in the same manner as used to calculate such readmission rates for hospitals with respect to this title and posted on the CMS Hospital Compare website.

(B) POSTING OF HOSPITAL SPECIFIC ALL PATIENT READMISSION RATES.—The Secretary shall make information on all patient readmission rates calculated under subparagraph (A) available on the CMS Hospital Compare website in a form and manner determined appropriate by the Secretary. The Secretary may also make other information determined appropriate by the Secretary available on such website.

(C) HOSPITAL SUBMISSION OF ALL PATIENT DATA.—

(i) Except as provided for in clause (ii), each specified hospital (as defined in subparagraph (D)(ii)) shall submit to the Secretary, in a form, manner and time specified by the Secretary, data and information determined necessary by the Secretary for the Secretary to calculate the all patient readmission rates described in subparagraph (A).

(ii) Instead of a specified hospital submitting to the Secretary the data and information described in clause (i), such data and information may be submitted to the Secretary, on behalf of such a specified hospital, by a state or an entity determined appropriate by the Secretary.

(D) DEFINITIONS.—For purposes of this paragraph:

(i) The term "all patients" means patients who are treated on an inpatient basis and discharged from a specified hospital (as defined in clause (ii)).

(ii) The term "specified hospital" means a subsection (d) hospital, hospitals described in clauses (i) through (v) of subsection (d)(1)(B) and, as determined feasible and appropriate by the Secretary, other hospitals not otherwise described in this subparagraph.

(r) ADJUSTMENTS TO MEDICARE DSH PAYMENTS.—

(1) EMPIRICALLY JUSTIFIED DSH PAYMENTS.—For fiscal year 2014 and each subsequent fiscal year, instead of the amount of disproportionate share hospital payment that would other-

wise be made under subsection (d)(5)(F) to a subsection (d) hospital for the fiscal year, the Secretary shall pay to the subsection (d) hospital 25 percent of such amount (which represents the empirically justified amount for such payment, as determined by the Medicare Payment Advisory Commission in its March 2007 Report to the Congress).

(2) ADDITIONAL PAYMENT.—In addition to the payment made to a subsection (d) hospital under paragraph (1), for fiscal year 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospitals an additional amount equal to the product of the following factors:

(A) FACTOR ONE.—A factor equal to the difference between—

(i) the aggregate amount of payments that would be made to subsection (d) hospitals under subsection (d)(5)(F) if this subsection did not apply for such fiscal year (as estimated by the Secretary); and

(ii) the aggregate amount of payments that are made to subsection (d) hospitals under paragraph (1) for such fiscal year (as so estimated).

(B) FACTOR TWO.—

(i) FISCAL YEARS 2014, 2015, 2016, AND 2017.—For each of fiscal years 2014, 2015, 2016, and 2017, a factor equal to 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, as determined by comparing the percent of such individuals—

(I) who are uninsured in 2013, the last year before coverage expansion under the Patient Protection and Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment); and

(II) who are uninsured in the most recent period for which data is available (as so calculated),

minus 0.1 percentage points for fiscal year 2014 and minus 0.2 percentage points for each of fiscal years 2015, 2016, and 2017.

(ii) 2018 AND SUBSEQUENT YEARS.—For fiscal year 2018 and each subsequent fiscal year, a factor equal to 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals—

(I) who are uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of the Centers for Medicare & Medicaid Services); and

(II) who are uninsured in the most recent period for which data is available (as so estimated and certified),

minus 0.2 percentage points for each of fiscal years 2018 and 2019.

(C) FACTOR THREE.—A factor equal to the percent, for each subsection (d) hospital, that represents the quotient of—

(i) the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines that alternative data is available which is a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and

(ii) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under this subsection for such period (as so estimated, based on such data).

(3) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(A) Any estimate of the Secretary for purposes of determining the factors described in paragraph (2).

(B) Any period selected by the Secretary for such purposes.

(s) PROSPECTIVE PAYMENT FOR PSYCHIATRIC HOSPITALS.—

(1) REFERENCE TO ESTABLISHMENT AND IMPLEMENTATION OF SYSTEM.—For provisions related to the establishment and implementation of a prospective payment system for payments under this title for inpatient hospital services furnished by psychiatric hospitals (as described in clause (i) of subsection (d)(1)(B)) and psychiatric units (as described in the matter following clause (v) of such subsection), see section 124 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999.

(2) IMPLEMENTATION FOR RATE YEAR BEGINNING IN 2010 AND SUBSEQUENT RATE YEARS.—

(A) IN GENERAL.—In implementing the system described in paragraph (1) for the rate year beginning in 2010 and any subsequent rate year, any update to a base rate for days during the rate year for a psychiatric hospital or unit, respectively, shall be reduced—

(i) for the rate year beginning in 2012 and each subsequent rate year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(ii) for each of the rate years beginning in 2010 through 2019, by the other adjustment described in paragraph (3).

(B) SPECIAL RULE.—The application of this paragraph may result in such update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(3) OTHER ADJUSTMENT.—For purposes of paragraph (2)(A)(ii), the other adjustment described in this paragraph is—

(A) for each of the rate years beginning in 2010 and 2011, 0.25 percentage point;

(B) for each of the rate years beginning in 2012 and 2013, 0.1 percentage point;

(C) for the rate year beginning in 2014, 0.3 percentage point;

(D) for each of the rate years beginning in 2015 and 2016, 0.2 percentage point; and

(E) for each of the rate years beginning in 2017, 2018, and 2019, 0.75 percentage point.

(4) QUALITY REPORTING.—

(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

(i) IN GENERAL.—Under the system described in paragraph (1), for rate year 2014 and each subsequent rate year, in the case of a psychiatric hospital or psychiatric unit that does not submit data to the Secretary in accordance with subparagraphs (C) and (E) with respect to such a rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, and after application of paragraph (2), shall be reduced by 2 percentage points.

(ii) SPECIAL RULE.—The application of this subparagraph may result in such annual update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(B) NONCUMULATIVE APPLICATION.—Any reduction under subparagraph (A) shall apply only with respect to the rate year involved and the Secretary shall not take into account such reduction in computing the payment amount under the system described in paragraph (1) for a subsequent rate year.

(C) SUBMISSION OF QUALITY DATA.—For rate year 2014 and each subsequent rate year, each psychiatric hospital and psychiatric unit shall submit to the Secretary data on quality measures specified under subparagraph (D). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(D) QUALITY MEASURES.—

(i) IN GENERAL.—Subject to clause (ii), any measure specified by the Secretary under this subparagraph must have been endorsed by the entity with a contract under section 1890(a).

(ii) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(iii) TIME FRAME.—Not later than October 1, 2012, the Secretary shall publish the measures selected under this subparagraph that will be applicable with respect to rate year 2014.

(iv) PATIENTS' PERSPECTIVE ON CARE.—Not later than for rate year 2031, the quality measures specified under this subparagraph shall include a quality measure of patients' perspective on care.

(E) STANDARDIZED PATIENT ASSESSMENT DATA.—

(i) IN GENERAL.—For rate year 2028 and each subsequent rate year, in addition to such data on the quality measures described in subparagraph (C), each psychiatric hospital and psychiatric unit shall submit to the Secretary, through the use of a standardized assessment instrument implemented under clause (iii), the standardized patient assessment data described in clause (ii). Such data shall be submitted with respect to admission and discharge of an individual (and may be submitted more frequently as the Secretary determines appropriate).

(ii) STANDARDIZED PATIENT ASSESSMENT DATA DESCRIBED.—For purposes of clause (i), the standardized patient assessment data described in this clause, with respect to a psychiatric hospital or psychiatric unit, is data with respect to the following categories:

(I) Functional status, such as mobility and self-care at admission to a psychiatric hospital or unit and before discharge from a psychiatric hospital or unit.

(II) Cognitive function, such as ability to express ideas and to understand, and mental status, such as depression and dementia.

(III) Special services, treatments, and interventions for psychiatric conditions.

(IV) Medical conditions and co-morbidities, such as diabetes, congestive heart failure, and pressure ulcers.

(V) Impairments, such as incontinence and an impaired ability to hear, see, or swallow.

(VI) Other categories as determined appropriate by the Secretary.

(iii) STANDARDIZED ASSESSMENT INSTRUMENT.—

(I) IN GENERAL.—For purposes of clause (i), the Secretary shall implement a standardized assessment instrument that provides for the submission of standardized patient assessment data under this title with respect to psychiatric hospitals and psychiatric units which enables comparison of such assessment data across all such hospitals and units to which such data are applicable.

(II) FUNDING.—The Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 to the Centers for Medicare & Medicaid Services Program Manage-

ment Account, of $10,000,000 for purposes of carrying out subclause (I).

(F) PUBLIC AVAILABILITY OF DATA SUBMITTED.—The Secretary shall establish procedures for making data submitted under subparagraphs (C) and (F) available to the public. Such procedures shall ensure that a psychiatric hospital and a psychiatric unit has the opportunity to review the data that is to be made public with respect to the hospital or unit prior to such data being made public. The Secretary shall report quality measures that relate to services furnished in inpatient settings in psychiatric hospitals and psychiatric units on the Internet website of the Centers for Medicare & Medicaid Services.

(5) ADDITIONAL DATA AND INFORMATION.—

(A) IN GENERAL.—The Secretary shall collect data and information as the Secretary determines appropriate to revise payments under the system described in paragraph (1) for psychiatric hospitals and psychiatric units pursuant to subparagraph (D) and for other purposes as determined appropriate by the Secretary. The Secretary shall begin to collect such data by not later than October 1, 2023.

(B) DATA AND INFORMATION.—The data and information to be collected under subparagraph (A) may include—

(i) charges, including those related to ancillary services;

(ii) the required intensity of behavioral monitoring, such as cognitive deficit, suicide ideations, violent behavior, and need for physical restraint; and

(iii) interventions, such as detoxification services for substance abuse, dependence on respirator, total parenteral nutritional support, dependence on renal dialysis, and burn care.

(C) METHOD OF COLLECTION.—The Secretary may collect the additional data and information under subparagraph (A) on cost reports, on claims, or otherwise.

(D) REVISIONS TO PAYMENT RATES.—

(i) IN GENERAL.—Notwithstanding the preceding paragraphs of this subsection or section 124 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, for rate year 2025 (and for any subsequent rate year, if determined appropriate by the Secretary), the Secretary shall, by regulation, implement revisions to the methodology for determining the payment rates under the system described in paragraph (1) for psychiatric hospitals and psychiatric units, as the Secretary determines to be appropriate. Such revisions may be based on a review of data and information collected under subparagraph (A).

(ii) REVIEW.—The Secretary may make revisions to the diagnosis-related group classifications, in accordance with subsection (d)(4)(C), to reflect nursing and staff resource use and costs involved in furnishing services at such hospitals and units, including considerations for patient complexity and prior admission to an inpatient psychiatric facility, which may be based

on review of data and information collected under subparagraph (A), as the Secretary determines to be appropriate.

(iii) BUDGET NEUTRALITY.—Revisions in payment implemented pursuant to clause (i) for a rate year shall result in the same estimated amount of aggregate expenditures under this title for psychiatric hospitals and psychiatric units furnished in the rate year as would have been made under this title for such care in such rate year if such revisions had not been implemented.

(6) ADDITIONAL CONSIDERATIONS FOR DIAGNOSIS-RELATED GROUP CLASSIFICATIONS.—

(A) IN GENERAL.—Notwithstanding the preceding paragraphs of this subsection (other than paragraph (5)) or section 124 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, beginning not later than rate year 2031, in addition to any revisions pursuant to paragraph (5), the Secretary shall, by regulation, implement revisions to the methodology for determining the payment rates under the system described in paragraph (1) for psychiatric hospitals and psychiatric units, as the Secretary determines to be appropriate, to take into account the patient assessment data described in paragraph (4)(E)(ii).

(B) BUDGET NEUTRALITY.—Revisions in payment implemented pursuant to subparagraph (A) for a rate year shall result in the same estimated amount of aggregate expenditures under this title for psychiatric hospitals and psychiatric units furnished in the rate year as would have been made under this title for such care in such rate year if such revisions had not been implemented.

(t) RELATING SIMILAR INPATIENT AND OUTPATIENT HOSPITAL SERVICES.—

(1) DEVELOPMENT OF HCPCS VERSION OF MS–DRG CODES.—Not later than January 1, 2018, the Secretary shall develop HCPCS versions for MS–DRGs that are similar to the ICD–10–PCS for such MS–DRGs such that, to the extent possible, the MS–DRG assignment shall be similar for a claim coded with the HCPCS version as an identical claim coded with a ICD–10–PCS code.

(2) COVERAGE OF SURGICAL MS–DRGS.—In carrying out paragraph (1), the Secretary shall develop HCPCS versions of MS–DRG codes for not fewer than 10 surgical MS–DRGs.

(3) PUBLICATION AND DISSEMINATION OF THE HCPCS VERSIONS OF MS–DRGS.—

(A) IN GENERAL.—The Secretary shall develop a HCPCS MS–DRG definitions manual and software that is similar to the definitions manual and software for ICD–10–PCS codes for such MS–DRGs. The Secretary shall post the HCPCS MS–DRG definitions manual and software on the Internet website of the Centers for Medicare & Medicaid Services. The HCPCS MS–DRG definitions manual and software shall be in the public domain and available for use and redistribution without charge.

(B) USE OF PREVIOUS ANALYSIS DONE BY MEDPAC.—In developing the HCPCS MS–DRG definitions manual and software under subparagraph (A), the Secretary shall consult with the Medicare Payment Advisory Commission and shall consider the analysis done by such Commission in translating outpatient surgical claims into inpatient surgical MS–DRGs in preparing chapter 7 (relating to hospital short-stay policy issues) of its "Medicare and the Health Care Delivery System" report submitted to Congress in June 2015.

(4) DEFINITION AND REFERENCE.—In this subsection:

(A) HCPCS.—The term "HCPCS" means, with respect to hospital items and services, the code under the Healthcare Common Procedure Coding System (HCPCS) (or a successor code) for such items and services.

(B) ICD–10–PCS.—The term "ICD–10–PCS" means the International Classification of Diseases, 10th Revision, Procedure Coding System, and includes any subsequent revision of such International Classification of Diseases, Procedure Coding System.

*(u) PUBLICATION OF HOSPITAL COMPLIANCE WITH PRICE TRANSPARENCY REQUIREMENTS.—*

*(1) IN GENERAL.—Beginning January 1, 2026, the Secretary shall, for each hospital with respect to which the Secretary has conducted a review of such hospital's compliance with the provisions of section 1899C(a) and found such hospital noncompliant with such provisions—*

*(A) indicate such noncompliance on such hospital's entry on the Hospital Compare internet website (or a successor website); and*

*(B) specify whether such hospital—*

*(i) submitted a corrective action plan described in subsection (a)(5)(A)(ii) of such section (and, if so, the date such plan was received by the Secretary); or*

*(ii) was subject to a civil monetary penalty imposed under subsection (a)(5)(B) of such section (and, if so, the date of the imposition of such penalty and the amount of such penalty).*

*(2) ADDITIONS AND UPDATES.—The Secretary shall update any specification described in subparagraph (A) or (B) of paragraph (1) with respect to such hospital—*

*(A) in the case of the specification described in such paragraph (1)(A), as soon as practicable after sending the notification described in section 1899C(a)(5)(A)(i); and*

*(B) in the case of the specification described in such paragraph (1)(B)(ii), as soon as practicable after the imposition of a civil monetary penalty described in such paragraph.*

* * * * * * *

***SEC. 1899C. HEALTH CARE PROVIDER PRICE TRANSPARENCY.***

*(a) HOSPITAL PRICE TRANSPARENCY.—*

*(1) IN GENERAL.—Beginning January 1, 2026, each specified hospital (as defined in paragraph (6)) that receives payment under this title for furnishing items and services shall comply*

*with the price transparency requirement described in paragraph (2).*

*(2) REQUIREMENT DESCRIBED.—*

*(A) IN GENERAL.—For purposes of paragraph (1), the price transparency requirement described in this paragraph is, with respect to a specified hospital, that such hospital, in accordance with a method and format established by the Secretary under subparagraph (C), compile and make public (without subscription and free of charge) for each year—*

*(i) one or more lists, in a format specified by the Secretary (which may be a machine-readable format), of the hospital's standard charges (including the information described in subparagraph (B)) for each item and service furnished by such hospital; and*

*(ii) information in a consumer-friendly format (as specified by the Secretary)—*

*(I) on the hospital's prices (including the information described in subparagraph (B)) for as many of the Centers for Medicare & Medicaid Services-specified shoppable services that are furnished by the hospital, and as many additional hospital-selected shoppable services (or all such additional services, if such hospital furnishes fewer than 300 shoppable services) as may be necessary for a combined total of at least 300 shoppable services; and*

*(II) that includes, with respect to each Centers for Medicare & Medicaid Services-specified shoppable service that is not furnished by the hospital, an indication that such service is not so furnished.*

*(B) INFORMATION DESCRIBED.—For purposes of subparagraph (A), the information described in this subparagraph is, with respect to standard charges and prices (as applicable) made public by a specified hospital, the following:*

*(i) A description of each item or service, accompanied by, as applicable, the Healthcare Common Procedure Coding System code, the diagnosis-related group, the national drug code, or other identifier used or approved by the Centers for Medicare & Medicaid Services.*

*(ii) The gross charge, expressed as a dollar amount, for each such item or service, when provided in, as applicable, the inpatient setting and outpatient department setting.*

*(iii) The discounted cash price, expressed as a dollar amount, for each such item or service when provided in, as applicable, the inpatient setting and outpatient department setting (or, in the case no discounted cash price is available for an item or service, the median price charged by the hospital for such item or service when provided in such settings for the previous three years, expressed as a dollar amount).*

*(iv) Any other information the Secretary may require for purposes of promoting public awareness of specified*

*hospital standard charges or prices in advance of receiving an item or service from such a hospital, except information that is duplicative of any other reporting requirement under this section. Such information may include any current payer-specific negotiated charges, clearly associated with the name of the third party payer and plan and expressed as a dollar amount, that apply to each such item or service when provided in, as applicable, the inpatient setting and outpatient department setting.*

*(C) METHOD AND FORMAT.—Not later than January 1, 2026, the Secretary shall establish one or more methods and formats for specified facilities to use in compiling and making public standard charges and prices (as applicable) pursuant to subparagraph (A). Any such method and format—*

*(i) may be similar to any template made available by the Centers for Medicare & Medicaid Services as of the date of the enactment of this subparagraph;*

*(ii) shall meet such standards as determined appropriate by the Secretary in order to ensure the accessibility and usability of such charges and prices; and*

*(iii) shall be updated as determined appropriate by the Secretary, in consultation with stakeholders.*

*(3) DEEMED COMPLIANCE WITH SHOPPABLE SERVICES REQUIREMENT FOR HOSPITALS WITH A PRICE ESTIMATOR TOOL.—*

*(A) IN GENERAL.—With respect to each year until the effective date of regulations implementing the provisions of sections 2799A–1(f) and 2799B–6 of the Public Health Service Act (relating to advanced explanations of benefits), including regulations on establishing data transfer standards to effectuate such provisions, a specified hospital shall be deemed to have complied with the requirement described in paragraph (2)(A)(ii)(I) (relating to shoppable services) if such hospital maintains a price estimator tool described in subparagraph (B).*

*(B) PRICE ESTIMATOR TOOL DESCRIBED.—For purposes of subparagraph (A), the price estimator tool described in this subparagraph is, with respect to a specified hospital, a tool that meets the following requirements:*

*(i) Such tool allows an individual to immediately obtain a price estimate (taking into account whether such individual is covered under any plan, coverage, or program described in clause (iv)(III)) and the discounted cash price charged by a specified hospital, for each Centers for Medicare & Medicaid Services-specified shoppable service that is furnished by such hospital, and for each additional shoppable service as such hospital may select, such that price estimates are available through such tool for at least 300 shoppable services (or for all such services, if such hospital furnishes fewer than 300 shoppable services).*

*(ii) Such tool allows an individual to obtain such an estimate by billing code and by service description.*

*(iii) Such tool is prominently displayed on the public internet website of such hospital.*

*(iv) Such tool does not require an individual seeking such an estimate to create an account or otherwise input personal information, except that such tool may require that such individual provide information specified by the Secretary, which may include the following:*

*(I) The name of such individual.*

*(II) The date of birth of such individual.*

*(III) In the case such individual is covered under a group health plan, group or individual health insurance coverage, a Federal health care program, or the program established under chapter 89 of title 5, United States Code, an identifying number assigned by such plan, coverage, or program to such individual.*

*(IV) In the case of an individual described in subclause (III), an indication as to whether such individual is the primary insured individual under such plan, coverage, or program (and, if such individual is not the primary insured individual, a description of the individual's relationship to such primary insured individual).*

*(V) Any other information specified by the Secretary.*

*(v) Such tool contains a statement confirming the accuracy and completeness of information presented through such tool as of the date such request is made.*

*(vi) Such tool meets any other requirement specified by the Secretary.*

*(4) MONITORING COMPLIANCE.—The Secretary shall, through notice and comment rulemaking and in consultation with the Inspector General of the Department of Health and Human Services, establish a process to monitor compliance with this subsection. Such process shall ensure that each specified hospital's compliance with this subsection is reviewed not less frequently than once every 3 years.*

*(5) ENFORCEMENT.—*

*(A) IN GENERAL.—In the case of a specified hospital that fails to comply with the requirements of this subsection—*

*(i) the Secretary shall notify such hospital of such failure not later than 30 days after the date on which the Secretary determines such failure exists; and*

*(ii) upon request of the Secretary, the hospital shall submit to the Secretary, not later than 45 days after the date of such request, a corrective action plan to comply with such requirements.*

*(B) CIVIL MONETARY PENALTY.—*

*(i) IN GENERAL.—In addition to any other enforcement actions or penalties that may apply under another provision of law, a specified hospital that has received a notification under subparagraph (A)(i) and fails to comply with the requirements of this subsection by the date that is 90 days after such notification (or, in the case of such a hospital that has submitted a cor-*

*rective action plan described in subparagraph (A)(ii) in response to a request so described, by the date that is 90 days after the Secretary identifies the failure of such hospital to satisfactorily complete such corrective action plan) shall be subject to a civil monetary penalty of an amount specified by the Secretary for each subsequent day during which such failure is ongoing. Such amount shall not exceed—*

*(I) in the case of a specified hospital that is a hospital or critical access hospital with 30 or fewer beds, $300 per day; and*

*(II) in the case of any specified hospital and except as provided in clause (iii), $2,000,000 for a 1-year period.*

*(ii) INCREASE AUTHORITY.—In applying this subparagraph with respect to violations occurring in 2029 or a subsequent year, the Secretary may through notice and comment rulemaking increase—*

*(I) the limitation on the per day amount of any penalty applicable to a specified hospital that is a hospital or critical access hospital with 30 or fewer beds under clause (i)(I);*

*(II) the limitation on the amount of any penalty applicable for a 1-year period under clause (i)(II); and*

*(III) the limitation on the increase of any penalty applied under clause (iii).*

*(iii) PERSISTENT NONCOMPLIANCE.—In the case of a specified hospital (other than a specified hospital that is a hospital or critical access hospital with 30 or fewer beds) that the Secretary has determined to be knowingly and willfully noncompliant with the provisions of this subsection two or more times during a 1-year period, the Secretary may increase any penalty otherwise applicable under this subparagraph by not more than $1,000,000 and may require such hospital to complete such additional corrective actions plans as the Secretary may specify.*

*(iv) APPLICATION OF CERTAIN PROVISIONS.—The provisions of section 1128A (other than subsections (a) and (b) of such section) shall apply to a civil monetary penalty imposed under this subparagraph in the same manner as such provisions apply to a civil monetary penalty imposed under subsection (a) of such section.*

*(v) AUTHORITY TO WAIVE OR REDUCE PENALTY.—The Secretary may waive or reduce any penalty otherwise applicable with respect to a specified hospital under this subparagraph if the Secretary determines that imposition of such penalty would result in a significant hardship for such hospital (such as in the case of a hospital located in a rural or underserved area where imposition of such penalty may result in, or contribute to, a lack of access to care for individuals in such area).*

*(C) PUBLICATION OF HOSPITAL PRICE TRANSPARENCY INFORMATION.—Beginning on January 1, 2026, the Secretary shall make publicly available on the public website of the Centers for Medicare & Medicaid Services information with respect to compliance with the requirements of this subsection and enforcement activities undertaken by the Secretary under this subsection. Such information shall be updated not less than annually and include, with respect to each year—*

*(i) the number of reviews of compliance with this subsection undertaken by the Secretary;*

*(ii) the number of notifications described in subparagraph (A)(i) sent by the Secretary;*

*(iii) the identify of each specified hospital that was sent such a notification and a description of the nature of such hospital's noncompliance with this subsection;*

*(iv) the amount of any civil monetary penalty imposed on such hospital under subparagraph (B);*

*(v) whether such hospital subsequently came into compliance with this subsection; and*

*(vi) any other information as determined by the Secretary.*

*(6) DEFINITIONS.—For purposes of this subsection:*

*(A) DISCOUNTED CASH PRICE.—The term "discounted cash price" means the charge that applies to an individual who pays cash, or cash equivalent, for a specified hospital-furnished item or service.*

*(B) FEDERAL HEALTH CARE PROGRAM.—The term "Federal health care program" has the meaning given such term in section 1128B.*

*(C) GROSS CHARGE.—The term "gross charge" means the charge for an individual item or service that is reflected on a specified hospital's chargemaster, absent any discounts.*

*(D) GROUP HEALTH PLAN; GROUP HEALTH INSURANCE COVERAGE; INDIVIDUAL HEALTH INSURANCE COVERAGE.—The terms "group health plan", "group health insurance coverage", and "individual health insurance coverage" have the meaning given such terms in section 2791 of the Public Health Service Act.*

*(E) PAYER-SPECIFIC NEGOTIATED CHARGE.—The term "payer-specific negotiated charge" means the charge that a specified hospital has negotiated with a third party payer for an item or service.*

*(F) SHOPPABLE SERVICE.—The term "shoppable service" means a service that can be scheduled by a health care consumer in advance and includes all ancillary items and services customarily furnished as part of such service.*

*(G) SPECIFIED HOSPITAL.—The term "specified hospital" means a hospital (as defined in section 1861(e)), a critical access hospital (as defined in section 1861(mmm)(1)), or a rural emergency hospital (as defined in section 1861(kkk)).*

*(H) THIRD PARTY PAYER.—The term "third party payer" means an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service.*

*(b) AMBULATORY SURGICAL CENTER PRICE TRANSPARENCY.—*

*(1) IN GENERAL.—Beginning January 1, 2028, each ambulatory surgical center that receives payment under this title for furnishing items and services shall comply with the price transparency requirement described in paragraph (2).*

*(2) REQUIREMENT DESCRIBED.—*

*(A) IN GENERAL.—For purposes of paragraph (1), the price transparency requirement described in this subsection is, with respect to an ambulatory surgical center, that such surgical center in accordance with a method and format established by the Secretary under subparagraph (C)), compile and make public (without subscription and free of charge), for each year—*

*(i) one or more lists, in a format specified by the Secretary (which may be machine-readable), of the ambulatory surgical center's standard charges (including the information described in subparagraph (B)) for each item and service furnished by such surgical center;*

*(ii) information on the ambulatory surgical center's prices (including the information described in subparagraph (B)) for as many of the Centers for Medicare & Medicaid Services-specified shoppable services that are furnished by such surgical center, and as many additional ambulatory surgical center-selected shoppable services (or all such additional services, if such surgical center furnishes fewer than 300 shoppable services) as may be necessary for a combined total of at least 300 shoppable services; and*

*(iii) with respect to each Centers for Medicare & Medicaid Services-specified shoppable service that is not furnished by the ambulatory surgical center, an indication that such service is not so furnished.*

*(B) INFORMATION DESCRIBED.—For purposes of subparagraph (A), the information described in this subparagraph is, with respect to standard charges and prices (as applicable) made public by an ambulatory surgical center, the following:*

*(i) A description of each item or service, accompanied by, as applicable, the Healthcare Common Procedure Coding System code, the diagnosis-related group, the national drug code, or other identifier used or approved by the Centers for Medicare & Medicaid Services.*

*(ii) The gross charge, expressed as a dollar amount, for each such item or service.*

*(iii) The discounted cash price, expressed as a dollar amount, for each such item or service (or, in the case no discounted cash price is available for an item or service, the gross charge for such item or service for the previous three years, expressed as a dollar amount).*

*(iv) Any other information the Secretary may require that is not duplicative of any other reporting requirement under this subsection for purposes of promoting public awareness of ambulatory surgical center prices in advance of receiving an item or service from such an*

*ambulatory surgical center, which may include any current payer-specific negotiated charges, clearly associated with the name of the third party payer and plan and expressed as a dollar amount, that applies to each such item or service.*

*(C) METHOD AND FORMAT.—Not later than January 1, 2028, the Secretary shall establish one or more methods and formats for ambulatory surgical centers to use in making public standard charges and prices (as applicable) pursuant to subparagraph (A). Any such method and format—*

*(i) may be similar to any template made available by the Centers for Medicare & Medicaid Services as of the date of the enactment of this paragraph;*

*(ii) shall meet such standards as determined appropriate by the Secretary in order to ensure the accessibility and usability of such charges and prices; and*

*(iii) shall be updated as determined appropriate by the Secretary, in consultation with stakeholders.*

*(3) DEEMED COMPLIANCE WITH SHOPPABLE SERVICES REQUIREMENT FOR AMBULATORY SURGICAL CENTERS WITH A PRICE ESTIMATOR TOOL.—*

*(A) IN GENERAL.—With respect to each year until the effective date of regulations implementing the provisions of sections 2799A–1(f) and 2799B–6 of the Public Health Service Act (relating to advanced explanations of benefits), including regulations on establishing data transfer standards to effectuate such provisions, an ambulatory surgical center shall be deemed to have complied with the requirement described in subsection (b)(2)(A) (relating to shoppable services) if such surgical center maintains a price estimator tool described in subparagraph (B).*

*(B) PRICE ESTIMATOR TOOL DESCRIBED.—For purposes of subparagraph (A), the price estimator tool described in this subparagraph is, with respect to an ambulatory surgical center, a tool that meets the following requirements:*

*(i) Such tool allows an individual to immediately obtain a price estimate (taking into account whether such individual is covered under any plan, coverage, or program described in clause (iv)(III)) for each Centers for Medicare & Medicaid Services-specified shoppable service that is furnished by such surgical center, and for each additional shoppable service as such surgical center may select, such that price estimates are available through such tool for at least 300 shoppable services (or for all such services, if such surgical center furnishes fewer than 300 shoppable services).*

*(ii) Such tool allows an individual to obtain such an estimate by billing code and by service description.*

*(iii) Such tool is prominently displayed on the public internet website of such ambulatory surgical center.*

*(iv) Such tool does not require an individual seeking such an estimate to create an account or otherwise input personal information, except that such tool may require that such individual provide information specified by the Secretary, which may include the following:*

*(I) The name of such individual.*

*(II) The date of birth of such individual.*

*(III) In the case such individual is covered under a group health plan, group or individual health insurance coverage, a Federal health care program, or the program established under chapter 89 of title 5, United States Code, an identifying number assigned by such plan, coverage, or program to such individual.*

*(IV) In the case of an individual described in subclause (III), an indication as to whether such individual is the primary insured individual under such plan, coverage, or program (and, if such individual is not the primary insured individual, a description of the individual's relationship to such primary insured individual).*

*(V) Any other information specified by the Secretary.*

*(v) Such tool contains a statement confirming the accuracy and completeness of information presented through such tool as of the date such request is made.*

*(vi) Such tool meets any other requirement specified by the Secretary.*

*(4) MONITORING COMPLIANCE.—The Secretary shall, through notice and comment rulemaking and in consultation with the Inspector General of the Department of Health and Human Services, establish a process to monitor compliance with this subsection. Such process shall ensure that each ambulatory surgical center's compliance with this subsection is reviewed not less frequently than once every 3 years.*

*(5) ENFORCEMENT.—*

*(A) IN GENERAL.—In the case of an ambulatory surgical center that fails to comply with the requirements of this subsection—*

*(i) the Secretary shall notify such ambulatory surgical center of such failure not later than 30 days after the date on which the Secretary determines such failure exists; and*

*(ii) upon request of the Secretary, the ambulatory surgical center shall submit to the Secretary, not later than 45 days after the date of such request, a corrective action plan to comply with such requirements.*

*(B) CIVIL MONETARY PENALTY.—*

*(i) IN GENERAL.—In addition to any other enforcement actions or penalties that may apply under another provision of law, an ambulatory surgical center that has received a notification under subparagraph (A)(i) and fails to comply with the requirements of this subsection by the date that is 90 days after such notification (or, in the case of an ambulatory surgical center that has submitted a corrective action plan described in subparagraph (A)(ii) in response to a request so described, by the date that is 90 days after such submission) shall be subject to a civil monetary penalty of an amount specified by the Secretary for each subsequent*

*day during which such failure is ongoing (not to exceed $300 per day).*

*(ii) INCREASE AUTHORITY.—In applying this subparagraph with respect to violations occurring in 2029 or a subsequent year, the Secretary may through notice and comment rulemaking increase the limitation on the per day amount of any penalty applicable to an ambulatory surgical center under clause (i).*

*(iii) APPLICATION OF CERTAIN PROVISIONS.—The provisions of section 1128A (other than subsections (a) and (b) of such section) shall apply to a civil monetary penalty imposed under this subparagraph in the same manner as such provisions apply to a civil monetary penalty imposed under subsection (a) of such section.*

*(iv) AUTHORITY TO WAIVE OR REDUCE PENALTY.—The Secretary may waive or reduce any penalty otherwise applicable with respect to an ambulatory surgical center under this subparagraph if the Secretary determines that imposition of such penalty would result in a significant hardship for such ambulatory surgical center (such as in the case of an ambulatory surgical center located in a rural or underserved area where imposition of such penalty may result in, or contribute to, a lack of access to care for individuals in such area).*

*(6) DEFINITIONS.—For purposes of this section:*

*(A) DISCOUNTED CASH PRICE.—The term "discounted cash price" means the charge that applies to an individual who pays cash, or cash equivalent, for a item or service furnished by an ambulatory surgical center.*

*(B) FEDERAL HEALTH CARE PROGRAM.—The term "Federal health care program" has the meaning given such term in section 1128B.*

*(C) GROSS CHARGE.—The term "gross charge" means the charge for an individual item or service that is reflected on a specified surgical center's chargemaster, absent any discounts.*

*(D) GROUP HEALTH PLAN; GROUP HEALTH INSURANCE COVERAGE; INDIVIDUAL HEALTH INSURANCE COVERAGE.—The terms "group health plan", "group health insurance coverage", and "individual health insurance coverage" have the meaning given such terms in section 2791 of the Public Health Service Act.*

*(E) PAYER-SPECIFIC NEGOTIATED CHARGE.—The term "payer-specific negotiated charge" means the charge that a specified surgical center has negotiated with a third party payer for an item or service.*

*(F) SHOPPABLE SERVICE.—The term "shoppable service" means a service that can be scheduled by a health care consumer in advance and includes all ancillary items and services customarily furnished as part of such service.*

*(G) THIRD PARTY PAYER.—The term "third party payer" means an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service.*

*(c) IMAGING SERVICES PRICE TRANSPARENCY.—*

*(1) IN GENERAL.—Beginning January 1, 2028, each provider of services and supplier that receives payment under this title for furnishing a specified imaging service shall—*

*(A) make publicly available (in a form and manner specified by the Secretary) on an Internet website the information described in paragraph (2) with respect to each such service that such provider of services or supplier furnishes; and*

*(B) ensure that such information is updated not less frequently than annually.*

*(2) INFORMATION DESCRIBED.—For purposes of paragraph (1), the information described in this subsection is, with respect to a provider of services or supplier and a specified imaging service, the following:*

*(A) The discounted cash price for such service (or, if no such price exists, the gross charge for such service).*

*(B) If required by the Secretary, the deidentified minimum negotiated rate in effect between such provider or supplier and any group health plan or group or individual health insurance coverage for such service and the deidentified maximum negotiated rate in effect between such provider or supplier and any such plan or coverage for such service.*

*(3) METHOD AND FORMAT.—Not later than January 1, 2028, the Secretary shall establish one or more methods and formats for each provider of services and supplier to use in compiling and making public standard charges and prices (as applicable) pursuant to paragraph (1). Any such method and format—*

*(A) may be similar to any template made available by the Centers for Medicare & Medicaid Services as of the date of the enactment of this subsection;*

*(B) shall meet such standards as determined appropriate by the Secretary in order to ensure the accessibility and usability of such charges and prices; and*

*(C) shall be updated as determined appropriate by the Secretary, in consultation with stakeholders.*

*(4) MONITORING COMPLIANCE.—The Secretary shall, through notice and comment rulemaking and in consultation with the Inspector General of the Department of Health and Human Services, establish a process to monitor compliance with this subsection.*

*(5) SPECIFICATION OF SERVICES.—Not later than January 1, 2028, the Secretary shall publish a list of at least 50 imaging services that the Secretary determines are shoppable (or all such services, if the Secretary determines that fewer than 50 such services are shoppable) between providers of services and suppliers of such services. The Secretary shall update such list as determined appropriate by the Secretary.*

*(6) ENFORCEMENT.—*

*(A) IN GENERAL.—In the case that the Secretary determines that a provider of services or supplier is not in compliance with paragraph (1)—*

*(i) not later than 30 days after such determination, the Secretary shall notify such provider or supplier of such determination;*

*(ii) upon request of the Secretary, such provider or supplier shall submit to the Secretary, not later than 45 days after the date of such request, a corrective action plan to comply with such paragraph; and*

*(iii) if such provider or supplier continues to fail to comply with such paragraph after the date that is 90 days after such notification is sent (or, in the case of such a provider or supplier that has submitted a corrective action plan described in clause (ii) in response to a request so described, after the date that is 90 days after such submission), the Secretary may impose a civil monetary penalty in an amount not to exceed $300 for each subsequent day during which such failure to comply or failure to submit is ongoing.*

*(B) INCREASE AUTHORITY.—In applying this paragraph with respect to violations occurring in 2029 or a subsequent year, the Secretary may through notice and comment rulemaking increase the amount of the civil monetary penalty under subparagraph (A)(iii).*

*(C) APPLICATION OF CERTAIN PROVISIONS.—The provisions of section 1128A (other than subsections (a) and (b) of such section) shall apply to a civil monetary penalty imposed under this paragraph in the same manner as such provisions apply to a civil monetary penalty imposed under subsection (a) of such section.*

*(D) AUTHORITY TO WAIVE OR REDUCE PENALTY.—The Secretary may waive or reduce any penalty otherwise applicable with respect to a provider of services or supplier under this subparagraph if the Secretary determines that imposition of such penalty would result in a significant hardship for such provider or supplier (such as in the case of a provider or supplier located in a rural or underserved area where imposition of such penalty may result in, or contribute to, a lack of access to care for individuals in such area).*

*(E) CLARIFICATION OF NONAPPLICABILITY OF OTHER ENFORCEMENT PROVISIONS.—Notwithstanding any other provision of this title, this paragraph shall be the sole means of enforcing the provisions of this subsection.*

*(7) DEFINITIONS.—In this subsection:*

*(A) GROUP HEALTH PLAN; GROUP HEALTH INSURANCE COVERAGE; INDIVIDUAL HEALTH INSURANCE COVERAGE.—The terms "group health plan", "group health insurance coverage", and "individual health insurance coverage" have the meaning given such terms in section 2791 of the Public Health Service Act.*

*(B) SPECIFIED IMAGING SERVICE.—the term "specified imaging service" means an imaging service that is included on the list published by the Secretary under subsection (e).*

*(d) CLINICAL LABORATORY PRICE TRANSPARENCY.—*

*(1) IN GENERAL.—Beginning January 1, 2028, each applicable laboratory that receives payment under this title for furnishing a specified clinical diagnostic laboratory test shall—*

*(A) make publicly available (in a manner and form specified by the Secretary) on an Internet website the informa-*

*tion described in paragraph (2) with respect to each such specified clinical diagnostic laboratory test that such laboratory is so available to furnish; and*

*(B) ensure that such information is updated not less frequently than annually.*

*(2) INFORMATION DESCRIBED.—For purposes of paragraph (1), the information described in this subsection is, with respect to an applicable laboratory and a specified clinical diagnostic laboratory test, the following:*

*(A) The discounted cash price for such test (or, if no such price exists, the gross charge for such test).*

*(B) If required by the Secretary, the deidentified minimum negotiated rate in effect between such laboratory and any group health plan or group or individual health insurance coverage for such test and the deidentified maximum negotiated rate in effect between such laboratory and any such plan or coverage for such test.*

*(3) METHOD AND FORMAT.—Not later than January 1, 2028, the Secretary shall establish one or more methods and formats for each provider of services and supplier to use in compiling and making public standard charges and prices (as applicable) pursuant to paragraph (1). Any such method and format—*

*(A) may be similar to any template made available by the Centers for Medicare & Medicaid Services as of the date of the enactment of this subsection;*

*(B) shall meet such standards as determined appropriate by the Secretary in order to ensure the accessibility and usability of such charges and prices; and*

*(C) shall be updated as determined appropriate by the Secretary, in consultation with stakeholders.*

*(4) MONITORING COMPLIANCE.—The Secretary shall, through notice and comment rulemaking and in consultation with the Inspector General of the Department of Health and Human Services, establish a process to monitor compliance with this subsection.*

*(5) ENFORCEMENT.—*

*(A) IN GENERAL.—In the case that the Secretary determines that an applicable laboratory is not in compliance with paragraph (1)—*

*(i) not later than 30 days after such determination, the Secretary shall notify such laboratory of such determination;*

*(ii) upon request of the Secretary, such laboratory shall submit to the Secretary, not later than 45 days after such request is sent, a corrective action plan to comply with such subsection; and*

*(iii) if such laboratory continues to fail to comply with such paragraph after the date that is 90 days after such notification is sent (or, in the case of such a laboratory that has submitted a corrective action plan described in clause(ii) in response to a request so described, after the date that is 90 days after such submission), the Secretary may impose a civil monetary penalty in an amount not to exceed $300 for each sub-*

*sequent day during which such failure to comply is ongoing.*

*(B) INCREASE AUTHORITY.—In applying this paragraph with respect to violations occurring in 2029 or a subsequent year, the Secretary may through notice and comment rulemaking increase the amount of the civil monetary penalty under subparagraph (A)(iii).*

*(C) APPLICATION OF CERTAIN PROVISIONS.—The provisions of section 1128A (other than subsections (a) and (b) of such section) shall apply to a civil monetary penalty imposed under this paragraph in the same manner as such provisions apply to a civil monetary penalty imposed under subsection (a) of such section.*

*(D) AUTHORITY TO WAIVE OR REDUCE PENALTY.—The Secretary may waive or reduce any penalty otherwise applicable with respect to an applicable laboratory under this paragraph if the Secretary determines that imposition of such penalty would result in a significant hardship for such laboratory (such as in the case of an applicable laboratory located in a rural or underserved area where imposition of such penalty may result in, or contribute to, a lack of access to care for individuals in such area).*

*(E) CLARIFICATION OF NONAPPLICABILITY OF OTHER ENFORCEMENT PROVISIONS.—Notwithstanding any other provision of this title, this subsection shall be the sole means of enforcing the provisions of this section.*

*(6) DEFINITIONS.—In this subsection:*

*(A) APPLICABLE LABORATORY.—The term "applicable laboratory" has the meaning given such term in section 414.502, of title 42, Code of Federal Regulations (or any successor regulation).*

*(B) GROUP HEALTH PLAN; GROUP HEALTH INSURANCE COVERAGE; INDIVIDUAL HEALTH INSURANCE COVERAGE.—The terms "group health plan", "group health insurance coverage", and "individual health insurance coverage" have the meaning given such terms in section 2791 of the Public Health Service Act.*

*(C) SPECIFIED CLINICAL DIAGNOSTIC LABORATORY TEST.—The term "specified clinical diagnostic laboratory test" means a clinical diagnostic laboratory test that is included on the list of shoppable services specified by the Centers for Medicare & Medicaid Services pursuant to section 180.60 of title 45, Code of Federal Regulations (or a successor regulation), other than such a test that is an advanced diagnostic laboratory test (as defined in section 1834A(d)(5)).*

***SEC. 1899D. REPORTS ON VERTICAL INTEGRATION UNDER MEDICARE.***

*(a) IN GENERAL.—Not later than June 15, 2029, and every 3 years thereafter, the Medicare Payment Advisory Commission shall submit to Congress a report on the state of vertical integration in the health care sector during the applicable year with respect to entities participating in the Medicare program, including health care providers, pharmacies, prescription drug plan sponsors, Medicare Advantage organizations, and pharmacy benefit managers. Such report shall include—*

*(1) with respect to Medicare Advantage organizations, the evaluation described in subsection (b);*

*(2) with respect to prescription drug plans, pharmacy benefit managers, and pharmacies, the comparisons and evaluations described in subsection (c);*

*(3) with respect to Medicare Advantage plans under which benefits are available for physician-administered drugs, the information described in subsection (d); and*

*(4) the identifications described in subsection (e); and*

*(5) an analysis of the impact of such integration on health care access, price, quality, and outcomes.*

*(b) MEDICARE ADVANTAGE ORGANIZATIONS.—For purposes of subsection (a)(1), the evaluation described in this subsection is, with respect to Medicare Advantage organizations and an applicable year, an evaluation, taking into account patient acuity and the types of areas serviced by such organization, of—*

*(1) the average number of qualifying diagnoses made during such year with respect to enrollees of a Medicare Advantage plan offered by such organization who, during such year, received a health risk assessment from a specified health care provider;*

*(2) the average risk score for such enrollees who received such an assessment during such year;*

*(3) any relationship between such risk scores for such enrollees receiving such an assessment from such a provider during such year and incentive payments made to such providers;*

*(4) the average risk score for enrollees of such plan who received any item or service from a specified health care provider during such year;*

*(5) any relationship between the risk scores of enrollees under such plan and whether the enrollees have received any item or service from a specified provider; and*

*(6) any relationship between the risk scores of enrollees under such plan that have received any item or service from a specified provider and incentive payments made under the plan to specified providers.*

*(c) PRESCRIPTION DRUG PLANS.—For purposes of subsection (a)(2), the comparisons and evaluations described in this subsection are, with respect to prescription drug plans and an applicable year, the following:*

*(1) For each covered part D drug for which benefits are available under such a plan, a comparison of the average negotiated rate in effect with specified pharmacies with such rates in effect for in-network pharmacies that are not specified pharmacies.*

*(2) Comparisons of the following:*

*(A) The total amount paid by pharmacy benefit managers to specified pharmacies for covered part D drugs and the total amount so paid to pharmacies that are not specified pharmacies for such drugs.*

*(B) The total amount paid by such sponsors to specified pharmacy benefit managers as reimbursement for covered part D drugs and the total amount so paid to pharmacy benefit managers that are not specified pharmacy benefit managers as such reimbursement.*

*(C) Fees paid under by plan to specified pharmacy benefit managers compared to such fees paid to pharmacy benefit managers that are not specified pharmacy benefit managers.*

*(3) An evaluation of the total amount of direct and indirect remuneration for covered part D drugs passed through to prescription drug plan sponsors and the total amount retained by pharmacy benefit managers (including entities under contract with such a manager).*

*(4) To the extent that the available data permits, an evaluation of fees charged by rebate aggregators that are affiliated with plan sponsors.*

*(d) PHYSICIAN-ADMINISTERED DRUGS.—For purposes of subsection (a)(3), the information described in this subsection is, with respect to physician-administered drugs for which benefits are available under a Medicare Advantage plan during an applicable year, the following:*

*(1) With respect to each such plan, an identification of each drug for which benefits were available under such plan only when administered by a health care provider that acquired such drug from an affiliated pharmacy.*

*(2) An evaluation of the difference between the total number of drugs administered by a health care provider that were acquired from affiliated pharmacies compared to the number of such drugs so administered that were acquired from pharmacies other than affiliated pharmacies, and an evaluation of the difference in payments for such drugs so administered when acquired from a specified pharmacy and when acquired from a pharmacy that is not a specified pharmacy.*

*(3) An evaluation of the dollar value of all such drugs that were not so administered because of a delay attributable to an affiliated pharmacy compared to the dollar value of all such drugs that were not so administered because of a delay attributable to pharmacy that is not an affiliated pharmacy.*

*(4) The number of enrollees administered such a drug that was acquired from an affiliated pharmacy.*

*(5) The number of enrollees furnished such a drug that was acquired from a pharmacy that is not an affiliated pharmacy.*

*(e) IDENTIFICATIONS.—For purposes of subsection (a)(4), the identifications described in this subsection are, with respect to an applicable year, identifications of each health care entity participating under the Medicare program with respect to which another health care entity so participating is a person with an ownership or control interest (as defined in section 1124(a)(3)).*

*(f) DEFINITIONS.—In this section:*

*(1) AFFILIATED PHARMACY.—The term "affiliated pharmacy" means, with respect to a Medicare Advantage plan offered by a Medicare Advantage organization, a pharmacy with respect to which such organization (or any person with an ownership or control interest (as defined in section 1124(a)(3)) in such organization) is a person with an ownership or control interest (as so defined).*

*(2) APPLICABLE YEAR.—The term "applicable year" means, with respect to a report submitted under subsection (a), the first*

*calendar year beginning at least 4 years prior to the date of the submission of such report.*

*(3) COVERED PART D DRUG.—The term "covered part D drug" has the meaning given such term in section 1860D–2(e).*

*(4) DIRECT AND INDIRECT REMUNERATION.—The term "direct and indirect remuneration" has the meaning given such term in section 423.308 of title 42, Code of Federal Regulations (or any successor regulation).*

*(5) QUALIFYING DIAGNOSIS.—The term "qualifying diagnosis" means, with respect to an enrollee of a Medicare Advantage plan, a diagnosis that is taken into account in calculating a risk score for such enrollee under the risk adjustment methodology established by the Secretary pursuant to section 1853(a)(3).*

*(6) RISK SCORE.—The term "risk score" means, with respect to an enrollee of a Medicare Advantage plan, the score calculated for such individual using the methodology described in paragraph (5).*

*(7) PHYSICIAN-ADMINISTERED DRUG.—The term "physician-administered drug" means a drug furnished to an individual that, had such individual been enrolled under part B and not enrolled under part C, would have been payable under section 1842(o).*

*(8) SPECIFIED HEALTH CARE PROVIDER.—The term "specified health care provider" means, with respect to a Medicare Advantage plan offered by a Medicare Advantage organization, a health care provider with respect to which such organization (or any person with an ownership or control interest (as defined in section 1124(a)(3)) in such organization) is a person with an ownership or control interest (as so defined).*

*(9) SPECIFIED PHARMACY.—The term "specified pharmacy" means, with respect to a prescription drug plan offered by a prescription drug plan sponsor, a pharmacy with respect to which—*

*(A) such sponsor (or any person with an ownership or control interest (as defined in section 1124(a)(3)) in such sponsor) is a person with an ownership or control interest (as so defined); or*

*(B) a pharmacy benefit manager offering services under such plan (or any person with an ownership or control interest (as so defined) in such sponsor) is a person with an ownership or control interest (as so defined).*

*(10) SPECIFIED PHARMACY BENEFIT MANAGER.—The term "specified pharmacy benefit manager" means, with respect to a prescription drug plan offered by a prescription drug plan sponsor, a pharmacy benefit manager with respect to which such sponsor (or any person with an ownership or control interest (as defined in section 1124(a)(3)) in such sponsor) is a person with an ownership or control interest (as so defined).*

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## PUBLIC HEALTH SERVICE ACT

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TITLE XXVII—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

# PART A—INDIVIDUAL AND GROUP MARKET REFORMS

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## Subpart II—Improving Coverage

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**SEC. 2718. BRINGING DOWN THE COST OF HEALTH CARE COVERAGE.**

(a) CLEAR ACCOUNTING FOR COSTS.—A health insurance issuer offering group or individual health insurance coverage (including a grandfathered health plan) shall, with respect to each plan year, submit to the Secretary a report concerning the ratio of the incurred loss (or incurred claims) plus the loss adjustment expense (or change in contract reserves) to earned premiums. Such report shall include the percentage of total premium revenue, after accounting for collections or receipts for risk adjustment and risk corridors and payments of reinsurance, that such coverage expends—

(1) on reimbursement for clinical services provided to enrollees under such coverage;

(2) for activities that improve health care quality; and

(3) on all other non-claims costs, including an explanation of the nature of such costs, and excluding Federal and State taxes and licensing or regulatory fees.

The Secretary shall make reports received under this section available to the public on the Internet website of the Department of Health and Human Services.

(b) ENSURING THAT CONSUMERS RECEIVE VALUE FOR THEIR PREMIUM PAYMENTS.—

(1) REQUIREMENT TO PROVIDE VALUE FOR PREMIUM PAYMENTS.—

(A) REQUIREMENT.—Beginning not later than January 1, 2011, a health insurance issuer offering group or individual health insurance coverage (including a grandfathered health plan) shall, with respect to each plan year, provide an annual rebate to each enrollee under such coverage, on a pro rata basis, if the ratio of the amount of premium revenue expended by the issuer on costs described in paragraphs (1) and (2) of subsection (a) to the total amount of premium revenue (excluding Federal and State taxes and licensing or regulatory fees and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act) for the plan year (except as provided in subparagraph (B)(ii)), is less than—

(i) with respect to a health insurance issuer offering coverage in the large group market, 85 percent, or such higher percentage as a State may by regulation determine; or

(ii) with respect to a health insurance issuer offering coverage in the small group market or in the individual market, 80 percent, or such higher percentage as a State may by regulation determine, except that the Secretary may adjust such percentage with respect to a State if the Secretary determines that the application of such 80 percent may destabilize the individual market in such State.

(B) REBATE AMOUNT.—

(i) CALCULATION OF AMOUNT.—The total amount of an annual rebate required under this paragraph shall be in an amount equal to the product of—

(I) the amount by which the percentage described in clause (i) or (ii) of subparagraph (A) exceeds the ratio described in such subparagraph; and

(II) the total amount of premium revenue (excluding Federal and State taxes and licensing or regulatory fees and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act) for such plan year.

(ii) CALCULATION BASED ON AVERAGE RATIO.—Beginning on January 1, 2014, the determination made under subparagraph (A) for the year involved shall be based on the averages of the premiums expended on the costs described in such subparagraph and total premium revenue for each of the previous 3 years for the plan.

(2) CONSIDERATION IN SETTING PERCENTAGES.—In determining the percentages under paragraph (1), a State shall seek to ensure adequate participation by health insurance issuers, competition in the health insurance market in the State, and value for consumers so that premiums are used for clinical services and quality improvements.

(3) ENFORCEMENT.—The Secretary shall promulgate regulations for enforcing the provisions of this section and may provide for appropriate penalties.

(c) DEFINITIONS.—Not later than December 31, 2010, and subject to the certification of the Secretary, the National Association of Insurance Commissioners shall establish uniform definitions of the activities reported under subsection (a) and standardized methodologies for calculating measures of such activities, including definitions of which activities, and in what regard such activities, constitute activities described in subsection (a)(2). Such methodologies shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans.

(d) ADJUSTMENTS.—The Secretary may adjust the rates described in subsection (b) if the Secretary determines appropriate on account of the volatility of the individual market due to the establishment of State Exchanges.

(e) STANDARD HOSPITAL CHARGES.—Each hospital operating within the United States shall for each year establish (and update) and make public (in accordance with guidelines developed by the

Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act. *The preceding sentence shall not apply beginning January 1, 2026.*

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Subpart 2—Exclusion of Plans; Enforcement; Preemption

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**SEC. 2723. ENFORCEMENT.**

(a) STATE ENFORCEMENT.—

(1) STATE AUTHORITY.—Subject to section 2723, each State may require that health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State in the individual or group market meet the requirements of this part and part D *(other than subsections (a) and (b) of section 2799A–11)* with respect to such issuers.

(2) FAILURE TO IMPLEMENT PROVISIONS.—In the case of a determination by the Secretary that a State has failed to substantially enforce a provision (or provisions) in this part or part D *(other than subsections (a) and (b) of section 2799A–11)* with respect to health insurance issuers in the State, the Secretary shall enforce such provision (or provisions) under subsection (b) insofar as they relate to the issuance, sale, renewal, and offering of health insurance coverage in connection with group health plans or individual health insurance coverage in such State.

(b) SECRETARIAL ENFORCEMENT AUTHORITY.—

(1) LIMITATION.—The provisions of this subsection shall apply to enforcement of a provision (or provisions) of this part or part D *(other than subsections (a) and (b) of section 2799A–11)* only—

(A) as provided under subsection (a)(2); and

(B) with respect to individual health insurance coverage or group health plans that are non-Federal governmental plans.

(2) IMPOSITION OF PENALTIES.—In the cases described in paragraph (1)—

(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, any non-Federal governmental plan that is a group health plan and any health insurance issuer that fails to meet a provision of this part or part D *(other than subsections (a) and (b) of section 2799A–11)* applicable to such plan or issuer is subject to a civil money penalty under this subsection.

(B) LIABILITY FOR PENALTY.—In the case of a failure by—

(i) a health insurance issuer, the issuer is liable for such penalty, or

(ii) a group health plan that is a non-Federal governmental plan which is—

(I) sponsored by 2 or more employers, the plan is liable for such penalty, or

(II) not so sponsored, the employer is liable for such penalty.

(C) AMOUNT OF PENALTY.—

(i) IN GENERAL.—The maximum amount of penalty imposed under this paragraph is $100 for each day for each individual with respect to which such a failure occurs.

(ii) CONSIDERATIONS IN IMPOSITION.—In determining the amount of any penalty to be assessed under this paragraph, the Secretary shall take into account the previous record of compliance of the entity being assessed with the applicable provisions of this part and part D *(other than subsections (a) and (b) of section 2799A–11)* and the gravity of the violation.

(iii) LIMITATIONS.—

(I) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No civil money penalty shall be imposed under this paragraph on any failure during any period for which it is established to the satisfaction of the Secretary that none of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

(II) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN 30 DAYS.—No civil money penalty shall be imposed under this paragraph on any failure if such failure was due to reasonable cause and not to willful neglect, and such failure is corrected during the 30-day period beginning on the first day any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

(D) ADMINISTRATIVE REVIEW.—

(i) OPPORTUNITY FOR HEARING.—The entity assessed shall be afforded an opportunity for hearing by the Secretary upon request made within 30 days after the date of the issuance of a notice of assessment. In such hearing the decision shall be made on the record pursuant to section 554 of title 5, United States Code. If no hearing is requested, the assessment shall constitute a final and unappealable order.

(ii) HEARING PROCEDURE.—If a hearing is requested, the initial agency decision shall be made by an administrative law judge, and such decision shall become the final order unless the Secretary modifies or vacates the decision. Notice of intent to modify or vacate the decision of the administrative law judge shall be issued to the parties within 30 days after the date of the decision of the judge. A final order which takes effect under this paragraph shall be subject to review only as provided under subparagraph (E).

(E) JUDICIAL REVIEW.—

(i) FILING OF ACTION FOR REVIEW.—Any entity against whom an order imposing a civil money penalty has been entered after an agency hearing under this paragraph may obtain review by the United States district court for any district in which such entity is located or the United States District Court for the District of Columbia by filing a notice of appeal in such court within 30 days from the date of such order, and simultaneously sending a copy of such notice by registered mail to the Secretary.

(ii) CERTIFICATION OF ADMINISTRATIVE RECORD.—The Secretary shall promptly certify and file in such court the record upon which the penalty was imposed.

(iii) STANDARD FOR REVIEW.—The findings of the Secretary shall be set aside only if found to be unsupported by substantial evidence as provided by section 706(2)(E) of title 5, United States Code.

(iv) APPEAL.—Any final decision, order, or judgment of the district court concerning such review shall be subject to appeal as provided in chapter 83 of title 28 of such Code.

(F) FAILURE TO PAY ASSESSMENT; MAINTENANCE OF ACTION.—

(i) FAILURE TO PAY ASSESSMENT.—If any entity fails to pay an assessment after it has become a final and unappealable order, or after the court has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General who shall recover the amount assessed by action in the appropriate United States district court.

(ii) NONREVIEWABILITY.—In such action the validity and appropriateness of the final order imposing the penalty shall not be subject to review.

(G) PAYMENT OF PENALTIES.—Except as otherwise provided, penalties collected under this paragraph shall be paid to the Secretary (or other officer) imposing the penalty and shall be available without appropriation and until expended for the purpose of enforcing the provisions with respect to which the penalty was imposed.

(3) ENFORCEMENT AUTHORITY RELATING TO GENETIC DISCRIMINATION.—

(A) GENERAL RULE.—In the cases described in paragraph (1), notwithstanding the provisions of paragraph (2)(C), the succeeding subparagraphs of this paragraph shall apply with respect to an action under this subsection by the Secretary with respect to any failure of a health insurance issuer in connection with a group health plan, to meet the requirements of subsection (a)(1)(F), (b)(3), (c), or (d) of section 2702 or section 2701 or 2702(b)(1) with respect to genetic information in connection with the plan.

(B) AMOUNT.—

(i) IN GENERAL.—The amount of the penalty imposed under this paragraph shall be $100 for each day in the noncompliance period with respect to each participant or beneficiary to whom such failure relates.

(ii) NONCOMPLIANCE PERIOD.—For purposes of this paragraph, the term "noncompliance period" means, with respect to any failure, the period—

(I) beginning on the date such failure first occurs; and

(II) ending on the date the failure is corrected.

(C) MINIMUM PENALTIES WHERE FAILURE DISCOVERED.—Notwithstanding clauses (i) and (ii) of subparagraph (D):

(i) IN GENERAL.—In the case of 1 or more failures with respect to an individual—

(I) which are not corrected before the date on which the plan receives a notice from the Secretary of such violation; and

(II) which occurred or continued during the period involved;

the amount of penalty imposed by subparagraph (A) by reason of such failures with respect to such individual shall not be less than $2,500.

(ii) HIGHER MINIMUM PENALTY WHERE VIOLATIONS ARE MORE THAN DE MINIMIS.—To the extent violations for which any person is liable under this paragraph for any year are more than de minimis, clause (i) shall be applied by substituting "$15,000" for "$2,500" with respect to such person.

(D) LIMITATIONS.—

(i) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.

(ii) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.—No penalty shall be imposed by subparagraph (A) on any failure if—

(I) such failure was due to reasonable cause and not to willful neglect; and

(II) such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such penalty knew, or exercising reasonable diligence would have known, that such failure existed.

(iii) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of—

(I) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans; or

(II) $500,000.

(E) WAIVER BY SECRETARY.—In the case of a failure which is due to reasonable cause and not to willful neglect,

the Secretary may waive part or all of the penalty imposed by subparagraph (A) to the extent that the payment of such penalty would be excessive relative to the failure involved.

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## PART D—ADDITIONAL COVERAGE PROVISIONS

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**[SEC. 2799A–4. MAINTENANCE OF PRICE COMPARISON TOOL.**

[A group health plan or a health insurance issuer offering group or individual health insurance coverage shall offer price comparison guidance by telephone and make available on the Internet website of the plan or issuer a price comparison tool that (to the extent practicable) allows an individual enrolled under such plan or coverage, with respect to such plan year, such geographic region, and participating providers with respect to such plan or coverage, to compare the amount of cost-sharing that the individual would be responsible for paying under such plan or coverage with respect to the furnishing of a specific item or service by any such provider.]

***SEC. 2799A–4. PRICE TRANSPARENCY REQUIREMENTS.***

*(a) COST SHARING TRANSPARENCY.—*

*(1) IN GENERAL.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Health Care Price Transparency Act of 2023, a group health plan or a health insurance issuer offering group or individual health insurance coverage shall permit individuals to learn the amount of cost-sharing (including deductibles, copayments, and coinsurance) under the individual's plan or coverage that the individual would be responsible for paying with respect to the furnishing of a specific item or service by a provider in a timely manner upon the request of the individual. At a minimum, such information shall include the information specified in paragraph (2) and shall be made available to such individual through a self-service tool that meets the requirements of paragraph (3) or, at the option of such individual, through a paper disclosure or phone or other electronic disclosure (as selected by such individual and provided at no cost to such individual) that meets such requirements as the Secretary may specify.*

*(2) SPECIFIED INFORMATION.—For purposes of paragraph (1), the information specified in this paragraph is, with respect to an item or service for which benefits are available under a group health plan or group or individual health insurance coverage furnished by a health care provider to a participant or beneficiary of such plan, or enrollee in such coverage, the following:*

*(A) If such provider is a participating provider with respect to such item or service, the in-network rate (as defined in subsection (c)) for such item or service.*

*(B) If such provider is not described in subparagraph (A), the maximum allowed amount for such item or service.*

*(C) The estimated amount of cost sharing (including deductibles, copayments, and coinsurance) that the participant, beneficiary, or enrollee will incur for such item or*

*service (which, in the case such item or service is to be furnished by a provider described in subparagraph (B), shall be calculated using the maximum amount described in such subparagraph).*

*(D) The amount the participant, beneficiary, or enrollee has already accumulated with respect to any deductible or out of pocket maximum, whether for items and services furnished by a participating provider or for items and services furnished by a provider that is not a participating provider, under the plan or coverage (broken down, in the case separate deductibles or maximums apply to separate participants, beneficiaries or enrollees enrolled in the plan or coverage, by such separate deductibles or maximums, in addition to any cumulative deductible or maximum).*

*(E) In the case such plan or coverage imposes any frequency or volume limitations with respect to such item or service (excluding medical necessity determinations), the amount that such participant, beneficiary, or enrollee has accrued towards such limitation with respect to such item or service.*

*(F) Any prior authorization, concurrent review, step therapy, fail first, or similar requirements applicable to coverage of such item or service under such plan or coverage.*

*The Secretary may provide that information described in any of subparagraphs (A) through (F) not be treated as information specified in this paragraph, and specify additional information that shall be treated as information specified in this paragraph, if determined appropriate by the Secretary.*

*(3) SELF-SERVICE TOOL.—For purposes of paragraph (1), a self-service tool established by a group health plan or group or individual health insurance coverage meets the requirements of this paragraph if such tool—*

*(A) is based on an Internet website;*

*(B) provides for real-time responses to requests described in paragraph (1);*

*(C) is updated in a manner such that information provided through such tool is timely and accurate at the time such request is made;*

*(D) allows such a request to be made with respect to an item or service furnished by—*

*(i) a specific provider that is a participating provider with respect to such item or service;*

*(ii) all providers that are participating providers with respect to such item or service; or*

*(iii) a provider that is not described in clause (ii);*

*(E) provides that such a request may be made with respect to an item or service through use of the billing code for such item or service or through use of a descriptive term for such item or service; and*

*(F) meets any other requirement determined appropriate by the Secretary.*

*The Secretary may require such tool, as a condition of complying with subparagraph (E), to link multiple billing codes to a single descriptive term if the Secretary determines that the*

*billing codes to be so linked correspond to similar items and services.*

*(b) RATE AND PAYMENT INFORMATION.—*

*(1) IN GENERAL.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Health Care Price Transparency Act of 2023, each group health plan or group or individual health insurance coverage (other than a grandfathered health plan (as defined in section 1251(e) of the Patient Protection and Affordable Care Act)) shall, not less frequently than once every 3 months (or, in the case of information described in paragraph (2)(B), not less frequently than monthly), make available to the public the rate and payment information described in paragraph (2) in accordance with paragraph (3).*

*(2) RATE AND PAYMENT INFORMATION DESCRIBED.—For purposes of paragraph (1), the rate and payment information described in this paragraph is, with respect to a group health plan or group or individual health insurance coverage, the following:*

*(A) With respect to each item or service (other than a drug) for which benefits are available under such plan or coverage, the in-network rate in effect with each provider that is a participating provider with respect to such item or service, other than such a rate in effect with a provider that, during the 1-year period ending 10 business days before the date of the publication of such information, did not submit any claim for such item or service to such plan or coverage.*

*(B) With respect to each drug (identified by national drug code) for which benefits are available under such plan, the average amount paid by such plan or coverage (net of rebates, discounts, and price concessions) for such drug dispensed or administered during the 90-day period beginning 180 days before such date of publication to each provider that was a participating provider with respect to such drug, broken down by each such provider, other than such an amount paid to a provider that, during such period, submitted fewer than 20 claims for such drug to such plan or coverage.*

*(C) With respect to each item or service for which benefits are available under such plan or coverage, the amount billed, and the amount allowed by the plan or coverage, for each such item or service furnished during the 90-day period specified in subparagraph (B) by a provider that was not a participating provider with respect to such item or service, broken down by each such provider, other than items and services with respect to which fewer than 20 claims for such item or service were submitted to such plan or coverage during such period.*

*(3) MANNER OF PUBLICATION.—Rate and payment information required to be made available under this subsection shall be so made available in dollar amounts through 3 separate machine-readable files (or any successor technology, such as application program interface technology, determined appropriate by the Secretary) corresponding to the information described in*

*each of subparagraphs (A) through (C) of paragraph (2) that meet such requirements as specified by the Secretary. Such requirements shall ensure that such files are limited to an appropriate size, do not include disclosure of unnecessary duplicative information contained in other files made available under this subsection, are made available in a widely-available format through a publicly-available website that allows for information contained in such files to be compared across group health plans and group and individual health insurance coverage, and are accessible to individuals at no cost and without the need to establish a user account or provide other credentials.*

*(4) USER INSTRUCTIONS.—Each group health plan and group or individual health insurance coverage shall make available to the public instructions written in plain language explaining how individuals may search for information described in paragraph (2) in files submitted in accordance with paragraph (3). The Secretary shall develop and publish a template that such a plan or coverage may use in developing instructions for purposes of the preceding sentence.*

*(5) ATTESTATION.—Each group health plan and group or individual health insurance coverage shall post, along with rate and payment information made public by such plan or coverage, an attestation that such information is complete and accurate.*

*(c) DEFINITIONS.—In this section:*

*(1) PARTICIPATING PROVIDER.—The term "participating provider" has the meaning given such term in section 2791A–1(a)(3)(G)(ii).*

*(2) IN-NETWORK RATE.—The term "in-network rate" means, with respect to a health plan or coverage and an item or service furnished by a provider that is a participating provider with respect to such plan and item or service, the contracted rate in effect between such plan or coverage and such provider for such item or service.*

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***SEC. 2799A–11. OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.***

*(a) IN GENERAL.—For plan years beginning on or after the date that is 3 years after the date of enactment of this section, a group health plan or health insurance issuer offering group health insurance coverage, or an entity or subsidiary providing pharmacy benefits management services on behalf of such a plan or issuer, shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or issuer, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan or issuer, from making the report described in subsection (b).*

*(b) ANNUAL REPORT.—*

*(1) IN GENERAL.—With respect to plan years beginning on or after the date that is 3 years after the date of enactment of this section, for each such plan year, a group health plan or health insurance issuer offering group health insurance coverage, or*

*an entity providing pharmacy benefits management services on behalf of such a plan or an issuer, shall submit to the plan sponsor (as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974) of such plan or coverage a report in a machine-readable format. Each such report shall include, with respect to such plan or coverage provided for such plan year—*

*(A) to the extent feasible, information collected from drug manufacturers (or an entity administering copay assistance on behalf of such manufacturers) by such plan or issuer (or entity or subsidiary providing pharmacy benefits management services on behalf of such plan or issuer) on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the participants, beneficiaries, and enrollees in such plan or coverage;*

*(B) a list of each drug covered by such plan or coverage that was dispensed during the plan year, including, with respect to each such drug during such plan year—*

*(i) the brand name, chemical entity, and National Drug Code;*

*(ii) the number of participants, beneficiaries, and enrollees for whom the drug was dispensed during the plan year, the total number of prescription claims for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, disaggregated by dispensing channel (such as retail, mail order, or specialty pharmacy);*

*(iii) the wholesale acquisition cost, listed as cost per days supply and cost per pill, or in the case of a drug in another form, per dosage unit;*

*(iv) the total out-of-pocket spending by participants, beneficiaries, and enrollees on such drug, including participant, beneficiary, and enrollee spending through copayments, coinsurance, and deductibles;*

*(v) for any drug for which gross spending of the group health plan or health insurance coverage exceeded $10,000 during the plan year—*

*(I) a list of all other drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class as such drug; and*

*(II) the rationale for the formulary placement of such drug in that therapeutic category or class, if applicable;*

*(vi) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration for claims incurred for such drug during the plan year;*

*(vii) the total net spending, after deducting rebates, price concessions, alternative discounts or other remu-*

*neration from drug manufacturers, by the health plan or health insurance coverage on such drug; and*

*(viii) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, incurred by the health plan or health insurance coverage and its participants, beneficiaries, and enrollees, after manufacturer rebates, fees, and other remuneration for such drug dispensed during the plan year;*

*(C) a list of each therapeutic category or class of drugs that were dispensed under the health plan or health insurance coverage during the plan year, and, with respect to each such therapeutic category or class of drugs, during the plan year—*

*(i) total gross spending by the plan or coverage, before manufacturer rebates, fees, or other manufacturer remuneration;*

*(ii) the number of participants, beneficiaries, and enrollees who were dispensed a drug covered by such plan or coverage in that category or class, broken down by each such drug (identified by National Drug Code);*

*(iii) if applicable to that category or class, a description of the formulary tiers and utilization management (such as prior authorization or step therapy) employed for drugs in that category or class; and*

*(iv) the total out-of-pocket spending by participants, beneficiaries, and enrollees, including participant, beneficiary, and enrollee spending through copayments, coinsurance, and deductibles;*

*(D) total gross spending on prescription drugs by the plan or coverage during the plan year, before rebates and other manufacturer fees or remuneration;*

*(E) total amount received, or expected to be received, by the health plan or health insurance coverage in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug spending under that health plan or health insurance coverage during the plan year;*

*(F) the total net spending on prescription drugs by the health plan or health insurance coverage during the plan year; and*

*(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm for the referral of the group health plan's or health insurance issuer's business to the pharmacy benefits manager.*

*(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage and entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and shall restrict the use and disclosure of such information according to such privacy regulations.*

*(3) DISCLOSURE AND REDISCLOSURE.—*

*(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).*

*(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such issuer or entity may not restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, the Comptroller General of the United States, or applicable State agencies.*

*(C) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required of plan sponsors who are drug manufacturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anticompetitive behavior.*

*(4) REPORT TO GAO.—A group health plan or health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 4 reports submitted to a plan sponsor under paragraph (1) with respect to such coverage or plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (2), the disclosure and redisclosure standards under paragraph (3), the standards specified pursuant to paragraph (5), and such other information that the Comptroller General determines necessary to carry out the study under section 103(d) of the Health Care Price Transparency Act of 2023.*

*(5) STANDARD FORMAT.—Not later than 18 months after the date of enactment of this section, the Secretary shall specify through rulemaking standards for health insurance issuers and entities required to submit reports under paragraph (4) to submit such reports in a standard format.*

*(c) ENFORCEMENT.—*

*(1) IN GENERAL.—Notwithstanding section 2723, the Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall enforce this section.*

*(2) FAILURE TO PROVIDE TIMELY INFORMATION.—A health insurance issuer or an entity providing pharmacy benefits management services that violates subsection (a) or fails to provide information required under subsection (b) shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.*

*(3) FALSE INFORMATION.—A health insurance issuer or entity providing pharmacy benefits management services that know-*

*ingly provides false information under this section shall be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalty shall be in addition to other penalties as may be prescribed by law.*

*(4) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsection (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.*

*(5) WAIVERS.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that has made a good-faith effort to comply with this section.*

*(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary of Health and Human Services to a report described in subsection (b)(1) or information related to compliance with subsection (a) or (b) by such issuer, plan, or other entity subject to such subsections.*

*(e) DEFINITION.—In this section, the term "wholesale acquisition cost" has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.*

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**INTERNAL REVENUE CODE OF 1986**

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# Subtitle K—Group Health Plan Requirements

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## CHAPTER 100—GROUP HEALTH PLAN REQUIREMENTS

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## Subchapter B—OTHER REQUIREMENTS

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[Sec. 9819. Maintenance of price comparison tool.]
*Sec. 9819. Price transparency requirements.*

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*Sec. 9826. Oversight of pharmacy benefits manager services.*

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**[SEC. 9819. MAINTENANCE OF PRICE COMPARISON TOOL.**

**[**A group health plan shall offer price comparison guidance by telephone and make available on the Internet website of the plan or issuer a price comparison tool that (to the extent practicable) allows an individual enrolled under such plan, with respect to such plan year, such geographic region, and participating providers with respect to such plan or coverage, to compare the amount of cost-sharing that the individual would be responsible for paying under such plan with respect to the furnishing of a specific item or service by any such provider.**]**

***SEC. 9819. PRICE TRANSPARENCY REQUIREMENTS.***

*(a) COST SHARING TRANSPARENCY.—*

*(1) IN GENERAL.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Health Care Price Transparency Act of 2023, a group health plan shall permit individuals to learn the amount of cost-sharing (including deductibles, copayments, and coinsurance) under the individual's plan or coverage that the individual would be responsible for paying with respect to the furnishing of a specific item or service by a provider in a timely manner upon the request of the individual. At a minimum, such information shall include the information specified in paragraph (2) and shall be made available to such individual through a self-service tool that meets the requirements of paragraph (3) or, at the option of such individual, through a paper disclosure or phone or other electronic disclosure (as selected by such individual and provided at no cost to such individual) that meets such requirements as the Secretary may specify.*

*(2) SPECIFIED INFORMATION.—For purposes of paragraph (1), the information specified in this paragraph is, with respect to an item or service for which benefits are available under a group health plan furnished by a health care provider to a participant or beneficiary of such plan, the following:*

*(A) If such provider is a participating provider with respect to such item or service, the in-network rate (as defined in subsection (c)) for such item or service.*

*(B) If such provider is not described in subparagraph (A), the maximum allowed amount for such item or service.*

*(C) The estimated amount of cost sharing (including deductibles, copayments, and coinsurance) that the participant or beneficiary will incur for such item or service (which, in the case such item or service is to be furnished by a provider described in subparagraph (B), shall be calculated using the maximum amount described in such subparagraph).*

*(D) The amount the participant or beneficiary has already accumulated with respect to any deductible or out of pocket maximum, whether for items and services furnished by a participating provider or for items and services furnished by a provider that is not a participating provider, under the plan (broken down, in the case separate deductibles or maximums apply to separate participants and beneficiaries enrolled in the plan, by such separate deductibles or maximums, in addition to any cumulative deductible or maximum).*

*(E) In the case such plan imposes any frequency or volume limitations with respect to such item or service (excluding medical necessity determinations), the amount that such participant or beneficiary has accrued towards such limitation with respect to such item or service.*

*(F) Any prior authorization, concurrent review, step therapy, fail first, or similar requirements applicable to coverage of such item or service under such plan.*

*The Secretary may provide that information described in any of subparagraphs (A) through (F) not be treated as information specified in this paragraph, and specify additional information that shall be treated as information specified in this paragraph, if determined appropriate by the Secretary.*

*(3) SELF-SERVICE TOOL.—For purposes of paragraph (1), a self-service tool established by a group health plan meets the requirements of this paragraph if such tool—*

*(A) is based on an Internet website;*

*(B) provides for real-time responses to requests described in paragraph (1);*

*(C) is updated in a manner such that information provided through such tool is timely and accurate at the time such request is made;*

*(D) allows such a request to be made with respect to an item or service furnished by—*

*(i) a specific provider that is a participating provider with respect to such item or service;*

*(ii) all providers that are participating providers with respect to such item or service; or*

*(iii) a provider that is not described in clause (ii);*

*(E) provides that such a request may be made with respect to an item or service through use of the billing code for such item or service or through use of a descriptive term for such item or service; and*

*(F) meets any other requirement determined appropriate by the Secretary.*

*The Secretary may require such tool, as a condition of complying with subparagraph (E), to link multiple billing codes to a single descriptive term if the Secretary determines that the billing codes to be so linked correspond to similar items and services.*

*(b) RATE AND PAYMENT INFORMATION.—*

*(1) IN GENERAL.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Health Care Price Transparency Act of 2023, each group health plan (other than a grandfathered health plan (as defined in section 1251(e) of the Patient Protection and Affordable Care Act)) shall, not less frequently than once every 3 months (or, in the case of information described in paragraph (2)(B), not less frequently than monthly), make available to the public the rate and payment information described in paragraph (2) in accordance with paragraph (3).*

*(2) RATE AND PAYMENT INFORMATION DESCRIBED.—For purposes of paragraph (1), the rate and payment information described in this paragraph is, with respect to a group health plan, the following:*

*(A) With respect to each item or service (other than a drug) for which benefits are available under such plan, the in-network rate in effect with each provider that is a participating provider with respect to such item or service, other than such a rate in effect with a provider that, during the 1-year period ending 10 business days before the date of the publication of such information, did not submit any claim for such item or service to such plan.*

*(B) With respect to each drug (identified by national drug code) for which benefits are available under such plan, the average amount paid by such plan (net of rebates, discounts, and price concessions) for such drug dispensed or administered during the 90-day period beginning 180 days before such date of publication to each provider that was a participating provider with respect to such drug, broken down by each such provider, other than such an amount paid to a provider that, during such period, submitted fewer than 20 claims for such drug to such plan.*

*(C) With respect to each item or service for which benefits are available under such plan, the amount billed, and the amount allowed by the plan, for each such item or service furnished during the 90-day period specified in subparagraph (B) by a provider that was not a participating provider with respect to such item or service, broken down by each such provider, other than items and services with respect to which fewer than 20 claims for such item or service were submitted to such plan during such period.*

*(3) MANNER OF PUBLICATION.—Rate and payment information required to be made available under this subsection shall be so made available in dollar amounts through 3 separate machine-readable files (or any successor technology, such as application program interface technology, determined appropriate by the Secretary) corresponding to the information described in each of subparagraphs (A) through (C) of paragraph (2) that meet such requirements as specified by the Secretary. Such requirements shall ensure that such files are limited to an appropriate size, do not include disclosure of unnecessary duplicative information contained in other files made available under this subsection, are made available in a widely-available format through a publicly-available website that allows for information contained in such files to be compared across group health plans, and are accessible to individuals at no cost and without the need to establish a user account or provide other credentials.*

*(4) USER INSTRUCTIONS.—Each group health plan shall make available to the public instructions written in plain language explaining how individuals may search for information described in paragraph (2) in files submitted in accordance with paragraph (3). The Secretary shall develop and publish a template that such a plan may use in developing instructions for purposes of the preceding sentence.*

*(5) ATTESTATION.—Each group health plan shall post, along with rate and payment information made public by such plan, an attestation that such information is complete and accurate.*

*(c) DEFINITIONS.—In this section:*

*(1) PARTICIPATING PROVIDER.—The term "participating provider" has the meaning given such term in section 9816.*

*(2) IN-NETWORK RATE.—The term "in-network rate" means, with respect to a health plan and an item or service furnished by a provider that is a participating provider with respect to such plan and item or service, the contracted rate in effect between such plan and such provider for such item or service.*

* * * * * * *

***SEC. 9826. OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.***

*(a) IN GENERAL.—For plan years beginning on or after the date that is 3 years after the date of enactment of this section, a group health plan, or an entity or subsidiary providing pharmacy benefits management services on behalf of such a plan, shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan, from making the report described in subsection (b).*

*(b) ANNUAL REPORT.—*

*(1) IN GENERAL.—With respect to plan years beginning on or after the date that is 3 years after the date of enactment of this section, for each such plan year, a group health plan, or an entity providing pharmacy benefits management services on behalf of such a plan, shall submit to the plan sponsor (as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974) of such plan a report in a machine-readable format. Each such report shall include, with respect to such plan provided for such plan year—*

*(A) to the extent feasible, information collected from drug manufacturers (or an entity administering copay assistance on behalf of such manufacturers) by such plan (or entity or subsidiary providing pharmacy benefits management services on behalf of such plan) on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the participants and beneficiaries in such plan;*

*(B) a list of each drug covered by such plan that was dispensed during the plan year, including, with respect to each such drug during such plan year—*

*(i) the brand name, chemical entity, and National Drug Code;*

*(ii) the number of participants and beneficiaries for whom the drug was dispensed during the plan year, the total number of prescription claims for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, disaggregated by dispensing channel (such as retail, mail order, or specialty pharmacy);*

*(iii) the wholesale acquisition cost, listed as cost per days supply and cost per pill, or in the case of a drug in another form, per dosage unit;*

*(iv) the total out-of-pocket spending by participants and beneficiaries on such drug, including participant and beneficiary spending through copayments, coinsurance, and deductibles;*

*(v) for any drug for which gross spending of the group health plan exceeded $10,000 during the plan year—*

*(I) a list of all other drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class as such drug; and*

*(II) the rationale for the formulary placement of such drug in that therapeutic category or class, if applicable;*

*(vi) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration for claims incurred for such drug during the plan year;*

*(vii) the total net spending, after deducting rebates, price concessions, alternative discounts or other remuneration from drug manufacturers, by the health plan on such drug; and*

*(viii) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, incurred by the health plan and its participants and beneficiaries after manufacturer rebates, fees, and other remuneration for such drug dispensed during the plan year;*

*(C) a list of each therapeutic category or class of drugs that were dispensed under the health plan during the plan year, and, with respect to each such therapeutic category or class of drugs, during the plan year—*

*(i) total gross spending by the plan, before manufacturer rebates, fees, or other manufacturer remuneration;*

*(ii) the number of participants and beneficiaries who were dispensed a drug covered by such plan in that category or class, broken down by each such drug (identified by National Drug Code);*

*(iii) if applicable to that category or class, a description of the formulary tiers and utilization management (such as prior authorization or step therapy) employed for drugs in that category or class; and*

*(iv) the total out-of-pocket spending by participants and beneficiaries, including participant and beneficiary spending through copayments, coinsurance, and deductibles;*

*(D) total gross spending on prescription drugs by the plan during the plan year, before rebates and other manufacturer fees or remuneration;*

*(E) total amount received, or expected to be received, by the health plan in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from*

*the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug spending under that health plan during the plan year;*

*(F) the total net spending on prescription drugs by the health plan during the plan year; and*

*(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm for the referral of the group health plan's business to the pharmacy benefits manager.*

*(2) PRIVACY REQUIREMENTS.—Entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and shall restrict the use and disclosure of such information according to such privacy regulations.*

*(3) DISCLOSURE AND REDISCLOSURE.—*

*(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).*

*(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents an entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such entity may not restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, the Comptroller General of the United States, or applicable State agencies.*

*(C) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required of plan sponsors who are drug manufacturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anticompetitive behavior.*

*(4) REPORT TO GAO.—A group health plan, or an entity providing pharmacy benefits management services on behalf of a group health plan, shall submit to the Comptroller General of the United States each of the first 4 reports submitted to a plan sponsor under paragraph (1) with respect to such plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (2), the disclosure and redisclosure standards under paragraph (3), the standards specified pursuant to paragraph (5), and such other information that the Comptroller General determines necessary to carry out the study under section 103(d) of the Health Care Price Transparency Act of 2023.*

*(5) STANDARD FORMAT.—Not later than 18 months after the date of enactment of this section, the Secretary shall specify through rulemaking standards for entities required to submit*

*reports under paragraph (4) to submit such reports in a standard format.*

*(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a group health plan or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary of the Treasury to a report described in subsection (b)(1) or information related to compliance with subsection (a) or (b) by such plan or other entity subject to such subsections.*

*(d) DEFINITION.—In this section, the term "wholesale acquisition cost" has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.*

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## EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

SHORT TITLE AND TABLE OF CONTENTS

SECTION 1. This Act may be cited as the "Employee Retirement Income Security Act of 1974".

TABLE OF CONTENTS



## TITLE I—PROTECTION OF EMPLOYEE BENEFIT RIGHTS

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### SUBTITLE B—REGULATORY PROVISIONS

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### PART 5—ADMINISTRATION AND ENFORCEMENT

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CIVIL ENFORCEMENT

SEC. 502. (a) A civil action may be brought—

(1) by a participant or beneficiary—

(A) for the relief provided for in subsection (c) of this section, or

(B) to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan;

(2) by the Secretary, or by a participant, beneficiary or fiduciary for appropriate relief under section 409;

(3) by a participant, beneficiary, or fiduciary (A) to enjoin any act or practice which violates any provision of this title or the terms of the plan, or (B) to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of this title or the terms of the plan;

(4) by the Secretary, or by a participant, or beneficiary for appropriate relief in the case of a violation of section 105(c) or 113(a);

(5) except as otherwise provided in subsection (b), by the Secretary (A) to enjoin any act or practice which violates any provision of this title, or (B) to obtain other appropriate equitable relief (i) to redress such violation or (ii) to enforce any provision of this title;

(6)by the Secretary to collect any civil penalty under paragraph (2), (4), (5), (6), (7), (8), ⟦or (9)⟧ *(9), or (13)* of subsection (c) or under subsection (i) or (l);

(7) by a State to enforce compliance with a qualified medical child support order (as defined in section 609(a)(2)(A));

(8) by the Secretary, or by an employer or other person referred to in section 101(f)(1), (A) to enjoin any act or practice which violates subsection (f) of section 101, or (B) to obtain appropriate equitable relief (i) to redress such violation or (ii) to enforce such subsection;

(9) in the event that the purchase of an insurance contract or insurance annuity in connection with termination of an individual's status as a participant covered under a pension plan with respect to all or any portion of the participant's pension benefit under such plan constitutes a violation of part 4 of this title or the terms of the plan, by the Secretary, by any individual who was a participant or beneficiary at the time of the alleged violation, or by a fiduciary, to obtain appropriate relief, including the posting of security if necessary, to assure receipt by the participant or beneficiary of the amounts provided or to be provided by such insurance contract or annuity, plus reasonable prejudgment interest on such amounts;

(10) in the case of a multiemployer plan that has been certified by the actuary to be in endangered or critical status under section 305, if the plan sponsor—

(A) has not adopted a funding improvement or rehabilitation plan under that section by the deadline established in such section, or

(B) fails to update or comply with the terms of the funding improvement or rehabilitation plan in accordance with the requirements of such section,

by an employer that has an obligation to contribute with respect to the multiemployer plan or an employee organization that represents active participants in the multiemployer plan, for an order compelling the plan sponsor to adopt a funding improvement or rehabilitation plan or to update or comply

with the terms of the funding improvement or rehabilitation plan in accordance with the requirements of such section and the funding improvement or rehabilitation plan; [or]

(11) in the case of a multiemployer plan, by an employee representative, or any employer that has an obligation to contribute to the plan, (A) to enjoin any act or practice which violates subsection (k) of section 101 (or, in the case of an employer, subsection (l) of such section), or (B) to obtain appropriate equitable relief (i) to redress such violation or (ii) to enforce such subsection[.]*; or*

*(12) by the Secretary, in consultation with the Secretary of Health and Human Services, and the Secretary of the Treasury, to enforce section 726.*

(b)(1) In the case of a plan which is qualified under section 401(a), 403(a), or 405(a) of the Internal Revenue Code of 1986 (or with respect to which an application to so qualify has been filed and has not been finally determined) the Secretary may exercise his authority under subsection (a)(5) with respect to a violation of, or the enforcement of, parts 2 and 3 of this subtitle (relating to participation, vesting, and funding), only if—

(A) requested by the Secretary of the Treasury, or

(B) one or more participants, beneficiaries, or fiduciaries, of such plan request in writing (in such manner as the Secretary shall prescribe by regulation) that he exercise such authority on their behalf. In the case of such a request under this paragraph he may exercise such authority only if he determines that such violation affects, or such enforcement is necessary to protect, claims of participants or beneficiaries to benefits under the plan.

(2) The Secretary shall not initiate an action to enforce section 515.

(3) Except as provided in subsections (c)(9) and (a)(6) (with respect to collecting civil penalties under subsection (c)(9)) *and subsections (a)(12) and (c)(13)*, the Secretary is not authorized to enforce under this part any requirement of part 7 against a health insurance issuer offering health insurance coverage in connection with a group health plan (as defined in section 706(a)(1)). Nothing in this paragraph shall affect the authority of the Secretary to issue regulations to carry out such part.

(c)(1) Any administrator (A) who fails to meet the requirements of paragraph (1) or (4) of section 606, section 101(e)(1), section 101(f),, section 105(a), or section 113(a) with respect to a participant or beneficiary, or (B) who fails or refuses to comply with a request for any information which such administrator is required by this title to furnish to a participant or beneficiary (unless such failure or refusal results from matters reasonably beyond the control of the administrator) by mailing the material requested to the last known address of the requesting participant or beneficiary within 30 days after such request may in the court's discretion be personally liable to such participant or beneficiary in the amount of up to $100 a day from the date of such failure or refusal, and the court may in its discretion order such other relief as it deems proper. For purposes of this paragraph, each violation described in subparagraph (A) with respect to any single participant, and each violation

described in subparagraph (B) with respect to any single participant or beneficiary, shall be treated as a separate violation.

(2) The Secretary may assess a civil penalty against any plan administrator of up to $1,000 a day from the date of such plan administrator's failure or refusal to file the annual report required to be filed with the Secretary under section 101(b)(1). For purposes of this paragraph, an annual report that has been rejected under section 104(a)(4) for failure to provide material information shall not be treated as having been filed with the Secretary.

(3) Any employer maintaining a plan who fails to meet the notice requirement of section 101(d) with respect to any participant or beneficiary or who fails to meet the requirements of section 101(e)(2) with respect to any person or who fails to meet the requirements of section 302(d)(12)(E) with respect to any person may in the court's discretion be liable to such participant or beneficiary or to such person in the amount of up to $100 a day from the date of such failure, and the court may in its discretion order such other relief as it deems proper.

(4) The Secretary may assess a civil penalty of not more than $1,000 a day for each violation by any person of subsection (j), (k), or (l) of section 101 or section 514(e)(3).

(5) The Secretary may assess a civil penalty against any person of up to $1,000 a day from the date of the person's failure or refusal to file the information required to be filed by such person with the Secretary under regulations prescribed pursuant to section 101(g).

(6) If, within 30 days of a request by the Secretary to a plan administrator for documents under section 104(a)(6), the plan administrator fails to furnish the material requested to the Secretary, the Secretary may assess a civil penalty against the plan administrator of up to $100 a day from the date of such failure (but in no event in excess of $1,000 per request). No penalty shall be imposed under this paragraph for any failure resulting from matters reasonably beyond the control of the plan administrator.

(7) The Secretary may assess a civil penalty against a plan administrator of up to $100 a day from the date of the plan administrator's failure or refusal to provide notice to participants and beneficiaries in accordance with subsection (i) or (m) of section 101. For purposes of this paragraph, each violation with respect to any single participant or beneficiary shall be treated as a separate violation.

(8) The Secretary may assess against any plan sponsor of a multiemployer plan a civil penalty of not more than $1,100 per day—

(A) for each violation by such sponsor of the requirement under section 305 to adopt by the deadline established in that section a funding improvement plan or rehabilitation plan with respect to a multiemployer plan which is in endangered or critical status, or

(B) in the case of a plan in endangered status which is not in seriously endangered status, for failure by the plan to meet the applicable benchmarks under section 305 by the end of the funding improvement period with respect to the plan.

(9)(A) The Secretary may assess a civil penalty against any employer of up to $100 a day from the date of the employer's failure to meet the notice requirement of section 701(f)(3)(B)(i)(I). For purposes of this subparagraph, each violation with respect to any single employee shall be treated as a separate violation.

(B) The Secretary may assess a civil penalty against any plan administrator of up to $100 a day from the date of the plan administrator's failure to timely provide to any State the information required to be disclosed under section 701(f)(3)(B)(ii). For purposes of this subparagraph, each violation with respect to any single participant or beneficiary shall be treated as a separate violation.

(10) SECRETARIAL ENFORCEMENT AUTHORITY RELATING TO USE OF GENETIC INFORMATION.—

(A) GENERAL RULE.—The Secretary may impose a penalty against any plan sponsor of a group health plan, or any health insurance issuer offering health insurance coverage in connection with the plan, for any failure by such sponsor or issuer to meet the requirements of subsection (a)(1)(F), (b)(3), (c), or (d) of section 702 or section 701 or 702(b)(1) with respect to genetic information, in connection with the plan.

(B) AMOUNT.—

(i) IN GENERAL.—The amount of the penalty imposed by subparagraph (A) shall be $100 for each day in the noncompliance period with respect to each participant or beneficiary to whom such failure relates.

(ii) NONCOMPLIANCE PERIOD.—For purposes of this paragraph, the term "noncompliance period" means, with respect to any failure, the period—

(I) beginning on the date such failure first occurs; and

(II) ending on the date the failure is corrected.

(C) MINIMUM PENALTIES WHERE FAILURE DISCOVERED.—Notwithstanding clauses (i) and (ii) of subparagraph (D):

(i) IN GENERAL.—In the case of 1 or more failures with respect to a participant or beneficiary—

(I) which are not corrected before the date on which the plan receives a notice from the Secretary of such violation; and

(II) which occurred or continued during the period involved;

the amount of penalty imposed by subparagraph (A) by reason of such failures with respect to such participant or beneficiary shall not be less than $2,500.

(ii) HIGHER MINIMUM PENALTY WHERE VIOLATIONS ARE MORE THAN DE MINIMIS.—To the extent violations for which any person is liable under this paragraph for any year are more than de minimis, clause (i) shall be applied by substituting "$15,000" for "$2,500" with respect to such person.

(D) LIMITATIONS.—

(i) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to

the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.

(ii) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.—No penalty shall be imposed by subparagraph (A) on any failure if—

(I) such failure was due to reasonable cause and not to willful neglect; and

(II) such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such penalty knew, or exercising reasonable diligence would have known, that such failure existed.

(iii) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of—

(I) 10 percent of the aggregate amount paid or incurred by the plan sponsor (or predecessor plan sponsor) during the preceding taxable year for group health plans; or

(II) $500,000.

(E) WAIVER BY SECRETARY.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the penalty imposed by subparagraph (A) to the extent that the payment of such penalty would be excessive relative to the failure involved.

(F) DEFINITIONS.—Terms used in this paragraph which are defined in section 733 shall have the meanings provided such terms in such section.

(11) The Secretary and the Secretary of Health and Human Services shall maintain such ongoing consultation as may be necessary and appropriate to coordinate enforcement under this subsection with enforcement under section 1144(c)(8) of the Social Security Act.

(12) The Secretary may assess a civil penalty against any sponsor of a CSEC plan of up to $100 a day from the date of the plan sponsor's failure to comply with the requirements of section 306(j)(3) to establish or update a funding restoration plan.

*(13) SECRETARIAL ENFORCEMENT AUTHORITY RELATING TO OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.—*

*(A) FAILURE TO PROVIDE TIMELY INFORMATION.—The Secretary, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, may impose a penalty against any group health plan or health insurance issuer offering group health insurance coverage, or entity providing pharmacy benefits management services on behalf of such plan or coverage, that violates section 726(a) or fails to provide information required under section 726(b), in the amount of $10,000 for each day during*

*which such violation continues or such information is not disclosed or reported.*

*(B) FALSE INFORMATION.—The Secretary, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, may impose a penalty against a group health plan or health insurance issuer offering group health coverage, or an entity providing pharmacy benefits management services on behalf of such plan or coverage, that knowingly provides false information under section 726 in an amount not to exceed $100,000 for each item of false information. Such penalty shall be in addition to other penalties as may be prescribed by law.*

*(C) WAIVERS.—The Secretary may waive penalties under subparagraph (A), or extend the period of time for compliance with a requirement of section 726, for an entity in violation of such section that has made a good-faith effort to comply with such section.*

(d)(1) An employee benefit plan may sue or be sued under this title as an entity. Service of summons, subpena, or other legal process of a court upon a trustee or an administrator of an employee benefit plan in his capacity as such shall constitute service upon the employee benefit plan. In a case where a plan has not designated in the summary plan description of the plan an individual as agent for the service of legal process, service upon the Secretary shall constitute such service. The Secretary, not later than 15 days after receipt of service under the preceding sentence, shall notify the administrator or any trustee of the plan of receipt of such service.

(2) Any money judgment under this title against an employee benefit plan shall be enforceable only against the plan as an entity and shall not be enforceable against any other person unless liability against such person is established in his individual capacity under this title.

(e)(1) Except for actions under subsection (a)(1)(B) of this section, the district courts of the United States shall have exclusive jurisdiction of civil actions under this title brought by the Secretary or by a participant, beneficiary, fiduciary, or any person referred to in section 101(f)(1). State courts of competent jurisdiction and district courts of the United States shall have concurrent jurisdiction of actions under paragraphs (1)(B) and (7) of subsection (a) of this section.

(2) Where an action under this title is brought in a district court of the United States, it may be brought in the district where the plan is administered, where the breach took place, or where a defendant resides or may be found, and process may be served in any other district where a defendant resides or may be found.

(f) The district courts of the United States shall have jurisdiction, without respect to the amount in controversy or the citizenship of the parties, to grant the relief provided for in subsection (a) of this section in any action.

(g)(1) In any action under this title (other than an action described in paragraph (2)) by a participant, beneficiary, or fiduciary, the court in its discretion may allow a reasonable attorney's fee and costs of action to either party.

(2) In any action under this title by a fiduciary for or on behalf of a plan to enforce section 515 in which a judgment in favor of the plan is awarded, the court shall award the plan—

(A) the unpaid contributions,

(B) interest on the unpaid contributions,

(C) an amount equal to the greater of—

(i) interest on the unpaid contributions, or

(ii) liquidated damages provided for under the plan in an amount not in excess of 20 percent (or such higher percentage as may be permitted under Federal or State law) of the amount determined by the court under subparagraph (A),

(D) reasonable attorney's fees and costs of the action, to be paid by the defendant, and

(E) such other legal or equitable relief as the court deems appropriate.

For purposes of this paragraph, interest on unpaid contributions shall be determined by using the rate provided under the plan, or, if none, the rate prescribed under section 6621 of the Internal Revenue Code of 1986.

(h) A copy of the complaint in any action under this title by a participant, beneficiary, or fiduciary (other than an action brought by one or more participants or beneficiaries under subsection (a)(1)(B) which is solely for the purpose of recovering benefits due such participants under the terms of the plan) shall be served upon the Secretary and the Secretary of the Treasury by certified mail. Either Secretary shall have the right in his discretion to intervene in any action, except that the Secretary of the Treasury may not intervene in any action under part 4 of this subtitle. If the Secretary brings an action under subsection (a) on behalf of a participant or beneficiary, he shall notify the Secretary of the Treasury.

(i) In the case of a transaction prohibited by section 406 by a party in interest with respect to a plan to which this part applies, the Secretary may assess a civil penalty against such party in interest. The amount of such penalty may not exceed 5 percent of the amount involved in each such transaction (as defined in section 4975(f)(4) of the Internal Revenue Code of 1986) for each year or part thereof during which the prohibited transaction continues, except that, if the transaction is not corrected (in such manner as the Secretary shall prescribe in regulations which shall be consistent with section 4975(f)(5) of such Code) within 90 days after notice from the Secretary (or such longer period as the Secretary may permit), such penalty may be in an amount not more than 100 percent of the amount involved. This subsection shall not apply to a transaction with respect to a plan described in section 4975(e)(1) of such Code.

(j) In all civil actions under this title, attorneys appointed by the Secretary may represent the Secretary (except as provided in section 518(a) of title 28, United States Code), but all such litigation shall be subject to the direction and control of the Attorney General.

(k) Suits by an administrator, fiduciary, participant, or beneficiary of an employee benefit plan to review a final order of the Secretary, to restrain the Secretary from taking any action contrary to the provisions of this Act, or to compel him to take action

required under this title, may be brought in the district court of the United States for the district where the plan has its principal office, or in the United States District Court for the District of Columbia.

(l)(1) In the case of—

(A) any breach of fiduciary responsibility under (or other violation of) part 4 by a fiduciary, or

(B) any knowing participation in such a breach or violation by any other person,

the Secretary shall assess a civil penalty against such fiduciary or other person in an amount equal to 20 percent of the applicable recovery amount.

(2) For purposes of paragraph (1), the term "applicable recovery amount" means any amount which is recovered from a fiduciary or other person with respect to a breach or violation described in paragraph (1)—

(A) pursuant to any settlement agreement with the Secretary, or

(B) ordered by a court to be paid by such fiduciary or other person to a plan or its participants and beneficiaries in a judicial proceeding instituted by the Secretary under subsection (a)(2) or (a)(5).

(3) The Secretary may, in the Secretary's sole discretion, waive or reduce the penalty under paragraph (1) if the Secretary determines in writing that—

(A) the fiduciary or other person acted reasonably and in good faith, or

(B) it is reasonable to expect that the fiduciary or other person will not be able to restore all losses to the plan (or to provide the relief ordered pursuant to subsection (a)(9)) without severe financial hardship unless such waiver or reduction is granted.

(4) The penalty imposed on a fiduciary or other person under this subsection with respect to any transaction shall be reduced by the amount of any penalty or tax imposed on such fiduciary or other person with respect to such transaction under subsection (i) of this section and section 4975 of the Internal Revenue Code of 1986.

(m) In the case of a distribution to a pension plan participant or beneficiary in violation of section 206(e) by a plan fiduciary, the Secretary shall assess a penalty against such fiduciary in an amount equal to the value of the distribution. Such penalty shall not exceed $10,000 for each such distribution.

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PART 7—GROUP HEALTH PLAN REQUIREMENTS

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SUBPART B—OTHER REQUIREMENTS

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**[SEC. 719. MAINTENANCE OF PRICE COMPARISON TOOL.**

[A group health plan or a health insurance issuer offering group health insurance coverage shall offer price comparison guidance by telephone and make available on the Internet website of the plan

or issuer a price comparison tool that (to the extent practicable) allows an individual enrolled under such plan or coverage, with respect to such plan year, such geographic region, and participating providers with respect to such plan or coverage, to compare the amount of cost-sharing that the individual would be responsible for paying under such plan or coverage with respect to the furnishing of a specific item or service by any such provider.]

***SEC. 719. PRICE TRANSPARENCY REQUIREMENTS.***

*(a) COST SHARING TRANSPARENCY.—*

*(1) IN GENERAL.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Health Care Price Transparency Act of 2023, a group health plan or a health insurance issuer offering group health insurance coverage shall permit individuals to learn the amount of cost-sharing (including deductibles, copayments, and coinsurance) under the individual's plan or coverage that the individual would be responsible for paying with respect to the furnishing of a specific item or service by a provider in a timely manner upon the request of the individual. At a minimum, such information shall include the information specified in paragraph (2) and shall be made available to such individual through a self-service tool that meets the requirements of paragraph (3) or, at the option of such individual, through a paper disclosure or phone or other electronic disclosure (as selected by such individual and provided at no cost to such individual) that meets such requirements as the Secretary may specify.*

*(2) SPECIFIED INFORMATION.—For purposes of paragraph (1), the information specified in this paragraph is, with respect to an item or service for which benefits are available under a group health plan or group health insurance coverage furnished by a health care provider to a participant or beneficiary of such plan, or enrollee in such coverage, the following:*

*(A) If such provider is a participating provider with respect to such item or service, the in-network rate (as defined in subsection (c)) for such item or service.*

*(B) If such provider is not described in subparagraph (A), the maximum allowed amount for such item or service.*

*(C) The estimated amount of cost sharing (including deductibles, copayments, and coinsurance) that the participant, beneficiary, or enrollee will incur for such item or service (which, in the case such item or service is to be furnished by a provider described in subparagraph (B), shall be calculated using the maximum amount described in such subparagraph).*

*(D) The amount the participant, beneficiary, or enrollee has already accumulated with respect to any deductible or out of pocket maximum, whether for items and services furnished by a participating provider or for items and services furnished by a provider that is not a participating provider, under the plan or coverage (broken down, in the case separate deductibles or maximums apply to separate participants, beneficiaries or enrollees enrolled in the plan or coverage, by such separate deductibles or maximums, in addition to any cumulative deductible or maximum).*

*(E) In the case such plan or coverage imposes any frequency or volume limitations with respect to such item or service (excluding medical necessity determinations), the amount that such participant, beneficiary, or enrollee has accrued towards such limitation with respect to such item or service.*

*(F) Any prior authorization, concurrent review, step therapy, fail first, or similar requirements applicable to coverage of such item or service under such plan or coverage.*

*The Secretary may provide that information described in any of subparagraphs (A) through (F) not be treated as information specified in this paragraph, and specify additional information that shall be treated as information specified in this paragraph, if determined appropriate by the Secretary.*

*(3) SELF-SERVICE TOOL.—For purposes of paragraph (1), a self-service tool established by a group health plan or group health insurance coverage meets the requirements of this paragraph if such tool—*

*(A) is based on an Internet website;*

*(B) provides for real-time responses to requests described in paragraph (1);*

*(C) is updated in a manner such that information provided through such tool is timely and accurate at the time such request is made;*

*(D) allows such a request to be made with respect to an item or service furnished by—*

*(i) a specific provider that is a participating provider with respect to such item or service;*

*(ii) all providers that are participating providers with respect to such item or service; or*

*(iii) a provider that is not described in clause (ii);*

*(E) provides that such a request may be made with respect to an item or service through use of the billing code for such item or service or through use of a descriptive term for such item or service; and*

*(F) meets any other requirement determined appropriate by the Secretary.*

*The Secretary may require such tool, as a condition of complying with subparagraph (E), to link multiple billing codes to a single descriptive term if the Secretary determines that the billing codes to be so linked correspond to similar items and services.*

*(b) RATE AND PAYMENT INFORMATION.—*

*(1) IN GENERAL.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Health Care Price Transparency Act of 2023, each group health plan or group health insurance coverage (other than a grandfathered health plan (as defined in section 1251(e) of the Patient Protection and Affordable Care Act)) shall, not less frequently than once every 3 months (or, in the case of information described in paragraph (2)(B), not less frequently than monthly), make available to the public the rate and payment information described in paragraph (2) in accordance with paragraph (3).*

*(2) RATE AND PAYMENT INFORMATION DESCRIBED.—For purposes of paragraph (1), the rate and payment information de-*

*scribed in this paragraph is, with respect to a group health plan or group health insurance coverage, the following:*

*(A) With respect to each item or service (other than a drug) for which benefits are available under such plan or coverage, the in-network rate in effect with each provider that is a participating provider with respect to such item or service, other than such a rate in effect with a provider that, during the 1-year period ending 10 business days before the date of the publication of such information, did not submit any claim for such item or service to such plan or coverage.*

*(B) With respect to each drug (identified by national drug code) for which benefits are available under such plan, the average amount paid by such plan or coverage (net of rebates, discounts, and price concessions) for such drug dispensed or administered during the 90-day period beginning 180 days before such date of publication to each provider that was a participating provider with respect to such drug, broken down by each such provider, other than such an amount paid to a provider that, during such period, submitted fewer than 20 claims for such drug to such plan or coverage.*

*(C) With respect to each item or service for which benefits are available under such plan or coverage, the amount billed, and the amount allowed by the plan or coverage, for each such item or service furnished during the 90-day period specified in subparagraph (B) by a provider that was not a participating provider with respect to such item or service, broken down by each such provider, other than items and services with respect to which fewer than 20 claims for such item or service were submitted to such plan or coverage during such period.*

*(3) MANNER OF PUBLICATION.—Rate and payment information required to be made available under this subsection shall be so made available in dollar amounts through 3 separate machine-readable files (or any successor technology, such as application program interface technology, determined appropriate by the Secretary) corresponding to the information described in each of subparagraphs (A) through (C) of paragraph (2) that meet such requirements as specified by the Secretary. Such requirements shall ensure that such files are limited to an appropriate size, do not include disclosure of unnecessary duplicative information contained in other files made available under this subsection, are made available in a widely-available format through a publicly-available website that allows for information contained in such files to be compared across group health plans and group and individual health insurance coverage, and are accessible to individuals at no cost and without the need to establish a user account or provide other credentials.*

*(4) USER INSTRUCTIONS.—Each group health plan and group health insurance coverage shall make available to the public instructions written in plain language explaining how individuals may search for information described in paragraph (2) in files submitted in accordance with paragraph (3). The Secretary shall develop and publish a template that such a plan or cov-*

*erage may use in developing instructions for purposes of the preceding sentence.*

*(5) ATTESTATION.—Each group health plan and group health insurance coverage shall post, along with rate and payment information made public by such plan or coverage, an attestation that such information is complete and accurate.*

*(c) DEFINITIONS.—In this section:*

*(1) PARTICIPATING PROVIDER.—The term "participating provider" has the meaning given such term in section 716(a)(3)(G)(ii).*

*(2) IN-NETWORK RATE.—The term "in-network rate" means, with respect to a health plan or coverage and an item or service furnished by a provider that is a participating provider with respect to such plan and item or service, the contracted rate in effect between such plan or coverage and such provider for such item or service.*

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***SEC. 726. OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.***

*(a) IN GENERAL.—For plan years beginning on or after the date that is 3 years after the date of enactment of this section, a group health plan or health insurance issuer offering group health insurance coverage, or an entity or subsidiary providing pharmacy benefits management services on behalf of such a plan or issuer, shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or issuer, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan or issuer, from making the report described in subsection (b).*

*(b) ANNUAL REPORT.—*

*(1) IN GENERAL.—With respect to plan years beginning on or after the date that is 3 years after the date of enactment of this section, for each such plan year, a group health plan or health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefits management services on behalf of such a plan or an issuer, shall submit to the plan sponsor (as defined in section 3(16)(B)) of such plan or coverage a report in a machine-readable format. Each such report shall include, with respect to such plan or coverage provided for such plan year—*

*(A) to the extent feasible, information collected from drug manufacturers (or an entity administering copay assistance on behalf of such manufacturers) by such plan or issuer (or entity or subsidiary providing pharmacy benefits management services on behalf of such plan or issuer) on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the participants, beneficiaries, and enrollees in such plan or coverage;*

*(B) a list of each drug covered by such plan or coverage that was dispensed during the plan year, including, with respect to each such drug during such plan year—*

*(i) the brand name, chemical entity, and National Drug Code;*

*(ii) the number of participants, beneficiaries, and enrollees for whom the drug was dispensed during the plan year, the total number of prescription claims for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, disaggregated by dispensing channel (such as retail, mail order, or specialty pharmacy);*

*(iii) the wholesale acquisition cost, listed as cost per days supply and cost per pill, or in the case of a drug in another form, per dosage unit;*

*(iv) the total out-of-pocket spending by participants, beneficiaries, and enrollees on such drug, including participant, beneficiary, and enrollee spending through copayments, coinsurance, and deductibles;*

*(v) for any drug for which gross spending of the group health plan or health insurance coverage exceeded $10,000 during the plan year—*

*(I) a list of all other drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class as such drug; and*

*(II) the rationale for the formulary placement of such drug in that therapeutic category or class, if applicable;*

*(vi) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration for claims incurred for such drug during the plan year;*

*(vii) the total net spending, after deducting rebates, price concessions, alternative discounts or other remuneration from drug manufacturers, by the health plan or health insurance coverage on such drug; and*

*(viii) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, incurred by the health plan or health insurance coverage and its participants, beneficiaries, and enrollees, after manufacturer rebates, fees, and other remuneration for such drug dispensed during the plan year;*

*(C) a list of each therapeutic category or class of drugs that were dispensed under the health plan or health insurance coverage during the plan year, and, with respect to each such therapeutic category or class of drugs, during the plan year—*

*(i) total gross spending by the plan or coverage, before manufacturer rebates, fees, or other manufacturer remuneration;*

*(ii) the number of participants, beneficiaries, and enrollees who were dispensed a drug covered by such plan or coverage in that category or class, broken down by each such drug (identified by National Drug Code);*

*(iii) if applicable to that category or class, a description of the formulary tiers and utilization management (such as prior authorization or step therapy) employed for drugs in that category or class; and*

*(iv) the total out-of-pocket spending by participants, beneficiaries, and enrollees, including participant, beneficiary, and enrollee spending through copayments, coinsurance, and deductibles;*

*(D) total gross spending on prescription drugs by the plan or coverage during the plan year, before rebates and other manufacturer fees or remuneration;*

*(E) total amount received, or expected to be received, by the health plan or health insurance coverage in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug spending under that health plan or health insurance coverage during the plan year;*

*(F) the total net spending on prescription drugs by the health plan or health insurance coverage during the plan year; and*

*(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm for the referral of the group health plan's or health insurance issuer's business to the pharmacy benefits manager.*

*(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage and entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and shall restrict the use and disclosure of such information according to such privacy regulations.*

*(3) DISCLOSURE AND REDISCLOSURE.—*

*(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).*

*(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such issuer or entity may not restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, the Comptroller General of the United States, or applicable State agencies.*

*(C) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under*

*paragraph (1) required of plan sponsors who are drug manufacturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.*

*(4) REPORT TO GAO.—A group health plan or health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 4 reports submitted to a plan sponsor under paragraph (1) with respect to such coverage or plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (2), the disclosure and redisclosure standards under paragraph (3), the standards specified pursuant to paragraph (5), and such other information that the Comptroller General determines necessary to carry out the study under section 103(d) of the Health Care Price Transparency Act of 2023.*

*(5) STANDARD FORMAT.—Not later than 18 months after the date of enactment of this section, the Secretary shall specify through rulemaking standards for health insurance issuers and entities required to submit reports under paragraph (4) to submit such reports in a standard format.*

*(c) ENFORCEMENT.—*

*(1) IN GENERAL.—Notwithstanding section 502, the Secretary, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, shall enforce this section.*

*(2) FAILURE TO PROVIDE TIMELY INFORMATION.—A health insurance issuer or an entity providing pharmacy benefits management services that violates subsection (a) or fails to provide information required under subsection (b) shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.*

*(3) FALSE INFORMATION.—A health insurance issuer or entity providing pharmacy benefits management services that knowingly provides false information under this section shall be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalty shall be in addition to other penalties as may be prescribed by law.*

*(4) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsection (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.*

*(5) WAIVERS.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that has made a good-faith effort to comply with this section.*

*(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary of Labor to a report described in subsection (b)(1) or*

*information related to compliance with subsection (a) or (b) by such issuer, plan, or other entity subject to such subsections.*

*(e) DEFINITION.—In this section, the term "wholesale acquisition cost" has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.*

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## BALANCED BUDGET AND EMERGENCY DEFICIT CONTROL ACT OF 1985

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## PART C—EMERGENCY POWERS TO ELIMINATE DEFICITS IN EXCESS OF MAXIMUM DEFICIT AMOUNT

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**SEC. 251A. ENFORCEMENT OF BUDGET GOAL.**

Discretionary appropriations and direct spending accounts shall be reduced in accordance with this section as follows:

(1) CALCULATION OF TOTAL DEFICIT REDUCTION.—OMB shall calculate the amount of the deficit reduction required by this section for each of fiscal years 2013 through 2021 by—

(A) starting with $1,200,000,000,000;

(B) subtracting the amount of deficit reduction achieved by the enactment of a joint committee bill, as provided in section 401(b)(3)(B)(i)(II) of the Budget Control Act of 2011;

(C) reducing the difference by 18 percent to account for debt service;

(D) dividing the result by 9; and

(E) for fiscal year 2013, reducing the amount calculated under subparagraphs (A) through (D) by $24,000,000,000.

(2) ALLOCATION TO FUNCTIONS.—On March 1, 2013, for fiscal year 2013, and in its sequestration preview report for fiscal years 2014 through 2021 pursuant to section 254(c), OMB shall allocate half of the total reduction calculated pursuant to paragraph (1) for that year to discretionary appropriations and direct spending accounts within function 050 (defense function) and half to accounts in all other functions (nondefense functions).

(3) DEFENSE FUNCTION REDUCTION.—OMB shall calculate the reductions to discretionary appropriations and direct spending for each of fiscal years 2013 through 2021 for defense function spending as follows:

(A) DISCRETIONARY.—OMB shall calculate the reduction to discretionary appropriations by—

(i) taking the total reduction for the defense function allocated for that year under paragraph (2);

(ii) multiplying by the discretionary spending limit for the revised security category for that year; and

(iii) dividing by the sum of the discretionary spending limit for the security category and OMB's baseline estimate of nonexempt outlays for direct spending programs within the defense function for that year.

(B) DIRECT SPENDING.—OMB shall calculate the reduction to direct spending by taking the total reduction for the defense function required for that year under paragraph (2) and subtracting the discretionary reduction calculated pursuant to subparagraph (A).

(4) NONDEFENSE FUNCTION REDUCTION.—OMB shall calculate the reduction to discretionary appropriations and to direct spending for each of fiscal years 2013 through 2021 for programs in nondefense functions as follows:

(A) DISCRETIONARY.—OMB shall calculate the reduction to discretionary appropriations by—

(i) taking the total reduction for nondefense functions allocated for that year under paragraph (2);

(ii) multiplying by the discretionary spending limit for the revised nonsecurity category for that year; and

(iii) dividing by the sum of the discretionary spending limit for the revised nonsecurity category and OMB's baseline estimate of nonexempt outlays for direct spending programs in nondefense functions for that year.

(B) DIRECT SPENDING.—OMB shall calculate the reduction to direct spending programs by taking the total reduction for nondefense functions required for that year under paragraph (2) and subtracting the discretionary reduction calculated pursuant to subparagraph (A).

(5) IMPLEMENTING DISCRETIONARY REDUCTIONS.—

(A) FISCAL YEAR 2013.—On March 1, 2013, for fiscal year 2013, OMB shall calculate and the President shall order a sequestration, effective upon issuance and under the procedures set forth in section 253(f), to reduce each account within the security category or nonsecurity category by a dollar amount calculated by multiplying the baseline level of budgetary resources in that account at that time by a uniform percentage necessary to achieve—

(i) for the revised security category, an amount equal to the defense function discretionary reduction calculated pursuant to paragraph (3); and

(ii) for the revised nonsecurity category, an amount equal to the nondefense function discretionary reduction calculated pursuant to paragraph (4).

(B) FISCAL YEARS 2014–2021.—Except as provided by paragraphs (10), (11), (12), and (13), on the date of the submission of its sequestration preview report for fiscal years 2014 through 2021 pursuant to section 254(c) for each of fiscal years 2014 through 2021, OMB shall reduce the discretionary spending limit—

(i) for the revised security category by the amount of the defense function discretionary reduction calculated pursuant to paragraph (3); and

(ii) for the revised nonsecurity category by the amount of the nondefense function discretionary reduction calculated pursuant to paragraph (4).

(6) IMPLEMENTING DIRECT SPENDING REDUCTIONS.—(A) On the date specified in paragraph (2) during each applicable year, OMB shall prepare and the President shall order a sequestra-

tion, effective upon issuance, of nonexempt direct spending to achieve the direct spending reduction calculated pursuant to paragraphs (3) and (4). When implementing the sequestration of direct spending pursuant to this paragraph, OMB shall follow the procedures specified in section 6 of the Statutory Pay-As-You-Go Act of 2010, the exemptions specified in section 255, and the special rules specified in section 256, except that the percentage reduction for the Medicare programs specified in section 256(d) shall not be more than 2 percent for a fiscal year.

(B) On the date on which the President submits the budget under section 1105 of title 31, United States Code, for each of fiscal years 2022 through 2031, the President shall order a sequestration, effective upon issuance such that—

(i) the percentage reduction for nonexempt direct spending for the defense function is the same percent as the percentage reduction for nonexempt direct spending for the defense function for fiscal year 2021 calculated under paragraph (3)(B); and

(ii) the percentage reduction for nonexempt direct spending for nondefense functions is the same percent as the percentage reduction for nonexempt direct spending for nondefense functions for fiscal year 2021 calculated under paragraph (4)(B).

(C) Notwithstanding the 2 percent limit specified in subparagraph (A) for payments for the Medicare programs specified in section 256(d), the sequestration order of the President under such subparagraph for fiscal year 2022 shall be applied to such payments so that with respect to the period beginning on April 1, 2022, and ending on June 30, 2022, the payment reduction shall be 1.0 percent.

(D) On the date on which the President submits the budget under section 1105 of title 31, United States Code, for fiscal year 2032, the President shall order a sequestration of payments for the Medicare programs specified in section 256(d), effective upon issuance, such that, notwithstanding the 2 percent limit specified in subparagraph (A) for such payments—

(i) with respect to the first 6 months in which such order is effective for such fiscal year, the payment reduction shall be 2.0 percent**[**; and**]***;*

(ii) with respect to the **[**second 6 months in which such order is effective for such fiscal year, the payment reduction shall be 0 percent.**]** *2 month period beginning on the day after the last day of the period described in clause (i) in which such order is effective for such fiscal year, the payment reduction shall be 1.5 percent; and*

*(iii) with respect to the last 4 months in which such order is effective for such fiscal year, the payment reduction shall be 0 percent.*

(7) ADJUSTMENT FOR MEDICARE.—If the percentage reduction for the Medicare programs would exceed 2 percent for a fiscal year in the absence of paragraph (6), OMB shall increase the reduction for all other discretionary appropriations and direct spending under paragraph (4) by a uniform percentage to a

level sufficient to achieve the reduction required by paragraph (4) in the non-defense function.

(8) IMPLEMENTATION OF REDUCTIONS.—Any reductions imposed under this section shall be implemented in accordance with section 256(k).

(9) REPORT.—On the dates specified in paragraph (2), OMB shall submit a report to Congress containing information about the calculations required under this section, the adjusted discretionary spending limits, a listing of the reductions required for each nonexempt direct spending account, and any other data and explanations that enhance public understanding of this title and actions taken under it.

(10) IMPLEMENTING DIRECT SPENDING REDUCTIONS FOR FISCAL YEARS 2014 AND 2015.—(A) OMB shall make the calculations necessary to implement the direct spending reductions calculated pursuant to paragraphs (3) and (4) without regard to the amendment made to section 251(c) revising the discretionary spending limits for fiscal years 2014 and 2015 by the Bipartisan Budget Act of 2013.

(B) Paragraph (5)(B) shall not be implemented for fiscal years 2014 and 2015.

(11) IMPLEMENTING DIRECT SPENDING REDUCTIONS FOR FISCAL YEARS 2016 AND 2017.—(A) OMB shall make the calculations necessary to implement the direct spending reductions calculated pursuant to paragraphs (3) and (4) without regard to the amendment made to section 251(c) revising the discretionary spending limits for fiscal years 2016 and 2017 by the Bipartisan Budget Act of 2015.

(B) Paragraph (5)(B) shall not be implemented for fiscal years 2016 and 2017.

(12) IMPLEMENTING DIRECT SPENDING REDUCTIONS FOR FISCAL YEARS 2018 AND 2019.—(A) OMB shall make the calculations necessary to implement the direct spending reductions calculated pursuant to paragraphs (3) and (4) without regard to the amendment made to section 251(c) revising the discretionary spending limits for fiscal years 2018 and 2019 by the Bipartisan Budget Act of 2018.

(B) Paragraph (5)(B) shall not be implemented for fiscal years 2018 and 2019.

(13) IMPLEMENTING DIRECT SPENDING REDUCTIONS FOR FISCAL YEARS 2020 AND 2021.—(A) OMB shall make the calculations necessary to implement the direct spending reductions calculated pursuant to paragraphs (3) and (4) without regard to the amendment made to section 251(c) revising the discretionary spending limits for fiscal years 2020 and 2021 by the Bipartisan Budget Act of 2019.

(B) Paragraph (5)(B) shall not be implemented for fiscal years 2020 and 2021.

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## VII. DISSENTING VIEWS

H.R. 4822 (Smith, R–MO) codifies existing Department of Health and Human Services (HHS) transparency regulations, with some modifications, relating to health insurers, hospitals, and insurance companies operating in the group and individual market, and proposed new requirements for laboratories, imaging providers and ambulatory surgical sites. It also provides additional oversight of pharmacy benefit managers serving group and individual market customers.

Unfortunately, H.R 4822 fails to provide key data needed for transparency in the health care marketplace to better understand the forces of consolidation and integration that are harming consumers and driving up costs. This legislation presented an opportunity to put forth a meaningful bipartisan bill that would grant to all Americans, regardless of their provider or plan, information they need to make informed decisions about their health care. It also offered the opportunity to ensure that the Secretary has critical information to examine horizontal and vertical consolidation affecting the cost, quality, and access to care. Instead of collaborating across party lines, the Republicans put forward a package that leaves critical gaps in transparency relating to plans, agents, and brokers operating in Medicare Advantage, as well as private equity (PE) ownership of health providers.

### THE LEGISLATION FAILS TO PROVIDE CRITICAL TRANSPARENCY RELATED TO PRIVATE EQUITY OWNERSHIP OF HEALTH CARE ENTITIES

Private equity investment in health care has increased significantly in recent years, with 2019 transactions totaling $119.9 billion.[1] The PE business model, which is primarily focused on short-term revenue and consolidation, is misaligned with sound health care that serves patients and focuses on their long-term wellbeing. The fundamental principle of PE is to acquire and sell assets for maximum profit within 3 to 5 years, which is at odds with the goals of quality care and safeguarding taxpayer dollars in the Medicare program.

*Private Equity Motives: Profits Over Patient Care.* PE firms have been acquiring physician practices, nursing homes, hospice care centers, urgent care facilities, surgical centers, and other similar enterprises, leading to consolidation in the health care sector. This consolidation has led to higher prices for patients and taxpayers, while allowing PE firms to avoid scrutiny under antitrust laws.[2] In

[1] Scheffler, Alexander, & Godwin. (2021). *Soaring Private Equity Investment in the Healthcare Sector: Consolidation Accelerated, Competition Unermined, and Patients at Risk.* https://publichealth.berkeley.edu/wp-content/uploads/2021/05/Private-Equity-I-Healthcare-Report-FINAL.pdf.

[2] Appelbaum, E and Batt, R (2020). Private Equity's Engagement with Health Care: Cause for Concern? Center for Economic and Policy Research.

more than 25 percent of local markets, in places like Tucson, AZ, Columbus, OH, and Providence, RI, a single PE firm owned more than 30 percent of practices in a given specialty in 2021.[3] This consolidation leads to higher prices, and evidence of degrading healthcare quality.[4]

*Hampering Access to High Quality Patient Care*. Research shows that PE ownership of a nursing facility is correlated with a significant decrease in the CMS star rating, a quality-of-care metric.[5] Recent studies also show that PE ownership is associated with worse health outcomes.[6] The National Bureau of Economic Research found that PE nursing home ownership has led to the premature death of over 20,000 patients over a 12-year period.[7] In some instances, PE has been associated with debt-laden providers declaring bankruptcy, reducing access to care.[8]

*Importance of Transparency into Private Equity Ownership*. Transparency and public reporting of PE ownership data is critical to ensure regulators and consumers are aware of the incentives facing their community providers and to ensure regulators can understand the relationship between ownership, quality, and cost. Heightened transparency in health care is essential across all entities, especially PE, to ensure patient protection.

H.R. 4822 fails to provide accurate and complete data related to how these firms operate and affect healthcare. The Committee on Energy and Commerce reported out a bill earlier this year that would have provided some of that information, yet Republicans refused to provide that data here.

In 2020, the Ways and Means Committee passed H.R. 5825 (Neal) by voice vote, which provided critical reporting requirements for private equity firms that owned specified health care entities. That legislation would have given the Secretary of the Treasury and the Secretary of Health and Human Services critical information relating to private equity ownership.

During the markup of H.R. 4822, Representative Pascrell (D–NJ) offered that legislation from 2020 as an amendment. Despite these provisions garnering wide support from both sides just three years ago, not a single Republican supported them in this markup.

*30 million Medicare Advantage (MA) beneficiaries are left in the dark*. Republicans voted to pass legislation that improves healthcare transparency, such as consumer-facing price estimator tools, but they excluded MA plans from these transparency requirements. Representative Doggett (D–TX) offered an amendment to ensure that Medicare Advantage plans—which today provide care

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[3] Scheffler, R. M., Alexander, L., Fulton, B. D., Arnold, D. R., & Abdelhadi, O. A. (2023). *Monetizing Medicine: Private Equity and Competition in Physician Practice Markets. Antitrustinstitute.org.*

[4] Borsa A, Bejarano G, Ellen M, Bruch J D. (2023) Evaluating trends in private equity ownership and impacts on health outcomes, costs, and quality: systematic review The BMJ.

[5] Atkins, M. (2021, April). *The Impact pf Private Equity on Nursing Home Care: Recommendations for Policy Makers*. Rooseveltinstitute.org.

[6] Scheffler, Alexander, & Godwin. (2021). *Soaring Private Equity Investment in the Healthcare Sector: Consolidation Accelerated, Competition Unermined, and Patients at Risk.* https://publichealth.berkeley.edu/wp-content/uploads/2021/05/Private-Equity-I-Healthcare-Report-FINAL.pdf.

[7] Atul Gupta et al., *Does Private Equity Investment in Healthcare Benefit Patients? Evidence from Nursing Homes,* NATIONAL BUREAU OF ECONOMIC RESEARCH (2021 working paper 28474), https://www.nber.org/papers/w28474.

[8] Goozner, M. (2023). Private equity takeovers are harming patients. *BMJ (Clinical Research Ed.)*, 382, 1396. https://doi.org/10.1136/bmj.p1396.

to more than 30 million seniors—meet the same requirements as other plans serving individuals in the group and individual market. Every Republican present voted against it. The Doggett amendment would also have required agents and brokers selling Medicare Advantage plans to make the same disclosures to consumers that apply to their sales of group and individual products in the non-Medicare market. These incentives influence consumer plan selection and there is no reason a person should stop receiving this information once they turn 65. Private health insurance markets have already implemented these crucial transparency provisions, pursuant to the No Surprises Act, and all Americans should benefit from these protections, not those belonging to select age groups.

*Cutting Medicare provider payments to cancer hospitals may restrict access to cutting-edge cancer treatment for millions of Americans seeking care*. H.R. 4822 institutes an across-the-board site-neutral payment policy for prescription drugs administered in off-campus settings that will reduce reimbursement to eleven cancer hospitals across the country. Since 1983, these cancer hospitals have been exempted from the inpatient prospective payment system with bipartisan, bicameral agreement due to the unique and complex nature of the patients these institutions serve. Republicans' cuts to committed cancer hospitals not only breaks decades-long precedent but will harm patients across the country. Representative DelBene's (D–WA) amendment to exempt dedicated cancer centers from this payment cut was rejected by a party line vote (15–25).

*Any increased transparency must protect patients seeking reproductive care*. The aftermath of Roe v. Wade showed that extremist Republicans will use any possible measure to regulate the reproductive health of women. Representative Chu (D–CA) offered an amendment to ensure that the transparency information provided under the legislation does not come at the expense of patient and physician privacy protections. This amendment would have ensured that no information disclosed, submitted, or otherwise made available pursuant to the provisions of, and the amendments made by, this Act may be used or disclosed for purposes of investigating or prosecuting a patient for accessing health care, including for their pregnancy outcomes, or a provider who is engaged in providing comprehensive sexual and reproductive health care. Despite all Democrats voting in favor, the amendment failed due to unified Republican opposition. As a result, the privacy and safety of millions of patients and providers could be put in jeopardy. Republicans did not even offer a defense as to why they could not support this commonsense amendment.

Democrats have staunchly supported patient protections, most notably in the many provisions of the Affordable Care Act that placed their needs first. Unfortunately, this bill missed the mark by failing to promote transparency across the entire health care continuum.

Sincerely,

RICHARD E. NEAL.

## DISSENTING VIEWS

Increasing health care consolidation combined with flawed system design and policies that sanction monopolistic behavior is failing patients across the health care system. Prices increase year after year, emergency room wait times lengthen, doctors' offices close, and quality of care suffers.

As a long-time advocate for greater transparency, I certainly support the overarching goal of today's markup to ensure more and better data concerning health care prices. Data cannot directly lower costs, but with data we can identify inefficiencies and waste of taxpayer dollars with the potential to lower costs if policymakers show the courage to do it.

Unfortunately, what could have been a meaningful, bipartisan product advancing new policies and strengthening prior work has instead become a partisan effort to weaken bipartisan legislation unanimously approved by the Energy and Commerce Committee. This bill largely codifies what is already required of hospitals and some insurers.

Meanwhile, some of the worst actors are shielded from any meaningful accountability. Once again, Medicare Advantage is given special treatment, omitted from the transparency requirements of today's legislation. Charging over $1,500 more per person each year than would have otherwise been spent if the patient were in Traditional Medicare, private insurers are making huge profits off MA. This bill continues to advantage private insurance executives over disadvantaged health care consumers and taxpayers.

And this legislation completely ignores the growing impact of private equity with its rapid takeover of many health care sectors, often resulting in soaring costs and worsening health inequities. Despite modest, bipartisan, unanimous approval of measures to address both Medicare Advantage and private equity in another committee, today's legislation is silent.

Transparency can lead to better oversight, but only if it is targeted toward the right information and the right actors and is paired with enforcement. Unfortunately, this markup misses the mark in addressing these issues and offers very little toward lowering outrageous prices.

Nor does this legislation do anything to provide better transparency into the pharmaceutical industry, let alone reduce price gouging or even record the enormous contributions taxpayers make as angel investors in research and development, American taxpayers—the single largest contributors to pharma R&D in the world.

We all want to encourage cures and treatments for dreaded diseases long before we or a loved one face a troubling diagnosis. But pharmaceutical monopolies and oligopolies have been more con-

cerned with manipulating the system to delay competitors and extract the highest prices the sick and dying will pay rather than create more innovative treatments.

Over a decade (2005–15), 78% of new drug patents were not for the new cures we need, but were small modifications to existing drugs designed to extend monopoly power and monopoly prices. By one new estimate, about $40 billion in taxpayer dollars were wasted in 2019 alone on drugs that violated antitrust laws when delaying competitors.

30% percent of adults report not picking up prescriptions or skipping doses because they could not afford their medications. Yet nothing in this bill concerning Big Pharma.

Nothing to help the half of Americans who cannot afford a $500 medical emergency, but will likely be charged thousands if they receive a dreaded diagnosis, suffer a heart attack, or are in a horrific car accident. Unlike shopping for most consumer products, health care is absolutely essential. Patients do not have a choice, yet they are forced to navigate a complex system and are charged outrageous prices by a highly consolidated and broken market.

While consumers get sticker shock and medical debt, corporate interests get a shield from meaningful action. Moving forward, we need bipartisan action to lower prices, not just bigger font when prices are disclosed.

Sincerely,

LLOYD DOGGETT.

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