I

107TH CONGRESS
2D SESSION

H. R. 3626

To amend title XVIII of the Social Security Act to provide for an outpatient prescription drug benefit under the Medicare Program.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 24, 2002

Mrs. EMERSON (for herself and Mr. ROSS) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title XVIII of the Social Security Act to provide for an outpatient prescription drug benefit under the Medicare Program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; FINDINGS.

(a) SHORT TITLE.—This Act may be cited as the ''Medicare Drug and Service Coverage Act of 2002''.

(b) FINDINGS.—Congress makes the following findings:

(1) It is important for seniors to have access to prescription drugs for life and health. Prescription drugs are an important part of medical therapy, but medicare does not have a voluntary prescription drug benefit for seniors who need and want drug coverage.

(2) A comprehensive prescription drug benefit program for seniors would help assure that seniors have access to necessary prescription drugs and medication therapy management services, which are among the most cost-effective medical interventions available in the health care system.

(3) Seniors use more pharmaceuticals than any other population group, and are in greater need of medication therapy management services to assist them in proper medication utilization. These services will help reduce the chance for adverse medication events, which result in increased medicare spending for hospitalizations, nursing home stays, emergency room visits, and physician office visits.

(4) A new prescription drug benefit for seniors should be structured so that seniors have access to the distribution method of their choice without any form of economic or other inducement to use an alternative distribution system.

(5) To assure appropriate and meaningful cost controls under the program, and in order to have their drugs covered, manufacturers should be required to contribute to cost reductions in the medicare program.

SEC. 2. PRESCRIPTION DRUG BENEFIT PROGRAM.

(a) IN GENERAL.—Title XVIII of the Social Security Act is amended—

(1) by redesignating part D as part E; and

(2) by inserting after part C the following new part:

''PART D—OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM

''OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM ESTABLISHED

''SEC. 1860. There is established a voluntary prescription drug benefit program to provide covered outpatient drugs and medication therapy management services in accordance with the provisions of this part for beneficiaries who elect to enroll under such program, to be financed with contributions from funds appropriated by the Federal Government and premiums collected from participating beneficiaries.

''SCOPE OF BENEFITS

''SEC. 1860A. (a) COVERED OUTPATIENT PRESCRIPTION DRUGS AND ASSOCIATED SERVICES.—

''(1) IN GENERAL.—The benefits provided to a beneficiary under this part shall consist of payments made in accordance with the provisions of this part for the following services furnished by any pharmacy provider (as defined in section 1860I(e):

''(A) PRESCRIPTION DRUGS.—Covered outpatient prescription drugs, as specified in subsection (b).

''(B) MEDICATION PREPARATION SERVICES.—Covered medication preparation services, as specified in subsection (c).

''(C) MEDICATION THERAPY MANAGEMENT SERVICES.—Covered medication therapy management services, as specified in subsection(d).

''(2) WILLING PHARMACY PROVIDERS.—Any pharmacy provider that is authorized by the applicable State agency to engage in the practice of pharmacy may participate in the program established under this part.

''(b) COVERED OUTPATIENT PRESCRIPTION DRUGS.—

''(1) IN GENERAL.—Subject to paragraph (2), benefits under this part for outpatient prescription drugs means, subject to section 1860B, payment for all prescribed drugs within the meaning of the term

covered outpatient prescription drugs, as defined in section 1860I(a).

''(2) AVOIDANCE OF DUPLICATE PAYMENT UNDER MEDICARE.—Payment under paragraph (1) for covered outpatient prescription drugs may only be made, with respect to such drugs for which payment may be made under part A or B, only if benefits under part A or part B for such drugs have been exhausted.

''(c) COVERED MEDICATION PREPARATION SERVICES.—Covered medication preparation services, for purposes of this part, means services provided by pharmacy providers involving prescription drug compounding, the provision of special packaging, and such other services involved in the preparation and delivery of prescription drugs as the Secretary may prescribe.

''(d) COVERED MEDICATION THERAPY MANAGEMENT SERVICES.—

''(1) IN GENERAL.—Covered medication therapy management services means—

''(A) services or programs furnished by a pharmacy provider which are designed—

''(i) to assure that medications are used appropriately by beneficiaries;

''(ii) to enhance beneficiaries' understanding of the appropriate use of medications;

''(iii) to increase beneficiaries' compliance with prescription medication regimens;

''(iv) to reduce the risk of potential adverse events associated with medications; and

''(v) to reduce the need for other costly medical services through better management of medication therapy; and

''(B) services provided in collaboration with physicians, pharmacists, and other health care professionals when necessary, involving case management, disease management, patient training and education, medication refill reminders, medication therapy problem resolution, laboratory testing conducted to monitor medication therapy, other services that enhance the use of prescription medications, and such other professional services consistent with the scope of the practice of pharmacy as defined by applicable State law or regulation.

''(2) PROGRAM OPERATION.—The program established under this subsection will—

''(A) identify and provide medication therapy management services to beneficiaries at risk for potential medication problems, such as beneficiaries taking multiple medications and beneficiaries with complex or chronic medical conditions;

''(B) be developed and structured in cooperation with organizations representing pharmacy providers, including identifying those medication therapy management services that will be provided, as well as payment mechanisms for such services;

''(C) structure and update payments to reflect the resources and time involved in the provision of such services, the level of risk associated with the use of particular medications, and the health status of beneficiaries to whom medication therapy management services are provided; and

''(D) provide for ongoing evaluation and documentation of these services in improving quality of care and reducing health care costs.

''PAYMENT OF BENEFITS; BENEFIT LIMITS; BENEFICIARY COPAY

''SEC. 1860B. (a) ESTABLISHMENT OF ACCOUNT.—There is established within the Supplementary Medical Insurance Trust Fund an account to be known as the Prescription Drug Benefit Insurance Account (hereinafter in this part referred to as the 'Account').

''(b) PAYMENT OF BENEFITS.—Subject to the succeeding provisions of this section, there shall be paid from the Account to a pharmacy provider that furnishes services for which payment may be made under this part to an individual who is enrolled under this part an amount, for each such service, equal to the lesser of—

''(1) the reasonable charges for the benefits, as determined under section 1860G; or

''(2) the pharmacy provider's customary charges with respect to such benefits.

''(c) ANNUAL DEDUCTIBLE.—Before applying subsection (b) with respect to expenses incurred by an individual enrolled under this part 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 (b) are determinable) shall be reduced by a deductible of $250.

''(d) COINSURANCE.—

''(1) IN GENERAL.—Subject to paragraphs (3) and (4), the amount payable for services for which payment may be made under this part furnished an individual enrolled under this part shall be reduced by a coinsurance amount equal to established under paragraph (2).

''(2) ESTABLISHING ANNUAL COINSURANCE PERCENTAGE.—Each year the Secretary shall, with the advice of the Medicare Prescription Drug Benefit Advisory Commission established in section 1860H, determine and promulgate a coinsurance amount (as a percentage of the benefits provided) that qualified beneficiaries pay with benefits covered under this program for the next calendar year and in accordance with the limitations of this subsection.

''(3) MAXIMUM COINSURANCE.—The coinsurance established in paragraph (2) may not exceed 20 percent.

''(4) LIMITS ON VARYING COINSURANCE AMOUNTS.—The Secretary may not vary the coinsurance amounts or make any differentiation of scope or quantity of benefits coverage provided based on the method of providing the services.

''PROCEDURE FOR PAYMENT OF CLAIMS

''SEC. 1860C. Payment for services described in section 1860A may be made only to pharmacy providers and only if a claim is filed for such payment in such form and manner as the Secretary may by regulation require. In no case may payment be made later than 12 months following the year in which such services are furnished.

''ELIGIBILITY AND ENROLLMENT

''SEC. 1860D. Every individual who, during or after 2003, is entitled to hospital insurance benefits under part A and is enrolled in part B shall be eligible to enroll in the program under this part in such form and manner as the Secretary may require by regulation.

''PREMIUM FEES AND PAYMENT

''SEC. 1860E. (a) ANNUAL ESTABLISHMENT OF PREMIUM AMOUNT.—Each year the Secretary shall, with the advice of the Medicare Prescription Drug Benefit Advisory Commission established in section 1860H, determine and promulgate a monthly premium for beneficiaries who enroll under this part, taking into account the total amount of payments expected to be made from Account for furnishing services under this part for the next calendar year and in accordance with the provisions of this section.

''(b) PAYMENT OF PREMIUMS.—An individual enrolled in the program under this part shall pay the pre-

mium established under subsection (a) to the Secretary at such times and in such manner as the Secretary shall by regulation require.

''(c) DEPOSIT OF FUNDS.—Amounts paid to the Secretary under subsection (a) shall be deposited in the Treasury to the credit of the Account.

''ADMINISTRATION OF BENEFITS THROUGH CARRIERS

''SEC. 1860F. (a) IN GENERAL.—The Secretary shall contract with carriers designated in accordance with subsection (d), based on a competitive bid, fixed fee per transaction basis, to perform some or all of the following administrative functions:

''(1) PROCESS AND ADJUDICATE CLAIMS.—The carrier shall receive, process, and make payment for claims to pharmacy providers through an online, real time claims adjudication system that conforms to current industry standards, and shall disburse and account for funds in making payments to pharmacy providers under this part.

''(2) COMMUNICATE INFORMATION.—The carrier shall serve as a channel of communication of eligibility and coverage information to beneficiaries and pharmacy providers.

''(3) QUALITY ASSURANCE.—The carrier shall provide the information and computer system support, either directly or through a contract with an

outside entity, for the pharmacy provider to conduct a drug utilization review program conforming to the standards established by section 1927(g)(2), with modifications as the Secretary determines by regulation to be appropriate.

''(4) PROTECTION AGAINST FRAUD AND ABUSE.—The carrier shall conduct activities to control fraud, abuse, and waste in accordance with regulations promulgated by the Secretary.

''(5) COLLECTION OF PAYMENTS.—The carrier shall collect payments from participating pharmaceutical manufacturers as specified in subsection (e).

''(b) LIMITS ON CARRIER FUNCTION.—The Secretary shall not contract with carriers—

''(1) to make determinations of the rates and amounts of payments to be made to pharmacy providers under this part;

''(2) to make determinations of any limitations on covered benefits, such as the nature, scope, choice, or amount of benefits available, as referred to in section 1860A;

''(3) to make determinations of pharmacy provider eligibility;

''(4) to carry out any tasks beyond the administrative and ministerial duties authorized by this section, including aggregate purchasing; or

''(5) to practice medicine or pharmacy.

''(c) REQUIREMENTS FOR PAYING CLAIMS AND GRIEVANCE PROCEDURES.—Each contract under this section that provides for the disbursement of funds as described in subsection (a)(1) shall provide that—

''(1) payment shall be issued, mailed, or otherwise transmitted for claims submitted under this part in accordance with the procedures established by section 1842(c); and

''(2) each carrier shall have in place such procedures as the Secretary shall specify for hearing and resolving grievances brought by enrolled beneficiaries against the carrier or pharmacy provider and the pharmacy provider against the carrier concerning benefits under this part.

''(d) ELIGIBLE ENTITIES.—Each carrier responsible for administering the program established under this part shall meet at least the following criteria:

''(1) PERFORMANCE CAPABILITY.—The entity shall have sufficient expertise, personnel, and resources to perform the contracted benefit administrations.

''(2) PERFORMANCE RATING.—The entity shall be subject to such review as required by the Secretary, both prior to issuing a contract under this part and in review of performance administering contracts under this part.

''(3) FINANCIAL INTEGRITY.—The entity and its officers, directors, agents, and managing employees shall have a satisfactory record of professional competence and professional and financial integrity, and the entity shall have adequate financial resources to perform services under the contract without risk of insolvency.

''(4) CAPABILITY TO MAINTAIN RECORDS.—The entity shall have systems to maintain adequate records and afford the Secretary access to such records (including for audit purposes).

''(5) COMPLIANCE WITH INDUSTRY STANDARDS.—The entity shall comply with standards adopted by the National Council on Prescription Drug Programs for uniform identification cards, telecommunication standards, and drug utilization review messaging.

''(6) COST AND PRICING DATA.—The entity shall submit to the Secretary as part of its bid submission all relevant cost and pricing data, including

all fees charged by the entity for performing the administrative functions pursuant to any competitively bid contract awarded to the carrier under this section, plus any and all administrative fees or other payments received by the entity from drug manufacturers pursuant to the contract award.

''(7) CAPABILITY TO GENERATE REPORTS.—The entity shall have systems to make such reports and submissions of financial and utilization data as the Secretary may require, including reports describing the nature and type of direct and indirect manufacturers' payments received by the carrier, assurance that payments made to pharmacy providers are based on such standards as the Secretary may prescribe, and any other types of administrative or claims processing fees received by the carrier.

''(e) MANUFACTURER PAYMENTS.—

''(1) IN GENERAL.—The Secretary shall only make payment under this part for innovator multiple source drugs or single source drugs (as defined in clauses (ii) and (iv), respectively, of section 1927(k)(7)(A)) for which payment may be made under this part of a manufacturer if that manufacturer has entered into and has in effect an agreement with the Secretary that requires the manufac-

turer to make periodic payments in the amount described in this subsection. A payment agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than 1 year.

''(2) AMOUNT OF PAYMENT.—

''(A) IN GENERAL.—The payment amount for a covered outpatient prescription drug furnished under this part shall be equal to not less than the sum of the basic rebate amount (determined under subparagraph (B)) for each dosage form and strength of such drug increased by the amount of the inflation adjustment rebate (determined under subparagraph (C)) for each dosage form and strength of such drug.

''(B) BASIC REBATE AMOUNT.—The basic rebate amount shall be equal to the product of the total number of units of each dosage form and strength paid for by the carrier in the payment period (as defined in section 1927(b)), and the average manufacturers' price (as defined in section 1860I) for the quarter for the dosage form and strength of the covered outpatient drug minus not less than 18 percent of the average manufacturers' price for the quar-

ter, or such amount as determined by the Secretary through negotiations with the manufacturer of such drug.

"(C) INFLATION ADJUSTMENT AMOUNT.—The amount of the basic rebate payment shall be increased by an amount equal to the product of the number of units of each dosage form and strength paid for by the carrier in the payment period and the amount by which the average manufacturers' price for such drug and dosage form and strength for the calendar quarter increased in excess of the percentage by which the consumer price index for all urban consumers increased during the calendar quarter.

"(3) CARRIER RESPONSIBILITY.—The carrier shall report to each manufacturer not later than 60 days after the end of each payment period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed in the quarter for which payment was made under the plan during the period, and shall promptly transmit a copy of such report to the Secretary.

''(4) MANUFACTURER RESPONSIBILITY.—The manufacturer shall remit payments to the Secretary through the carrier not later than 30 days after receiving information from the carrier on the total number of units of each dosage form and strength of the manufacturers' drugs paid for by the carrier in the quarter.

''(5) COLLECTION OF PAYMENTS.—The Secretary shall deposit the payments collected under this subsection from manufacturers in the Account, and shall use the payments to reduce the premiums paid by beneficiaries for the purpose of providing the prescription drug benefit.

''PHARMACY PROVIDER ELIGIBILITY AND PAYMENT AMOUNTS

''SEC. 1860G. (a) IN GENERAL.—Any pharmacy provider that meets the requirements of this section shall be eligible to enter into an agreement with the Secretary to furnish covered benefits to enrolled beneficiaries.

''(b) TERMS OF AGREEMENT.—An agreement under this section shall include the following terms and requirements:

''(1) LICENSING.—The pharmacy provider shall meet (and throughout the contract period will continue to meet) all applicable Federal, State, and local licensing requirements.

''(2) PERFORMANCE STANDARDS.—The pharmacy provider shall comply with quality assurance standards applicable to pharmacists under section 1927(g).

''(3) PAYMENT.—The Secretary shall, after consultation with the Medicare Prescription Drug Benefit Advisory Commission established in section 1860H, establish payment rates to—

''(A) pharmacy providers that—

''(i) are reasonable and adequate to cover all direct and indirect costs of furnishing the items and services covered by this part, and a reasonable return;

''(ii) are sufficient to enlist enough pharmacy providers to ensure that items and services covered under this part are available to beneficiaries at least to the extent that such items and services are available to the general public;

''(iii) do not vary based on the size or corporate structure of the pharmacy provider or factors commonly associated with the size of the provider, such as prescription volume;

''(iv) provide appropriate incentives for dispensing lower cost multiple source prescription drugs; and

''(v) recognize and provide appropriate payment incentives for pharmacy providers located in rural and underserved areas (as the Secretary may define by regulation); and

''(B) carriers that reflect the administrative costs of providing administration of the prescription drug benefit as specified under section 1860F.

''MEDICARE PRESCRIPTION DRUG BENEFIT ADVISORY COMMISSION

''SEC. 1860H. (a) ESTABLISHMENT.—There is established the Medicare Prescription Drug Benefit Advisory Commission.

''(b) COMPOSITION.—The Commission, appointed by the Secretary, shall consist of an equal number of actively practicing physicians, consumers, and actively practicing pharmacists. Other individuals may advise the Commission as necessary, but may not participate as Commission members.

''(c) DUTIES.—

''(1) CONSULTATION WITH SECRETARY.—The Medicare Prescription Drug Benefit Advisory Com-

mission shall consult with the Secretary as required by this part.

''(2) REVIEW OF PAYMENT POLICIES AND ANNUAL REPORTS.—The Medicare Prescription Drug Benefit Advisory Commission shall—

''(A) review payment and eligibility policies under this part and make recommendations to Congress concerning such payment policies;

''(B) review the impact on cost and quality of care of medication therapy management services; and

''(C) by not later than May 1 of each year (beginning in 2004), submit a report to Congress containing the results of such reviews and recommendations concerning such policies.

''DEFINITIONS

''SEC. 1860I. In this part:

''(a) COVERED OUTPATIENT PRESCRIPTION DRUG.—

''(1) IN GENERAL.—Subject to paragraph (2), the term 'covered outpatient prescription drug' means—

''(A) a drug or biological that may be dispensed only upon a prescription;

''(B) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act, and

needles, syringes, and disposable pumps for the administration of such insulin; and

''(C) such nonprescription drugs as defined under section 503 of the Federal Food, Drug, and Cosmetic Act that are prescribed and determined medically necessary by a physician or other health care provider licensed by the State to prescribe medications.

''(2) EXCLUSION OF COSMETIC AGENTS AND FERTILITY AGENTS.—Such term does not include medications or classes of outpatient prescription drugs described in subparagraphs (B) and (C) of section 1927(d)(2).

''(b) AVERAGE MANUFACTURERS' PRICE.—The term 'average manufacturers' price' means, with respect to a prescription drug of a manufacturer provided under this part for a calendar quarter, the average unit price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations, and wholesalers where the drug is relabeled under the distributor's national drug code.) Average manufacturers' price includes cash discounts allowed and all other price reductions that reduce the actual price paid.

''(c) CARRIER.—The term 'carrier' means the entity responsible for administering the prescription drug benefit program under this part. A carrier may be a prescription claims processing vendor, wholesale and community pharmacy delivery system, health care provider, insurer, or any other type of entity as the Secretary may specify.

''(d) PHARMACY PROVIDER.—The term 'pharmacy provider' means a pharmacist or pharmacy that—

''(1) is authorized by applicable State agencies to engage in the practice of pharmacy;

''(2) meets the requirements of section 1860G; and

''(3) participates in the program under this part.''.

(b) CONFORMING AMENDMENTS.—

(1) AMENDMENTS TO FEDERAL SUPPLEMENTARY HEALTH INSURANCE TRUST FUND.—Section 1841 of the Social Security Act (42 U.S.C. 1395t) is amended—

(A) in the last sentence of subsection (a)—

(i) by striking ''and'' after ''section 201(i)(I)''; and

(ii) by inserting before the period the following: '', and such amounts as may be deposited in, or appropriated to, the Pre-

scription Drug Benefit Insurance Account established by section 1860B''; and

(B) in subsection (g), by inserting after ''by this part,'' the following: ''the payments provided for under part D (in which case the payments shall come from the Prescription Drug Benefit Insurance Account in the Supplementary Medical Insurance Trust Fund),''.

(2) EXCLUSIONS FROM COVERAGE.—

(A) APPLICATION TO PART D.—Section 1862(a) of such Act (42 U.S.C. 1395y(a)) is amended in the matter preceding paragraph (1) by striking ''part A or part B'' and inserting ''part A, B, or D''.

(B) PRESCRIPTION MEDICATIONS NOT EXCLUDED FROM COVERAGE IF APPROPRIATELY PRESCRIBED.—Section 1862(a)(1) of such Act (42 U.S.C. 1395y(a)(1)) is amended—

(i) in subparagraph (H), by striking ''and'' at the end;

(ii) in subparagraph (I), by striking the semicolon at the end and inserting '', and''; and

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

"(J) in the case of prescription medications covered under part D, which are not prescribed in accordance with such part;".

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of the enactment of this Act, and shall apply with respect to benefits for prescription drugs furnished on or after January 1, 2003.

SEC. 3. GAO STUDY AND BIENNIAL REPORTS ON SAVINGS.

(a) ONGOING STUDY.—The Comptroller General of the United States, in consultation with the Medicare Prescription Drug Benefit Advisory Commission established under section 1860H of the Social Security Act (as added by section 2(a)), shall conduct an ongoing study and analysis of the prescription drug benefit program under part D of the Social Security Act (as added by such section), with an analysis of the savings to the medicare program resulting from such drug benefit program, including savings to medicare parts A and B, by reason of, for example, the reduction in the number or length of hospital visits.

(b) REPORT.—Not later than January 1, 2004, and every 2 years thereafter, the Comptroller General of the United States shall submit to Congress a report on the results of the study conducted under this section, together with any recommendation for legislation determined to be appropriate as a result of such study.

SEC. 4. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Prescription Drug Benefit Insurance Account within the Supplementary Medical Insurance Trust Fund established under section 1841, an amount equal to the amount by which the benefits and administrative costs of providing the benefits under this part exceed the premiums collected under section 1860E.

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