IB

Union Calendar No. 170

116TH CONGRESS
1ST SESSION

H. R. 2296

[Report No. 116–215]

To require reporting regarding certain drug price increases, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 12, 2019

Ms. SCHAKOWSKY (for herself and Mr. ROONEY of Florida) introduced the following bill; which was referred to the Committee on Energy and Commerce

SEPTEMBER 24, 2019

Additional sponsors: Mr. DOGGETT, Mr. SARBANES, Ms. UNDERWOOD, Mr. GRIFFITH, Mr. SUOZZI, Mr. POCAN, and Mr. CARTER of Georgia

SEPTEMBER 24, 2019

Reported with amendments, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on April 12, 2019]

A BILL

To require reporting regarding certain drug price increases, and for other purposes.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "More Efficient Tools to Realize Information for Consumers Act" or the "METRIC Act".

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

SEC. 2. REPORTING ON EXPLANATION FOR DRUG PRICE INCREASES.

(a) IN GENERAL.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

"PART W—DRUG PRICE REPORTING; DRUG VALUE FUND

"SEC. 399OO. REPORTING ON EXPLANATION FOR DRUG PRICE INCREASES.

"(a) DEFINITIONS.—In this section:

"(1) MANUFACTURER.—The term 'manufacturer' means the person—

"(A) that holds the application for a drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act; or

"(B) who is responsible for setting the wholesale acquisition cost for the drug.

"(2) QUALIFYING DRUG.—The term 'qualifying drug' means any drug that is approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under subsection (a) or (k) of section 351 of this Act—

"(A) that has a wholesale acquisition cost of $100 or more, adjusted for inflation occurring after the date of enactment of the More Efficient Tools to Realize Information for Consumers Act, for a month's supply or a typical course of treatment that lasts less than a month, and is—

"(i) subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act;

"(ii) administered or otherwise dispensed to treat a disease or condition affecting more than 200,000 persons in the United States; and

"(iii) not a vaccine; and

"(B) for which, during the previous calendar year, at least 1 dollar of the total amount of sales were for individuals enrolled under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) or under a State Medicaid plan under title XIX of such Act (42 U.S.C. 1396 et seq.) or under a waiver of such plan.

"(3) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given that term in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).

"(b) REPORT.—

"(1) REPORT REQUIRED.—The manufacturer of a qualifying drug shall submit a report to the Secretary for each increase in the price of a qualifying drug that results in an increase in the wholesale acquisition cost of that drug that is equal to—

"(A) 10 percent or more within a single calendar year beginning on or after January 1, 2019; or

"(B) 25 percent or more within three consecutive calendar years for which the first such

calendar year begins on or after January 1, 2019.

"(2) REPORT DEADLINE.—Each report described in paragraph (1) shall be submitted to the Secretary—

"(A) in the case of a report with respect to an increase in the price of a qualifying drug that occurs during the period beginning on January 1, 2019, and ending on the day that is 60 days after the date of the enactment of the More Efficient Tools to Realize Information for Consumers Act, not later than 90 days after such date of enactment; and

"(B) in the case of a report with respect to an increase in the price of a qualifying drug that occurs after the period described in subparagraph (A), not later than 30 days prior to the planned effective date of such price increase for such qualifying drug.

"(c) CONTENTS.—A report under subsection (b), consistent with the standard for disclosures described in section 213.3(d) of title 12, Code of Federal Regulations (as in effect on the date of enactment of the More Efficient Tools to Realize Information for Consumers Act), shall, at a minimum, include—

"(1) with respect to the qualifying drug—

"(A) the percentage by which the manufacturer will raise the wholesale acquisition cost of the drug within the calendar year or three consecutive calendar years as described in subsection (b)(1)(A) or (b)(1)(B), and the effective date of such price increase;

"(B) an explanation for, and description of, each price increase for such drug that will occur during the calendar year period described in subsection (b)(1)(A) or the three consecutive calendar year period described in subsection (b)(1)(B), as applicable;

"(C) if known and different from the manufacturer of the qualifying drug, the identity of—

"(i) the sponsor or sponsors of any investigational new drug applications under section 505(i) of the Federal Food, Drug, and Cosmetic Act for clinical investigations with respect to such drug, for which the full reports are submitted as part of the application—

"(I) for approval of the drug under section 505 of such Act; or

"(II) for licensure of the drug under section 351 of this Act; and

"(ii) the sponsor of an application for the drug approved under such section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act;

"(D) a description of the history of the manufacturer's price increases for the drug since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351 of this Act, or since the manufacturer acquired such approved application or license, if applicable;

"(E) the current wholesale acquisition cost of the drug;

"(F) the total expenditures of the manufacturer on—

"(i) materials and manufacturing for such drug; and

"(ii) acquiring patents and licensing for such drug;

"(G) the percentage of total expenditures of the manufacturer on research and development

for such drug that was derived from Federal funds;

"(H) the total expenditures of the manufacturer on research and development for such drug that is necessary to demonstrate that it meets applicable statutory standards for approval under section 505 of the Federal Food, Drug, and Cosmetic Act or licensure under section 351 of this Act, as applicable;

"(I) the total expenditures of the manufacturer on pursuing new or expanded indications or dosage changes for such drug under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act;

"(J) the total expenditures of the manufacturer on carrying out postmarket requirements related to such drug, including under section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act;

"(K) the total revenue and the net profit generated from the qualifying drug for each calendar year since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351, or

since the manufacturer acquired such approved application or license; and

"(L) the total costs associated with marketing and advertising for the qualifying drug;

"(2) with respect to the manufacturer—

"(A) the total revenue and the net profit of the manufacturer for each of the 1-year period described in subsection (b)(1)(A) or the 3-year period described in subsection (b)(1)(B), as applicable;

"(B) all stock-based performance metrics used by the manufacturer to determine executive compensation for each of the 1-year period described in subsection (b)(1)(A) or the 3-year period described in subsection (b)(1)(B), as applicable; and

"(C) any additional information the manufacturer chooses to provide related to drug pricing decisions, such as total expenditures on—

"(i) drug research and development; or

"(ii) clinical trials, including on drugs that failed to receive approval by the Food and Drug Administration; and

"(3) such other related information as the Secretary considers appropriate and as specified by the Secretary through notice-and-comment rulemaking.

"(d) INFORMATION PROVIDED.—The manufacturer of a qualifying drug that is required to submit a report under subsection (b), shall ensure that such report and any explanation for, and description of, each price increase described in subsection (c)(1)(B) shall be truthful, not misleading, and accurate.

"(e) CIVIL MONETARY PENALTY.—Any manufacturer of a qualifying drug that fails to submit a report for the drug as required by this section, following notification by the Secretary to the manufacturer that the manufacturer is not in compliance with this section, shall be subject to a civil monetary penalty of $75,000 for each day on which the violation continues.

"(f) FALSE INFORMATION.—Any manufacturer that submits a report for a drug as required by this section that knowingly provides false information in such report is subject to a civil monetary penalty in an amount not to exceed $75,000 for each item of false information.

"(g) PUBLIC POSTING.—

"(1) IN GENERAL.—Subject to paragraph (3), the Secretary shall post each report submitted under subsection (b) on the public website of the Department of

Health and Human Services the day the price increase of a qualifying drug is scheduled to go into effect.

"(2) FORMAT.—In developing the format in which reports will be publicly posted under paragraph (1), the Secretary shall consult with stakeholders, including beneficiary groups, and shall seek feedback from consumer advocates and readability experts on the format and presentation of the content of such reports to ensure that such reports are—

"(A) user-friendly to the public; and

"(B) written in plain language that consumers can readily understand.

"(3) PROTECTED INFORMATION.—Nothing in this section shall be construed to authorize the public disclosure of information submitted by a manufacturer that is prohibited from disclosure by applicable laws concerning the protection of trade secrets, commercial information, and other information covered under such laws.

"SEC. 399OO–1. ANNUAL REPORT TO CONGRESS.

"(a) IN GENERAL.—Subject to subsection (b), the Secretary shall submit to Congress, and post on the public website of the Department of Health and Human Services in a way that is user-friendly to the public and written

in plain language that consumers can readily understand, an annual report—

"(1) summarizing the information reported pursuant to section 399OO;

"(2) including copies of the reports and supporting detailed economic analyses submitted pursuant to such section;

"(3) detailing the costs and expenditures incurred by the Department of Health and Human Services in carrying out section 399OO; and

"(4) explaining how the Department of Health and Human Services is improving consumer and provider information about drug value and drug price transparency.

"(b) PROTECTED INFORMATION.—Nothing in this section shall be construed to authorize the public disclosure of information submitted by a manufacturer that is prohibited from disclosure by applicable laws concerning the protection of trade secrets, commercial information, and other information covered under such laws.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) takes effect on the date of enactment of this Act.

SEC. 3. PUBLIC DISCLOSURE OF DRUG DISCOUNTS.

Section 1150A of the Social Security Act (42 U.S.C. 1320b–23) is amended—

(1) in subsection (c), in the matter preceding paragraph (1), by inserting "(other than as permitted under subsection (e))" after "disclosed by the Secretary"; and

(2) by adding at the end the following new subsection:

"(e) PUBLIC AVAILABILITY OF CERTAIN INFORMATION.—

"(1) IN GENERAL.—In order to allow the comparison of PBMs' ability to negotiate rebates, discounts, direct and indirect remuneration fees, administrative fees, and price concessions and the amount of such rebates, discounts, direct and indirect remuneration fees, administrative fees, and price concessions that are passed through to plan sponsors, beginning January 1, 2020, the Secretary shall make available on the Internet website of the Department of Health and Human Services the information with respect to the second preceding calendar year provided to the Secretary on generic dispensing rates (as described in paragraph (1) of subsection (b)) and information provided to the Secretary under paragraphs (2) and (3) of such subsection that, as determined by the Secretary, is with respect to each PBM.

"(2) AVAILABILITY OF DATA.—In carrying out paragraph (1), the Secretary shall ensure the following:

"(A) CONFIDENTIALITY.—The information described in such paragraph is displayed in a manner that prevents the disclosure of information, with respect to an individual drug or an individual plan, on rebates, discounts, direct and indirect remuneration fees, administrative fees, and price concessions.

"(B) CLASS OF DRUG.—The information described in such paragraph is made available by class of drug, using an existing classification system, but only if the class contains such number of drugs, as specified by the Secretary (but not fewer than three drugs), to ensure confidentiality of proprietary information or other information that is prevented to be disclosed under subparagraph (A).".

SEC. 4. STUDY OF PHARMACEUTICAL SUPPLY CHAIN INTERMEDIARIES AND MERGER ACTIVITY.

(a) INITIAL REPORT.—Not later than 1 year after the date of enactment of this Act, the Commission shall submit to the appropriate committees of Congress a report that—

(1) addresses at minimum—

(A) whether pharmacy benefit managers—

(i) charge payers a higher price than the reimbursement rate at which the pharmacy benefit managers reimburse competing pharmacies;

(ii) steer patients for anticompetitive purposes to any pharmacies, including retail, mail-order, or any other type of pharmacy, in which the pharmacy benefit manager has an ownership interest;

(iii) audit or review proprietary data, including acquisition costs, patient information, or dispensing information, of competing pharmacies that can be used for anticompetitive purposes; or

(iv) use formulary designs to increase the market share of higher cost prescription drugs and depress the market share of lower cost prescription drugs (each net of rebates and discounts);

(B) how companies and payers assess the benefits, costs, and risks of contracting with intermediaries, including pharmacy services administrative organizations, and whether more information about the roles of intermediaries

should be available to consumers and payers; and

(C) whether there are any specific legal or regulatory obstacles the Commission currently faces in ensuring a competitive and transparent marketplace in the pharmaceutical supply chain, including the pharmacy benefit manager marketplace and pharmacy services administrative organizations; and

(2) provides—

(A) observations or conclusions drawn from the November 2017 roundtable entitled "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics", and any similar efforts;

(B) specific actions the Commission intends to take as a result of the November 2017 roundtable, and any similar efforts, including a detailed description of relevant forthcoming actions, additional research or roundtable discussions, consumer education efforts, or enforcement actions; and

(C) policy or legislative recommendations to—

(i) improve transparency and competition in the pharmaceutical supply chain;

(ii) prevent and deter anticompetitive behavior in the pharmaceutical supply chain; and

(iii) best ensure that consumers benefit from any cost savings or efficiencies that may result from mergers and consolidations.

(b) INTERIM REPORT.—Not later than 180 days after the date of enactment of this Act, the Commission shall submit to the appropriate committees of Congress an interim report on the progress of the report required by subsection (a), along with preliminary findings and conclusions based on information collected to that date.

(c) DEFINITIONS.—In this section:

(1) APPROPRIATE COMMITTEES OF CONGRESS.—The term "appropriate committees of Congress" means—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on the Judiciary of the Senate; and

(C) the Committee on the Judiciary of the House of Representatives.

(2) COMMISSION.—The term "Commission" means the Federal Trade Commission.

SEC. 5. REQUIRING CERTAIN MANUFACTURERS TO REPORT DRUG PRICING INFORMATION WITH RESPECT TO DRUGS UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—Section 1847A of the Social Security Act (42 U.S.C. 1395w–3a) is amended—

(1) in subsection (b)—

(A) in paragraph (2)(A), by inserting "or subsection (f)(2), as applicable" before the period at the end;

(B) in paragraph (3), in the matter preceding subparagraph (A), by inserting "or subsection (f)(2), as applicable," before "determined by"; and

(C) in paragraph (6)(A), in the matter preceding clause (i), by inserting "or subsection (f)(2), as applicable," before "determined by"; and

(2) in subsection (f)—

(A) by striking "For requirements" and inserting the following:

"(1) IN GENERAL.—For requirements"; and

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

"(2) MANUFACTURERS WITHOUT A REBATE AGREEMENT UNDER TITLE XIX.—

"(A) IN GENERAL.—If the manufacturer of a drug or biological described in subparagraph (C), (E), or (G) of section 1842(o)(1) or in section 1881(b)(14)(B) that is payable under this part has not entered into and does not have in effect a rebate agreement described in subsection (b) of section 1927, for calendar quarters beginning on or after January 1, 2020, such manufacturer shall report to the Secretary the information described in subsection (b)(3)(A)(iii) of such section 1927 with respect to such drug or biological in a time and manner specified by the Secretary. For purposes of applying this paragraph, a drug or biological described in the previous sentence includes items, services, supplies, and products that are payable under this part as a drug or biological.

"(B) AUDIT.—Information reported under subparagraph (A) is subject to audit by the Inspector General of the Department of Health and Human Services.

"(C) VERIFICATION.—The Secretary may survey wholesalers and manufacturers that di-

rectly distribute drugs described in subparagraph (A), when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of such a drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

"(D) CONFIDENTIALITY.—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph (other than the wholesale acquisition cost for purposes of carrying out this section) is confidential and shall not be disclosed by the

Secretary in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs by such manufacturer or wholesaler, except—

"(i) as the Secretary determines to be necessary to carry out this section (including the determination and implementation of the payment amount), or to carry out section 1847B;

"(ii) to permit the Comptroller General of the United States to review the information provided; and

"(iii) to permit the Director of the Congressional Budget Office to review the information provided.".

(b) ENFORCEMENT.—Section 1847A of such Act (42 U.S.C. 1395w–3a) is further amended—

(1) in subsection (d)(4)—

(A) in subparagraph (A), by striking "IN GENERAL" and inserting "MISREPRESENTATION";

(B) in subparagraph (B), by striking "subparagraph (B)" and inserting "subparagraph (A), (B), or (C)";

(C) by redesignating subparagraph (B) as subparagraph (D); and

(D) by inserting after subparagraph (A) the following new subparagraphs:

"(B) FAILURE TO PROVIDE TIMELY INFORMATION.—If the Secretary determines that a manufacturer described in subsection (f)(2) has failed to report on information described in section 1927(b)(3)(A)(iii) with respect to a drug or biological in accordance with such subsection, the Secretary shall apply a civil money penalty in an amount of $10,000 for each day the manufacturer has failed to report such information and such amount shall be paid to the Treasury.

"(C) FALSE INFORMATION.—Any manufacturer required to submit information under subsection (f)(2) that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law."; and

(2) in subsection (c)(6)(A), by striking the period at the end and inserting ", except that, for purposes of subsection (f)(2), the Secretary may, if the Sec-

retary determines appropriate, exclude repackagers of a drug or biological from such term.".

(c) MANUFACTURERS WITH A REBATE AGREEMENT.—

(1) IN GENERAL.—Section 1927(b)(3)(A) of the Social Security Act (42 U.S.C. 1396r-8(b)(3)(A)) is amended by adding at the end the following new sentence: "For purposes of applying clause (iii), a drug or biological described in the flush matter following such clause includes items, services, supplies, and products that are payable under this part as a drug or biological.".

(2) TECHNICAL AMENDMENT.—Section 1927(b)(3)(A)(iii) of the Social Security Act (42 U.S.C. 1396r-8(b)(3)(A)(iii)) is amended by striking "section 1881(b)(13)(A)(ii)" and inserting "section 1881(b)(14)(B)".

(d) REPORT.—Not later than January 1, 2021, the Inspector General of the Department of Health and Human Services shall assess and submit to Congress a report on the accuracy of average sales price information submitted by manufacturers under section 1847A of the Social Security Act (42 U.S.C. 1395w–3a). Such report shall include any recommendations on how to improve the accuracy of such information.

SEC. 6. MAKING PRESCRIPTION DRUG MARKETING SAMPLE INFORMATION REPORTED BY MANUFACTURERS AVAILABLE TO CERTAIN INDIVIDUALS AND ENTITIES.

(a) IN GENERAL.—Section 1128H of the Social Security Act (42 U.S.C. 1320a–7i) is amended—

(1) by redesignating subsection (b) as subsection (e); and

(2) by inserting after subsection (a) the following new subsections:

"(b) DATA SHARING AGREEMENTS.—

"(1) IN GENERAL.—The Secretary shall enter into agreements with the specified data sharing individuals and entities described in paragraph (2) under which—

"(A) upon request of such an individual or entity, as applicable, the Secretary makes available to such individual or entity the information submitted under subsection (a) by manufacturers and authorized distributors of record; and

"(B) such individual or entity agrees to not disclose publicly or to another individual or entity any information that identifies a particular practitioner or health care facility.

"(2) SPECIFIED DATA SHARING INDIVIDUALS AND ENTITIES.—For purposes of paragraph (1), the

specified data sharing individuals and entities described in this paragraph are the following:

"(A) OVERSIGHT AGENCIES.—Health oversight agencies (as defined in section 164.501 of title 45, Code of Federal Regulations), including the Centers for Medicare & Medicaid Services, the Office of the Inspector General of the Department of Health and Human Services, the Government Accountability Office, the Congressional Budget Office, the Medicare Payment Advisory Commission, and the Medicaid and CHIP Payment and Access Commission.

"(B) RESEARCHERS.—Individuals who conduct scientific research (as defined in section 164.501 of title 45, Code of Federal Regulations) in relevant areas as determined by the Secretary.

"(C) PAYERS.—Private and public health care payers, including group health plans, health insurance coverage offered by health insurance issuers, Federal health programs, and State health programs.

"(3) EXEMPTION FROM FREEDOM OF INFORMATION ACT.—Except as described in paragraph (1), the Secretary may not be compelled to disclose the information submitted under subsection (a) to any indi-

vidual or entity. For purposes of section 552 of title 5, United States Code (commonly referred to as the Freedom of Information Act), this paragraph shall be considered a statute described in subsection (b)(3)(B) of such section.

"(c) PENALTIES.—

"(1) DATA SHARING AGREEMENTS.—Subject to paragraph (3), any specified data sharing individual or entity described in subsection (b)(2) that violates the terms of a data sharing agreement the individual or entity has with the Secretary under subsection (b)(1) shall be subject to a civil money penalty of not less than $1,000, but not more than $10,000, for each such violation. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

"(2) FAILURE TO REPORT.—Subject to paragraph (3), any manufacturer or authorized distributor of record of an applicable drug under subsection (a) that fails to submit information required under such subsection in a timely manner in accordance with rules or regulations promulgated to carry out such subsection shall be subject to a civil money penalty of not less than $1,000, but not more than

$10,000, for each such failure. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

"(3) LIMITATION.—The total amount of civil money penalties imposed under paragraph (1) or (2) with respect to a year and an individual or entity described in subparagraph (A) or a manufacturer or distributor described in subparagraph (B), respectively, shall not exceed $150,000.

"(d) DRUG SAMPLE DISTRIBUTION INFORMATION.—

"(1) IN GENERAL.—Not later than January 1 of each year (beginning with 2021), the Secretary shall maintain a list containing information related to the distribution of samples of applicable drugs. Such list shall provide the following information with respect to the preceding year:

"(A) The name of the manufacturer or authorized distributor of record of an applicable drug for which samples were requested or distributed under this section.

"(B) The quantity and class of drug samples requested.

"(C) The quantity and class of drug samples distributed.

"(2) PUBLIC AVAILABILITY.—The Secretary shall make the information in such list available to the public on the Internet Web site of the Food and Drug Administration.".

(b) FDA MAINTENANCE OF INFORMATION.—The Food and Drug Administration shall maintain information available to affected reporting companies to ensure their ability to fully comply with the requirements of section 1128H of the Social Security Act.

(c) PROHIBITION ON DISTRIBUTION OF SAMPLES OF OPIOIDS.—Section 503(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(d)) is amended—

(1) by moving the margin of paragraph (4) 2 ems to the left; and

(2) by adding at the end the following:

"(5) No person may distribute a drug sample of a drug that is—

"(A) an applicable drug (as defined in section 1128H(d) of the Social Security Act);

"(B) a controlled substance (as defined in section 102 of the Controlled Substances Act) for which the findings required under section 202(b)(2) of such Act have been made; and

"(C) approved under section 505 for use in the management or treatment of pain (other than for the

management or treatment of a substance use disorder).".

(d) MEDPAC REPORT.—Not later than 3 years after the date of the enactment of this Act, the Medicare Payment Advisory Commission shall conduct a study on the impact of drug samples on provider prescribing practices and health care costs and may, as the Commission deems appropriate, make recommendations on such study.

SEC. 7. REQUIRING PRESCRIPTION DRUG PLAN SPONSORS TO INCLUDE REAL-TIME BENEFIT INFORMATION AS PART OF SUCH SPONSOR'S ELECTRONIC PRESCRIPTION PROGRAM UNDER THE MEDICARE PROGRAM.

Section 1860D–4(e)(2) of the Social Security Act (42 U.S.C. 1395w–104(e)(2)) is amended—

(1) in subparagraph (D), by striking "To the extent" and inserting "Except as provided in subparagraph (F), to the extent"; and

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

"(F) REAL-TIME BENEFIT INFORMATION.—

"(i) IN GENERAL.—Not later than January 1, 2021, the program shall implement real-time benefit tools that are capable of integrating with a prescribing health care

professional's electronic prescribing or electronic health record system for the transmission of formulary and benefit information in real time to prescribing health care professionals. With respect to a covered part D drug, such tools shall be capable of transmitting such information specific to an individual enrolled in a prescription drug plan. Such information shall include the following:

"(I) A list of any clinically-appropriate alternatives to such drug included in the formulary of such plan.

"(II) Cost-sharing information for such drug and such alternatives, including a description of any variance in cost sharing based on the pharmacy dispensing such drug or such alternatives.

"(III) Information relating to whether such drug is included in the formulary of such plan and any prior authorization or other utilization management requirements applicable to

such drug and such alternatives so included.

"(ii) ELECTRONIC TRANSMISSION.—The provisions of subclauses (I) and (II) of clause (ii) of subparagraph (E) shall apply to an electronic transmission described in clause (i) in the same manner as such provisions apply with respect to an electronic transmission described in clause (i) of such subparagraph.

"(iii) SPECIAL RULE FOR 2021.—The program shall be deemed to be in compliance with clause (i) for 2021 if the program complies with the provisions of section 423.160(b)(7) of title 42, Code of Federal Regulations (or a successor regulation), for such year.

"(iv) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed as to allow a real time benefits tool to steer an individual, without the consent of the individual, to a particular pharmacy or pharmacy setting over their preferred pharmacy setting nor prohibit the designation of a preferred pharmacy under such tool.".

SEC. 8. SENSE OF CONGRESS REGARDING THE NEED TO EXPAND COMMERCIALLY AVAILABLE DRUG PRICING COMPARISON PLATFORMS.

It is the sense of Congress that—

(1) commercially available drug pricing comparison platforms can, at no cost, help patients find the lowest price for their medications at their local pharmacy;

(2) such platforms should be integrated, to the maximum extent possible, in the health care delivery ecosystem; and

(3) pharmacy benefit managers should work to disclose generic and brand name drug prices to such platforms to ensure that—

(A) patients can benefit from the lowest possible price available to them; and

(B) overall drug prices can be reduced as more educated purchasing decisions are made based on price transparency.

SEC. 9. TECHNICAL CORRECTIONS.

(a) IN GENERAL.—Section 3022(b) of the Public Health Service Act (42 U.S.C. 300jj–52(b)) is amended by adding at the end the following new paragraph:

"(4) APPLICATION OF AUTHORITIES UNDER INSPECTOR GENERAL ACT OF 1978.—In carrying out this subsection, the Inspector General shall have the

same authorities as provided under section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect as if included in the enactment of the 21st Century Cures Act (Public Law 114–255).

Amend the title so as to read: ''A bill to require reporting for certain drug price information, and for other purposes.''.

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