AMENDMENT TO H.R. 2296

OFFERED BY M__. _____

[Page and line numbers to Committee Print for H.R. 2296]

Page 2, line 1, strike ''**JUSTIFICATION**'' and insert ''**EXPLANATION**'' (and conform the table of contents accordingly).

Page 3, line 15, strike ''or''.

Page 6, strike lines 7 through 11, and insert the following:

''(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;

Page 7, strike lines 7 through 21, and insert the following:

"(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;

Page 7, line 22, redesignate the subparagraph (I) as subparagraph (K).

Page 8, line 5, redesignate the subparagraph (J) as subparagraph (L).

Page 9, after line 6, insert the following:

''(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.

Page 9, line 7, redesignate the subsection (d) as subsection (e).

Page 9, line 14, redesignate the subsection (e) as subsection (f).

Page 9, line 19, redesignate the subsection (f) as subsection (g).

Page 10, strike lines 12 through 18 and insert the following:

''(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.

Page 11, strike lines 13 through 18 and insert the following:

''(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.''.

Page 17, strike line 3 and all that follows through page 22, line 10, and insert the following:

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 directly 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 ex-

ceed $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 (includ-

ing 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 Secretary 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.

Page 22, line 18, strike ''(d)'' and insert ''(e)''.

Page 25, line 22, strike the end quotation and second period.

Page 25, after line 22, insert the following:

''(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.''.

Page 25, strike line 23 and all that follows through page 26, line 2, and insert the following:

(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.

Page 26, after line 20, insert the following:

(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.

Page 27, strike line 1 and all that follows through page 29, line 2, and insert the following (and conform the table of contents accordingly):

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.''.

Page 29, after line 21, insert the following (and conform the table of contents accordingly):

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).

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