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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 *italie*]

[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.

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*

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

4 (a) *SHORT TITLE.*—*This Act may be cited as the*
 5 *“More Efficient Tools to Realize Information for Consumers*
 6 *Act” or the “METRIC Act”.*

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

Sec. 1. Short title; table of contents.

Sec. 2. Reporting on explanation for drug price increases.

Sec. 3. Public disclosure of drug discounts.

Sec. 4. Study of pharmaceutical supply chain intermediaries and merger activ-
ity.

Sec. 5. Requiring certain manufacturers to report drug pricing information with
respect to drugs under the Medicare program.

Sec. 6. Making prescription drug marketing sample information reported by
manufacturers available to certain individuals and entities.

Sec. 7. Requiring prescription drug plan sponsors to include real-time benefit in-
formation as part of such sponsor’s electronic prescription pro-
gram under the Medicare program.

Sec. 8. Sense of Congress regarding the need to expand commercially available
drug pricing comparison platforms.

Sec. 9. Technical corrections.

9 **SEC. 2. REPORTING ON EXPLANATION FOR DRUG PRICE IN-**
 10 **CREASES.**

11 (a) *IN GENERAL.*—*Title III of the Public Health Serv-*
 12 *ice Act (42 U.S.C. 241 et seq.) is amended by adding at*
 13 *the end the following:*

14 **“PART W—DRUG PRICE REPORTING; DRUG VALUE**
 15 **FUND**

16 **“SEC. 3990O. REPORTING ON EXPLANATION FOR DRUG**
 17 **PRICE INCREASES.**

18 “(a) *DEFINITIONS.*—*In this section:*

1 “(1) *MANUFACTURER.*—*The term ‘manufacturer’*
2 *means the person—*

3 “(A) *that holds the application for a drug*
4 *approved under section 505 of the Federal Food,*
5 *Drug, and Cosmetic Act or licensed under section*
6 *351 of this Act; or*

7 “(B) *who is responsible for setting the*
8 *wholesale acquisition cost for the drug.*

9 “(2) *QUALIFYING DRUG.*—*The term ‘qualifying*
10 *drug’ means any drug that is approved under sub-*
11 *section (c) or (j) of section 505 of the Federal Food,*
12 *Drug, and Cosmetic Act or licensed under subsection*
13 *(a) or (k) of section 351 of this Act—*

14 “(A) *that has a wholesale acquisition cost of*
15 *\$100 or more, adjusted for inflation occurring*
16 *after the date of enactment of the More Efficient*
17 *Tools to Realize Information for Consumers Act,*
18 *for a month’s supply or a typical course of treat-*
19 *ment that lasts less than a month, and is—*

20 “(i) *subject to section 503(b)(1) of the*
21 *Federal Food, Drug, and Cosmetic Act;*

22 “(ii) *administered or otherwise dis-*
23 *persed to treat a disease or condition affect-*
24 *ing more than 200,000 persons in the*
25 *United States; and*

1 “(iii) not a vaccine; and

2 “(B) for which, during the previous cal-
3 endar year, at least 1 dollar of the total amount
4 of sales were for individuals enrolled under the
5 Medicare program under title XVIII of the So-
6 cial Security Act (42 U.S.C. 1395 et seq.) or
7 under a State Medicaid plan under title XIX of
8 such Act (42 U.S.C. 1396 et seq.) or under a
9 waiver of such plan.

10 “(3) *WHOLESALE ACQUISITION COST.*—The term
11 ‘wholesale acquisition cost’ has the meaning given
12 that term in section 1847A(c)(6)(B) of the Social Se-
13 curity Act (42 U.S.C. 1395w-3a(c)(6)(B)).

14 “(b) *REPORT.*—

15 “(1) *REPORT REQUIRED.*—The manufacturer of
16 a qualifying drug shall submit a report to the Sec-
17 retary for each increase in the price of a qualifying
18 drug that results in an increase in the wholesale ac-
19 quisition cost of that drug that is equal to—

20 “(A) 10 percent or more within a single cal-
21 endar year beginning on or after January 1,
22 2019; or

23 “(B) 25 percent or more within three con-
24 secutive calendar years for which the first such

1 *calendar year begins on or after January 1,*
2 *2019.*

3 “(2) *REPORT DEADLINE.*—*Each report described*
4 *in paragraph (1) shall be submitted to the Sec-*
5 *retary—*

6 “(A) *in the case of a report with respect to*
7 *an increase in the price of a qualifying drug*
8 *that occurs during the period beginning on Jan-*
9 *uary 1, 2019, and ending on the day that is 60*
10 *days after the date of the enactment of the More*
11 *Efficient Tools to Realize Information for Con-*
12 *sumers Act, not later than 90 days after such*
13 *date of enactment; and*

14 “(B) *in the case of a report with respect to*
15 *an increase in the price of a qualifying drug*
16 *that occurs after the period described in subpara-*
17 *graph (A), not later than 30 days prior to the*
18 *planned effective date of such price increase for*
19 *such qualifying drug.*

20 “(c) *CONTENTS.*—*A report under subsection (b), con-*
21 *sistent with the standard for disclosures described in section*
22 *213.3(d) of title 12, Code of Federal Regulations (as in effect*
23 *on the date of enactment of the More Efficient Tools to Real-*
24 *ize Information for Consumers Act), shall, at a minimum,*
25 *include—*

1 “(1) with respect to the qualifying drug—

2 “(A) the percentage by which the manufac-
3 turer will raise the wholesale acquisition cost of
4 the drug within the calendar year or three con-
5 secutive calendar years as described in subsection
6 (b)(1)(A) or (b)(1)(B), and the effective date of
7 such price increase;

8 “(B) an explanation for, and description of,
9 each price increase for such drug that will occur
10 during the calendar year period described in
11 subsection (b)(1)(A) or the three consecutive cal-
12 endar year period described in subsection
13 (b)(1)(B), as applicable;

14 “(C) if known and different from the manu-
15 facturer of the qualifying drug, the identity of—

16 “(i) the sponsor or sponsors of any in-
17 vestigational new drug applications under
18 section 505(i) of the Federal Food, Drug,
19 and Cosmetic Act for clinical investigations
20 with respect to such drug, for which the full
21 reports are submitted as part of the appli-
22 cation—

23 “(I) for approval of the drug
24 under section 505 of such Act; or

1 “(II) for licensure of the drug
2 under section 351 of this Act; and

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

7 “(D) a description of the history of the
8 manufacturer’s price increases for the drug since
9 the approval of the application for the drug
10 under section 505 of the Federal Food, Drug,
11 and Cosmetic Act or the issuance of the license
12 for the drug under section 351 of this Act, or
13 since the manufacturer acquired such approved
14 application or license, if applicable;

15 “(E) the current wholesale acquisition cost
16 of the drug;

17 “(F) the total expenditures of the manufac-
18 turer on—

19 “(i) materials and manufacturing for
20 such drug; and

21 “(ii) acquiring patents and licensing
22 for such drug;

23 “(G) the percentage of total expenditures of
24 the manufacturer on research and development

1 *for such drug that was derived from Federal*
2 *funds;*

3 “(H) *the total expenditures of the manufac-*
4 *turer on research and development for such drug*
5 *that is necessary to demonstrate that it meets*
6 *applicable statutory standards for approval*
7 *under section 505 of the Federal Food, Drug,*
8 *and Cosmetic Act or licensure under section 351*
9 *of this Act, as applicable;*

10 “(I) *the total expenditures of the manufac-*
11 *turer on pursuing new or expanded indications*
12 *or dosage changes for such drug under section*
13 *505 of the Federal Food, Drug, and Cosmetic Act*
14 *or section 351 of this Act;*

15 “(J) *the total expenditures of the manufac-*
16 *turer on carrying out postmarket requirements*
17 *related to such drug, including under section*
18 *505(o)(3) of the Federal Food, Drug, and Cos-*
19 *metic Act;*

20 “(K) *the total revenue and the net profit*
21 *generated from the qualifying drug for each cal-*
22 *endar year since the approval of the application*
23 *for the drug under section 505 of the Federal*
24 *Food, Drug, and Cosmetic Act or the issuance of*
25 *the license for the drug under section 351, or*

1 *since the manufacturer acquired such approved*
2 *application or license; and*

3 *“(L) the total costs associated with mar-*
4 *keting and advertising for the qualifying drug;*
5 *“(2) with respect to the manufacturer—*

6 *“(A) the total revenue and the net profit of*
7 *the manufacturer for each of the 1-year period*
8 *described in subsection (b)(1)(A) or the 3-year*
9 *period described in subsection (b)(1)(B), as ap-*
10 *plicable;*

11 *“(B) all stock-based performance metrics*
12 *used by the manufacturer to determine executive*
13 *compensation for each of the 1-year period de-*
14 *scribed in subsection (b)(1)(A) or the 3-year pe-*
15 *riod described in subsection (b)(1)(B), as appli-*
16 *cable; and*

17 *“(C) any additional information the manu-*
18 *facturer chooses to provide related to drug pric-*
19 *ing decisions, such as total expenditures on—*

20 *“(i) drug research and development; or*

21 *“(ii) clinical trials, including on drugs*
22 *that failed to receive approval by the Food*
23 *and Drug Administration; and*

1 “(3) such other related information as the Sec-
2 retary considers appropriate and as specified by the
3 Secretary through notice-and-comment rulemaking.

4 “(d) *INFORMATION PROVIDED.*—The manufacturer of
5 a qualifying drug that is required to submit a report under
6 subsection (b), shall ensure that such report and any expla-
7 nation for, and description of, each price increase described
8 in subsection (c)(1)(B) shall be truthful, not misleading,
9 and accurate.

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

17 “(f) *FALSE INFORMATION.*—Any manufacturer that
18 submits a report for a drug as required by this section that
19 knowingly provides false information in such report is sub-
20 ject to a civil monetary penalty in an amount not to exceed
21 \$75,000 for each item of false information.

22 “(g) *PUBLIC POSTING.*—

23 “(1) *IN GENERAL.*—Subject to paragraph (3), the
24 Secretary shall post each report submitted under sub-
25 section (b) on the public website of the Department of

1 *Health and Human Services the day the price in-*
2 *crease of a qualifying drug is scheduled to go into ef-*
3 *fect.*

4 “(2) *FORMAT.*—*In developing the format in*
5 *which reports will be publicly posted under para-*
6 *graph (1), the Secretary shall consult with stake-*
7 *holders, including beneficiary groups, and shall seek*
8 *feedback from consumer advocates and readability ex-*
9 *erts on the format and presentation of the content of*
10 *such reports to ensure that such reports are—*

11 “(A) *user-friendly to the public; and*

12 “(B) *written in plain language that con-*
13 *sumers can readily understand.*

14 “(3) *PROTECTED INFORMATION.*—*Nothing in*
15 *this section shall be construed to authorize the public*
16 *disclosure of information submitted by a manufac-*
17 *turer that is prohibited from disclosure by applicable*
18 *laws concerning the protection of trade secrets, com-*
19 *mercial information, and other information covered*
20 *under such laws.*

21 **“SEC. 39900-1. ANNUAL REPORT TO CONGRESS.**

22 “(a) *IN GENERAL.*—*Subject to subsection (b), the Sec-*
23 *retary shall submit to Congress, and post on the public*
24 *website of the Department of Health and Human Services*
25 *in a way that is user-friendly to the public and written*

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

3 “(1) *summarizing the information reported pur-*
4 *suant to section 39900;*

5 “(2) *including copies of the reports and sup-*
6 *porting detailed economic analyses submitted pursu-*
7 *ant to such section;*

8 “(3) *detailing the costs and expenditures in-*
9 *curring by the Department of Health and Human*
10 *Services in carrying out section 39900; and*

11 “(4) *explaining how the Department of Health*
12 *and Human Services is improving consumer and pro-*
13 *vider information about drug value and drug price*
14 *transparency.*

15 “(b) *PROTECTED INFORMATION.—Nothing in this sec-*
16 *tion shall be construed to authorize the public disclosure of*
17 *information submitted by a manufacturer that is prohibited*
18 *from disclosure by applicable laws concerning the protection*
19 *of trade secrets, commercial information, and other infor-*
20 *mation covered under such laws.”.*

21 “(b) *EFFECTIVE DATE.—The amendment made by sub-*
22 *section (a) takes effect on the date of enactment of this Act.*

23 **SEC. 3. PUBLIC DISCLOSURE OF DRUG DISCOUNTS.**

24 *Section 1150A of the Social Security Act (42 U.S.C.*
25 *1320b–23) is amended—*

1 (1) *in subsection (c), in the matter preceding*
2 *paragraph (1), by inserting “(other than as permitted*
3 *under subsection (e))” after “disclosed by the Sec-*
4 *retary”; and*

5 (2) *by adding at the end the following new sub-*
6 *section:*

7 “(e) *PUBLIC AVAILABILITY OF CERTAIN INFORMA-*
8 *TION.—*

9 “(1) *IN GENERAL.—In order to allow the com-*
10 *parison of PBMs’ ability to negotiate rebates, dis-*
11 *counts, direct and indirect remuneration fees, admin-*
12 *istrative fees, and price concessions and the amount*
13 *of such rebates, discounts, direct and indirect remu-*
14 *neration fees, administrative fees, and price conces-*
15 *sions that are passed through to plan sponsors, begin-*
16 *ning January 1, 2020, the Secretary shall make*
17 *available on the Internet website of the Department of*
18 *Health and Human Services the information with re-*
19 *spect to the second preceding calendar year provided*
20 *to the Secretary on generic dispensing rates (as de-*
21 *scribed in paragraph (1) of subsection (b)) and infor-*
22 *mation provided to the Secretary under paragraphs*
23 *(2) and (3) of such subsection that, as determined by*
24 *the Secretary, is with respect to each PBM.*

1 “(2) *AVAILABILITY OF DATA.*—*In carrying out*
2 *paragraph (1), the Secretary shall ensure the fol-*
3 *lowing:*

4 “(A) *CONFIDENTIALITY.*—*The information*
5 *described in such paragraph is displayed in a*
6 *manner that prevents the disclosure of informa-*
7 *tion, with respect to an individual drug or an*
8 *individual plan, on rebates, discounts, direct and*
9 *indirect remuneration fees, administrative fees,*
10 *and price concessions.*

11 “(B) *CLASS OF DRUG.*—*The information*
12 *described in such paragraph is made available*
13 *by class of drug, using an existing classification*
14 *system, but only if the class contains such num-*
15 *ber of drugs, as specified by the Secretary (but*
16 *not fewer than three drugs), to ensure confiden-*
17 *tiality of proprietary information or other infor-*
18 *mation that is prevented to be disclosed under*
19 *subparagraph (A).”.*

20 **SEC. 4. STUDY OF PHARMACEUTICAL SUPPLY CHAIN INTER-**
21 **MEDIARIES AND MERGER ACTIVITY.**

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

25 (1) *addresses at minimum—*

1 (A) whether pharmacy benefit managers—

2 (i) charge payers a higher price than
3 the reimbursement rate at which the phar-
4 macy benefit managers reimburse competing
5 pharmacies;

6 (ii) steer patients for anticompetitive
7 purposes to any pharmacies, including re-
8 tail, mail-order, or any other type of phar-
9 macy, in which the pharmacy benefit man-
10 ager has an ownership interest;

11 (iii) audit or review proprietary data,
12 including acquisition costs, patient infor-
13 mation, or dispensing information, of com-
14 peting pharmacies that can be used for
15 anticompetitive purposes; or

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

21 (B) how companies and payers assess the
22 benefits, costs, and risks of contracting with
23 intermediaries, including pharmacy services ad-
24 ministrative organizations, and whether more
25 information about the roles of intermediaries

1 *should be available to consumers and payers;*
2 *and*

3 (C) *whether there are any specific legal or*
4 *regulatory obstacles the Commission currently*
5 *faces in ensuring a competitive and transparent*
6 *marketplace in the pharmaceutical supply chain,*
7 *including the pharmacy benefit manager market-*
8 *place and pharmacy services administrative or-*
9 *ganizations; and*

10 (2) *provides—*

11 (A) *observations or conclusions drawn from*
12 *the November 2017 roundtable entitled “Under-*
13 *standing Competition in Prescription Drug Mar-*
14 *kets: Entry and Supply Chain Dynamics”, and*
15 *any similar efforts;*

16 (B) *specific actions the Commission intends*
17 *to take as a result of the November 2017 round-*
18 *table, and any similar efforts, including a de-*
19 *tailed description of relevant forthcoming ac-*
20 *tions, additional research or roundtable discus-*
21 *sions, consumer education efforts, or enforcement*
22 *actions; and*

23 (C) *policy or legislative recommendations*
24 *to—*

1 (i) *improve transparency and competi-*
2 *tion in the pharmaceutical supply chain;*

3 (ii) *prevent and deter anticompetitive*
4 *behavior in the pharmaceutical supply*
5 *chain; and*

6 (iii) *best ensure that consumers benefit*
7 *from any cost savings or efficiencies that*
8 *may result from mergers and consolida-*
9 *tions.*

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

16 (c) *DEFINITIONS.*—*In this section:*

17 (1) *APPROPRIATE COMMITTEES OF CONGRESS.*—
18 *The term “appropriate committees of Congress”*
19 *means—*

20 (A) *the Committee on Energy and Com-*
21 *merce of the House of Representatives;*

22 (B) *the Committee on the Judiciary of the*
23 *Senate; and*

24 (C) *the Committee on the Judiciary of the*
25 *House of Representatives.*

1 (2) *COMMISSION.*—*The term “Commission”*
2 *means the Federal Trade Commission.*

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

6 (a) *IN GENERAL.*—*Section 1847A of the Social Secu-*
7 *rity Act (42 U.S.C. 1395w–3a) is amended—*

8 (1) *in subsection (b)—*

9 (A) *in paragraph (2)(A), by inserting “or*
10 *subsection (f)(2), as applicable” before the period*
11 *at the end;*

12 (B) *in paragraph (3), in the matter pre-*
13 *ceding subparagraph (A), by inserting “or sub-*
14 *section (f)(2), as applicable,” before “determined*
15 *by”; and*

16 (C) *in paragraph (6)(A), in the matter pre-*
17 *ceding clause (i), by inserting “or subsection*
18 *(f)(2), as applicable,” before “determined by”;*
19 *and*

20 (2) *in subsection (f)—*

21 (A) *by striking “For requirements” and in-*
22 *serting the following:*

23 *“(1) IN GENERAL.—For requirements”; and*

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

1 “(2) *MANUFACTURERS WITHOUT A REBATE*
2 *AGREEMENT UNDER TITLE XIX.*—

3 “(A) *IN GENERAL.*—*If the manufacturer of*
4 *a drug or biological described in subparagraph*
5 *(C), (E), or (G) of section 1842(o)(1) or in sec-*
6 *tion 1881(b)(14)(B) that is payable under this*
7 *part has not entered into and does not have in*
8 *effect a rebate agreement described in subsection*
9 *(b) of section 1927, for calendar quarters begin-*
10 *ning on or after January 1, 2020, such manu-*
11 *facturer shall report to the Secretary the infor-*
12 *mation described in subsection (b)(3)(A)(iii) of*
13 *such section 1927 with respect to such drug or*
14 *biological in a time and manner specified by the*
15 *Secretary. For purposes of applying this para-*
16 *graph, a drug or biological described in the pre-*
17 *vious sentence includes items, services, supplies,*
18 *and products that are payable under this part as*
19 *a drug or biological.*

20 “(B) *AUDIT.*—*Information reported under*
21 *subparagraph (A) is subject to audit by the In-*
22 *pector General of the Department of Health and*
23 *Human Services.*

24 “(C) *VERIFICATION.*—*The Secretary may*
25 *survey wholesalers and manufacturers that di-*

1 *rectly distribute drugs described in subparagraph*
2 *(A), when necessary, to verify manufacturer*
3 *prices and manufacturer’s average sales prices*
4 *(including wholesale acquisition cost) if required*
5 *to make payment reported under subparagraph*
6 *(A). The Secretary may impose a civil monetary*
7 *penalty in an amount not to exceed \$100,000 on*
8 *a wholesaler, manufacturer, or direct seller, if the*
9 *wholesaler, manufacturer, or direct seller of such*
10 *a drug refuses a request for information about*
11 *charges or prices by the Secretary in connection*
12 *with a survey under this subparagraph or know-*
13 *ingly provides false information. The provisions*
14 *of section 1128A (other than subsections (a)*
15 *(with respect to amounts of penalties or addi-*
16 *tional assessments) and (b)) shall apply to a*
17 *civil money penalty under this subparagraph in*
18 *the same manner as such provisions apply to a*
19 *penalty or proceeding under section 1128A(a).*

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

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

5 *“(i) as the Secretary determines to be*
6 *necessary to carry out this section (includ-*
7 *ing the determination and implementation*
8 *of the payment amount), or to carry out*
9 *section 1847B;*

10 *“(ii) to permit the Comptroller General*
11 *of the United States to review the informa-*
12 *tion provided; and*

13 *“(iii) to permit the Director of the*
14 *Congressional Budget Office to review the*
15 *information provided.”.*

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

18 *(1) in subsection (d)(4)—*

19 *(A) in subparagraph (A), by striking “IN*
20 *GENERAL” and inserting “MISREPRESENTA-*
21 *TION”;*

22 *(B) in subparagraph (B), by striking “sub-*
23 *paragraph (B)” and inserting “subparagraph*
24 *(A), (B), or (C)”;*

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

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

5 “(B) *FAILURE TO PROVIDE TIMELY INFOR-*
6 *MATION.—If the Secretary determines that a*
7 *manufacturer described in subsection (f)(2) has*
8 *failed to report on information described in sec-*
9 *tion 1927(b)(3)(A)(iii) with respect to a drug or*
10 *biological in accordance with such subsection, the*
11 *Secretary shall apply a civil money penalty in*
12 *an amount of \$10,000 for each day the manufac-*
13 *turer has failed to report such information and*
14 *such amount shall be paid to the Treasury.*

15 “(C) *FALSE INFORMATION.—Any manufac-*
16 *turer required to submit information under sub-*
17 *section (f)(2) that knowingly provides false infor-*
18 *mation is subject to a civil money penalty in an*
19 *amount not to exceed \$100,000 for each item of*
20 *false information. Such civil money penalties are*
21 *in addition to other penalties as may be pre-*
22 *scribed by law.”; and*

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

1 retary determines appropriate, exclude repackagers of
2 a drug or biological from such term.”.

3 (c) *MANUFACTURERS WITH A REBATE AGREEMENT.*—

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

12 (2) *TECHNICAL AMENDMENT.*—Section
13 1927(b)(3)(A)(iii) of the *Social Security Act (42*
14 *U.S.C. 1396r-8(b)(3)(A)(iii))* is amended by striking
15 “section 1881(b)(13)(A)(ii)” and inserting “section
16 1881(b)(14)(B)”.

17 (d) *REPORT.*—Not later than January 1, 2021, the In-
18 spector General of the Department of Health and Human
19 Services shall assess and submit to Congress a report on
20 the accuracy of average sales price information submitted
21 by manufacturers under section 1847A of the *Social Secu-*
22 *rity Act (42 U.S.C. 1395w-3a)*. Such report shall include
23 any recommendations on how to improve the accuracy of
24 such information.

1 **SEC. 6. MAKING PRESCRIPTION DRUG MARKETING SAMPLE**
2 **INFORMATION REPORTED BY MANUFACTUR-**
3 **ERS AVAILABLE TO CERTAIN INDIVIDUALS**
4 **AND ENTITIES.**

5 (a) *IN GENERAL.*—Section 1128H of the Social Secu-
6 rity Act (42 U.S.C. 1320a–7i) is amended—

7 (1) *by redesignating subsection (b) as subsection*
8 *(e); and*

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

11 “(b) *DATA SHARING AGREEMENTS.*—

12 “(1) *IN GENERAL.*—The Secretary shall enter
13 into agreements with the specified data sharing indi-
14 viduals and entities described in paragraph (2) under
15 which—

16 “(A) upon request of such an individual or
17 entity, as applicable, the Secretary makes avail-
18 able to such individual or entity the information
19 submitted under subsection (a) by manufacturers
20 and authorized distributors of record; and

21 “(B) such individual or entity agrees to not
22 disclose publicly or to another individual or en-
23 tity any information that identifies a particular
24 practitioner or health care facility.

25 “(2) *SPECIFIED DATA SHARING INDIVIDUALS*
26 *AND ENTITIES.*—For purposes of paragraph (1), the

1 *specified data sharing individuals and entities de-*
2 *scribed in this paragraph are the following:*

3 “(A) *OVERSIGHT AGENCIES.*—*Health over-*
4 *sight agencies (as defined in section 164.501 of*
5 *title 45, Code of Federal Regulations), including*
6 *the Centers for Medicare & Medicaid Services,*
7 *the Office of the Inspector General of the Depart-*
8 *ment of Health and Human Services, the Gov-*
9 *ernment Accountability Office, the Congressional*
10 *Budget Office, the Medicare Payment Advisory*
11 *Commission, and the Medicaid and CHIP Pay-*
12 *ment and Access Commission.*

13 “(B) *RESEARCHERS.*—*Individuals who con-*
14 *duct scientific research (as defined in section*
15 *164.501 of title 45, Code of Federal Regulations)*
16 *in relevant areas as determined by the Secretary.*

17 “(C) *PAYERS.*—*Private and public health*
18 *care payers, including group health plans, health*
19 *insurance coverage offered by health insurance*
20 *issuers, Federal health programs, and State*
21 *health programs.*

22 “(3) *EXEMPTION FROM FREEDOM OF INFORMA-*
23 *TION ACT.*—*Except as described in paragraph (1), the*
24 *Secretary may not be compelled to disclose the infor-*
25 *mation submitted under subsection (a) to any indi-*

1 *vidual or entity. For purposes of section 552 of title*
2 *5, United States Code (commonly referred to as the*
3 *Freedom of Information Act), this paragraph shall be*
4 *considered a statute described in subsection (b)(3)(B)*
5 *of such section.*

6 *“(c) PENALTIES.—*

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

18 *“(2) FAILURE TO REPORT.—Subject to para-*
19 *graph (3), any manufacturer or authorized dis-*
20 *tributor of record of an applicable drug under sub-*
21 *section (a) that fails to submit information required*
22 *under such subsection in a timely manner in accord-*
23 *ance with rules or regulations promulgated to carry*
24 *out such subsection shall be subject to a civil money*
25 *penalty of not less than \$1,000, but not more than*

1 \$10,000, for each such failure. Such penalty shall be
2 imposed and collected in the same manner as civil
3 money penalties under subsection (a) of section 1128A
4 are imposed and collected under that section.

5 “(3) *LIMITATION.*—The total amount of civil
6 money penalties imposed under paragraph (1) or (2)
7 with respect to a year and an individual or entity de-
8 scribed in subparagraph (A) or a manufacturer or
9 distributor described in subparagraph (B), respec-
10 tively, shall not exceed \$150,000.

11 “(d) *DRUG SAMPLE DISTRIBUTION INFORMATION.*—

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

18 “(A) The name of the manufacturer or au-
19 thorized distributor of record of an applicable
20 drug for which samples were requested or distrib-
21 uted under this section.

22 “(B) The quantity and class of drug sam-
23 ples requested.

24 “(C) The quantity and class of drug sam-
25 ples distributed.

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

5 (b) *FDA MAINTENANCE OF INFORMATION.*—*The Food*
6 *and Drug Administration shall maintain information*
7 *available to affected reporting companies to ensure their*
8 *ability to fully comply with the requirements of section*
9 *1128H of the Social Security Act.*

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

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

15 (2) *by adding at the end the following:*

16 “(5) *No person may distribute a drug sample of a drug*
17 *that is—*

18 “(A) *an applicable drug (as defined in section*
19 *1128H(d) of the Social Security Act);*

20 “(B) *a controlled substance (as defined in section*
21 *102 of the Controlled Substances Act) for which the*
22 *findings required under section 202(b)(2) of such Act*
23 *have been made; and*

24 “(C) *approved under section 505 for use in the*
25 *management or treatment of pain (other than for the*

1 management or treatment of a substance use dis-
2 order).”.

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

9 **SEC. 7. REQUIRING PRESCRIPTION DRUG PLAN SPONSORS**
10 **TO INCLUDE REAL-TIME BENEFIT INFORMA-**
11 **TION AS PART OF SUCH SPONSOR’S ELEC-**
12 **TRONIC PRESCRIPTION PROGRAM UNDER**
13 **THE MEDICARE PROGRAM.**

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

16 (1) in subparagraph (D), by striking “To the ex-
17 tent” and inserting “Except as provided in subpara-
18 graph (F), to the extent”; and

19 (2) by adding at the end the following new sub-
20 paragraph:

21 “(F) *REAL-TIME BENEFIT INFORMATION*.—

22 “(i) *IN GENERAL*.—Not later than Jan-
23 uary 1, 2021, the program shall implement
24 real-time benefit tools that are capable of
25 integrating with a prescribing health care

1 professional's electronic prescribing or elec-
2 tronic health record system for the trans-
3 mission of formulary and benefit informa-
4 tion in real time to prescribing health care
5 professionals. With respect to a covered part
6 D drug, such tools shall be capable of trans-
7 mitting such information specific to an in-
8 dividual enrolled in a prescription drug
9 plan. Such information shall include the
10 following:

11 “(I) A list of any clinically-ap-
12 propriate alternatives to such drug in-
13 cluded in the formulary of such plan.

14 “(II) Cost-sharing information for
15 such drug and such alternatives, in-
16 cluding a description of any variance
17 in cost sharing based on the pharmacy
18 dispensing such drug or such alter-
19 natives.

20 “(III) Information relating to
21 whether such drug is included in the
22 formulary of such plan and any prior
23 authorization or other utilization man-
24 agement requirements applicable to

1 *such drug and such alternatives so in-*
2 *cluded.*

3 “(ii) *ELECTRONIC TRANSMISSION.*—
4 *The provisions of subclauses (I) and (II) of*
5 *clause (ii) of subparagraph (E) shall apply*
6 *to an electronic transmission described in*
7 *clause (i) in the same manner as such pro-*
8 *visions apply with respect to an electronic*
9 *transmission described in clause (i) of such*
10 *subparagraph.*

11 “(iii) *SPECIAL RULE FOR 2021.*—*The*
12 *program shall be deemed to be in compli-*
13 *ance with clause (i) for 2021 if the program*
14 *complies with the provisions of section*
15 *423.160(b)(7) of title 42, Code of Federal*
16 *Regulations (or a successor regulation), for*
17 *such year.*

18 “(iv) *RULE OF CONSTRUCTION.*—*Noth-*
19 *ing in this subparagraph shall be construed*
20 *as to allow a real time benefits tool to steer*
21 *an individual, without the consent of the in-*
22 *dividual, to a particular pharmacy or*
23 *pharmacy setting over their preferred phar-*
24 *macy setting nor prohibit the designation of*
25 *a preferred pharmacy under such tool.”.*

1 **SEC. 8. SENSE OF CONGRESS REGARDING THE NEED TO EX-**
2 **PAND COMMERCIALLY AVAILABLE DRUG**
3 **PRICING COMPARISON PLATFORMS.**

4 *It is the sense of Congress that—*

5 *(1) commercially available drug pricing com-*
6 *parison platforms can, at no cost, help patients find*
7 *the lowest price for their medications at their local*
8 *pharmacy;*

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

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

15 *(A) patients can benefit from the lowest pos-*
16 *sible price available to them; and*

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

20 **SEC. 9. TECHNICAL CORRECTIONS.**

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

24 *“(4) APPLICATION OF AUTHORITIES UNDER IN-*
25 *SPECTOR GENERAL ACT OF 1978.—In carrying out*
26 *this subsection, the Inspector General shall have the*

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

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

Amend the title so as to read: “A bill to require re-
porting for certain drug price information, and for other
purposes.”.

Union Calendar No. 170

116TH CONGRESS
1ST Session

H. R. 2296

[Report No. 116-215]

A BILL

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

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