

Committee Print

[SHOWING THE TEXT OF H.R. 2296, AS FAVORABLY FORWARDED BY THE ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH ON JULY 11, 2019]

116TH CONGRESS
1ST SESSION

H. R. 2296

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

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 Con-
6 sumers 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 justification for drug price increases.
- Sec. 3. Public disclosure of drug discounts.
- Sec. 4. Study of pharmaceutical supply chain intermediaries and merger activity.
- 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 information as part of such sponsor's electronic prescription program under the Medicare program.
- Sec. 8. Sense of Congress regarding the need to expand commercially available drug pricing comparison platforms.

1 **SEC. 2. REPORTING ON JUSTIFICATION FOR DRUG PRICE**
2 **INCREASES.**

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

6 **“PART W—DRUG PRICE REPORTING; DRUG**
7 **VALUE FUND**

8 **“SEC. 3990O. REPORTING ON EXPLANATION FOR DRUG**
9 **PRICE INCREASES.**

10 “(a) DEFINITIONS.—In this section:

11 “(1) MANUFACTURER.—The term ‘manufac-
12 turer’ means the person—

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

17 “(B) who is responsible for setting the
18 wholesale acquisition cost for the drug.

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

6 “(A) that has a wholesale acquisition cost
7 of \$100 or more, adjusted for inflation occur-
8 ring after the date of enactment of the More
9 Efficient Tools to Realize Information for Con-
10 sumers Act, for a month’s supply or a typical
11 course of treatment that lasts less than a
12 month, and is—

13 “(i) subject to section 503(b)(1) of
14 the Federal Food, Drug, and Cosmetic
15 Act; or

16 “(ii) administered or otherwise dis-
17 pensed to treat a disease or condition af-
18 fecting more than 200,000 persons in the
19 United States; and

20 “(iii) not a vaccine; and

21 “(B) for which, during the previous cal-
22 endar year, at least 1 dollar of the total amount
23 of sales were for individuals enrolled under the
24 Medicare program under title XVIII of the So-
25 cial Security Act (42 U.S.C. 1395 et seq.) or

1 under a State Medicaid plan under title XIX of
2 such Act (42 U.S.C. 1396 et seq.) or under a
3 waiver of such plan.

4 “(3) WHOLESALE ACQUISITION COST.—The
5 term ‘wholesale acquisition cost’ has the meaning
6 given that term in section 1847A(c)(6)(B) of the So-
7 cial Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).

8 “(b) REPORT.—

9 “(1) REPORT REQUIRED.—The manufacturer of
10 a qualifying drug shall submit a report to the Sec-
11 retary for each increase in the price of a qualifying
12 drug that results in an increase in the wholesale ac-
13 quisition cost of that drug that is equal to—

14 “(A) 10 percent or more within a single
15 calendar year beginning on or after January 1,
16 2019; or

17 “(B) 25 percent or more within three con-
18 secutive calendar years for which the first such
19 calendar year begins on or after January 1,
20 2019.

21 “(2) REPORT DEADLINE.—Each report de-
22 scribed in paragraph (1) shall be submitted to the
23 Secretary—

24 “(A) in the case of a report with respect
25 to an increase in the price of a qualifying drug

1 that occurs during the period beginning on Jan-
2 uary 1, 2019, and ending on the day that is 60
3 days after the date of the enactment of the
4 More Efficient Tools to Realize Information for
5 Consumers Act, not later than 90 days after
6 such date of enactment; and

7 “(B) in the case of a report with respect
8 to an increase in the price of a qualifying drug
9 that occurs after the period described in sub-
10 paragraph (A), not later than 30 days prior to
11 the planned effective date of such price increase
12 for such qualifying drug.

13 “(c) CONTENTS.—A report under subsection (b), con-
14 sistent with the standard for disclosures described in sec-
15 tion 213.3(d) of title 12, Code of Federal Regulations (as
16 in effect on the date of enactment of the More Efficient
17 Tools to Realize Information for Consumers Act), shall,
18 at a minimum, include—

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

20 “(A) the percentage by which the manufac-
21 turer will raise the wholesale acquisition cost of
22 the drug within the calendar year or three con-
23 secutive calendar years as described in sub-
24 section (b)(1)(A) or (b)(1)(B), and the effective
25 date of such price increase;

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

7 “(C) the identity of the initial holder of an
8 approved application under section 505 of the
9 Federal Food, Drug, and Cosmetics Act or
10 under section 351 of this Act for the drug, if
11 known and different from the manufacturer;

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

20 “(E) the current wholesale acquisition cost
21 of the drug;

22 “(F) the total expenditures of the manu-
23 facturer on—

24 “(i) materials and manufacturing for
25 such drug; and

1 “(ii) acquiring patents and licensing
2 for such drug;

3 “(G) the percentage of total expenditures
4 of the manufacturer on research and develop-
5 ment for such drug that was derived from Fed-
6 eral funds;

7 “(H) the total expenditures of the manu-
8 facturer on research and development for such
9 drug which may include expenditures for—

10 “(i) basic and preclinical research;

11 “(ii) clinical research;

12 “(iii) new drug development;

13 “(iv) pursuing new or expanded indi-
14 cations or dosage changes for such drug
15 under section 505 of the Federal Food,
16 Drug, and Cosmetic Act or section 351 of
17 this Act; and

18 “(v) carrying out postmarket require-
19 ments related to such drug, including
20 under section 505(o)(3) of the Federal
21 Food, Drug, and Cosmetic Act;

22 “(I) the total revenue and the net profit
23 generated from the qualifying drug for each cal-
24 endar year since the approval of the application
25 for the drug under section 505 of the Federal

1 Food, Drug, and Cosmetic Act or the issuance
2 of the license for the drug under section 351,
3 or since the manufacturer acquired such ap-
4 proved application or license; and

5 “(J) the total costs associated with mar-
6 keting and advertising for the qualifying drug;

7 “(2) with respect to the manufacturer—

8 “(A) the total revenue and the net profit
9 of the manufacturer for each of the 1-year pe-
10 riod described in subsection (b)(1)(A) or the 3-
11 year period described in subsection (b)(1)(B),
12 as applicable;

13 “(B) all stock-based performance metrics
14 used by the manufacturer to determine execu-
15 tive compensation for each of the 1-year period
16 described in subsection (b)(1)(A) or the 3-year
17 period described in subsection (b)(1)(B), as ap-
18 plicable; and

19 “(C) any additional information the manu-
20 facturer chooses to provide related to drug prie-
21 ing decisions, such as total expenditures on—

22 “(i) drug research and development;

23 or

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

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

7 “(d) CIVIL MONETARY PENALTY.—Any manufac-
8 turer of a qualifying drug that fails to submit a report
9 for the drug as required by this section, following notifica-
10 tion by the Secretary to the manufacturer that the manu-
11 facturer is not in compliance with this section, shall be
12 subject to a civil monetary penalty of \$75,000 for each
13 day on which the violation continues.

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

19 “(f) PUBLIC POSTING.—

20 “(1) IN GENERAL.—Subject to paragraph (3),
21 the Secretary shall post each report submitted under
22 subsection (b) on the public website of the Depart-
23 ment of Health and Human Services the day the
24 price increase of a qualifying drug is scheduled to go
25 into effect.

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

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

10 “(B) written in plain language that con-
11 sumers can readily understand.

12 “(3) **TRADE SECRETS AND CONFIDENTIAL IN-**
13 **FORMATION.**—Nothing in this section shall be con-
14 strued to authorize the public disclosure of informa-
15 tion submitted by a manufacturer that is privileged
16 or confidential, subject to applicable law concerning
17 the protection of trade secrets and commercial or fi-
18 nancial information.

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

20 “(a) **IN GENERAL.**—Subject to subsection (b), the
21 Secretary shall submit to Congress, and post on the public
22 website of the Department of Health and Human Services
23 in a way that is user-friendly to the public and written
24 in plain language that consumers can readily understand,
25 an annual report—

1 “(1) summarizing the information reported pur-
2 suant to section 39900;

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

6 “(3) detailing the costs and expenditures in-
7 curred by the Department of Health and Human
8 Services in carrying out section 39900; and

9 “(4) explaining how the Department of Health
10 and Human Services is improving consumer and
11 provider information about drug value and drug
12 price transparency.

13 “(b) **TRADE SECRETS AND CONFIDENTIAL INFORMA-**
14 **TION.**—Nothing in this section shall be construed to au-
15 thorize the public disclosure of information submitted by
16 a manufacturer that is privileged or confidential, subject
17 to applicable law concerning the protection of trade secrets
18 and commercial or financial information.”.

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

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

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

1 (1) in subsection (e), in the matter preceding
2 paragraph (1), by inserting “(other than as per-
3 mitted under subsection (e))” after “disclosed by the
4 Secretary”; 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, ad-
12 ministrative fees, and price concessions and the
13 amount of such rebates, discounts, direct and indi-
14 rect remuneration fees, administrative fees, and
15 price concessions that are passed through to plan
16 sponsors, beginning January 1, 2020, the Secretary
17 shall make available on the Internet website of the
18 Department of Health and Human Services the in-
19 formation with respect to the second preceding cal-
20 endar year provided to the Secretary on generic dis-
21 pensing rates (as described in paragraph (1) of sub-
22 section (b)) and information provided to the Sec-
23 retary under paragraphs (2) and (3) of such sub-
24 section that, as determined by the Secretary, is with
25 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
9 and indirect remuneration fees, administrative
10 fees, 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**
21 **INTERMEDIARIES AND MERGER ACTIVITY.**

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

1 (1) addresses at minimum—

2 (A) whether pharmacy benefit managers—

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

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

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

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

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

1 information about the roles of intermediaries
2 should be available to consumers and payers;
3 and

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

11 (2) provides—

12 (A) observations or conclusions drawn
13 from the November 2017 roundtable entitled
14 “Understanding Competition in Prescription
15 Drug Markets: Entry and Supply Chain Dy-
16 namics”, and any similar efforts;

17 (B) specific actions the Commission in-
18 tends to take as a result of the November 2017
19 roundtable, and any similar efforts, including a
20 detailed description of relevant forthcoming ac-
21 tions, additional research or roundtable discus-
22 sions, consumer education efforts, or enforce-
23 ment actions; and

24 (C) policy or legislative recommendations
25 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 ben-
7 efit from any cost savings or efficiencies
8 that may result from mergers and consoli-
9 dations.

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

16 (c) DEFINITIONS.—In this section:

17 (1) APPROPRIATE COMMITTEES OF CON-
18 GRESS.—The term “appropriate committees of Con-
19 gress” 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 RE-**
5 **SPECT TO DRUGS UNDER THE MEDICARE**
6 **PROGRAM.**

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

9 (1) in subsection (b)—

10 (A) in paragraph (2)(A), by inserting “or
11 subsection (f)(2), as applicable” before the pe-
12 riod at the end;

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

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

21 (2) in subsection (f)—

22 (A) by striking “For requirements” and
23 inserting the following:

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

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

3 “(2) MANUFACTURERS WITHOUT A REBATE
4 AGREEMENT UNDER TITLE XIX.—

5 “(A) IN GENERAL.—In the case of a man-
6 ufacturer of a drug or biological described in
7 subparagraph (C), (E), or (G) of section
8 1842(o)(1) or in section 1881(b)(14)(B) that is
9 payable under this part as a drug or biological,
10 if such manufacturer has not entered into and
11 have in effect a rebate agreement described in
12 subsection (b) of section 1927, for calendar
13 quarters beginning on or after January 1,
14 2020, such manufacturer shall report to the
15 Secretary the information described in sub-
16 section (b)(3)(A)(iii) of such section 1927 with
17 respect to such drug or biological in a time and
18 manner specified by the Secretary.

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

23 “(C) VERIFICATION.—The Secretary may
24 survey wholesalers and manufacturers that di-
25 rectly distribute drugs described in subpara-

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

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

1 closed by the Secretary in a form which dis-
2 closes the identity of a specific manufacturer or
3 wholesaler or prices charged for drugs by such
4 manufacturer or 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 Gen-
11 eral of the United States to review the in-
12 formation 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)
4 the 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,
11 the Secretary shall apply a civil money penalty
12 in an amount of \$10,000 for each day the man-
13 ufacturer has failed to report such information
14 and such amount shall be paid to the Treasury.

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

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

1 Secretary determines appropriate, exclude repack-
2 agers of a drug or biological from such term.”.

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

11 **SEC. 6. MAKING PRESCRIPTION DRUG MARKETING SAMPLE**
12 **INFORMATION REPORTED BY MANUFACTUR-**
13 **ERS AVAILABLE TO CERTAIN INDIVIDUALS**
14 **AND ENTITIES.**

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

17 (1) by redesignating subsection (b) as sub-
18 section (d); and

19 (2) by inserting after subsection (a) the fol-
20 lowing new subsections:

21 “(b) DATA SHARING AGREEMENTS.—

22 “(1) IN GENERAL.—The Secretary shall enter
23 into agreements with the specified data sharing indi-
24 viduals and entities described in paragraph (2)
25 under which—

1 “(A) upon request of such an individual or
2 entity, as applicable, the Secretary makes avail-
3 able to such individual or entity the information
4 submitted under subsection (a) by manufactur-
5 ers and authorized distributors of record; and

6 “(B) such individual or entity agrees to
7 not disclose publicly or to another individual or
8 entity any information that identifies a par-
9 ticular practitioner or health care facility.

10 “(2) SPECIFIED DATA SHARING INDIVIDUALS
11 AND ENTITIES.—For purposes of paragraph (1), the
12 specified data sharing individuals and entities de-
13 scribed in this paragraph are the following:

14 “(A) OVERSIGHT AGENCIES.—Health over-
15 sight agencies (as defined in section 164.501 of
16 title 45, Code of Federal Regulations), includ-
17 ing the Centers for Medicare & Medicaid Serv-
18 ices, the Office of the Inspector General of the
19 Department of Health and Human Services, the
20 Government Accountability Office, the Congres-
21 sional Budget Office, the Medicare Payment
22 Advisory Commission, and the Medicaid and
23 CHIP Payment and Access Commission.

24 “(B) RESEARCHERS.—Individuals who
25 conduct scientific research (as defined in sec-

1 tion 164.501 of title 45, Code of Federal Regu-
2 lations) in relevant areas as determined by the
3 Secretary.

4 “(C) PAYERS.—Private and public health
5 care payers, including group health plans,
6 health insurance coverage offered by health in-
7 surance issuers, Federal health programs, and
8 State health programs.

9 “(3) EXEMPTION FROM FREEDOM OF INFORMA-
10 TION ACT.—Except as described in paragraph (1),
11 the Secretary may not be compelled to disclose the
12 information submitted under subsection (a) to any
13 individual or entity. For purposes of section 552 of
14 title 5, United States Code (commonly referred to as
15 the Freedom of Information Act), this paragraph
16 shall be considered a statute described in subsection
17 (b)(3)(B) of such section.

18 “(c) PENALTIES.—

19 “(1) DATA SHARING AGREEMENTS.—Subject to
20 paragraph (3), any specified data sharing individual
21 or entity described in subsection (b)(2) that violates
22 the terms of a data sharing agreement the individual
23 or entity has with the Secretary under subsection
24 (b)(1) shall be subject to a civil money penalty of
25 not less than \$1,000, but not more than \$10,000,

1 for each such violation. Such penalty shall be im-
2 posed and collected in the same manner as civil
3 money penalties under subsection (a) of section
4 1128A are imposed and collected under that section.

5 “(2) FAILURE TO REPORT.—Subject to para-
6 graph (3), any manufacturer or authorized dis-
7 tributor of record of an applicable drug under sub-
8 section (a) that fails to submit information required
9 under such subsection in a timely manner in accord-
10 ance with rules or regulations promulgated to carry
11 out such subsection shall be subject to a civil money
12 penalty of not less than \$1,000, but not more than
13 \$10,000, for each such failure. Such penalty shall be
14 imposed and collected in the same manner as civil
15 money penalties under subsection (a) of section
16 1128A are imposed and collected under that section.

17 “(3) LIMITATION.—The total amount of civil
18 money penalties imposed under paragraph (1) or (2)
19 with respect to a year and an individual or entity de-
20 scribed in subparagraph (A) or a manufacturer or
21 distributor described in subparagraph (B), respec-
22 tively, shall not exceed \$150,000.”.

23 (b) GUIDANCE.—Not later than one year after the
24 date of the enactment of this Act, the Secretary of Health
25 and Human Services shall issue guidance (or revise exist-

1 ing guidance) on implementing the provisions of section
2 1128H of the Social Security Act (42 U.S.C. 1320a–7i).

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

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

8 (2) by adding at the end the following:

9 “(5) No person may distribute a drug sample of a
10 drug that is—

11 “(A) an applicable drug (as defined in section
12 1128H(d) of the Social Security Act);

13 “(B) a controlled substance (as defined in sec-
14 tion 102 of the Controlled Substances Act) for which
15 the findings required under section 202(b)(2) of
16 such Act have been made; and

17 “(C) approved under section 505 for use in the
18 management or treatment of pain (other than for
19 the management or treatment of a substance use
20 disorder).”.

1 **SEC. 7. REQUIRING PRESCRIPTION DRUG PLAN SPONSORS**
2 **TO INCLUDE REAL-TIME BENEFIT INFORMA-**
3 **TION AS PART OF SUCH SPONSOR'S ELEC-**
4 **TRONIC PRESCRIPTION PROGRAM UNDER**
5 **THE MEDICARE PROGRAM.**

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

8 (1) in subparagraph (D), by striking “To the
9 extent” and inserting “Except as provided in sub-
10 paragraph (F), to the extent”; and

11 (2) by adding at the end the following new sub-
12 paragraph:

13 “(F) REAL-TIME BENEFIT INFORMA-
14 TION.—

15 “(i) IN GENERAL.—Not later than
16 January 1, 2021, the program shall pro-
17 vide for the real-time electronic trans-
18 mission to prescribing health care profes-
19 sionals, using technology capable of inte-
20 grating with such professionals’ electronic
21 prescribing and electronic health record
22 systems, of individual-specific formulary
23 and benefit information under a prescrip-
24 tion drug plan with respect to an indi-
25 vidual enrolled in such plan. Such informa-
26 tion shall include, with respect to the pre-

1 scribing of a covered part D drug to such
2 individual, the following:

3 “(I) A description of any clini-
4 cally-appropriate alternatives to such
5 drug included in the formulary of
6 such plan.

7 “(II) Information relating to ap-
8 plicable cost-sharing requirements for
9 such drug and such alternatives, in-
10 cluding a description of any variance
11 in such requirements based on the
12 pharmacy dispensing such drug or
13 such alternatives.

14 “(III) Information relating to
15 any prior authorization or other utili-
16 zation management requirements ap-
17 plicable to such drug and such alter-
18 natives within the formulary of such
19 plan.

20 “(ii) SPECIAL RULE FOR 2021.—The
21 program shall be deemed to be in compli-
22 ance with clause (i) for 2021 if the pro-
23 gram complies with the provisions of sec-
24 tion 423.160(b)(7) of title 42, Code of

1 Federal Regulations (or a successor regula-
2 tion), for such year.”.

3 **SEC. 8. SENSE OF CONGRESS REGARDING THE NEED TO EX-**
4 **PAND COMMERCIALY AVAILABLE DRUG**
5 **PRICING COMPARISON PLATFORMS.**

6 It is the sense of Congress that—

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

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

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

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

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

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