

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 2296
OFFERED BY M . _____**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

2 (a) SHORT TITLE.—This Act may be cited as the
3 “More Efficient Tools to Realize Information for Con-
4 sumers Act” or the “METRIC Act”.

5 (b) TABLE OF CONTENTS.—The table of contents for
6 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.

**7 SEC. 2. REPORTING ON JUSTIFICATION FOR DRUG PRICE
8 INCREASES.**

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

1 **“PART W—DRUG PRICE REPORTING; DRUG**
2 **VALUE FUND**
3 **“SEC. 39900. REPORTING ON EXPLANATION FOR DRUG**
4 **PRICE INCREASES.**

5 “(a) DEFINITIONS.—In this section:

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

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

12 “(B) who is responsible for setting the
13 wholesale acquisition cost for the drug.

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

19 “(A) that has a wholesale acquisition cost
20 of \$100 or more, adjusted for inflation occur-
21 ring after the date of enactment of the More
22 Efficient Tools to Realize Information for Con-
23 sumers Act, for a month’s supply or a typical
24 course of treatment that lasts less than a
25 month, and is—

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

4 “(ii) administered or otherwise dis-
5 pensed to treat a disease or condition af-
6 fecting more than 200,000 persons in the
7 United States; and

8 “(iii) not a vaccine; and

9 “(B) for which, during the previous cal-
10 endar year, at least 1 dollar of the total amount
11 of sales were for individuals enrolled under the
12 Medicare program under title XVIII of the So-
13 cial Security Act (42 U.S.C. 1395 et seq.) or
14 under a State Medicaid plan under title XIX of
15 such Act (42 U.S.C. 1396 et seq.) or under a
16 waiver of such plan.

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

21 “(b) REPORT.—

22 “(1) REPORT REQUIRED.—The manufacturer of
23 a qualifying drug shall submit a report to the Sec-
24 retary for each increase in the price of a qualifying

1 drug that results in an increase in the wholesale ac-
2 quisition cost of that drug that is equal to—

3 “(A) 10 percent or more within a single
4 calendar year beginning on or after January 1,
5 2019; or

6 “(B) 25 percent or more within three con-
7 secutive calendar years for which the first such
8 calendar year begins on or after January 1,
9 2019.

10 “(2) REPORT DEADLINE.—Each report de-
11 scribed in paragraph (1) shall be submitted to the
12 Secretary—

13 “(A) in the case of a report with respect
14 to an increase in the price of a qualifying drug
15 that occurs during the period beginning on Jan-
16 uary 1, 2019, and ending on the day that is 60
17 days after the date of the enactment of the
18 More Efficient Tools to Realize Information for
19 Consumers Act, not later than 90 days after
20 such date of enactment; and

21 “(B) in the case of a report with respect
22 to an increase in the price of a qualifying drug
23 that occurs after the period described in sub-
24 paragraph (A), not later than 30 days prior to

1 the planned effective date of such price increase
2 for such qualifying drug.

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

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

10 “(A) the percentage by which the manufac-
11 turer will raise the wholesale acquisition cost of
12 the drug within the calendar year or three con-
13 secutive calendar years as described in sub-
14 section (b)(1)(A) or (b)(1)(B), and the effective
15 date of such price increase;

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

22 “(C) the identity of the initial holder of an
23 approved application under section 505 of the
24 Federal Food, Drug, and Cosmetics Act or

1 under section 351 of this Act for the drug, if
2 known and different from the manufacturer;

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

11 “(E) the current wholesale acquisition cost
12 of the drug;

13 “(F) the total expenditures of the manu-
14 facturer on—

15 “(i) materials and manufacturing for
16 such drug; and

17 “(ii) acquiring patents and licensing
18 for such drug;

19 “(G) the percentage of total expenditures
20 of the manufacturer on research and develop-
21 ment for such drug that was derived from Fed-
22 eral funds;

23 “(H) the total expenditures of the manu-
24 facturer on research and development for such
25 drug which may include expenditures for—

1 “(i) basic and preclinical research;

2 “(ii) clinical research;

3 “(iii) new drug development;

4 “(iv) pursuing new or expanded indi-
5 cations or dosage changes for such drug
6 under section 505 of the Federal Food,
7 Drug, and Cosmetic Act or section 351 of
8 this Act; and

9 “(v) carrying out postmarket require-
10 ments related to such drug, including
11 under section 505(o)(3) of the Federal
12 Food, Drug, and Cosmetic Act;

13 “(I) the total revenue and the net profit
14 generated from the qualifying drug for each cal-
15 endar year since the approval of the application
16 for the drug under section 505 of the Federal
17 Food, Drug, and Cosmetic Act or the issuance
18 of the license for the drug under section 351,
19 or since the manufacturer acquired such ap-
20 proved application or license; and

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

23 “(2) with respect to the manufacturer—

24 “(A) the total revenue and the net profit
25 of the manufacturer for each of the 1-year pe-

1 riod described in subsection (b)(1)(A) or the 3-
2 year period described in subsection (b)(1)(B),
3 as applicable;

4 “(B) all stock-based performance metrics
5 used by the manufacturer to determine execu-
6 tive compensation for each of the 1-year period
7 described in subsection (b)(1)(A) or the 3-year
8 period described in subsection (b)(1)(B), as ap-
9 plicable; and

10 “(C) any additional information the manu-
11 facturer chooses to provide related to drug pric-
12 ing decisions, such as total expenditures on—

13 “(i) drug research and development;

14 or

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

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

21 “(d) CIVIL MONETARY PENALTY.—Any manufac-
22 turer of a qualifying drug that fails to submit a report
23 for the drug as required by this section, following notifica-
24 tion by the Secretary to the manufacturer that the manu-
25 facturer is not in compliance with this section, shall be

1 subject to a civil monetary penalty of \$75,000 for each
2 day on which the violation continues.

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

8 “(f) PUBLIC POSTING.—

9 “(1) IN GENERAL.—Subject to paragraph (3),
10 the Secretary shall post each report submitted under
11 subsection (b) on the public website of the Depart-
12 ment of Health and Human Services the day the
13 price increase of a qualifying drug is scheduled to go
14 into effect.

15 “(2) FORMAT.—In developing the format in
16 which reports will be publicly posted under para-
17 graph (1), the Secretary shall consult with stake-
18 holders, including beneficiary groups, and shall seek
19 feedback from consumer advocates and readability
20 experts on the format and presentation of the con-
21 tent of such reports to ensure that such reports
22 are—

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

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

1 “(3) TRADE SECRETS AND CONFIDENTIAL IN-
2 FORMATION.—Nothing in this section shall be con-
3 strued to authorize the public disclosure of informa-
4 tion submitted by a manufacturer that is privileged
5 or confidential, subject to applicable law concerning
6 the protection of trade secrets and commercial or fi-
7 nancial information.

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

9 “(a) IN GENERAL.—Subject to subsection (b), the
10 Secretary shall submit to Congress, and post on the public
11 website of the Department of Health and Human Services
12 in a way that is user-friendly to the public and written
13 in plain language that consumers can readily understand,
14 an annual report—

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

17 “(2) including copies of the reports and sup-
18 porting detailed economic analyses submitted pursu-
19 ant to such section;

20 “(3) detailing the costs and expenditures in-
21 curred by the Department of Health and Human
22 Services in carrying out section 39900; and

23 “(4) explaining how the Department of Health
24 and Human Services is improving consumer and

1 provider information about drug value and drug
2 price transparency.

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

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

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

13 Section 1150A of the Social Security Act (42 U.S.C.
14 1320b–23) is amended—

15 (1) in subsection (c), in the matter preceding
16 paragraph (1), by inserting “(other than as per-
17 mitted under subsection (e))” after “disclosed by the
18 Secretary”; and

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

21 “(e) **PUBLIC AVAILABILITY OF CERTAIN INFORMA-**
22 **TION.**—

23 “(1) **IN GENERAL.**—In order to allow the com-
24 parison of PBMs’ ability to negotiate rebates, dis-
25 counts, direct and indirect remuneration fees, ad-

1 ministrative fees, and price concessions and the
2 amount of such rebates, discounts, direct and indi-
3 rect remuneration fees, administrative fees, and
4 price concessions that are passed through to plan
5 sponsors, beginning January 1, 2020, the Secretary
6 shall make available on the Internet website of the
7 Department of Health and Human Services the in-
8 formation with respect to the second preceding cal-
9 endar year provided to the Secretary on generic dis-
10 pensing rates (as described in paragraph (1) of sub-
11 section (b)) and information provided to the Sec-
12 retary under paragraphs (2) and (3) of such sub-
13 section that, as determined by the Secretary, is with
14 respect to each PBM.

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

18 “(A) CONFIDENTIALITY.—The information
19 described in such paragraph is displayed in a
20 manner that prevents the disclosure of informa-
21 tion, with respect to an individual drug or an
22 individual plan, on rebates, discounts, direct
23 and indirect remuneration fees, administrative
24 fees, and price concessions.

1 “(B) CLASS OF DRUG.—The information
2 described in such paragraph is made available
3 by class of drug, using an existing classification
4 system, but only if the class contains such num-
5 ber of drugs, as specified by the Secretary (but
6 not fewer than three drugs), to ensure confiden-
7 tiality of proprietary information or other infor-
8 mation that is prevented to be disclosed under
9 subparagraph (A).”.

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

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

16 (1) addresses at minimum—

17 (A) whether pharmacy benefit managers—

18 (i) charge payers a higher price than
19 the reimbursement rate at which the phar-
20 macy benefit managers reimburse com-
21 peting pharmacies;

22 (ii) steer patients for anticompetitive
23 purposes to any pharmacies, including re-
24 tail, mail-order, or any other type of phar-

1 macy, in which the PBM has an ownership
2 interest;

3 (iii) audit or review proprietary data,
4 including acquisition costs, patient infor-
5 mation, or dispensing information, of com-
6 peting pharmacies that can be used for
7 anticompetitive purposes; or

8 (iv) use formulary designs to increase
9 the market share of higher cost prescrip-
10 tion drugs and depress the market share of
11 lower cost prescription drugs (each net of
12 rebates and discounts);

13 (B) how companies and payers assess the
14 benefits, costs, and risks of contracting with
15 intermediaries, including pharmacy services ad-
16 ministrative organizations, and whether more
17 information about the roles of intermediaries
18 should be available to consumers and payers;
19 and

20 (C) whether there are any specific legal or
21 regulatory obstacles the Commission currently
22 faces in ensuring a competitive and transparent
23 marketplace in the pharmaceutical supply
24 chain, including the pharmacy benefit manager

1 marketplace and pharmacy services administra-
2 tive organizations; and

3 (2) provides—

4 (A) observations or conclusions drawn
5 from the November 2017 roundtable entitled
6 “Understanding Competition in Prescription
7 Drug Markets: Entry and Supply Chain Dy-
8 namics”, and any similar efforts;

9 (B) specific actions the Commission in-
10 tends to take as a result of the November 2017
11 roundtable, and any similar efforts, including a
12 detailed description of relevant forthcoming ac-
13 tions, additional research or roundtable discus-
14 sions, consumer education efforts, or enforce-
15 ment actions; and

16 (C) policy or legislative recommendations
17 to—

18 (i) improve transparency and competi-
19 tion in the pharmaceutical supply chain;

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

23 (iii) best ensure that consumers ben-
24 efit from any cost savings or efficiencies

1 that may result from mergers and consoli-
2 dations.

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

9 (c) DEFINITIONS.—In this section:

10 (1) APPROPRIATE COMMITTEES OF CON-
11 GRESS.—The term “appropriate committees of Con-
12 gress” means—

13 (A) the Committee on Energy and Com-
14 merce of the House of Representatives;

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

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

19 (2) COMMISSION.—The term “Commission”
20 means the Federal Trade Commission.

1 **SEC. 5. REQUIRING CERTAIN MANUFACTURERS TO REPORT**
2 **DRUG PRICING INFORMATION WITH RE-**
3 **SPECT TO DRUGS UNDER THE MEDICARE**
4 **PROGRAM.**

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

7 (1) in subsection (b)—

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

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

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

19 (2) in subsection (f)—

20 (A) by striking “For requirements” and
21 inserting the following:

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

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

25 “(2) MANUFACTURERS WITHOUT A REBATE
26 AGREEMENT UNDER TITLE XIX.—

1 “(A) IN GENERAL.—In the case of a man-
2 ufacturer of a drug or biological described in
3 subparagraph (C), (E), or (G) of section
4 1842(o)(1) or in section 1881(b)(14)(B) that is
5 payable under this part as a drug or biological,
6 if such manufacturer has not entered into and
7 have in effect a rebate agreement described in
8 subsection (b) of section 1927, for calendar
9 quarters beginning on or after January 1,
10 2020, such manufacturer shall report to the
11 Secretary the information described in sub-
12 section (b)(3)(A)(iii) of such section 1927 with
13 respect to such drug or biological in a time and
14 manner specified by the Secretary.

15 “(B) AUDIT.—Information reported under
16 subparagraph (A) is subject to audit by the In-
17 spector General of the Department of Health
18 and Human Services.

19 “(C) VERIFICATION.—The Secretary may
20 survey wholesalers and manufacturers that di-
21 rectly distribute drugs described in subpara-
22 graph (A), when necessary, to verify manufac-
23 turer prices and manufacturer’s average sales
24 prices (including wholesale acquisition cost) if
25 required to make payment reported under sub-

1 paragraph (A). The Secretary may impose a
2 civil monetary penalty in an amount not to ex-
3 ceed \$100,000 on a wholesaler, manufacturer,
4 or direct seller, if the wholesaler, manufacturer,
5 or direct seller of such a drug refuses a request
6 for information about charges or prices by the
7 Secretary in connection with a survey under
8 this subparagraph or knowingly provides false
9 information. The provisions of section 1128A
10 (other than subsections (a) (with respect to
11 amounts of penalties or additional assessments)
12 and (b)) shall apply to a civil money penalty
13 under this subparagraph in the same manner as
14 such provisions apply to a penalty or proceeding
15 under section 1128A(a).

16 “(D) CONFIDENTIALITY.—Notwith-
17 standing any other provision of law, information
18 disclosed by manufacturers or wholesalers
19 under this paragraph (other than the wholesale
20 acquisition cost for purposes of carrying out
21 this section) is confidential and shall not be dis-
22 closed by the Secretary in a form which dis-
23 closes the identity of a specific manufacturer or
24 wholesaler or prices charged for drugs by such
25 manufacturer or wholesaler, except—

1 “(i) as the Secretary determines to be
2 necessary to carry out this section (includ-
3 ing the determination and implementation
4 of the payment amount), or to carry out
5 section 1847B;

6 “(ii) to permit the Comptroller Gen-
7 eral to review the information provided;
8 and

9 “(iii) to permit the Director of the
10 Congressional Budget Office to review the
11 information provided.”.

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

14 (1) in subsection (d)(4)—

15 (A) in subparagraph (A), by striking “IN
16 GENERAL” and inserting “MISREPRESENTA-
17 TION”;

18 (B) in subparagraph (B), by striking “sub-
19 paragraph (B)” and inserting “subparagraph
20 (A), (B), or (C)”;

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

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

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

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

19 (2) in subsection (c)(6)(A), by striking the pe-
20 riod at the end and inserting “, except that, for pur-
21 poses of subsection (f)(2), the Secretary may, if the
22 Secretary determines appropriate, exclude repack-
23 agers of a drug or biological from such term.”.

24 (c) REPORT.—Not later than January 1, 2021, the
25 Inspector General of the Department of Health and

1 Human Services shall assess and submit to Congress a
2 report on the accuracy of average sales price information
3 submitted by manufacturers under section 1847A of the
4 Social Security Act (42 U.S.C. 1395w–3a). Such report
5 shall include any recommendations on how to improve the
6 accuracy of such information.

7 **SEC. 6. MAKING PRESCRIPTION DRUG MARKETING SAMPLE**
8 **INFORMATION REPORTED BY MANUFACTUR-**
9 **ERS AVAILABLE TO CERTAIN INDIVIDUALS**
10 **AND ENTITIES.**

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

13 (1) by redesignating subsection (b) as sub-
14 section (d); and

15 (2) by inserting after subsection (a) the fol-
16 lowing new subsections:

17 “(b) DATA SHARING AGREEMENTS.—

18 “(1) IN GENERAL.—The Secretary shall enter
19 into agreements with the specified data sharing indi-
20 viduals and entities described in paragraph (2)
21 under which—

22 “(A) upon request of such an individual or
23 entity, as applicable, the Secretary makes avail-
24 able to such individual or entity the information

1 submitted under subsection (a) by manufactur-
2 ers and authorized distributors of record; and

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

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

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

21 “(B) RESEARCHERS.—Individuals who
22 conduct scientific research (as defined in sec-
23 tion 164.501 of title 45, Code of Federal Regu-
24 lations) in relevant areas as determined by the
25 Secretary.

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

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

15 “(c) PENALTIES.—

16 “(1) DATA SHARING AGREEMENTS.—Subject to
17 paragraph (3), any specified data sharing individual
18 or entity described in subsection (b)(2) that violates
19 the terms of a data sharing agreement the individual
20 or entity has with the Secretary under subsection
21 (b)(1) shall be subject to a civil money penalty of
22 not less than \$1,000, but not more than \$10,000,
23 for each such violation. Such penalty shall be im-
24 posed and collected in the same manner as civil

1 money penalties under subsection (a) of section
2 1128A are imposed and collected under that section.

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

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

21 (b) GUIDANCE.—Not later than one year after the
22 date of the enactment of this Act, the Secretary of Health
23 and Human Services shall issue guidance (or revise exist-
24 ing guidance) on implementing the provisions of section
25 1128H of the Social Security Act (42 U.S.C. 1320a–7i).

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

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

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

7 “(5) No person may distribute a drug sample of a
8 drug that is—

9 “(A) an applicable drug (as defined in section
10 1128H(d) of the Social Security Act);

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

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

19 **SEC. 7. REQUIRING PRESCRIPTION DRUG PLAN SPONSORS**
20 **TO INCLUDE REAL-TIME BENEFIT INFORMA-**
21 **TION AS PART OF SUCH SPONSOR’S ELEC-**
22 **TRONIC PRESCRIPTION PROGRAM UNDER**
23 **THE MEDICARE PROGRAM.**

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

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

4 (2) by adding at the end the following new sub-
5 paragraph:

6 “(F) REAL-TIME BENEFIT INFORMA-
7 TION.—

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

22 “(I) A description of any clini-
23 cally-appropriate alternatives to such
24 drug included in the formulary of
25 such plan.

1 “(II) Information relating to ap-
2 plicable cost-sharing requirements for
3 such drug and such alternatives, in-
4 cluding a description of any variance
5 in such requirements based on the
6 pharmacy dispensing such drug or
7 such alternatives.

8 “(III) Information relating to
9 any prior authorization or other utili-
10 zation management requirements ap-
11 plicable to such drug and such alter-
12 natives within the formulary of such
13 plan.

14 “(ii) SPECIAL RULE FOR 2021.—The
15 program shall be deemed to be in compli-
16 ance with clause (i) for 2021 if the pro-
17 gram complies with the provisions of sec-
18 tion 423.160(b)(7) of title 42, Code of
19 Federal Regulations (or a successor regula-
20 tion), for such year.”.

21 **SEC. 8. SENSE OF CONGRESS REGARDING THE NEED TO EX-**
22 **PAND COMMERCIALY AVAILABLE DRUG**
23 **PRICING COMPARISON PLATFORMS.**

24 It is the sense of Congress that—

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

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

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

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

13 (B) overall drug prices can be reduced as
14 more educated purchasing decisions are made
15 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.”.

