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116TH CONGRESS
2^D SESSION

H. R. 2113

[Report No. 116–688, Part I]

To amend titles XI and XVIII of the Social Security Act to provide for drug manufacturer price transparency, to require certain manufacturers to report on product samples provided to certain health care providers, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 8, 2019

Mr. NEAL (for himself and Mr. BRADY) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

DECEMBER 24, 2020

Additional sponsors: Mr. VAN DREW, Ms. FINKENAUER, Ms. HOULAHAN, Mr. RASKIN, Mr. MCADAMS, Ms. UNDERWOOD, Ms. SLOTKIN, Mr. LIPINSKI, Ms. LOFGREN, and Mr. AMODEI

DECEMBER 24, 2020

Reported from the Committee on Ways and Means with an amendment

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

DECEMBER 24, 2020

Committee on Energy and Commerce discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[For text of introduced bill, see copy of bill as introduced on April 8, 2019]

A BILL

To amend titles XI and XVIII of the Social Security Act to provide for drug manufacturer price transparency, to require certain manufacturers to report on product samples provided to certain health care providers, 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.**

4 *This Act may be cited as the “Prescription Drug Sun-*
 5 *shine, Transparency, Accountability and Reporting Act” or*
 6 *the “Prescription Drug STAR Act”.*

7 **SEC. 2. DRUG MANUFACTURER PRICE TRANSPARENCY.**

8 *(a) IN GENERAL.—Title XI of the Social Security Act*
 9 *(42 U.S.C. 1301 et seq.) is amended by inserting after sec-*
 10 *tion 1128K the following new section:*

11 **“SEC. 1128L. DRUG MANUFACTURER PRICE TRANSPARENCY.**

12 *“(a) IN GENERAL.—With respect to each year, begin-*
 13 *ning with 2021, the Secretary shall, at least once during*
 14 *such year, determine if there is a triggered SPIKE increase*
 15 *(in accordance with subsection (b)) with respect to an ap-*
 16 *plicable drug (as defined in subsection (f)(1)). If the Sec-*
 17 *retary determines, with respect to a year, there is such an*
 18 *increase with respect to an applicable drug, the manufac-*
 19 *turer of the applicable drug shall submit to the Secretary*
 20 *the justification described in subsection (c), subject to sub-*
 21 *section (b)(4), for each such triggered SPIKE increase in*
 22 *accordance with the timing described in subsection (d)).*

23 **“(b) TRIGGERED SPIKE INCREASE.—**

24 **“(1) IN GENERAL.—A triggered SPIKE increase**
 25 *occurs, with respect an applicable drug and year (be-*

1 *ginning with 2021 and referred to in this paragraph*
2 *as the ‘applicable year’), in any of the following cases:*

3 *“(A) If there is at least a 10 percent (or*
4 *\$10,000) cumulative increase with respect to the*
5 *wholesale acquisition cost (or alternative cost*
6 *measure specified by the Secretary under para-*
7 *graph (3)) of such drug during a calendar-year*
8 *period beginning and ending within the lookback*
9 *period that is the 5-year period preceding such*
10 *applicable year.*

11 *“(B) If there is at least a 25 percent (or*
12 *\$25,000) cumulative increase with respect to the*
13 *wholesale acquisition cost (or such alternative*
14 *cost measure) of such drug during any three-cal-*
15 *endar-year period beginning and ending within*
16 *such lookback period.*

17 *“(C) In the case of such a drug that is first*
18 *covered under title XVIII with respect to such*
19 *applicable year, if the estimated cost or spending*
20 *under such title per individual or per user of*
21 *such drug (as estimated by the Secretary) for*
22 *such applicable year (or per course of treatment*
23 *in such applicable year, as defined by the Sec-*
24 *retary) is at least \$26,000.*

1 “(2) *INDEXING DOLLAR AMOUNTS.*—*The dollar*
2 *amounts applied under paragraph (1) for 2022 and*
3 *each subsequent year shall be the dollar amounts spec-*
4 *ified in such paragraph for the previous year in-*
5 *creased by the annual percentage increase in the con-*
6 *sumer price index (all items; U.S. city average) as of*
7 *September of such previous year. If any amount es-*
8 *tablished under paragraph (1), after application of*
9 *this paragraph, for a year is not a multiple of \$10,*
10 *it shall be rounded to the nearest multiple of \$10.*

11 “(3) *ALTERNATIVE TO WAC.*—*The Secretary*
12 *may, for purposes of making determinations under*
13 *paragraph (1), in addition to using the wholesale ac-*
14 *quisition cost for an applicable drug, use alternative*
15 *cost measures of such drug, or use such alternative*
16 *cost measure if the wholesale acquisition cost is not*
17 *available.*

18 “(4) *EXCEPTION.*—*A justification under sub-*
19 *section (c) shall not be required for a triggered*
20 *SPIKE increase described in paragraph (1) of an ap-*
21 *plicable drug of a manufacturer if—*

22 “(A) *there is any portion of the lookback pe-*
23 *riod described in the respective subparagraph of*
24 *such paragraph for such increase that is in-*
25 *cluded within the lookback period for another*

1 *triggered SPIKE increase (or combination of*
2 *such increases) for which a justification is made*
3 *under this section for such drug by such manu-*
4 *facturer; or*

5 *“(B) such increase is less than the wholesale*
6 *acquisition cost (or alternative cost measure*
7 *specified by the Secretary under paragraph (3))*
8 *of such drug during the calendar-year period de-*
9 *scribed in paragraph (1)(A) or the three-cal-*
10 *endar-year period described in paragraph*
11 *(1)(B), as applicable, for such increase, increased*
12 *by the percentage increase in the consumer price*
13 *index for all urban consumers (all items; United*
14 *States city average) for the 12-month period end-*
15 *ing six months prior to the calendar-year period*
16 *so described and for the 36-month period ending*
17 *six months prior to the three-calendar-year pe-*
18 *riod so described, respectively.*

19 *“(5) UNIT DETERMINATION.—For purposes of de-*
20 *termining the wholesale acquisition cost in carrying*
21 *out this section, the Secretary shall determine a unit*
22 *(such as a unit size) to apply.*

23 *“(6) PUBLIC POSTING.—Beginning with respect*
24 *to 2021, the Secretary shall publicly post on the*

1 *Internet website of the Department of Health and*
2 *Human Services—*

3 “(A) *alternative percentages, dollar*
4 *amounts, and lookback periods that, if applied*
5 *under paragraph (1), would be projected to in-*
6 *crease the number of applicable drugs for which*
7 *a triggered SPIKE increase would occur for such*
8 *year; and*

9 “(B) *the number of applicable drugs for*
10 *which a triggered SPIKE increase would occur*
11 *for such year if such an alternative percentage,*
12 *dollar amount, or period were applied for such*
13 *year.*

14 “(c) *JUSTIFICATION DESCRIBED.—*

15 “(1) *IN GENERAL.—The justification described in*
16 *this subsection, with respect to a triggered SPIKE in-*
17 *crease described in subsection (b)(1) of an applicable*
18 *drug of a manufacturer, is—*

19 “(A) *all of the information described in*
20 *paragraph (2);*

21 “(B) *all of the information and supporting*
22 *documentation described in paragraph (3), as*
23 *applicable to the increase and drug; and*

24 “(C) *a certification described in paragraph*
25 *(4).*

1 “(2) *REQUIRED INFORMATION.*—For purposes of
2 *paragraph (1), the information described in this*
3 *paragraph is the following:*

4 “(A) *The individual factors that have con-*
5 *tributed to the increase in the wholesale acquisi-*
6 *tion cost.*

7 “(B) *An explanation of the role of each fac-*
8 *tor in contributing to such increase.*

9 “(3) *INFORMATION AS APPLICABLE.*—For pur-
10 *poses of paragraph (1), the information and sup-*
11 *porting documentation described in this paragraph is*
12 *the following, as applicable to the increase of the*
13 *drug:*

14 “(A) *Total expenditures of the manufacturer*
15 *on—*

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

18 “(ii) *acquiring patents and licensing*
19 *for each drug of the manufacturer; and*

20 “(iii) *costs to purchase or acquire the*
21 *drug from another company, if applicable.*

22 “(B) *The percentage of total expenditures of*
23 *the manufacturer on research and development*
24 *for such drug that was derived from Federal*
25 *funds.*

1 “(C) *The total expenditures of the manufac-*
2 *turer on research and development for such drug.*

3 “(D) *The total revenue and net profit gen-*
4 *erated from the applicable drug for each calendar*
5 *year since drug approval.*

6 “(E) *The total costs associated with mar-*
7 *keting and advertising for the applicable drug.*

8 “(F) *Additional information specific to the*
9 *manufacturer of the applicable drug, such as—*

10 “(i) *the total revenue and net profit of*
11 *the manufacturer for the period of such in-*
12 *crease, as determined by the Secretary;*

13 “(ii) *metrics used to determine execu-*
14 *tive compensation;*

15 “(iii) *total expenditures on—*

16 “(I) *drug research and develop-*
17 *ment; or*

18 “(II) *clinical trials on drugs that*
19 *failed to receive approval by the Food*
20 *and Drug Administration; and*

21 “(iv) *any additional information re-*
22 *lated to drug pricing decisions of the manu-*
23 *facturer.*

1 “(G) *Any other relevant information and*
2 *supporting documentation necessary to justify*
3 *the triggering SPIKE increase.*

4 “(H) *Any other relevant information and*
5 *supporting documentation, as specified by the*
6 *Secretary.*

7 “(4) *CERTIFICATION.—For purposes of para-*
8 *graph (1), the certification described in this para-*
9 *graph is a certification, that all such information and*
10 *documentation is accurate and complete, by one of the*
11 *following:*

12 “(A) *The chief executive officer of the manu-*
13 *facturer.*

14 “(B) *The chief financial officer of the man-*
15 *ufacturer.*

16 “(C) *An individual who has delegated au-*
17 *thority to sign for, and who reports directly to,*
18 *such chief executive officer or chief financial offi-*
19 *cer.*

20 “(d) *TIMING.—*

21 “(1) *NOTIFICATION.—Not later than 60 days*
22 *after the date on which the Secretary makes the deter-*
23 *mination that there is a triggering SPIKE increase*
24 *with respect to an applicable drug, the Secretary shall*

1 *notify the manufacturer of the applicable drug of such*
2 *determination.*

3 “(2) *SUBMISSION OF JUSTIFICATION.*—*Not later*
4 *than 90 days after the date on which a manufacturer*
5 *receives a notification under paragraph (1), subject to*
6 *subsection (b)(4), the manufacturer shall submit to*
7 *the Secretary the justification required under sub-*
8 *section (a), including a summary of such justifica-*
9 *tion, in a form and manner specified by the Sec-*
10 *retary. In specifying such form, with respect to the*
11 *summary required under the previous sentence, the*
12 *Secretary shall provide that such summary shall be in*
13 *an easily understandable format, as specified by the*
14 *Secretary, and shall permit the manufacturer to ex-*
15 *clude proprietary information from such summary.*

16 “(3) *POSTING ON INTERNET WEBSITE.*—*Not later*
17 *than 30 days after receiving the complete justification*
18 *under paragraph (2), the Secretary shall post on the*
19 *Internet website of the Centers for Medicare & Med-*
20 *icaid Services the summary included for such jus-*
21 *tification.*

22 “(e) *PENALTIES.*—

23 “(1) *FAILURE TO SUBMIT TIMELY JUSTIFICA-*
24 *TION.*—*If the Secretary determines that a manufac-*
25 *turer has failed to submit a justification as required*

1 *under this section, including in accordance with the*
2 *timing and form required, with respect to an applica-*
3 *ble drug, the Secretary shall apply a civil monetary*
4 *penalty in an amount of \$10,000 for each day the*
5 *manufacturer has failed to submit such justification*
6 *as so required.*

7 “(2) *FALSE INFORMATION.*—*Any manufacturer*
8 *that submits a justification under this section that*
9 *knowingly provides false information in such jus-*
10 *tification is subject to a civil monetary penalty in an*
11 *amount not to exceed \$100,000 for each item of false*
12 *information.*

13 “(3) *APPLICATION OF PROCEDURES.*—*The provi-*
14 *sions of section 1128A (other than subsections (a) and*
15 *(b)) shall apply to a civil monetary penalty under*
16 *this subsection in the same manner as such provisions*
17 *apply to a penalty or proceeding under section*
18 *1128A(a). Civil monetary penalties imposed under*
19 *this subsection are in addition to other penalties as*
20 *may be prescribed by law.*

21 “(f) *DEFINITIONS.*—*In this section:*

22 “(1) *APPLICABLE DRUG.*—

23 “(A) *IN GENERAL.*—*Subject to subpara-*
24 *graph (B), the term ‘applicable drug’ means,*
25 *with respect to a lookback period described in*

1 subsection (b)(1), a covered outpatient drug (as
2 defined in paragraph (2) of section 1927(k),
3 without application of paragraph (3) of such sec-
4 tion) that is covered under title XVIII and is not
5 a low cost drug.

6 “(B) *EXCLUSION OF LOW COST DRUGS.*—
7 For purposes of subparagraph (A), not later than
8 January 1, 2021, the Secretary shall specify a
9 threshold (such as a cost or spending threshold)
10 for identifying (and shall identify) low cost
11 drugs to be excluded from the definition of the
12 term ‘applicable drug’, such as a drug that has
13 a wholesale acquisition cost of less than \$10 per
14 unit or less than \$100 in average estimated ex-
15 penditures under title XVIII per individual per
16 year or per user of such drug per year. For pur-
17 poses of this section, a drug shall not be consid-
18 ered specified as a low cost drug for a lookback
19 period described in subsection (b)(1) with respect
20 to a year unless such drug is identified as being
21 below the specified threshold for the entirety of
22 the lookback period.

23 “(2) *MANUFACTURER.*—The term ‘manufacturer’
24 has the meaning given that term in section
25 1847A(c)(6)(A).

1 “(3) *WHOLESALE ACQUISITION COST.*—*The term*
 2 *‘wholesale acquisition cost’ has the meaning given*
 3 *that term in section 1847A(c)(6)(B).*”.

4 **(b) *REPORTING TO THE SECRETARY OF THE TREAS-***
 5 ***URY.***—

6 **(1) *IN GENERAL.***—*Subpart A of part III of sub-*
 7 *chapter A of chapter 61 of the Internal Revenue Code*
 8 *of 1986 is amended by inserting after section 6039J*
 9 *the following new section:*

10 **“SEC. 6039K. DRUG PRICE SPIKE INCREASE REPORTING.**

11 *“Each manufacturer (within the meaning of section*
 12 *1128L of the Social Security Act) shall file a return (at*
 13 *such time and in such form and manner as the Secretary*
 14 *may provide) showing for such year with respect to which*
 15 *such section applies all information and supporting docu-*
 16 *mentation and the certification included within a justifica-*
 17 *tion reported by the manufacturer under subsection (c)(1)*
 18 *of such section.*”.

19 **(2) *CLERICAL AMENDMENT.***—*The table of sec-*
 20 *tions for subpart A of part III of subchapter A of*
 21 *chapter 61 of such Code is amended by inserting after*
 22 *the item relating to section 6039J the following new*
 23 *item:*

“Sec. 6039K. Drug price SPIKE increase reporting.”.

1 **SEC. 3. REQUIREMENT FOR MANUFACTURERS OF CERTAIN**
 2 **DRUGS, DEVICES, BIOLOGICALS, AND MED-**
 3 **ICAL SUPPLIES TO REPORT ON PRODUCT**
 4 **SAMPLES PROVIDED TO CERTAIN HEALTH**
 5 **CARE PROVIDERS.**

6 (a) *IN GENERAL.*—Section 1128G(a) of the Social Se-
 7 curity Act (42 U.S.C. 1320a–7h(a)) is amended by adding
 8 at the end the following new paragraph:

9 “(3) *CERTAIN PRODUCT SAMPLES.*—

10 “(A) *IN GENERAL.*—In addition to the re-
 11 quirements under paragraphs (1)(A) and (2), on
 12 the 90th day of each calendar year (beginning
 13 with 2023), any applicable manufacturer that
 14 provides a payment or other transfer of value
 15 that is a product sample described in subpara-
 16 graph (B) to any covered recipient (or to an en-
 17 tity or individual at the request of, or designated
 18 on behalf of, such a covered recipient) shall sub-
 19 mit to the Secretary, in such electronic form as
 20 the Secretary shall require, the following infor-
 21 mation (aggregated per each drug, device, bio-
 22 logical, or medical supply, as applicable) with
 23 respect to the preceding calendar year:

24 “(i) The total quantity of all such pay-
 25 ments or other transfers of value provided to
 26 all covered recipients.

1 “(ii) *The total value of all such pay-*
 2 *ments or other transfers of value provided to*
 3 *all covered recipients.*

4 “(iii) *If applicable, information de-*
 5 *scribed in clauses (vii) and (viii) of para-*
 6 *graph (1)(A) with respect to such a pay-*
 7 *ment or other transfer of value.*

8 “(B) *PRODUCT SAMPLE DESCRIBED.—For*
 9 *purposes of subparagraph (A), a product sample*
 10 *described in this subparagraph is a product sam-*
 11 *ple that is not intended to be sold and is in-*
 12 *tended for patient use.”.*

13 (b) *PUBLIC AVAILABILITY OF INFORMATION.—Section*
 14 *1128G(c)(1)(C)(ii) of the Social Security Act (42 U.S.C.*
 15 *1320a–7h(c)(1)(C)(ii)) is amended—*

16 (1) *by striking “(ii) contains” and inserting*
 17 *“(ii)(I) with respect to information that is not infor-*
 18 *mation submitted under paragraph (3) of subsection*
 19 *(a), contains”;*

20 (2) *by striking “, as applicable;” and inserting*
 21 *“, as applicable; and”; and*

22 (3) *by adding at the end the following new sub-*
 23 *clause:*

24 *“(II) with respect to information sub-*
 25 *mitted under paragraph (3) of subsection*

1 (a), contains information that is presented
 2 by the name of the applicable manufacturer,
 3 the total amount of all payments or other
 4 transfers of value described in such para-
 5 graph provided to all covered recipients, the
 6 total value of all such payments or other
 7 transfers of value provided to all covered re-
 8 cipients, and the name of the covered drug,
 9 device, biological, or medical supply, as ap-
 10 plicable;”.

11 (c) CONFORMING AMENDMENT.—Section
 12 1128G(e)(10)(B)(ii) of the Social Security Act (42 U.S.C.
 13 1320a–7h(e)(10)(B)(ii)) is amended by striking “Product
 14 samples” and inserting “Except for purposes of paragraph
 15 (3) of subsection (a), product samples”.

16 (d) REPORTING TO THE SECRETARY OF THE TREAS-
 17 URY.—

18 (1) IN GENERAL.—Subpart A of part III of sub-
 19 chapter A of chapter 61 of the Internal Revenue Code
 20 of 1986, as amended by section 2, is further amended
 21 by inserting after section 6039K the following new
 22 section:

1 **“SEC. 6039L. PRODUCT SAMPLES OF APPLICABLE MANUFAC-**
 2 **TURERS.**

3 *“Each applicable manufacturer (within the meaning*
 4 *of section 1128G(a)(3) of the Social Security Act) shall file*
 5 *a return (at such time and in such form and manner as*
 6 *the Secretary may provide) showing for such year to which*
 7 *such section applies—*

8 *“(1) the amount described in section*
 9 *1128G(a)(3)(A)(ii) of such Act with respect to such*
 10 *year, and*

11 *“(2) the portion of such amount for which a de-*
 12 *duction was claimed under section 162.”.*

13 *(2) CLERICAL AMENDMENT.—The table of sec-*
 14 *tions for subpart A of part III of subchapter A of*
 15 *chapter 61 of such Code, as amended by section 2, is*
 16 *further amended by inserting after the item relating*
 17 *to section 6039K the following new item:*

“Sec. 6039L. Product samples of applicable manufacturers.”.

18 **SEC. 4. ANALYSIS AND REPORT ON INPATIENT HOSPITAL**
 19 **DRUG COSTS.**

20 *(a) ANALYSIS.—The Secretary of Health and Human*
 21 *Services shall conduct an analysis that, to the extent prac-*
 22 *ticable—*

23 *(1) focuses on drugs that are furnished in the in-*
 24 *patient setting;*

1 (2) *includes data on inpatient hospital drug*
2 *costs, Medicare spending, volume, and spending per*
3 *admission;*

4 (3) *considers trends in inpatient hospital drug*
5 *costs, such as trends by hospital size, classification of*
6 *urban or rural, whether the hospital is a teaching*
7 *hospital, or other categorization; and*

8 (4) *examines the impact of drug shortages on*
9 *services that are furnished in an inpatient hospital*
10 *setting.*

11 *In conducting such analysis, the Secretary may conduct*
12 *hospital surveys, use data from hospital cost reports, or use*
13 *other data as determined by the Secretary.*

14 (b) *REPORT.*—*Not later than January 1, 2021, the*
15 *Secretary shall submit to the Committee on Ways and*
16 *Means of the House of Representatives and the Finance*
17 *Committee of the Senate a report on drug costs in the inpa-*
18 *tient hospital setting, including the analyses described in*
19 *paragraphs (1) through (4) of subsection (a).*

20 (c) *FUNDING.*—*For purposes of carrying out this sec-*
21 *tion, there shall be transferred to the Secretary \$3,000,000*
22 *from the Federal Hospital Insurance Trust Fund under sec-*
23 *tion 1817 of the Social Security Act (42 U.S.C. 1395i).*

1 **SEC. 5. PUBLIC DISCLOSURE OF DRUG DISCOUNTS.**

2 *Section 1150A of the Social Security Act (42 U.S.C.*
3 *1320b–23) is amended—*

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

8 *(2) by adding at the end the following new sub-*
9 *section:*

10 *“(e) PUBLIC AVAILABILITY OF CERTAIN INFORMA-*
11 *TION.—*

12 *“(1) IN GENERAL.—In order to allow the com-*
13 *parison of PBMs’ ability to negotiate rebates, dis-*
14 *counts, and price concessions and the amount of such*
15 *rebates, discounts, and price concessions that are*
16 *passed through to plan sponsors, beginning January*
17 *1, 2020, the Secretary shall make available on the*
18 *Internet website of the Department of Health and*
19 *Human Services the information with respect to the*
20 *second preceding calendar year provided to the Sec-*
21 *retary on generic dispensing rates (as described in*
22 *paragraph (1) of subsection (b) and information pro-*
23 *vided to the Secretary under paragraphs (2) and (3)*
24 *of such subsection that, as determined by the Sec-*
25 *retary, 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 on rebates, discounts, and price concessions,*
 8 *with respect to an individual drug or an indi-*
 9 *vidual plan.*

10 “(B) *CLASS OF DRUG.*—*The information*
 11 *described in such paragraph is made available*
 12 *by class of drug, using an existing classification*
 13 *system, but only if the class contains such num-*
 14 *ber of drugs, as specified by the Secretary, to en-*
 15 *sure confidentiality of proprietary information*
 16 *or other information that is prevented to be dis-*
 17 *closed under subparagraph (A).”.*

18 **SEC. 6. REQUIRING CERTAIN MANUFACTURERS TO REPORT**
 19 **DRUG PRICING INFORMATION WITH RESPECT**
 20 **TO DRUGS UNDER THE MEDICARE PROGRAM.**

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

23 (1) *in subsection (b)—*

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

4 (B) in paragraph (3), in the matter pre-
5 ceding subparagraph (A), by inserting “or sub-
6 section (f)(2), as applicable,” before “determined
7 by”; and

8 (C) in paragraph (6)(A), in the matter pre-
9 ceding clause (i), by inserting “or subsection
10 (f)(2), as applicable,” before “determined by”;
11 and

12 (2) in subsection (f)—

13 (A) by striking “For requirements” and in-
14 serting the following:

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

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

18 “(2) MANUFACTURERS WITHOUT A REBATE
19 AGREEMENT UNDER TITLE XIX.—

20 “(A) IN GENERAL.—In the case of a manu-
21 facturer of a drug or biological described in sub-
22 paragraph (C), (E), or (G) of section 1842(o)(1)
23 or in clause (ii) or (iii) of section
24 1881(b)(14)(B) that does not have a rebate agree-
25 ment in effect under section 1927, for calendar

1 *quarters beginning on or after January 1, 2020,*
2 *such manufacturer shall report to the Secretary*
3 *the information described in subsection*
4 *(b)(3)(A)(iii) of such section 1927 with respect to*
5 *such drug or biological in a time and manner*
6 *specified by the Secretary.*

7 *“(B) AUDIT.—Information reported under*
8 *subparagraph (A) is subject to audit by the In-*
9 *spector General of the Department of Health and*
10 *Human Services.*

11 *“(C) VERIFICATION.—The Secretary may*
12 *survey wholesalers and manufacturers that di-*
13 *rectly distribute drugs described in subparagraph*
14 *(A), when necessary, to verify manufacturer*
15 *prices and manufacturer’s average sales prices*
16 *(including wholesale acquisition cost) if required*
17 *to make payment reported under subparagraph*
18 *(A). The Secretary may impose a civil monetary*
19 *penalty in an amount not to exceed \$100,000 on*
20 *a wholesaler, manufacturer, or direct seller, if the*
21 *wholesaler, manufacturer, or direct seller of such*
22 *a drug refuses a request for information about*
23 *charges or prices by the Secretary in connection*
24 *with a survey under this subparagraph or know-*
25 *ingly provides false information. The provisions*

1 of section 1128A (other than subsections (a)
2 (with respect to amounts of penalties or addi-
3 tional assessments) and (b)) shall apply to a
4 civil money penalty under this subparagraph in
5 the same manner as such provisions apply to a
6 penalty or proceeding under section 1128A(a).

7 “(D) *CONFIDENTIALITY.*—Notwithstanding
8 any other provision of law, information disclosed
9 by manufacturers or wholesalers under this
10 paragraph (other than the wholesale acquisition
11 cost for purposes of carrying out this section) is
12 confidential and shall not be disclosed by the
13 Secretary in a form which discloses the identity
14 of a specific manufacturer or wholesaler or prices
15 charged for drugs by such manufacturer or
16 wholesaler, except—

17 “(i) as the Secretary determines to be
18 necessary to carry out this section (includ-
19 ing the determination and implementation
20 of the payment amount), or to carry out
21 section 1847B;

22 “(ii) to permit the Comptroller General
23 to review the information provided; and

1 “(iii) to permit the Director of the
2 Congressional Budget Office to review the
3 information provided.”.

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

6 (1) in subsection (d)(4)—

7 (A) in subparagraph (A), by striking “IN
8 GENERAL” and inserting “MISREPRESENTA-
9 TION”;

10 (B) in subparagraph (B), by striking “sub-
11 paragraph (B)” and inserting “subparagraph
12 (A), (B), or (C)”;

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

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

17 “(B) *FAILURE TO PROVIDE TIMELY INFOR-*
18 *MATION*.—If the Secretary determines that a
19 manufacturer described in subsection (f)(2) has
20 failed to report on information described in sec-
21 tion 1927(b)(3)(A)(iii) with respect to a drug or
22 biological in accordance with such subsection, the
23 Secretary shall apply a civil money penalty in
24 an amount of \$10,000 for each day the manufac-

1 *turer has failed to report such information and*
 2 *such amount shall be paid to the Treasury.*

3 *“(C) FALSE INFORMATION.—Any manufac-*
 4 *turer required to submit information under sub-*
 5 *section (f)(2) that knowingly provides false infor-*
 6 *mation is subject to a civil money penalty in an*
 7 *amount not to exceed \$100,000 for each item of*
 8 *false information. Such civil money penalties are*
 9 *in addition to other penalties as may be pre-*
 10 *scribed by law.”; and*

11 *(2) in subsection (c)(6)(A), by striking the period*
 12 *at the end and inserting “, except that, for purposes*
 13 *of subsection (f)(2), the Secretary may, if the Sec-*
 14 *retary determines appropriate, exclude repackagers of*
 15 *a drug or biological from such term.”.*

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

Union Calendar No. 571

116TH CONGRESS
2D Session

H. R. 2113

[Report No. 116-688, Part I]

A BILL

To amend titles XI and XVIII of the Social Security Act to provide for drug manufacturer price transparency, to require certain manufacturers to report on product samples provided to certain health care providers, and for other purposes.

DECEMBER 24, 2020

Reported from the Committee on Ways and Means with
an amendment

DECEMBER 24, 2020

Committee on Energy and Commerce discharged; com-
mitted to the Committee of the Whole House on the
State of the Union and ordered to be printed