

116TH CONGRESS
1ST SESSION

H. R. 2113

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

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
5 Sunshine, Transparency, Accountability and Reporting
6 Act” or the “Prescription Drug STAR Act”.

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

2 (a) IN GENERAL.—Title XI of the Social Security Act
 3 (42 U.S.C. 1301 et seq.) is amended by inserting after
 4 section 1128K the following new section:

5 **“SEC. 1128L. DRUG MANUFACTURER PRICE TRANS-**
 6 **PARENCY.**

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

19 “(b) TRIGGERED SPIKE INCREASE.—

20 “(1) IN GENERAL.—A triggered SPIKE in-
 21 crease occurs, with respect an applicable drug and
 22 year (beginning with 2021 and referred to in this
 23 paragraph as the ‘applicable year’), in any of the fol-
 24 lowing cases:

25 “(A) If there is at least a 10 percent (or
 26 \$10,000) cumulative increase with respect to

1 the wholesale acquisition cost (or alternative
2 cost measure specified by the Secretary under
3 paragraph (3)) of such drug during a calendar-
4 year period beginning and ending within the
5 lookback period that is the 5-year period pre-
6 ceding such applicable year.

7 “(B) If there is at least a 25 percent (or
8 \$25,000) cumulative increase with respect to
9 the wholesale acquisition cost (or such alter-
10 native cost measure) of such drug during any
11 three-calendar-year period beginning and end-
12 ing within such lookback period.

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

21 “(2) INDEXING DOLLAR AMOUNTS.—The dollar
22 amounts applied under paragraph (1) for 2022 and
23 each subsequent year shall be the dollar amounts
24 specified in such paragraph for the previous year in-
25 creased by the annual percentage increase in the

1 consumer price index (all items; U.S. city average)
2 as of September of such previous year. If any
3 amount established under paragraph (1), after appli-
4 cation of this paragraph, for a year is not a multiple
5 of \$10, it shall be rounded to the nearest multiple
6 of \$10.

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

14 “(4) EXCEPTION.—A justification under sub-
15 section (c) shall not be required for a triggered
16 SPIKE increase described in paragraph (1) of an
17 applicable drug of a manufacturer if—

18 “(A) there is any portion of the lookback
19 period described in the respective subparagraph
20 of such paragraph for such increase that is in-
21 cluded within the lookback period for another
22 triggered SPIKE increase (or combination of
23 such increases) for which a justification is made
24 under this section for such drug by such manu-
25 facturer; or

“(B) such increase is less than the wholesale acquisition cost (or alternative cost measure specified by the Secretary under paragraph (3)) of such drug during the calendar-year period described in paragraph (1)(A) or the three-calendar-year period described in paragraph (1)(B), as applicable, for such increase, increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending six months prior to the calendar-year period so described and for the 36-month period ending six months prior to the three-calendar-year period so described, respectively.

“(5) UNIT DETERMINATION.—For purposes of determining the wholesale acquisition cost in carrying out this section, the Secretary shall determine a unit (such as a unit size) to apply.

“(6) PUBLIC POSTING.—Beginning with respect to 2021, the Secretary shall publicly post on the Internet website of the Department of Health and Human Services—

“(A) alternative percentages, dollar amounts, and lookback periods that, if applied

1 under paragraph (1), would be projected to in-
2 crease the number of applicable drugs for which
3 a triggered SPIKE increase would occur for
4 such year; and

5 “(B) the number of applicable drugs for
6 which a triggered SPIKE increase would occur
7 for such year of such an alternative percentage,
8 dollar amount, or period were applied for such
9 year.

10 “(c) JUSTIFICATION DESCRIBED.—

11 “(1) IN GENERAL.—The justification described
12 in this subsection, with respect to a triggered
13 SPIKE increase described in subsection (b)(1) of an
14 applicable drug of a manufacturer, is—

15 “(A) all of the information described in
16 paragraph (2);

17 “(B) all of the information and supporting
18 documentation described in paragraph (3), as
19 applicable to the increase and drug; and

20 “(C) a certification described in paragraph
21 (4).

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

1 “(A) The individual factors that have con-
2 tributed to the increase in the wholesale acqui-
3 sition cost.

4 “(B) An explanation of the role of each
5 factor in contributing to such increase.

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

11 “(A) Total expenditures of the manufac-
12 turer on—

13 “(i) materials and manufacturing for
14 such drug;

15 “(ii) acquiring patents and licensing
16 for each drug of the manufacturer; and

17 “(iii) costs to purchase or acquire the
18 drug from another company, if applicable.

19 “(B) 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 “(C) The total expenditures of the manu-
24 facturer on research and development for such
25 drug.

1 “(D) The total revenue and net profit gen-
2 erated from the applicable drug for each cal-
3 endar year since drug approval.

4 “(E) The total costs associated with mar-
5 keting and advertising for the applicable drug.

6 “(F) Additional information specific to the
7 manufacturer of the applicable drug, such as—

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

11 “(ii) metrics used to determine execu-
12 tive compensation;

13 “(iii) total expenditures on—

14 “(I) drug research and develop-
15 ment; or

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

19 “(iv) any additional information re-
20 lated to drug pricing decisions of the man-
21 ufacturer.

22 “(G) Any other relevant information and
23 supporting documentation necessary to justify
24 the triggering SPIKE increase.

1 “(H) Any other relevant information and
2 supporting documentation, as specified by the
3 Secretary.

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

9 “(A) The chief executive officer of the
10 manufacturer.

11 “(B) The chief financial officer of the
12 manufacturer.

13 “(C) An individual who has delegated au-
14 thority to sign for, and who reports directly to,
15 such chief executive officer or chief financial of-
16 ficer.

17 “(d) TIMING.—

18 “(1) NOTIFICATION.—Not later than 60 days
19 after the date on which the Secretary makes the de-
20 termination that there is a triggering SPIKE in-
21 crease with respect to an applicable drug, the Sec-
22 retary shall notify the manufacturer of the applica-
23 ble drug of such determination.

24 “(2) SUBMISSION OF JUSTIFICATION.—Not
25 later than 90 days after the date on which a manu-

1 facturer receives a notification under paragraph (1),
2 subject to subsection (b)(4), the manufacturer shall
3 submit to the Secretary the justification required
4 under subsection (a), including a summary of such
5 justification, in a form and manner specified by the
6 Secretary. In specifying such form, with respect to
7 the summary required under the previous sentence,
8 the Secretary shall provide that such summary shall
9 be in an easily understandable format, as specified
10 by the Secretary, and shall permit the manufacturer
11 to exclude proprietary information from such sum-
12 mary.

13 “(3) POSTING ON INTERNET WEBSITE.—Not
14 later than 30 days after receiving the complete jus-
15 tification under paragraph (2), the Secretary shall
16 post on the Internet website of the Centers for Medi-
17 care & Medicaid Services the summary included for
18 such justification.

19 “(e) PENALTIES.—

20 “(1) FAILURE TO SUBMIT TIMELY JUSTIFICA-
21 TION.—If the Secretary determines that a manufac-
22 turer has failed to submit a justification as required
23 under this section, including in accordance with the
24 timing and form required, with respect to an appli-
25 cable drug, the Secretary shall apply a civil mone-

1 tary penalty in an amount of \$10,000 for each day
2 the manufacturer has failed to submit such justifica-
3 tion as so required.

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

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

18 “(f) DEFINITIONS.—In this section:

19 “(1) APPLICABLE DRUG.—

20 “(A) IN GENERAL.—Subject to subpara-
21 graph (B), the term ‘applicable drug’ means,
22 with respect to a lookback period described in
23 subsection (b)(1), a covered outpatient drug (as
24 defined in paragraph (2) of section 1927(k),
25 without application of paragraph (3) of such

1 section) that is covered under title XVIII and
2 is not a low cost drug.

3 “(B) EXCLUSION OF LOW COST DRUGS.—

4 For purposes of subparagraph (A), not later
5 than January 1, 2021, the Secretary shall
6 specify a threshold (such as a cost or spending
7 threshold) for identifying (and shall identify)
8 low cost drugs to be excluded from the defini-
9 tion of the term ‘applicable drug’, such as a
10 drug that has a wholesale acquisition cost of
11 less than \$10 per unit or less than \$100 in av-
12 erage estimated expenditures under title XVIII
13 per individual per year or per user of such drug
14 per year. For purposes of this section, a drug
15 shall not be considered specified as a low cost
16 drug for a lookback period described in sub-
17 section (b)(1) with respect to a year unless such
18 drug is identified as being below the specified
19 threshold for the entirety of the lookback pe-
20 riod.

21 “(2) MANUFACTURER.—The term ‘manufac-
22 turer’ has the meaning given that term in section
23 1847A(c)(6)(A).

1 “(3) WHOLESALE ACQUISITION COST.—The
 2 term ‘wholesale acquisition cost’ has the meaning
 3 given 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
 7 subchapter A of chapter 61 of the Internal Revenue
 8 Code of 1986 is amended by inserting after section
 9 6039J 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 (as
 13 such time and in such form and manner as the Secretary
 14 may provide) showing for each 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
 22 after the item relating to section 6039J the fol-
 23 lowing new 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
7 Security Act (42 U.S.C. 1320a–7h(a)) is amended by add-
8 ing 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),
12 on the 90th day of each calendar year (begin-
13 ning with 2023), any applicable manufacturer
14 that provides a payment or other transfer of
15 value that is a product sample described in sub-
16 paragraph (B) to any covered recipient (or to
17 an entity or individual at the request of, or des-
18 ignated on behalf of, such a covered recipient)
19 shall submit to the Secretary, in such electronic
20 form as the Secretary shall require, the fol-
21 lowing information (aggregated per each drug,
22 device, biological, or medical supply, as applica-
23 ble) with respect to the preceding calendar year:

24 “(i) The total quantity of all such
25 payments or other transfers of value pro-
26 vided to all covered recipients.

1 “(ii) The total value of all such pay-
2 ments or other transfers of value provided
3 to 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 sam-
10 ple described in this subparagraph is a product
11 sample that is not intended to be sold and is in-
12 tended for patient use.”.

13 (b) PUBLIC AVAILABILITY OF INFORMATION.—Sec-
14 tion 1128G(e)(1)(C)(ii) of the Social Security Act (42
15 U.S.C. 1320a–7h(e)(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 manufac-
 3 turer, the total amount of all payments or
 4 other transfers of value described in such
 5 paragraph provided to all covered recipi-
 6 ents, the total value of all such payments
 7 or other transfers of value provided to all
 8 covered recipients, and the name of the
 9 covered drug, device, biological, or medical
 10 supply, as applicable;”.

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
 19 subchapter A of chapter 61 of the Internal Revenue
 20 Code of 1986, as amended by section 2, is further
 21 amended by inserting after section 6039K the fol-
 22 lowing new section:

1 **“SEC. 6039L. PRODUCT SAMPLES OF APPLICABLE MANU-**
 2 **FACTURERS.**

3 “Each applicable manufacturer (within the meaning
 4 of section 1128G(a)(3) of the Social Security Act) shall
 5 file a return (as such time and in such form and manner
 6 as the Secretary may provide) showing for each year to
 7 which 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,
 16 is further amended by inserting after the item relat-
 17 ing 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
 24 inpatient 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
6 of 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
13 use 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
18 inpatient hospital setting, including the analyses described
19 in 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
22 \$3,000,000 from the Federal Hospital Insurance Trust
23 Fund under section 1817 of the Social Security Act (42
24 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 per-
6 mitted under subsection (e))” after “disclosed by the
7 Secretary”; 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
15 such rebates, discounts, and price concessions that
16 are passed through to plan sponsors, beginning Jan-
17 uary 1, 2020, the Secretary shall make available on
18 the Internet website of the Department of Health
19 and Human Services the information with respect to
20 the second preceding calendar year provided to the
21 Secretary on generic dispensing rates (as described
22 in paragraph (1) of subsection (b)) and information
23 provided to the Secretary under paragraphs (2) and
24 (3) of such subsection that, as determined by the
25 Secretary, is with respect to each PBM.

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

4 “(A) CONFIDENTIALITY.—The information
5 described in such paragraph is displayed in a
6 manner that prevents the disclosure of informa-
7 tion on rebates, discounts, and price conces-
8 sions, with respect to an individual drug or an
9 individual 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
15 ensure confidentiality of proprietary informa-
16 tion or other information that is prevented to
17 be disclosed under subparagraph (A).”.

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

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

24 (1) in subsection (b)—

1 (A) in paragraph (2)(A), by inserting “or
2 subsection (f)(2), as applicable” before the pe-
3 riod 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 “deter-
7 mined by”; and

8 (C) in paragraph (6)(A), in the matter
9 preceding 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
14 inserting 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 man-
21 ufacturer of a drug or biological described in
22 subparagraph (C), (E), or (G) of section
23 1842(o)(1) or in clause (ii) or (iii) of section
24 1881(b)(14)(B) that does not have a rebate
25 agreement in effect under section 1927, for cal-

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

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

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

8 “(D) CONFIDENTIALITY.—Notwithstand-
9 ing any other provision of law, information dis-
10 closed by manufacturers or wholesalers under
11 this paragraph (other than the wholesale acqui-
12 sition cost for purposes of carrying out this sec-
13 tion) is confidential and shall not be disclosed
14 by the Secretary in a form which discloses the
15 identity of a specific manufacturer or whole-
16 saler or prices charged for drugs by such manu-
17 facturer or wholesaler, except—

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

23 “(ii) to permit the Comptroller Gen-
24 eral to review the information provided;
25 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)
16 the 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,
23 the Secretary shall apply a civil money penalty
24 in an amount of \$10,000 for each day the man-

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

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

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

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

○