



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

Page 7, strike lines 7 through 21, and insert the following:

8                   “(H) the total expenditures of the manu-  
9                   facturer on research and development for such  
10                  drug that is necessary to demonstrate that it  
11                  meets applicable statutory standards for ap-  
12                  proval under section 505 of the Federal Food,  
13                  Drug, and Cosmetic Act or licensure under sec-  
14                  tion 351 of this Act, as applicable;

15                  “(I) the total expenditures of the manufac-  
16                  turer on pursuing new or expanded indications  
17                  or dosage changes for such drug under section  
18                  505 of the Federal Food, Drug, and Cosmetic  
19                  Act or section 351 of this Act;

20                  “(J) the total expenditures of the manufac-  
21                  turer on carrying out postmarket requirements  
22                  related to such drug, including under section

1           505(o)(3) of the Federal Food, Drug, and Cos-  
2           metic Act;

Page 7, line 22, redesignate the subparagraph (I) as  
subparagraph (K).

Page 8, line 5, redesignate the subparagraph (J) as  
subparagraph (L).

Page 9, after line 6, insert the following:

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

Page 9, line 7, redesignate the subsection (d) as  
subsection (e).

Page 9, line 14, redesignate the subsection (e) as  
subsection (f).

Page 9, line 19, redesignate the subsection (f) as  
subsection (g).

Page 10, strike lines 12 through 18 and insert the  
following:

1           “(3) PROTECTED INFORMATION.—Nothing in  
2           this section shall be construed to authorize the pub-  
3           lic disclosure of information submitted by a manu-  
4           facturer that is prohibited from disclosure by appli-  
5           cable laws concerning the protection of trade secrets,  
6           commercial information, and other information cov-  
7           ered under such laws.

Page 11, strike lines 13 through 18 and insert the following:

8           “(b) PROTECTED INFORMATION.—Nothing in this  
9           section shall be construed to authorize the public dislo-  
10          sure of information submitted by a manufacturer that is  
11          prohibited from disclosure by applicable laws concerning  
12          the protection of trade secrets, commercial information,  
13          and other information covered under such laws.”.

Page 17, strike line 3 and all that follows through page 22, line 10, and insert the following:

14   **SEC. 5. REQUIRING CERTAIN MANUFACTURERS TO REPORT**  
15                   **DRUG PRICING INFORMATION WITH RE-**  
16                   **SPECT TO DRUGS UNDER THE MEDICARE**  
17                   **PROGRAM.**

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

20                  (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.—If the manufacturer  
21 of a drug or biological described in subpara-  
22 graph (C), (E), or (G) of section 1842(o)(1) or  
23 in section 1881(b)(14)(B) that is payable under  
24 this part has not entered into and does not  
25 have in effect a rebate agreement described in

1 subsection (b) of section 1927, for calendar  
2 quarters beginning on or after January 1,  
3 2020, such manufacturer shall report to the  
4 Secretary the information described in sub-  
5 section (b)(3)(A)(iii) of such section 1927 with  
6 respect to such drug or biological in a time and  
7 manner specified by the Secretary. For pur-  
8 poses of applying this paragraph, a drug or bio-  
9 logical described in the previous sentence in-  
10 cludes items, services, supplies, and products  
11 that are payable under this part as a drug or  
12 biological.

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

17 “(C) VERIFICATION.—The Secretary may  
18 survey wholesalers and manufacturers that di-  
19 rectly distribute drugs described in subpara-  
20 graph (A), when necessary, to verify manufac-  
21 turer prices and manufacturer’s average sales  
22 prices (including wholesale acquisition cost) if  
23 required to make payment reported under sub-  
24 paragraph (A). The Secretary may impose a  
25 civil monetary penalty in an amount not to ex-

1           ceed \$100,000 on a wholesaler, manufacturer,  
2           or direct seller, if the wholesaler, manufacturer,  
3           or direct seller of such a drug refuses a request  
4           for information about charges or prices by the  
5           Secretary in connection with a survey under  
6           this subparagraph or knowingly provides false  
7           information. The provisions of section 1128A  
8           (other than subsections (a) (with respect to  
9           amounts of penalties or additional assessments)  
10          and (b)) shall apply to a civil money penalty  
11          under this subparagraph in the same manner as  
12          such provisions apply to a penalty or proceeding  
13          under section 1128A(a).

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

24                         “(i) as the Secretary determines to be  
25                         necessary to carry out this section (includ-

1           ing the determination and implementation  
2           of the payment amount), or to carry out  
3           section 1847B;

4                   “(ii) to permit the Comptroller Gen-  
5           eral of the United States to review the in-  
6           formation provided; and

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

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

12           (1) in subsection (d)(4)—

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

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

19                   (C) by redesignating subparagraph (B) as  
20           subparagraph (D); and

21                   (D) by inserting after subparagraph (A)  
22           the following new subparagraphs:

23                   “(B) FAILURE TO PROVIDE TIMELY INFOR-  
24           MATION.—If the Secretary determines that a  
25           manufacturer described in subsection (f)(2) has



1 failed to report on information described in sec-  
2 tion 1927(b)(3)(A)(iii) with respect to a drug or  
3 biological in accordance with such subsection,  
4 the Secretary shall apply a civil money penalty  
5 in an amount of \$10,000 for each day the man-  
6 ufacturer has failed to report such information  
7 and such amount shall be paid to the Treasury.

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

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

21 (c) MANUFACTURERS WITH A REBATE AGREE-  
22 MENT.—

23 (1) IN GENERAL.—Section 1927(b)(3)(A) of the  
24 Social Security Act (42 U.S.C. 1396r-8(b)(3)(A)) is  
25 amended by adding at the end the following new

1 sentence: “For purposes of applying clause (iii), a  
2 drug or biological described in the flush matter fol-  
3 lowing such clause includes items, services, supplies,  
4 and products that are payable under this part as a  
5 drug or biological.”.

6 (2) TECHNICAL AMENDMENT.—Section  
7 1927(b)(3)(A)(iii) of the Social Security Act (42  
8 U.S.C. 1396r-8(b)(3)(A)(iii)) is amended by striking  
9 “section 1881(b)(13)(A)(ii)” and inserting “section  
10 1881(b)(14)(B)”.

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

Page 22, line 18, strike “(d)” and insert “(e)”.

Page 25, line 22, strike the end quotation and sec-  
ond period.

Page 25, after line 22, insert the following:

19 “(d) DRUG SAMPLE DISTRIBUTION INFORMATION.—

1           “(1) IN GENERAL.—Not later than January 1  
2 of each year (beginning with 2021), the Secretary  
3 shall maintain a list containing information related  
4 to the distribution of samples of applicable drugs.  
5 Such list shall provide the following information with  
6 respect to the preceding year:

7           “(A) The name of the manufacturer or au-  
8 thorized distributor of record of an applicable  
9 drug for which samples were requested or dis-  
10 tributed under this section.

11           “(B) The quantity and class of drug sam-  
12 ples requested.

13           “(C) The quantity and class of drug sam-  
14 ples distributed.

15           “(2) PUBLIC AVAILABILITY.—The Secretary  
16 shall make the information in such list available to  
17 the public on the Internet Web site of the Food and  
18 Drug Administration.”.

Page 25, strike line 23 and all that follows through  
page 26, line 2, and insert the following:

19           (b) FDA MAINTENANCE OF INFORMATION.—The  
20 Food and Drug Administration shall maintain information  
21 available to affected reporting companies to ensure their  
22 ability to fully comply with the requirements of section  
23 1128H of the Social Security Act.

Page 26, after line 20, insert the following:

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

Page 27, strike line 1 and all that follows through  
page 29, line 2, and insert the following (and conform the  
table of contents accordingly):

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

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

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

17 (2) by adding at the end the following new sub-  
18 paragraph:

19 “(F) REAL-TIME BENEFIT INFORMA-  
20 TION.—

1                   “(i) IN GENERAL.—Not later than  
2                   January 1, 2021, the program shall imple-  
3                   ment real-time benefit tools that are capa-  
4                   ble of integrating with a prescribing health  
5                   care professional’s electronic prescribing or  
6                   electronic health record system for the  
7                   transmission of formulary and benefit in-  
8                   formation in real time to prescribing health  
9                   care professionals. With respect to a cov-  
10                  ered part D drug, such tools shall be capa-  
11                  ble of transmitting such information spe-  
12                  cific to an individual enrolled in a prescrip-  
13                  tion drug plan. Such information shall in-  
14                  clude the following:

15                               “(I) A list of any clinically-appro-  
16                               priate alternatives to such drug in-  
17                               cluded in the formulary of such plan.

18                               “(II) Cost-sharing information  
19                               for such drug and such alternatives,  
20                               including a description of any vari-  
21                               ance in cost sharing based on the  
22                               pharmacy dispensing such drug or  
23                               such alternatives.

24                               “(III) Information relating to  
25                               whether such drug is included in the

1                   formulary of such plan and any prior  
2                   authorization or other utilization man-  
3                   agement requirements applicable to  
4                   such drug and such alternatives so in-  
5                   cluded.

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

14                  “(iii) 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                  “(iv) RULE OF CONSTRUCTION.—  
22                  Nothing in this subparagraph shall be con-  
23                  strued as to allow a real time benefits tool  
24                  to steer an individual, without the consent  
25                  of the individual, to a particular pharmacy

1 or pharmacy setting over their preferred  
2 pharmacy setting nor prohibit the designa-  
3 tion of a preferred pharmacy under such  
4 tool.”.

Page 29, after line 21, insert the following (and conform the table of contents accordingly):

5 **SEC. 9. TECHNICAL CORRECTIONS.**

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

9 “(4) APPLICATION OF AUTHORITIES UNDER IN-  
10 SPECTOR GENERAL ACT OF 1978.—In carrying out  
11 this subsection, the Inspector General shall have the  
12 same authorities as provided under section 6 of the  
13 Inspector General Act of 1978 (5 U.S.C. App.).”.

14 (b) EFFECTIVE DATE.—The amendment made by  
15 subsection (a) shall take effect as if included in the enact-  
16 ment of the 21st Century Cures Act (Public Law 114–  
17 255).

