

115TH CONGRESS  
2D SESSION

# H. R. 5739

To establish within the Department of Health and Human Services the Prescription Drug and Medical Device Price Review Board to regulate the prices of certain prescription drugs and medical devices, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 9, 2018

Ms. DELAURO (for herself, Mr. DOGGETT, and Ms. MOORE) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, and the Judiciary, 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

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## A BILL

To establish within the Department of Health and Human Services the Prescription Drug and Medical Device Price Review Board to regulate the prices of certain prescription drugs and medical devices, 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 and  
5 Medical Device Price Review Board Act of 2018”.

1 **SEC. 2. ESTABLISHMENT.**

2       There is established in the Department of Health and  
3 Human Services a board to be known as the Prescription  
4 Drug and Medical Device Price Review Board (in this Act  
5 referred to as the “Board”).

6 **SEC. 3. MEMBERSHIP; STAFF.**

7       (a) MEMBERS.—The Board shall be composed of 5  
8 members as follows:

9           (1) The Assistant Secretary for Planning and  
10       Evaluation of the Department of Health and Human  
11       Services (or the Assistant Secretary’s designee).

12           (2) The Administrator of the Centers for Medi-  
13       care & Medicaid Services (or the Administrator’s  
14       designee).

15           (3) The Assistant Director for the Health Serv-  
16       ices Division of the Federal Bureau of Prisons (or  
17       the Assistant Director’s designee).

18           (4) The Secretary of Defense (or the Sec-  
19       retary’s designee).

20           (5) The Secretary of Veterans Affairs (or the  
21       Secretary’s designee).

22           (6) The Commissioner of Food and Drugs (or  
23       the Commissioner’s designee).

24       (b) CHAIRPERSON.—The Board shall designate 1  
25 member of the Board to serve as the chairperson.

26       (c) DIRECTOR AND STAFF.—

1           (1) DIRECTOR.—The Board shall have a direc-  
2           tor who shall be appointed by the chairperson of the  
3           Board, subject to rules prescribed by the Board.

4           (2) STAFF.—The director may appoint and fix  
5           the pay of such additional personnel as the chair-  
6           person considers appropriate, subject to rules pre-  
7           scribed by the Board.

8           (3) APPLICABILITY OF CERTAIN CIVIL SERVICE  
9           LAWS.—The director and staff of the Board shall be  
10          appointed subject to the provisions of title 5, United  
11          States Code, governing appointments in the competi-  
12          tive service, and shall be paid in accordance with the  
13          requirements of chapter 51 and subchapter III of  
14          chapter 53 of such title relating to classification and  
15          General Schedule pay rates; except that an indi-  
16          vidual so appointed may not receive pay in excess of  
17          the maximum annual rate of basic pay payable for  
18          grade GS–15 of the General Schedule.

19          (d) ASSISTANCE FOR THE BOARD.—Subject to sec-  
20          tion 7(g), in carrying out this Act, the Board—

21                 (1) may seek assistance from outside experts in  
22                 the fields of consumer advocacy, medicine, pharma-  
23                 cology, pharmacy, and prescription drug reimburse-  
24                 ment; and

1           (2) shall establish and maintain an advisory  
2           group and a stakeholder group for purposes of seek-  
3           ing such assistance.

4           (e) INITIAL MEETING.—The Board shall hold its ini-  
5           tial meeting not later than 90 days after the date of the  
6           enactment of this Act.

7           **SEC. 4. REPORTING REQUIREMENTS.**

8           (a) REPORTING BY MANUFACTURERS.—The Board  
9           shall require each manufacturer of a prescription drug or  
10          medical device that is sold in the United States to submit  
11          to the Board on a periodic basis, at a level of specificity  
12          determined by the Board to be necessary to make a deter-  
13          mination under section 5, the following information with  
14          respect to the reporting period:

15               (1) Each type of prescription drug and medical  
16               device that is sold by the manufacturer or an affil-  
17               iate of the manufacturer—

18                       (A) in the United States; or

19                       (B) in a country that is a member of the  
20               Organization for Economic Co-operation and  
21               Development.

22               (2) The price charged by the manufacturer and  
23               the affiliate for the prescription drug or medical de-  
24               vice in the United States and in any such country,  
25               as applicable.

1           (3) The costs of the manufacturer and the affil-  
2           iate to produce and market the prescription drug or  
3           medical device for sale in the United States and in  
4           any such country, as applicable.

5           (b) REPORTING BY CBO.—The Director of the Con-  
6           gressional Budget Office shall submit an annual report to  
7           the Board on trends in the prices charged for prescription  
8           drugs and medical devices.

9           **SEC. 5. PROHIBITION AGAINST EXCESSIVE PRICE.**

10          (a) PROHIBITION.—Beginning on the effective date  
11          of the regulation required by subsection (b), the manufac-  
12          turer of a prescription drug or medical device shall not  
13          charge an excessive price, as determined pursuant to such  
14          regulation, for such drug or device.

15          (b) FORMULA.—The Board shall by regulation pre-  
16          scribe a formula for determining whether the average  
17          manufacturer price of such drug or device over an annual  
18          quarter is an excessive price.

19          (c) DETERMINATION OF EXCESSIVE PRICE.—If the  
20          Board determines, on its own initiative or in response to  
21          a petition submitted under subsection (d), that the manu-  
22          facturer of a prescription drug or medical device charges  
23          an excessive price for such drug or device in violation of  
24          subsection (a)—

25                 (1) the Board shall give the manufacturer—

1 (A) notice of such violation; and

2 (B) subject to subsection (d), a period to  
3 correct such violation; and

4 (2) if the manufacturer fails to correct the vio-  
5 lation by the end of such period, the manufacturer  
6 shall be subject to section 6 of this Act, section  
7 1927(e)(2)(E) of the Social Security Act, as added  
8 by subsection (c) of such section 6, and section 4192  
9 of the Internal Revenue Code of 1986, as added by  
10 subsection (d) of such section 6.

11 (d) PETITIONS.—Any person may petition the Board  
12 to make a determination under subsection (c) regarding  
13 the pricing of a prescription drug or medical device. Not  
14 later than 90 days after the date of receipt of such a peti-  
15 tion, the Board shall—

16 (1) make a determination under subsection (c)  
17 regarding such pricing; or

18 (2) decline to make such a determination.

19 (e) CONTINUING VIOLATION.—The Board shall not  
20 be required to give a manufacturer an opportunity to cor-  
21 rect a violation, as described in subsection (c)(1)(B), be-  
22 fore the manufacturer becomes subject to the provisions  
23 described in subsection (c)(2) for such violation, if—

24 (1) the Board has already provided such an op-  
25 portunity to correct to the manufacturer; and

1           (2) the Board finds that the violation of sub-  
2           section (a) is a continuation of an earlier violation  
3           with respect to which such an opportunity was pro-  
4           vided.

5           (f) CONSIDERATIONS.—The formula required by sub-  
6           section (a) shall at a minimum take into consideration—

7           (1) the average manufacturer price of the pre-  
8           scription drug or medical device over the respective  
9           annual quarter or quarters;

10          (2) the average manufacturer price of other  
11          prescription drugs or medical devices in the same  
12          therapeutic class over the same quarter or quarters;

13          (3) the average price at which the prescription  
14          drug or medical device and other prescription drugs  
15          and medical devices in the same therapeutic class  
16          have been sold by manufacturers in countries other  
17          than the United States;

18          (4) the costs associated with producing and  
19          marketing the prescription drug or medical device,  
20          the value of the drug or device to patients where suf-  
21          ficient data is available to determine such value, the  
22          total Federal investment in the development of the  
23          drug or device, the size of the patient population re-  
24          ceiving the drug or device, and other factors deter-  
25          minative as to the true cost of production; and

1           (5) whether the price of the prescription drug  
2           or medical device increased during any annual quar-  
3           ter by a percentage that is more than 2 percent  
4           greater than the CPI increase percentage (as defined  
5           in section 215(i) of the Social Security Act (42  
6           U.S.C. 415)) for the respective annual quarter.

7 **SEC. 6. ENFORCEMENT PROVISIONS.**

8           (a) **REDUCED PATENT TERM.**—If the Board finds  
9           that the manufacturer of a prescription drug or medical  
10          device, who is also an owner of a patent for such drug  
11          or device, charged an excessive price for such drug or de-  
12          vice in violation of section 5(a), the Board may—

13               (1) reduce the term, by not more than 5 years,  
14               of any patent issued under title 35, United States  
15               Code, relating to such drug or device; or

16               (2) if the term of each patent for such drug or  
17               device has expired, reduce the term, by not more  
18               than 5 years, of another patent owned by the patent  
19               owner relating to a prescription drug or medical de-  
20               vice.

21           (b) **CIVIL PENALTIES.**—If the Board determines  
22          under section 5(c) that a manufacturer of a prescription  
23          drug or medical device charged an excessive price for a  
24          prescription drug or medical device in violation of section  
25          5(a), the Board may impose a civil penalty on the manu-



1 manufacturer of not more than 10 percent of the manufactur-  
2 er's gross sales of the drug or device during the period  
3 beginning on the date on which an excessive price is first  
4 charged and ending on the date on which the manufac-  
5 turer ceases to charge an excessive price.

6 (c) ENFORCEMENT THROUGH INCREASED MEDICAID  
7 REBATES.—

8 (1) IN GENERAL.—Section 1927(c)(2) of the  
9 Social Security Act (42 U.S.C. 1396r–8(c)(2)) is  
10 amended—

11 (A) in subparagraph (A), by inserting “,  
12 subject to subparagraph (E),” after “increased  
13 by”; and

14 (B) by adding at the end the following new  
15 subparagraph:

16 “(E) DISCOURAGING EXCESSIVE PRICES.—

17 “(i) IN GENERAL.—In the case of a  
18 manufacturer of a single source drug or an  
19 innovator multiple source drug with a re-  
20 bate agreement under this section, if the  
21 Prescription Drug and Medical Device  
22 Price Review Board established under sec-  
23 tion 2 of the Prescription Drug and Med-  
24 ical Device Price Review Board Act of  
25 2018 determines under section 5(a) of

1 such Act that such manufacturer charged,  
2 with respect to a 30-day period, an exces-  
3 sive price for such drug, and the Board de-  
4 termines under clause (ii) to apply an in-  
5 creased amount described in such clause  
6 with respect to such manufacturer and  
7 drug, the amount of the rebate determined  
8 under subparagraph (A) for such manufac-  
9 turer and drug shall be, subject to sub-  
10 paragraph (D), increased by such amount  
11 for the 4 rebate periods following such 30-  
12 day period.

13 “(ii) INCREASED AMOUNT DETER-  
14 MINATION.—For purposes of clause (i), if  
15 the Board described in such clause makes  
16 such a determination under such section  
17 5(a), with respect to a manufacturer and  
18 drug described in such clause, the Board  
19 may determine an increased amount to  
20 apply with respect to such manufacturer  
21 and drug and rebate period described in  
22 such clause. Such increased amount may  
23 not exceed the rebate amount that would  
24 otherwise be applied to such manufacturer  
25 and drug under this section for such rebate

1 period, without regard to this subpara-  
2 graph.”.

3 (2) EFFECTIVE DATE.—This subsection and the  
4 amendments made by this subsection shall apply  
5 with respect to rebate agreements entered into after  
6 the date that is 60 days after the date of the enact-  
7 ment of this Act.

8 (d) TAX ON EXCESS PRESCRIPTION DRUG AND MED-  
9 ICAL DEVICE PROFITS.—

10 (1) DETERMINATION OF AMOUNT.—If the  
11 Board determines under section 5(a) that a manu-  
12 facturer, producer, or importer of a prescription  
13 drug or medical device charged an excessive price for  
14 such prescription drug or medical device during a  
15 taxable year, the Board may determine under this  
16 paragraph a reasonable price for such drug or device  
17 for such taxable year.

18 (2) IMPOSITION OF TAX.—

19 (A) IN GENERAL.—The Internal Revenue  
20 Code of 1986 is amended by inserting after sec-  
21 tion 4191 the following new section:

22 **“SEC. 4192. EXCESSIVE PRESCRIPTION DRUG AND MEDICAL**  
23 **DEVICE PRICE.**

24 **“(a) IN GENERAL.—**There is hereby imposed on the  
25 sale of any prescription drug or medical device by the

1 manufacturer, producer, or importer a tax equal to the  
 2 difference between the price at which such drug or device  
 3 is so sold and the reasonable price determined by the Pre-  
 4 scription Drug and Medical Device Price Review Board  
 5 under section 6(d)(1) of the Prescription Drug and Med-  
 6 ical Device Price Review Board Act of 2018 for such drug  
 7 or device for the taxable year for sales after the determina-  
 8 tion.

9       “(b) PRESCRIPTION DRUG OR MEDICAL DEVICE.—  
 10 For purposes of this section, the term ‘prescription drug  
 11 or medical device’ means any prescription drug (as defined  
 12 in section 9008 of the Patient Protection and Affordable  
 13 Care Act) or device (as defined in section 201(h) of the  
 14 Federal Food, Drug, and Cosmetic Act) intended for hu-  
 15 mans.”.

16                   (B) CLERICAL AMENDMENT.—The table of  
 17 parts for chapter 32 of such Code is amended—

18                   (i) in the item relating to subchapter  
 19 E, by striking “Medical” and inserting  
 20 “Drugs and medical”, and

21                   (ii) by inserting after the item relating  
 22 to section 4191 the following new item:

“Sec. 4192. Excessive prescription drug and medical device price.”.

23                   (3) EFFECTIVE DATE.—This subsection and the  
 24 amendments made by this subsection shall apply  
 25 with respect to sales after December 31, 2018.

1 (e) SAFE AND AFFORDABLE DRUGS FROM AP-  
2 PROVED COUNTRIES.—Chapter VIII of the Federal Food,  
3 Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amend-  
4 ed by adding at the end the following:

5 **“SEC. 810. IMPORTATION BY INDIVIDUALS OF PRESCRIP-**  
6 **TION DRUGS, AND DEVICES, FROM AN AP-**  
7 **PROVED COUNTRY IF MANUFACTURERS ARE**  
8 **CHARGING AN EXCESSIVE PRICE FOR COM-**  
9 **PARABLE PRODUCTS IN THE UNITED STATES.**

10 “(a) IN GENERAL.—Notwithstanding any other pro-  
11 vision of this Act, not later than 180 days after the date  
12 of enactment of this section, the Prescription Drug and  
13 Medical Device Price Review Board (in this section re-  
14 ferred to as the ‘Board’) shall promulgate regulations per-  
15 mitting individuals to safely import from an approved  
16 country into the United States prescription drugs, and de-  
17 vices, that are comparable to prescription drugs, and de-  
18 vices, for which the Board makes a final determination  
19 that the manufacturer is charging or has charged an ex-  
20 cessive price in violation of section 5(a) of the Prescription  
21 Drug and Medical Device Price Review Board Act of  
22 2018.

23 “(b) COMPARABLE DEFINED.—For purposes of this  
24 section, the term ‘comparable’ means—

1           “(1) with respect to a drug, having the same  
2           active ingredient or ingredients, route of administra-  
3           tion, dosage form, and strength; and

4           “(2) with respect to a device, being substan-  
5           tially equivalent.

6           “(c) ASSURANCE OF SAFETY.—For purposes of this  
7           section, the term ‘approved country’ means a country that  
8           is determined by the Secretary to have in effect standards  
9           to ensure the safety of prescription drugs, and of devices,  
10          that are at least as protective as the standards applicable  
11          under Federal law in the United States.”.

12   **SEC. 7. AUTHORITY.**

13          (a) OBTAINING OFFICIAL DATA.—The chairperson of  
14          the Board may secure directly from any Federal agency  
15          information necessary to enable the Board to carry out  
16          its duties. Upon request of the chairperson, the head of  
17          the agency shall furnish such information to the Board  
18          to the extent such information is not prohibited from dis-  
19          closure by law.

20          (b) MAILS.—The Board may use the United States  
21          mails in the same manner and under the same conditions  
22          as other Federal agencies.

23          (c) ADMINISTRATIVE SUPPORT SERVICES.—Upon the  
24          request of the chairperson of the Board, the Administrator  
25          of General Services shall provide to the Board, on a reim-

1 bursable basis, the administrative support services nec-  
2 essary for the Board to carry out its duties.

3 (d) CONTRACT AUTHORITY.—The Board may con-  
4 tract with and compensate government and private agen-  
5 cies or persons for the purpose of conducting research,  
6 surveys, and other services necessary to enable the Board  
7 to carry out its duties.

8 (e) INVESTIGATIONS.—The Board may make such in-  
9 vestigations as it considers necessary to determine whether  
10 there is or may be a violation of any regulation promul-  
11 gated under this Act and may require or permit any per-  
12 son to file with it a statement in writing, under oath or  
13 otherwise as the Board shall determine, as to all the facts  
14 and circumstances concerning the matter to be inves-  
15 tigated.

16 (f) SUBPOENA POWER.—

17 (1) IN GENERAL.—The Board may issue sub-  
18 poenas requiring the attendance and testimony of  
19 witnesses and the production of any evidence relat-  
20 ing to any matter under investigation by the Board.  
21 The attendance of witnesses and the production of  
22 evidence may be required from any place within the  
23 United States at any designated place of hearing  
24 within the United States.

1           (2) FAILURE TO OBEY A SUBPOENA.—If a per-  
2           son refuses to obey a subpoena issued under para-  
3           graph (1), the Board may apply to a United States  
4           district court for an order requiring that person to  
5           appear before the Board to give testimony, produce  
6           evidence, or both, relating to the matter under inves-  
7           tigation. The application may be made within the ju-  
8           dicial district where the hearing is conducted or  
9           where that person is found, resides, or transacts  
10          business. Any failure to obey the order of the court  
11          may be punished by the court as civil contempt.

12          (3) SERVICE OF SUBPOENAS.—The subpoenas  
13          of the Board shall be served in the manner provided  
14          for subpoenas issued by a United States district  
15          court under the Federal Rules of Civil Procedure for  
16          the United States district courts.

17          (4) SERVICE OF PROCESS.—All process of any  
18          court to which application is made under paragraph  
19          (2) may be served in the judicial district in which  
20          the person required to be served resides or may be  
21          found.

22          (5) NOTICE.—Upon issuing any subpoena  
23          under this subsection, the Board shall give notice of  
24          such issuance to the appropriate committees of Con-  
25          gress, including the Committee on Appropriations of



1 the House of Representatives and the Committee on  
2 Appropriations of the Senate.

3 (g) CONFIDENTIALITY.—Nothing in this Act shall be  
4 construed as authorizing the Board to disclose any infor-  
5 mation that is a trade secret or confidential information  
6 subject to section 552(b)(4) of title 5, United States Code,  
7 or section 1905 of title 18, United States Code.

8 **SEC. 8. REGULATIONS.**

9 (a) IN GENERAL.—Not later than 1 year after the  
10 date of the initial meeting held under section 3(e), the  
11 Board shall issue final regulations to carry out this Act.

12 (b) NOTICE AND COMMENT REQUIREMENT.—The  
13 regulations developed under subsection (a) shall be issued  
14 in accordance with the notice and comment procedures es-  
15 tablished under section 553 of title 5, United States Code.

16 **SEC. 9. REPORT TO FEDERAL AGENCIES.**

17 Not later than 1 year after the effective date of the  
18 regulations under section 8 and annually thereafter, the  
19 Board shall submit to each Federal agency that dispenses  
20 or makes payments for the dispensing of prescription  
21 drugs or medical devices a report containing—

22 (1) a list of each prescription drug and medical  
23 device for which an excessive price was charged dur-  
24 ing the preceding calendar year, as determined by  
25 the Board under section 5;

1           (2) recommendations to the Federal agency  
2           against dispensing or making payments for the dis-  
3           pensing of the prescription drug or medical device;  
4           and

5           (3) recommendations to the Federal agency to  
6           substitute, in place of any drug or device listed pur-  
7           suant to paragraph (1), a similar prescription drug  
8           or medical device that is not sold at an excessive  
9           price.

10 **SEC. 10. REPORT TO CONGRESS.**

11           Not later than 1 year after the initial meeting of the  
12 Board under section 3(e), and annually thereafter, the  
13 Board shall submit to the Congress a report describing  
14 the activities of the Board for the preceding year.

15 **SEC. 11. DEFINITIONS.**

16           In this Act:

17           (1) The term “affiliate” means, with respect to  
18           a manufacturer, any entity that controls, is con-  
19           trolled by, or is under common control with such  
20           manufacturer.

21           (2) The term “average manufacturer price”  
22           means the average price charged by the manufac-  
23           turer of a prescription drug or medical device, as ap-  
24           plicable, for sales of the drug or device by the manu-

1        facturer in the United States over the respective an-  
2        nual quarter.

3            (3) The term “medical device” means a device  
4        (as defined in section 201 of the Federal Food,  
5        Drug, and Cosmetic Act (21 U.S.C. 321)).

6            (4) The term “prescription drug” means a drug  
7        (as defined in section 201 of the Federal Food,  
8        Drug, and Cosmetic Act (21 U.S.C. 321)) that is  
9        subject to section 503(b)(1) of such Act (21 U.S.C.  
10       353(b)(1)).

○