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(Original Signature of Member)

114TH CONGRESS
1ST SESSION

H. R.

To amend part D of title XVIII of the Social Security Act to require the Secretary of Health and Human Services to determine, on behalf of Medicare beneficiaries, covered part D drug prices for certain covered part D drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. SCHAKOWSKY introduced the following bill; which was referred to the Committee on _____

A BILL

To amend part D of title XVIII of the Social Security Act to require the Secretary of Health and Human Services to determine, on behalf of Medicare beneficiaries, covered part D drug prices for certain covered part D drugs, 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 “Medicare Fair Drug
5 Pricing Act of 2015”.

1 **SEC. 2. REQUIREMENT TO DETERMINE LOWER COVERED**
2 **PART D DRUG PRICES FOR CERTAIN COV-**
3 **ERED PART D DRUGS.**

4 (a) IN GENERAL.—Section 1860D–11(i) of the Social
5 Security Act (42 U.S.C. 1395w–111(i)) is amended—

6 (1) by striking “NONINTERFERENCE.—In” and
7 inserting the following:

8 “NONINTERFERENCE.—

9 “(1) IN GENERAL.—In”;

10 (2) by inserting “subject to paragraph (2),”
11 after “part,”; and

12 (3) by adding at the end the following new
13 paragraph:

14 “(2) EXCEPTION FOR SPECIFIED DRUGS.—

15 “(A) REQUIREMENT.—

16 “(i) IN GENERAL.—Notwithstanding
17 paragraph (1), the part D price for speci-
18 fied drugs shall be determined in accord-
19 ance with the process described in sub-
20 paragraph (B).

21 “(ii) SPECIFIED DRUGS.—For pur-
22 poses of this paragraph, the term ‘specified
23 drug’ means a covered part D drug—

24 “(I) that is—

25 “(aa) a single source drug
26 or biological;

1 “(bb) not a biological prod-
2 uct licensed pursuant to an appli-
3 cation under section 351(k) of
4 the Public Health Service Act;
5 and

6 “(cc) not both manufactured
7 by more than two drug manufac-
8 turers and manufactured by at
9 least one such manufacturer as a
10 generic drug; or

11 “(II) that—

12 “(aa) is selected by the Sec-
13 retary for purposes of this para-
14 graph; and

15 “(bb) the Secretary deter-
16 mines is a covered part D drug
17 with respect to which there is
18 limited ability for PDP sponsors
19 and MA organizations to nego-
20 tiate manufacturer rebates, such
21 that the Secretary determines
22 that the failure to apply this
23 paragraph will have a significant
24 fiscal impact on the program
25 under this title.

1 “(iii) PART D PRICE DEFINED.—For
2 purposes of this paragraph, the term ‘part
3 D price’ means, with respect to a covered
4 part D drug, the price (including dis-
5 counts, rebates, and other price conces-
6 sions) that may be charged to PDP spon-
7 sors and MA organizations for such drug
8 for part D eligible individuals who are en-
9 rolled under a prescription drug plan or
10 under an MA–PD plan.

11 “(iv) REGULATIONS FOR IDENTIFICA-
12 TION OF SPECIFIED DRUGS.—The Sec-
13 retary, not later than one year after the
14 date of the enactment of this paragraph,
15 shall promulgate regulations regarding the
16 identification of single source drugs and
17 biologicals as specified drugs.

18 “(v) PROCESS TO PETITION THAT
19 DRUG IS NO LONGER A SPECIFIED DRUG.—
20 The Secretary shall establish a process
21 under which a manufacturer for a specified
22 drug may petition the Secretary for the re-
23 scinding of a previous identification of a
24 drug as a specified drug under clause (ii)

1 based upon the drug involved no longer
2 being a specified drug.

3 “(B) PRICE DETERMINATION PROCESS.—

4 For purposes of subparagraph (A), the process
5 described in this subparagraph, with respect to
6 the part D price for a specified drug for a plan
7 year, is the following:

8 “(i) LIMITED PERIOD FOR NEGOTIA-
9 TION FOR FIRST PLAN YEAR.—

10 “(I) IN GENERAL.—The Sec-
11 retary shall negotiate such price with
12 the drug manufacturer involved for a
13 period of not more than 90 days be-
14 ginning on the date of identification
15 of the drug as a specified drug for
16 such plan year by the Secretary.

17 “(II) SUCCESSFUL NEGOTIA-
18 TIONS.—In the case that such nego-
19 tiation with respect to such 90-day pe-
20 riod results in a price that is agreed
21 to by both the Secretary and manu-
22 facturer, such price shall be the max-
23 imum part D price for such specified
24 drug through the end of the plan year
25 beginning after such period.

1 “(ii) SECRETARY SETS PRICE FOR
2 FIRST PLAN YEAR IN CASE OF FAILURE TO
3 NEGOTIATE PRICE.—In the case that nego-
4 tiations under clause (i), with respect to a
5 specified drug, do not result in a price for
6 such specified drug that is so agreed to by
7 the Secretary and drug manufacturer, the
8 Secretary shall determine a price for such
9 drug based on—

10 “(I) the information provided to
11 the Secretary by the drug manufac-
12 turer during the 90-day period de-
13 scribed in clause (i)(I) regarding costs
14 associated with such drug that are ap-
15 plicable with respect to such drug
16 manufacturer;

17 “(II) in the case that payment is
18 made for such drug by the Depart-
19 ment of Veterans Affairs or under
20 title XIX, the net priced paid for such
21 drug by such Department or under
22 such title, as applicable;

23 “(III) ensuring affordability of
24 such drug, and accessibility to such
25 drug, for individuals entitled to bene-

1 fits under part A or enrolled under
2 part B; and

3 “(IV) such other factors as the
4 Secretary determines appropriate.

5 The price determined under this clause
6 shall be the maximum part D price for
7 such specified drug through the end of the
8 plan year beginning after such determina-
9 tion of such price.

10 “(iii) PRICE IN SUBSEQUENT PLAN
11 YEARS.—For each plan year that is subse-
12 quent to the plan year for which a price is
13 determined for a specified drug under
14 clause (i) or (ii) and in which, on the first
15 day of such subsequent plan year, the iden-
16 tification of such drug as a specified drug
17 still applies, the maximum price for such
18 drug shall be the maximum part D price
19 for the previous year determined under
20 clause (i) or (ii), as applicable, increased
21 by the percentage increase in the consumer
22 price index for all urban consumers (all
23 items; U.S. city average) for the 12-month
24 period ending with June of the year before
25 such subsequent plan year.

1 “(iv) CONSULTATION.—In deter-
2 mining a price for a specified drug under
3 clause (ii), the Secretary may consult with
4 the Comptroller General, the Medicare
5 Payment Advisory Commission, the Med-
6 icaid and CHIP Payment and Access Com-
7 mission, or other outside, independent ex-
8 perts.

9 “(C) NO CHANGE IN RULES FOR
10 FORMULARIES.—

11 “(i) IN GENERAL.—Nothing in sub-
12 paragraph (A) or (B) shall be construed to
13 authorize the Secretary to establish or re-
14 quire a particular formulary.

15 “(ii) CONSTRUCTION.—Clause (i)
16 shall not be construed as affecting the Sec-
17 retary’s authority to ensure appropriate
18 and adequate access to covered part D
19 drugs under prescription drug plans and
20 under MA–PD plans, including compliance
21 of such plans with formulary requirements
22 under section 1860D–4(b)(3).

23 “(D) CONSTRUCTION.—Nothing in this
24 paragraph shall be construed as—

1 “(i) preventing the sponsor of a pre-
2 scription drug plan, or an organization of-
3 fering an MA–PD plan, from obtaining a
4 discount or reduction of the price for a
5 covered part D drug described in subpara-
6 graph (A) below the price negotiated under
7 such subparagraph or determined under
8 subparagraph (B); or

9 “(ii) permitting the Secretary to make
10 proprietary data available to the public.

11 “(E) DEFINITIONS.—In this paragraph:

12 “(i) DRUG MANUFACTURER.—The
13 term ‘drug manufacturer’ has the meaning
14 given the term ‘manufacturer’ in section
15 1860D–14A(g)(5).

16 “(ii) SINGLE SOURCE DRUG OR BIO-
17 LOGICAL.—The term ‘single source drug or
18 biological’ has the meaning given such
19 term in section 1847A(c)(6)(D).”.

20 (b) REQUIRING PARTICIPATION IN NEGOTIATION
21 PROCESS AS CONDITION OF PART D DRUG COVERAGE.—
22 Section 1860D–14A(b) of the Social Security Act (42
23 U.S.C. 1395w–114a(b)) is amended by adding at the end
24 the following new paragraph:

1 “(5) PARTICIPATION IN NEGOTIATION PROC-
2 ESS.—Each agreement under this subsection shall
3 include, with respect to plans years beginning with
4 plan year 2017, an agreement by the manufacturer,
5 with respect to each specified drug of such manufac-
6 turer under section 1860d–11(i)(2), to participate in
7 the negotiation process under such section for such
8 drug, including accepting the price resulting from
9 the negotiation (or, in the case that such negotiation
10 does not result in a price for such drug that is
11 agreed to by the Secretary and the manufacturer,
12 the price resulting from the application of subpara-
13 graph (B)(ii) of such section) as the maximum price
14 for such drug for the period provided under such
15 section.”.

16 **SEC. 3. STUDY AND REPORT.**

17 (a) STUDY.—The Secretary of Health and Human
18 Services shall conduct a study examining—

19 (1) the impact of the amendments made by sec-
20 tion 2 on—

21 (A) the cost of single source drugs and
22 biologicals (as defined in section
23 1847A(c)(6)(D) of the Social Security Act (42
24 U.S.C. 1395w–3a(c)(6)(D))) for which payment

1 is made under part B of title XVIII of such
2 Act; and

3 (B) the accessibility of such drugs and
4 biologicals for individuals entitled to benefits
5 under part A of such title or enrolled under
6 part B of such title; and

7 (2) options that would permit or require the
8 Secretary to create and implement, not later than
9 one year after the date of the report described in
10 subsection (b)—

11 (A) a method to apply to such single
12 source drugs and biologicals for which the Sec-
13 retary determines appropriate—

14 (i) an authority similar to the author-
15 ity granted to the Secretary under sub-
16 paragraph (A) of section 1860D–11(i)(2)
17 of such Act (relating to negotiating with
18 drug manufacturers the part D prices for
19 certain specified drugs); and

20 (ii) a negotiation process similar to
21 the process under subparagraph (B) of
22 such section; and

23 (B) a method, such as a rebate program,
24 to incorporate the rate negotiated for such
25 drugs and biologicals pursuant to the authority

1 described in subparagraph (A) into payments
2 for such drugs and biologicals under part B of
3 such Act.

4 (b) REPORT.—Not later than one year after the date
5 of the enactment of this Act, the Secretary of Health and
6 Human Services shall submit a report to Congress on the
7 results of the study conducted under subsection (a). Such
8 report shall include recommendations regarding the op-
9 tions examined pursuant to paragraph (2) of such sub-
10 section.