

115TH CONGRESS
2D SESSION

S. 2554

AN ACT

To ensure that health insurance issuers and group health plans do not prohibit pharmacy providers from providing certain information to enrollees.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Patient Right to Know
3 Drug Prices Act”.

4 **SEC. 2. PROHIBITION ON LIMITING CERTAIN INFORMATION**
5 **ON DRUG PRICES.**

6 Subpart II of part A of title XXVII of the Public
7 Health Service Act (42 U.S.C. 300gg–11 et seq.) is
8 amended by adding at the end the following:

9 **“SEC. 2729. INFORMATION ON PRESCRIPTION DRUGS.**

10 “(a) IN GENERAL.—A group health plan or a health
11 insurance issuer offering group or individual health insur-
12 ance coverage shall—

13 “(1) not restrict, directly or indirectly, any
14 pharmacy that dispenses a prescription drug to an
15 enrollee in the plan or coverage from informing (or
16 penalize such pharmacy for informing) an enrollee of
17 any differential between the enrollee’s out-of-pocket
18 cost under the plan or coverage with respect to ac-
19 quisition of the drug and the amount an individual
20 would pay for acquisition of the drug without using
21 any health plan or health insurance coverage; and

22 “(2) ensure that any entity that provides phar-
23 macy benefits management services under a contract
24 with any such health plan or health insurance cov-
25 erage does not, with respect to such plan or cov-
26 erage, restrict, directly or indirectly, a pharmacy

1 that dispenses a prescription drug from informing
2 (or penalize such pharmacy for informing) an en-
3 rollee of any differential between the enrollee’s out-
4 of-pocket cost under the plan or coverage with re-
5 spect to acquisition of the drug and the amount an
6 individual would pay for acquisition of the drug
7 without using any health plan or health insurance
8 coverage.

9 “(b) DEFINITION.—For purposes of this section, the
10 term ‘out-of-pocket cost’, with respect to acquisition of a
11 drug, means the amount to be paid by the enrollee under
12 the plan or coverage, including any cost-sharing (including
13 any deductible, copayment, or coinsurance) and, as deter-
14 mined by the Secretary, any other expenditure.”.

15 **SEC. 3. MODERNIZING THE REPORTING OF BIOLOGICAL**
16 **AND BIOSIMILAR PRODUCTS.**

17 Subtitle B of title XI of the Medicare Prescription
18 Drug, Improvement, and Modernization Act of 2003 (Pub-
19 lic Law 108–173) is amended—

20 (1) in section 1111—

21 (A) by redesignating paragraphs (3)
22 through (8) as paragraphs (6) through (11), re-
23 spectively;

24 (B) by inserting after paragraph (2) the
25 following:

1 “(3) BIOSIMILAR BIOLOGICAL PRODUCT.—The
2 term ‘biosimilar biological product’ means a biologi-
3 cal product for which an application under section
4 351(k) of the Public Health Service Act is approved.

5 “(4) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-
6 CANT.—The term ‘biosimilar biological product ap-
7 plicant’ means a person who has filed or received ap-
8 proval for a biosimilar biological product under sec-
9 tion 351(k) of the Public Health Service Act.

10 “(5) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-
11 CATION.—The term ‘biosimilar biological product ap-
12 plication’ means an application for licensure of a bi-
13 ological product under section 351(k) of the Public
14 Health Service Act.”;

15 (C) in paragraph (6), as so redesignated,
16 by inserting “, or a biological product for which
17 an application is approved under section 351(a)
18 of the Public Health Service Act” before the pe-
19 riod;

20 (D) in paragraph (7), as so redesignated—

21 (i) by striking “paragraph (3)” and
22 inserting “paragraph (6)”;

23 (ii) by inserting “or a reference prod-
24 uct in a biosimilar biological product appli-
25 cation” after “ANDA”; and

1 (iii) by inserting “or under section
2 351(a) of the Public Health Service Act”
3 before the period; and
4 (E) by adding at the end the following:

5 “(12) REFERENCE PRODUCT.—The term ‘ref-
6 erence product’ means a brand name drug for which
7 a license is in effect under section 351(a) of the
8 Public Health Service Act.”;

9 (2) in section 1112—

10 (A) in subsection (a)—

11 (i) in paragraph (1)—

12 (I) by inserting “or a biosimilar
13 biological product applicant who has
14 submitted a biosimilar biological prod-
15 uct application for which a statement
16 under section 351(l)(3)(B)(ii)(I) of
17 the Public Health Service Act has
18 been provided” after “Federal Food,
19 Drug, and Cosmetic Act”; and

20 (II) by inserting “or the bio-
21 similar biological product that is the
22 subject of the biosimilar biological
23 product application, as applicable”
24 after “the ANDA”; and

25 (ii) in paragraph (2)—

1 (I) in the matter preceding sub-
2 paragraph (A), by inserting “or a bio-
3 similar biological product applicant”
4 after “generic drug applicant”;

5 (II) in subparagraph (A)—

6 (aa) by striking “mar-
7 keting” and inserting “mar-
8 keting,”; and

9 (bb) by inserting “or the
10 reference product in the bio-
11 similar biological product applica-
12 tion” before “involved”;

13 (III) in subparagraph (B), by in-
14 serting “or of the biosimilar biological
15 product for which the biosimilar bio-
16 logical product application was sub-
17 mitted” after “submitted”; and

18 (IV) by amending subparagraph
19 (C) to read as follows:

20 “(C) as applicable—

21 “(i) the 180-day period referred to in
22 section 505(j)(5)(B)(iv) of the Federal
23 Food, Drug, and Cosmetic Act as it applies
24 to such ANDA or to any other ANDA
25 based on the same brand name drug; or

1 “(ii) the 1-year period referred to in
2 section 351(k)(6)(A) of the Public Health
3 Service Act as it applies to such biosimilar
4 biological product application or to any
5 other biosimilar biological product applica-
6 tion based on the same brand name
7 drug.”; and

8 (B) in subsection (b)—

9 (i) by amending paragraph (1) to read
10 as follows:

11 “(1) REQUIREMENT.—

12 “(A) GENERIC DRUGS.—A generic drug
13 applicant that has submitted an ANDA con-
14 taining a certification under section
15 505(j)(2)(A)(vii)(IV) of the Federal Food,
16 Drug, and Cosmetic Act with respect to a listed
17 drug and another generic drug applicant that
18 has submitted an ANDA containing such a cer-
19 tification for the same listed drug shall each file
20 the agreement in accordance with subsection
21 (c). The agreement shall be filed prior to the
22 date of the first commercial marketing of either
23 of the generic drugs for which such ANDAs
24 were submitted.

1 “(B) BIOSIMILAR BIOLOGICAL PROD-
2 UCTS.—A biosimilar biological product appli-
3 cant that has submitted a biosimilar biological
4 product application for which a statement
5 under section 351(l)(3)(B)(ii)(I) of the Public
6 Health Service Act has been provided with re-
7 spect to a reference product and another bio-
8 similar biological product applicant that has
9 submitted a biosimilar biological product appli-
10 cation for which such a statement for the same
11 reference product has been provided shall each
12 file the agreement in accordance with sub-
13 section (c). The agreement shall be filed prior
14 to the date of the first commercial marketing of
15 either of the biosimilar biological products for
16 which such biosimilar biological product appli-
17 cations were submitted.”; and

18 (ii) in paragraph (2)—

19 (I) by striking “between two ge-
20 neric drug applicants is an agree-
21 ment” and inserting “is, as applicable,
22 an agreement between 2 generic drug
23 applicants”; and

24 (II) by inserting “, or an agree-
25 ment between 2 biosimilar biological

1 product applicants regarding the 1-
2 year period referred to in section
3 351(k)(6)(A) of the Public Health
4 Service Act as it applies to the bio-
5 similar biological product applications
6 with which the agreement is con-
7 cerned” before the period;

8 (3) in section 1115, by striking “or generic
9 drug applicant” each place such term appears and
10 inserting “, generic drug applicant, or biosimilar bio-
11 logical product applicant”; and

12 (4) in section 1117, by striking “, or any agree-
13 ment between generic drug applicants” and inserting
14 “or a biosimilar biological product applicant, any
15 agreement between generic drug applicants, or any
16 agreement between biosimilar biological product ap-
17 plicants”.

Passed the Senate September 17, 2018.

Attest:

Secretary.

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