

115TH CONGRESS  
2D SESSION

# S. 2554

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## 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.*

115<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

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**AN ACT**

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