

**Calendar No. 549**115TH CONGRESS  
2D SESSION**S. 2554**

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

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## IN THE SENATE OF THE UNITED STATES

MARCH 14, 2018

Ms. COLLINS (for herself, Mrs. McCASKILL, Mr. BARRASSO, Ms. STABENOW, Mr. CASSIDY, Ms. SMITH, Mr. DONNELLY, Mrs. FEINSTEIN, Ms. MURKOWSKI, Mr. MENENDEZ, Ms. BALDWIN, Mr. KENNEDY, Ms. HASSAN, and Mr. BLUMENTHAL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JULY 31, 2018

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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**A BILL**

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 (a) **EXCHANGE PLANS.**—Section 1311(e) of the Pa-  
7 tient Protection and Affordable Care Act (42 U.S.C.  
8 18031(e)) is amended by adding at the end the following:

9 “(4) **INFORMATION ON PRESCRIPTION**  
10 **DRUGS.**—The Exchange shall require health plans  
11 seeking certification as qualified health plans to en-  
12 sure that—

13 “(A) the health insurance issuer does not  
14 restrict any pharmacy that dispenses a pre-  
15 scription drug to an enrollee in the plan from  
16 informing (or penalize such pharmacy for in-  
17 forming) an enrollee of any differential between  
18 the price of the drug to the enrollee under the  
19 plan and the price the individual would pay for  
20 the drug if the enrollee obtained the drug with-  
21 out using any health insurance coverage; and

22 “(B) any entity that provides pharmacy  
23 benefits management services under a contract  
24 with any such health plan does not, with re-  
25 spect to such plan or any health benefits plan  
26 that the entity contracts with to provide phar-



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

2       “(a) *IN GENERAL.*—A group health plan or a health  
3 insurance issuer offering group or individual health insur-  
4 ance coverage shall—

5               “(1) not restrict, directly or indirectly, any  
6 pharmacy that dispenses a prescription drug to an  
7 enrollee in the plan or coverage from informing (or  
8 penalize such pharmacy for informing) an enrollee of  
9 any differential between the enrollee’s out-of-pocket  
10 cost under the plan or coverage with respect to acqui-  
11 sition of the drug and the amount an individual  
12 would pay for acquisition of the drug without using  
13 any health plan or health insurance coverage; and

14               “(2) ensure that any entity that provides phar-  
15 macy benefits management services under a contract  
16 with any such health plan or health insurance cov-  
17 erage does not, with respect to such plan or coverage,  
18 restrict, directly or indirectly, a pharmacy that dis-  
19 penses a prescription drug from informing (or penal-  
20 ize such pharmacy for informing) an enrollee of any  
21 differential between the enrollee’s out-of-pocket cost  
22 under the plan or coverage with respect to acquisition  
23 of the drug and the amount an individual would pay  
24 for acquisition of the drug without using any health  
25 plan or health insurance coverage.

1       “(b) *DEFINITION.*—For purposes of this section, the  
 2 term ‘out-of-pocket cost’, with respect to acquisition of a  
 3 drug, means the amount to be paid by the enrollee under  
 4 the plan or coverage, including any cost-sharing (including  
 5 any deductible, copayment, or coinsurance) and, as deter-  
 6 mined by the Secretary, any other expenditure.”.

7 **SEC. 3. MODERNIZING THE REPORTING OF BIOLOGICAL**  
 8 **AND BIOSIMILAR PRODUCTS.**

9       *Subtitle B of title XI of the Medicare Prescription*  
 10 *Drug, Improvement, and Modernization Act of 2003 (Public*  
 11 *Law 108–173) is amended—*

12               (1) *in section 1111—*

13                       (A) *by redesignating paragraphs (3)*  
 14 *through (8) as paragraphs (6) through (11), re-*  
 15 *spectively;*

16                       (B) *by inserting after paragraph (2) the fol-*  
 17 *lowing:*

18               “(3) *BIOSIMILAR BIOLOGICAL PRODUCT.*—*The*  
 19 *term ‘biosimilar biological product’ means a biologi-*  
 20 *cal product for which an application under section*  
 21 *351(k) of the Public Health Service Act is approved.*

22               “(4) *BIOSIMILAR BIOLOGICAL PRODUCT APPLI-*  
 23 *CANT.*—*The term ‘biosimilar biological product appli-*  
 24 *cant’ means a person who has filed or received ap-*

1 *proval for a biosimilar biological product under sec-*  
 2 *tion 351(k) of the Public Health Service Act.*

3 *“(5) BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-*  
 4 *TION.—The term ‘biosimilar biological product appli-*  
 5 *cation’ means an application for licensure of a bio-*  
 6 *logical product under section 351(k) of the Public*  
 7 *Health Service Act.”;*

8 *(C) in paragraph (6), as so redesignated, by*  
 9 *inserting “, or a biological product for which an*  
 10 *application is approved under section 351(a) of*  
 11 *the Public Health Service Act” before the period;*

12 *(D) in paragraph (7), as so redesignated—*

13 *(i) by striking “paragraph (3)” and*  
 14 *inserting “paragraph (6)”;*

15 *(ii) by inserting “or a reference prod-*  
 16 *uct in a biosimilar biological product appli-*  
 17 *cation” after “ANDA”; and*

18 *(iii) by inserting “or under section*  
 19 *351(a) of the Public Health Service Act” be-*  
 20 *fore the period; and*

21 *(E) by adding at the end the following:*

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

1           (2) *in section 1112—*

2                   (A) *in subsection (a)—*

3                           (i) *in paragraph (1)—*

4                                   (I) *by inserting “or a biosimilar*  
5 *biological product applicant who has*  
6 *submitted a biosimilar biological prod-*  
7 *uct application for which a statement*  
8 *under section 351(l)(3)(B)(ii)(I) of the*  
9 *Public Health Service Act has been*  
10 *provided” after “Federal Food, Drug,*  
11 *and Cosmetic Act”; and*

12                                   (II) *by inserting “or the bio-*  
13 *similar biological product that is the*  
14 *subject of the biosimilar biological*  
15 *product application, as applicable”*  
16 *after “the ANDA”; and*

17                           (ii) *in paragraph (2)—*

18                                   (I) *in the matter preceding sub-*  
19 *paragraph (A), by inserting “or a bio-*  
20 *similar biological product applicant”*  
21 *after “generic drug applicant”;*

22                                   (II) *in subparagraph (A)—*

23   (aa) *by striking “marketing”*  
24 *and inserting “marketing,”; and*

1                   (bb) by inserting “or the ref-  
2                   erence product in the biosimilar  
3                   biological product application”  
4                   before “involved”;

5                   (III) in subparagraph (B), by in-  
6                   serting “or of the biosimilar biological  
7                   product for which the biosimilar bio-  
8                   logical product application was sub-  
9                   mitted” after “submitted”; and

10                  (IV) by amending subparagraph  
11                  (C) to read as follows:

12                  “(C) as applicable—

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

18                         “(ii) the 1-year period referred to in  
19                         section 351(k)(6)(A) of the Public Health  
20                         Service Act as it applies to such biosimilar  
21                         biological product application or to any  
22                         other biosimilar biological product applica-  
23                         tion based on the same brand name drug.”;  
24                         and

25                  (B) in subsection (b)—

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

3                   “(1) *REQUIREMENT.*—

4                   “(A) *GENERIC DRUGS.*—A generic drug ap-  
5                   plicant that has submitted an ANDA containing  
6                   a certification under section  
7                   505(j)(2)(A)(vii)(IV) of the Federal Food, Drug,  
8                   and Cosmetic Act with respect to a listed drug  
9                   and another generic drug applicant that has sub-  
10                  mitted an ANDA containing such a certification  
11                  for the same listed drug shall each file the agree-  
12                  ment in accordance with subsection (c). The  
13                  agreement shall be filed prior to the date of the  
14                  first commercial marketing of either of the ge-  
15                  neric drugs for which such ANDAs were sub-  
16                  mitted.

17                  “(B) *BIOSIMILAR BIOLOGICAL PRODUCTS.*—  
18                  A biosimilar biological product applicant that  
19                  has submitted a biosimilar biological product  
20                  application for which a statement under section  
21                  351(l)(3)(B)(ii)(I) of the Public Health Service  
22                  Act has been provided with respect to a reference  
23                  product and another biosimilar biological prod-  
24                  uct applicant that has submitted a biosimilar bi-  
25                  ological product application for which such a

1 *statement for the same reference product has been*  
2 *provided shall each file the agreement in accord-*  
3 *ance with subsection (c). The agreement shall be*  
4 *filed prior to the date of the first commercial*  
5 *marketing of either of the biosimilar biological*  
6 *products for which such biosimilar biological*  
7 *product applications were submitted.”; and*

8 *(ii) in paragraph (2)—*

9 *(I) by striking “between two ge-*  
10 *neric drug applicants is an agreement”*  
11 *and inserting “is, as applicable, an*  
12 *agreement between 2 generic drug ap-*  
13 *plicants”;* and

14 *(II) by inserting “, or an agree-*  
15 *ment between 2 biosimilar biological*  
16 *product applicants regarding the 1-*  
17 *year period referred to in section*  
18 *351(k)(6)(A) of the Public Health Serv-*  
19 *ice Act as it applies to the biosimilar*  
20 *biological product applications with*  
21 *which the agreement is concerned” be-*  
22 *fore the period;*

23 *(3) in section 1115, by striking “or generic drug*  
24 *applicant” each place such term appears and insert-*

1        *ing “, generic drug applicant, or biosimilar biological*  
2        *product applicant”*; and

3                *(4) in section 1117, by striking “, or any agree-*  
4        *ment between generic drug applicants” and inserting*  
5        *“or a biosimilar biological product applicant, any*  
6        *agreement between generic drug applicants, or any*  
7        *agreement between biosimilar biological product ap-*  
8        *plicants”.*

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