PUBLIC LAW 115–263—OCT. 10, 2018

PATIENT RIGHT TO KNOW DRUG PRICES ACT

Public Law 115–263
115th Congress

An Act

Oct. 10, 2018
[S. 2554]

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Patient Right to Know Drug Prices Act.
42 USC 201 note.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Patient Right to Know Drug Prices Act".

SEC. 2. PROHIBITION ON LIMITING CERTAIN INFORMATION ON DRUG PRICES.

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

42 USC 300gg–19b.

"SEC. 2729. INFORMATION ON PRESCRIPTION DRUGS.

"(a) IN GENERAL.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall—

"(1) not restrict, directly or indirectly, any pharmacy that dispenses a prescription drug to an enrollee in the plan or coverage from informing (or penalize such pharmacy for informing) an enrollee of any differential between the enrollee's out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage; and

"(2) ensure that any entity that provides pharmacy benefits management services under a contract with any such health plan or health insurance coverage does not, with respect to such plan or coverage, restrict, directly or indirectly, a pharmacy that dispenses a prescription drug from informing (or penalize such pharmacy for informing) an enrollee of any differential between the enrollee's out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage.

Determination.

"(b) DEFINITION.—For purposes of this section, the term 'out-of-pocket cost', with respect to acquisition of a drug, means the amount to be paid by the enrollee under the plan or coverage, including any cost-sharing (including any deductible, copayment, or coinsurance) and, as determined by the Secretary, any other expenditure.".

SEC. 3. MODERNIZING THE REPORTING OF BIOLOGICAL AND BIOSIMILAR PRODUCTS. 21 USC 355.

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

(1) in section 1111—

(A) by redesignating paragraphs (3) through (8) as paragraphs (6) through (11), respectively;

(B) by inserting after paragraph (2) the following: Definitions.

"(3) BIOSIMILAR BIOLOGICAL PRODUCT.—The term 'biosimilar biological product' means a biological product for which an application under section 351(k) of the Public Health Service Act is approved.

"(4) BIOSIMILAR BIOLOGICAL PRODUCT APPLICANT.—The term 'biosimilar biological product applicant' means a person who has filed or received approval for a biosimilar biological product under section 351(k) of the Public Health Service Act.

"(5) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION.—The term 'biosimilar biological product application' means an application for licensure of a biological product under section 351(k) of the Public Health Service Act.";

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

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

(i) by striking "paragraph (3)" and inserting "paragraph (6)";

(ii) by inserting "or a reference product in a biosimilar biological product application" after "ANDA"; and

(iii) by inserting "or under section 351(a) of the Public Health Service Act" before the period; and

(E) by adding at the end the following:

"(12) REFERENCE PRODUCT.—The term 'reference product' means a brand name drug for which a license is in effect under section 351(a) of the Public Health Service Act."; Definitions.

(2) in section 1112—

(A) in subsection (a)—

(i) in paragraph (1)—

(I) by inserting "or a biosimilar biological product applicant who has submitted a biosimilar biological product application for which a statement under section 351(l)(3)(B)(ii)(I) of the Public Health Service Act has been provided" after "Federal Food, Drug, and Cosmetic Act"; and

(II) by inserting "or the biosimilar biological product that is the subject of the biosimilar biological product application, as applicable" after "the ANDA"; and

(ii) in paragraph (2)—

(I) in the matter preceding subparagraph (A), by inserting "or a biosimilar biological product applicant" after "generic drug applicant";

(II) in subparagraph (A)—

(aa) by striking "marketing" and inserting "marketing,"; and

(bb) by inserting "or the reference product in the biosimilar biological product application" before "involved";

(III) in subparagraph (B), by inserting "or of the biosimilar biological product for which the biosimilar biological product application was submitted" after "submitted"; and

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

Time periods.

"(C) as applicable—

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

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

(B) in subsection (b)—

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

"(1) REQUIREMENT.—

"(A) GENERIC DRUGS.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act with respect to a listed drug and another generic drug applicant that has submitted an ANDA containing such a certification for the same listed drug shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of either of the generic drugs for which such ANDAs were submitted.

"(B) BIOSIMILAR BIOLOGICAL PRODUCTS.—A biosimilar biological product applicant that has submitted a biosimilar biological product application for which a statement under section 351(l)(3)(B)(ii)(I) of the Public Health Service Act has been provided with respect to a reference product and another biosimilar biological product applicant that has submitted a biosimilar biological product application for which such a statement for the same reference product has been provided shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of either of the biosimilar biological products for which such biosimilar biological product applications were submitted."; and

(ii) in paragraph (2)—

(I) by striking "between two generic drug applicants is an agreement" and inserting "is, as applicable, an agreement between 2 generic drug applicants"; and

(II) by inserting ", or an agreement between 2 biosimilar biological product applicants regarding the 1-year period referred to in section 351(k)(6)(A) of the Public Health Service Act as it applies to the biosimilar biological product applications with

which the agreement is concerned" before the period;

(3) in section 1115, by striking "or generic drug applicant" each place such term appears and inserting ", generic drug applicant, or biosimilar biological product applicant"; and

(4) in section 1117, by striking ", or any agreement between generic drug applicants" and inserting "or a biosimilar biological product applicant, any agreement between generic drug applicants, or any agreement between biosimilar biological product applicants".

Approved October 10, 2018.

LEGISLATIVE HISTORY—S. 2554:

CONGRESSIONAL RECORD, Vol. 164 (2018):
Sept. 17, considered and passed Senate.
Sept. 25, considered and passed House.
DAILY COMPILATION OF PRESIDENTIAL DOCUMENTS (2018):
Oct. 10, Presidential remarks.

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