ENGROSSED ORIGINAL

A BILL

23-430

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

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To amend the District of Columbia Prescription Drug Price Information Act to authorize licensed pharmacists to dispense interchangeable biological products, and to require notifications to physicians when interchangeable biological products are dispensed with certain exceptions.

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, That this act may be cited as the "Access to Biosimilars Amendment Act of 2020".

Sec. 2. The District of Columbia Prescription Drug Price Information Act, effective September 10, 1976 (D.C. Law 1-81; D.C. Official Code § 48-801.01 *et seq.*), is amended as follows:

(a) Section 2 (D.C. Official Code § 48-804.51) is amended by adding new paragraphs (1A) and (2A) to read as follows:

"(1A) "Biological product" shall have the same meaning as provided in 42 U.S.C. § 262.

"(2A) "Interchangeable biological product" means a biological product that is:

"(A) Licensed and determined by the United States Food and Drug Administration to meet the standards for interchangeability under 42 U.S.C. § 262(k)(4); or

"(B) Determined to be biosimilar or interchangeable with a reference biological product as stated in the latest edition of or supplement to the United States and Food and Drug administration's ("FDA") publication, "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations" (known as the Purple Book)."

(b) Section 301 (D.C. Official Code § 48-803.01) is amended by adding a new subsection (d) to read as follows:

"(d) The Boards of Pharmacy and Medicine shall maintain a link on their websites to the current list of biological products determined by the FDA to be interchangeable with a specific biological product.".

(c) Section 302 (D.C. Official Code § 48-803.02) is amended as follows:

(1) The section heading is amended to read as follows:

"Sec. 302. Dispensing of generically equivalent drug product or interchangeable biological product.".

(2) Subsection (a) is amended by striking the phrase "generically equivalent drug product" wherever it appears and inserting the phrase "generically equivalent drug product or interchangeable biological product" in its place.

(3) Subsection (b) is amended by striking the phrase "drug by generic name" and inserting the phrase "drug by generic name or interchangeable biological product" in its place.

(d) Section 303(2) (D.C. Official Code § 48-803.03(2)) is amended by striking the phrase "generically equivalent drug product" and inserting the phrase "generically equivalent drug product or interchangeable biological product" in its place.

(e) Section 303a(a) (D.C. Official Code § 48-803.03a(a)) is amended by striking the phrase "drug substitution" and inserting the phrase "drug substitution, including an interchangeable biological product," in its place.

(f) Section 304 (D.C. Official Code § 48-803.04) is amended by striking the phrase "substituted under this title," and inserting the phrase "substituted under this title, including the substitution of an interchangeable biological product," in its place.

(g) Section 305 (D.C. Official Code § 48-803.05) is amended as follows:

(1) Subsection (a) is amended by striking the phrase "under this title" and inserting the phrase "under this title, including the substitution of an interchangeable biological product" in its place.

(2) Subsection (b) is amended by striking the phrase "generically equivalent drug products drugs" and inserting the phrase "generically equivalent drugs products or an interchangeable biological product" in its place.

(h) A new section 306 is added to read as follows:

"Sec. 306. Pharmacist notification to prescriber of substitution of interchangeable biological product.

"(a) Within 5 business days after dispensing a biological product to a patient, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific biological product dispensed, including the name and manufacturer of the biological product; except, that this communication shall not be required if the FDA has not approved an interchangeable biological product for the biological product prescribed to the patient or a refill prescription is not changed from the biological product dispensed on the most recent filling of the prescription.

"(b)(1) Except as provided under subsection (c) of this section, the communication required under subsection (a) of this section shall be provided by making an entry that is electronically accessible to the health care provider through:

"(A) An interoperable electronic medical records system;

"(B) An electronic prescribing technology; or

"(C) A pharmacy benefits management system.

"(2) Making an entry through a mechanism listed in paragraph (1) of this subsection is presumed to provide the communication to the prescriber required under subsection (a) of this section.

"(c) If the mechanisms listed in subsection (b)(1) of this section are unavailable, the communication required under subsection (a) of this section may be provided by facsimile, telephone, electronic transmission, or other means.

"(d) The requirements under subsections (a) through (c) above shall not apply to dispensing pharmacists or their designees at a health maintenance organization that operates as a group model for services furnished through internal pharmacy operations for members and patients of the health maintenance organization.".

Sec. 3. Fiscal impact statement.

The Council adopts the fiscal impact statement in the committee report as the fiscal impact statement required by section 4a of the General Legislative Procedures Act of 1975, approved October 16, 2006 (120 Stat. 2038; D.C. Official Code § 1-301.47a).

Sec. 4. Effective date.

This act shall take effect following approval by the Mayor (or in the event of veto by the Mayor, action by the Council to override the veto), a 30-day period of congressional review as provided in section 602(c)(l) of the District of Columbia Home Rule Act, approved December 24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(l)), and publication in the District of Columbia Register.