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HOUSE . . . . . No. 3734

The Commonwealth of Massachusetts

In the Year Two Thousand Thirteen

An Act relative to the substitution of interchangeable biosimilars.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1 Section 1 of chapter 6D, as appearing in the 2012 Official Edition of the General Laws, is hereby amended in line 116 by inserting after the word "psychiatric," the following word:- pharmaceutical,

SECTION 2 Section 1 of said chapter 6D, as so appearing, is hereby further amended by striking out in line 211 the word "services." and inserting in place thereof the following words:- services, including pharmacy services.

SECTION 3 Section 1 of chapter 12C of the General Laws as so appearing, is hereby amended by striking out in line 210 the word "services." and inserting in place thereof the following words:- services, including pharmacy services.

SECTION 4 Chapter 112 of the General Laws as so appearing, is here by amended by inserting after Section 12DD the following new section:-

Section 12D ½ . Biosimilar products.-

(a). As used in this section, the following words shall have the following meanings:

"Biological product", means a virus, therapeutic serum, toxin, antitoxin, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings

“Biosimilar” or “Biosimilarity‘’, means a biological product that is highly similar to the prescribed biologic product and is the subject of

an approved application under subsection (k) of 42 U.S.C. 262 or subsection (b)(2) of 21 U.S.C. 355,

“Department”, the department of public health.

“Interchangeable biological product”, means a prescription biological product that has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed brand name biological product pursuant to Section 351 of the Public Health Service Act (42 U.S.C. 262)or that has been approved under21 U.S.C. 355 (b)(2) and determined by the fda to be therapeutically equivalent to the prescribed brand name Biological product.

“Practitioner”, a physician, dentist, veterinarian, podiatrist, scientific investigator or other person registered to distribute, dispense, conduct research with respect to, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in the commonwealth.

“Prescription”, with respect to a biological product, means an order for a product

that is subject to Section 503(b) of the Federal Food, Drug and Cosmetic Act (21

U.S.C. 353(b)).

(b). A biosimilar product determined to be interchangeable by the United

States Food and Drug Administration (FDA) shall be available for substitution in the

Commonwealth, in accordance with the provisions of this Act, Chapter 94 of the General Laws and any other applicable laws.

(c). Except as provided in subsection (d), a pharmacist filling a prescription

for a biological product prescribed by its trade or brand name may substitute any biosimilar

product that the FDA has determined to be interchangeable with the prescribed product.

(d). The pharmacist shall not substitute a biosimilar product that is

interchangeable with the prescribed product if the prescriber instructs otherwise, either orally or

in writing, pursuant to this section. Such instruction shall be on a patient-specific basis.

(e). No additional restrictions, limitations or requirements shall be imposed

related to biological product substitution unless such restrictions, limitations or requirements also

apply in the case of all other drug product substitution

(f). Within a reasonable time following any substitution, the dispensing pharmacist or the pharmacist's designee shall notify the prescribing practitioner of the substitution. Said notification shall not be required until full interoperability of electronic health records systems is reached, pursuant to section 7 of chapter 118I as inserted by section 134 of chapter 224 of the acts of 2012. Entry of the substitution in the patient's electronic health record shall constitute notification

(g). Following any substitution, the dispensing pharmacist or the pharmacist's designee shall notify the patient, or the patients authorized representative, of the substitution. Such notification shall be written and may be conveyed by, facsimile, electronic transmission, a notation in the patients record system shared with the prescriber, or other means consistent with prevailing pharmacy practice in accordance with section 12D of Chapter 112 of Massachusetts General Law

(h). Upon full interoperability of electronic health records systems, pursuant to section 7 of chapter 118I as inserted by section 134 of Chapter 224 of the Acts of 2012, the dispensing pharmacist or the pharmacist's designee, the prescribing provider and administering practitioner shall retain a record of any substitution for no less than one year from the date of the last entry in the profile record, of any interchangeable biological product dispensed on the patient's electronic health record. Entry in the electronic health record shall constitute retention of record. Nothing in this subsection shall limit the application of the Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Departments as promulgated by the board of registration in pharmacy.

SECTION 5 Section 1 of chapter 118I of the General Laws, as so appearing, is hereby amended by inserting after the ninth paragraph the following paragraph:- "Provider", any person, corporation, partnership, governmental unit, state institution or any other entity qualified under the laws of the commonwealth to perform or provide health care services, including pharmacy services.