H 3734

Chapter 143

THE COMMONWEALTH OF MASSACHUSETTS

In the Year Two Thousand and Fourteen

AN ACT RELATIVE TO THE SUBSTITUTION OF BIOSIMILARS.

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

Chapter 112 of the General Laws is hereby amended by inserting after Section 12DD the following section:-

Section 12EE. (a) As used in this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"Biological product" a virus; therapeutic serum; toxin; antitoxin; vaccine; 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.

"Department", the department of public health.

"Interchangeable biological product", a prescription biological product (i) that has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed brand name biological product pursuant to 42 U.S.C. § 262 or (ii) for which an application has been approved under subsection 21 U.S.C. § 355 (b)(2) and which has been determined by the United States Food and Drug Administration to be biosimilar and interchangeable with the prescribed brand name biological product. For the purposes of this definition the terms "biosimilar" and "interchangeable" shall have the same meaning as defined in section 351 of the Public Health Service Act, 42 U.S.C. §262.

"Practitioner", shall have the same meaning as defined in section 1 of chapter 94C.

"Written prescription", shall have the same meaning as defined in section 1 of chapter 94C.

(b) Except as provided in subsection (c), a pharmacist filling a prescription for a biological product prescribed by its trade or brand name may substitute an interchangeable biological product.

(c) A pharmacist shall not substitute an interchangeable biological product if the prescriber instructs otherwise in writing. The instruction shall be on a patient-specific basis.

(d) Within a reasonable time following any such substitution, the dispensing pharmacist or the pharmacist's designee shall notify the prescribing practitioner of the substitution. The notification shall be

conveyed by a notation in the interoperable electronic health record of the patient, as defined by section 1 of chapter 118I.

If the pharmacist does not have the ability to make a notation in the patient's interoperable electronic health record, then the notification shall be conveyed by facsimile, electronic transmission or by making a notation in the patient's record maintained by the pharmacy, which is accessible to the practitioner by request.

A pharmacist who utilizes an interoperable electronic prescribing technology shall enter the substitution into the patient's electronic health record.

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

(f) The dispensing pharmacist or the pharmacist's designee, the prescribing provider and administering practitioner shall retain a record of each substitution, for not less than 1 year from the date of the last entry in the profile record, of an interchangeable biological product dispensed. 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.

(g) In the event of noncompliance by a pharmacist or a practitioner, the purchaser or patient may inform the director of consumer affairs and business regulation of such noncompliance, as provided in subsection 12D of chapter 112.

(h) The department may promulgate regulations for implementation and enforcement of this section.

House of Representatives, June 19, 2014.

Passed to be enacted,

Paul J. Donato, Acting Speaker.

In Senate, June 19, 2014.

Passed to be enacted,

Richard T. Moore, Acting President.

23 June, 2014.

Approved,

Governor.