Sen. Bradley, Dist 3
Sen. Innis, Dist 24
May 2, 2018
2018-1875s
01/10

Floor Amendment to HB 1791-FN

Amend the title of the bill by replacing it with the following:

AN ACT allowing pharmacists to disclose information relative to lower cost drugs under the managed care law and relative to biological products dispensed by pharmacists.

Amend the bill by replacing all after section 1 with the following:

2 Prescription Labels. Amend RSA 318:47-a to read as follows:

318:47-a Prescription Labels. Whenever a pharmacist dispenses a noncontrolled drug pursuant to a prescription, he ***or she*** shall affix to the container in which such drug is dispensed a label showing at least the name and address of the pharmacy and the name or initials of the dispensing pharmacist or pharmacist-in-charge; the prescription identification number assigned by the pharmacy; the date dispensed; any directions as may be stated on the prescription; the name of the prescribing practitioner; the name of the patient; all pertinent auxiliary labels; and, unless otherwise indicated by the prescribing physician, dentist, veterinarian, or advanced practice registered nurse, the name, strength, and quantity of the drug dispensed. All drugs dispensed to a patient that have been filled using a centralized prescription processing system shall bear a label containing an identifiable code that provides a complete audit trail of the dispensing of the drug and pharmaceutical care activities. ***A biological product, as defined in RSA 318:47-dd, I, shall also be labeled as provided in RSA 318:47-dd, VII.*** No person shall alter, deface, or remove any label so affixed. A compounded drug product shall also be labeled as provided in RSA 318:14-a, II. The compound drug product shall bear the label of the pharmacy responsible for compounding and dispensing the product directly to the patient for administration, and the prescription shall be filed at that pharmacy. Compounded prescription labels shall include the phrase "compounded per subscriber request" or a similar statement on the prescription label or through the use of an auxiliary label attached to the prescription container.

3 Substituting Generic Drugs. Amend RSA 318:47-d to read as follows:

318:47-d Pharmacies; Substituting Generic Drugs. Pharmacies, including mail-order pharmacies, may substitute generically equivalent drug products for all legend and non-legend prescriptions unless the prescribing practitioner handwrites "medically necessary" on each paper prescription, or uses electronic indications when transmitted electronically, or gives instructions when transmitted orally that the brand name drug product is medically necessary. ***In this section,***

"drug product" does not include a biological product.

4 New Section; Substituting Biological Products. Amend RSA 318 by inserting after section 47-d the following new section:

318:47-dd Pharmacies; Substituting Biological Products.

I. In this section:

(a) "Biological product" means 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.

(b) "Proper name" means the nonproprietary name for a biological product designated by the federal Food and Drug Administration license for use upon each package of the product.

(c) "Interchangeable biological product" means a biological product that the federal Food and Drug Administration:

(1) Has licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. section 262(k)(4); or

(2) Has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations.

II. The board shall maintain a link on its website to the federal Food and Drug Administration's Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations.

III. A pharmacist may substitute a biological product pursuant to this section only if it has been licensed by the federal Food and Drug Administration as an interchangeable biological product for the prescribed biological product.

IV. When a pharmacist dispenses an interchangeable biological product for the prescribed biological product, the pharmacist or his or her designee shall inform the patient.

V. A pharmacist shall not substitute an interchangeable biological product pursuant to this section if the prescriber indicates that substitution is not authorized by specifying on the prescription "medically necessary" on a paper prescription, or uses electronic indications when transmitted electronically, or gives instructions when transmitted orally that the biological product prescribed is medically necessary.

VI.(a) Within 3 business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through:

(1) An interoperable electronic medical records system;

(2) An electronic prescribing technology; or

(3) A pharmacy benefit management system; or

(4) A pharmacy record.

(b) Entry into an electronic records system as described in this paragraph is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that the communication shall not be required where:

(1) There is no federal Food and Drug Administration-approved interchangeable biological product for the biological product prescribed; or

(2) A refill prescription is not changed from product dispensed on the prior filling of the prescription.

VII. The label of all biological products dispensed by a pharmacist shall include the proper name and the name of the manufacturer of the product.

5 New Section; Physicians and Surgeons; Annual Education Program. Amend RSA 329 by inserting after section 9-f the following new section:

329:9-g Annual Education Program. The board, in conjunction with the New Hampshire Medical Society and other prescribing and dispensing stakeholders, shall establish an annual education program that covers the prescribing of biosimilar and interchangeable biological products. Such program shall include a review of interchangeable biological products approved by the federal Food and Drug Administration (FDA) including any evaluation information in determining interchangeability. The annual education program shall be implemented by December 31, 2018 or prior to the first interchangeable biological product being approved by the FDA.

6 Effective Date.

I. Section 5 of this act shall take effect upon its passage.

II. The remainder of this act shall take effect January 1, 2019.

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AMENDED ANALYSIS

This bill declares that a contract between an insurance carrier or pharmacy benefit manager and a contracted pharmacy shall not contain a provision prohibiting the pharmacist from providing certain information to an insured or the insurance department.

This bill also establishes requirements for dispensing and substituting biological products by pharmacists and establishes an annual education program relative to biological products.