PA 18-74—SB 197
General Law Committee

AN ACT CONCERNING BIOLOGICAL PRODUCTS

S**UMMARY:** This act generally allows pharmacists to substitute a biological product for a prescribed biological product as long as the substitute is an interchangeable biological product (see definition below) and the prescribing practitioner has not prohibited the substitution. It extends to these substitutions many of existing law's provisions on substituting brand name drugs with generic ones.

The act also establishes requirements applicable only to biological and interchangeable biological products, including generally requiring:

1. practitioners to discuss with patients the treatment methods, alternatives to, and risks associated with using a biological product;
2. a dispensing pharmacist to inform prescribers and patients of a substitution; and
3. patients to be given the option of requesting that someone sign for a product's delivery.

A "biological product" is generally a virus; therapeutic serum; toxin or antitoxin; vaccine; blood or blood component or derivative; allergenic product; protein, but not a chemically synthesized polypeptide; or arsphenamine or a derivative of it, used to prevent, treat, or cure a human disease or condition.

The act also makes minor and technical changes, including (1) eliminating the option for a generic drug prescription label to have the distributor's name instead of the manufacturer's name, (2) allowing prescribers to order a biological product's name to be withheld from the prescription container's label, and (3) removing an unnecessary definition for "antiepileptic drug."
EFFECTIVE DATE: October 1, 2018

PRESCRIBING BIOLOGICAL PRODUCTS

The act requires practitioners to discuss with patients the treatment methods, alternatives to, and risks associated with using a biological product before prescribing one. Practitioners must also inform patients that they may opt to sign for delivery of a biological product (see below). Practitioners must document the discussion in the patient's medical record within 24 hours after the discussion.

But the act exempts from these requirements hospital inpatients, emergency care, federal Food and Drug Administration (FDA) approved vaccines, blood, and blood components.

BIOLOGICAL PRODUCT SUBSTITUTION

Interchangeability

The act defines "interchangeable biological product" as a biological product that (1) the FDA licensed and determined meets the interchangeability standards under federal law or (2) is therapeutically equivalent to another biological product, as set forth in the latest edition of, or supplement to, the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* publication (see BACKGROUND).

Under federal law, a biological product is considered interchangeable if the FDA finds that it is (1) biosimilar (i.e., highly similar, other than minor differences in inactive components, with no meaningful differences in safety, purity, and potency) to the original licensed product and (2) expected to produce the same clinical result in any given patient. For biological products administered to a patient more than once, the risk from switching between the biological product and the original licensed product must be no greater than if only the original product was used.

Notification

Under the act, upon dispensing an interchangeable biological product, a pharmacist or his or her authorized agent must inform the patient or the patient's representative of the substitution. Additionally, within 48 hours after dispensing the product, the pharmacist must (1) inform the prescribing practitioner and (2) document the substitution by making an entry into an electronic record (see below).

Labeling

As is the case for drug product substitutions, the act requires pharmacists to label the prescription container with the name of the interchangeable biological product, or if it does not have a brand name, the nonproprietary name of the product, along with the name of the manufacturer.

Signing for Delivery

The act specifies that patients or their representatives may request of a pharmacy that the patient or representative be present to sign for delivery of an interchangeable biological product. The request may be rescinded at any time by notifying the pharmacy.

Prohibited Substitutions

Prescriber order. Under the act, practitioners may prohibit substitutions for prescribed biological products in the same way that existing law authorizes them to prohibit substitutions for brand name drugs (e.g., specifying on the prescription form "no substitution" or "brand medically necessary").

Cost savings. Under the act, as is the case for drug product substitutions, there must be a cost savings to the purchaser for an interchangeable biological product substitution to occur. If a patient asks, the pharmacist must disclose the savings amount.

Purchaser objection. Like drug product substitutions, the act also allows purchasers to reject an interchangeable biological product substitution.

Epilepsy or seizure treatment. The act extends to biological products existing limitations on filling prescriptions for prescribed drugs to treat epilepsy or prevent seizures. Specifically, it prohibits filling a biological product prescription by using a different manufacturer or distributor unless the pharmacist (1) gives the patient and the prescribing practitioner prior notice of the substitution and (2) receives written consent from the practitioner.

ELECTRONIC RECORDS

The act requires pharmacists, or their designees, within 48 hours after dispensing an interchangeable biological product, to record its name and manufacturer in a way that notifies the prescribing practitioner. The information may be made available through:

1. an interoperable electronic medical records system,
2. an electronic prescribing technology,
3. a pharmacy benefit management system, or
4. a pharmacy record.

If an entry is not made by one of the above means, the pharmacist must let the prescriber know about the dispensed product, by fax, telephone, or electronic transmission. However, no such communication is necessary when (1) a refill prescription is the same as the originally dispensed product or (2) the product is dispensed by a hospital pharmacy.

MISCELLANEOUS PROVISIONS

Signs

Under existing law, pharmacies must post signs, near counters where prescriptions are dispensed, informing purchasers that they may substitute less expensive and therapeutically equivalent drug products. The act requires the signs to include notice that these rules also apply to interchangeable biological products.

Regulations

The act requires the consumer protection commissioner, with the assistance of the Commission of Pharmacy, to amend the department's regulations to carry out the act's provisions.

BACKGROUND

Approved Drug Products with Therapeutic Equivalence Evaluations

The *Approved Drug Products with Therapeutic Equivalence Evaluations* publication (i.e., the Orange Book) identifies drug products approved by the FDA on the basis of safety and effectiveness under the Federal Food, Drug, and Cosmetic Act and related patent and exclusivity information.