HB5631

LRB09818058ZMM53187b

98TH GENERAL ASSEMBLY

State of Illinois

2013 and 2014

HB5631

by Rep. Robyn Gabel

SYNOPSIS AS INTRODUCED:

225 ILCS 85/26.5 new

Amends the Pharmacy Practice Act. Defines "bleeding disorder", "blood clotting product", and "established patient". Establishes certain requirements, standards of care, and business practices that pharmacies and pharmacists shall comply with when dispensing blood clotting products.

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A BILL FOR

AN ACT concerning regulation.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 5. The Pharmacy Practice Act is amended by adding Section 26.5 as follows:

(225 ILCS 85/26.5 new)

Sec. 26.5. Blood clotting products.

(a) For the purposes of this Section:

"Bleeding disorder" means a medical condition characterized by a deficiency or absence of one or more essential blood clotting components in the human blood, including all forms of hemophilia, acquired hemophilia, von Willebrand disease, and other bleeding disorders that result in uncontrollable bleeding or abnormal blood clotting.

"Bleeding disorder" does not include a bleeding condition secondary to another medical condition or diagnosis, except for acquired hemophilia.

"Blood clotting product" means a medicine approved for distribution by the FDA that is used for the treatment and prevention of symptoms associated with bleeding disorders, including, but not limited to, recombinant and plasma derived factor products, von Willebrand factor products, antifibrinolytics, bypass products for patients with

inhibitors, prothrombin complex concentrates, and activated prothrombin complex concentrates. "Blood clotting product" does not include medical products approved solely for the treatment or prevention of side effects of a blood clotting drug.

"Established patient" means a bleeding disorder patient that has been dispensed a legend blood clotting product by the pharmacy on more than 3 occasions in a single year.

(b) All pharmacies and pharmacists shall comply with the following requirements when dispensing blood clotting products:

(1) Prescriptions for blood clotting products shall be dispensed as written or authorized by the prescribing physician and in accordance with State and federal law. No changes or substitutions shall be made unless approved by the prescriber. If the pharmacy has received prescriber authorization to change or substitute the blood clotting product originally prescribed, the patient or the patient's designee shall be notified and counseled through the preferred contact method identified by the patient or designee regarding the change or substitution prior to dispensing.

(2) If requested by the patient or the patient's designee, the pharmacy shall ship and deliver blood clotting products to the patient or the patient's designee as prescribed within 2 business days after receiving a

prescription or refill request from an established patient and within 3 business days after receiving a prescription or refill request from a new patient in nonemergency situations. Nonemergency situations include, but are not limited to, routine prophylaxis requests. Appropriate cold chain management and packaging practices shall be used to ensure that proper drug temperature, stability, integrity, and efficacy are maintained during shipment in accordance with manufacturer requirements.

(3) Patients shall be provided with a designated pharmacy contact telephone number for reporting problems with a delivery or product on each dispensing at no cost to the patient.

(4) Unless otherwise authorized by the patient or the patient's designee, the pharmacy shall contact the patient for authorization to dispense prior to shipping a refill of any blood clotting product to the patient. The date of patient authorization shall be documented in the pharmacy's prescription records.

(5) Barring extenuating circumstances, prescriptions for blood clotting products shall be dispensed within plus or minus 10% of prescribed assays, or as otherwise authorized or directed by the prescriber.

(c) Prior to dispensing any blood clotting product, the pharmacy shall ask the patient or the patient's designee to designate a preferred contact method for receiving

notifications in the event of a recall or withdrawal of the product dispensed or any related ancillary medical device or supplies dispensed by the pharmacy. The preferred contact method shall be documented with the patient information.

Notice of blood clotting product or ancillary medical device or supplies recalls and withdrawals shall be provided to the patient through the patient's preferred contact method within 24 hours of receipt of a recall or withdrawal notification from the manufacturer or any state or federal entity that requires or recommends patient notification. The pharmacy shall also notify the prescribing physician within 24 hours of such recall or withdrawal and shall obtain a prescription for an alternative blood clotting product if a new or amended prescription is required to dispense or deemed necessary and appropriate by the prescriber.

If attempts to contact the patient through the preferred contact method are unsuccessful, the pharmacy shall mail notification to the patient or the patient's authorized designee within the required 24 hours or the next business day.

The time, date, and method of notification to the patient and prescriber shall be documented in the pharmacy's records and maintained for 2 years after the date of recall or withdrawal.

(d) In addition to the provisions of subsections (b) and (c), pharmacies that dispense blood clotting products to established patients or that offer or advertise to provide

blood clotting products specifically for bleeding disorder patients shall comply with the following standards of care:

(1) The pharmacy shall annually notify the Board in writing of the pharmacy's intent to provide legend blood clotting products for bleeding disorder patients. Notification shall be made on or before January 31 of each year in a manner and form approved by the Board.

(2) The pharmacy shall identify in advance or make arrangements with a supplier or suppliers capable of providing all brands, assays, and vial sizes of blood clotting products approved by the FDA, including products manufactured from human plasma and those manufactured from recombinant technology techniques. A list of all designated or identified suppliers shall be maintained at the pharmacy and made available during inspection. This requirement shall not be construed to require a pharmacy to purchase products prior to receiving a valid prescription order.

(3) A pharmacist shall be available 24 hours a day, 7 days a week, every day of the year, either on site or on call, to fill prescriptions for blood clotting products within the time frames designated by this Section.

(4) Pharmacists engaged in dispensing blood clotting products or who provide patient counseling regarding blood clotting products to bleeding disorder patients shall have sufficient knowledge, experience, and training to perform

the duties assigned. To ensure continued competency, pharmacists engaged in counseling bleeding disorder patients shall complete 4 continuing education hours related to blood clotting products, infusion treatment or therapy, or blood clotting disorders and diseases that shall count towards the pharmacist's continuing education requirements under this Act. Proof of compliance with this paragraph (4) shall be maintained at the pharmacy for a minimum of 4 years and shall be made available during inspection or at the request of the Board.

(5) If requested by the patient or the patient's designee, the pharmacy shall provide for the shipment and delivery of blood clotting products to the patient or the patient's designee as prescribed within 2 business days after receiving a prescription or refill request from an established patient and within 3 business days after receiving a prescription or refill request from a new patient in nonemergency situations.

(6) Established patients shall be dispensed blood clotting products within 12 hours after notification from a physician of the patient's emergent need for a blood clotting product. For the purposes of this paragraph, determination of an emergent need shall be within the professional medical judgment of the physician. Emergent need requests shall be documented in the pharmacy's prescription records.

(7) The pharmacy shall provide or have available for purchase containers for the disposal of hazardous waste, including, but not limited to, sharp or equivalent biohazard waste containers.

(8) The pharmacy shall have ancillary medical devices and supplies required to infuse a blood clotting therapy product into a human vein, including syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, and cold compression packs available for purchase. If such supplies are depleted, the pharmacy shall restock the required ancillary medical devices and supplies in a reasonable amount of time, not to exceed 7 days.

(9) The pharmacy shall have contact information available for a nurse or nursing service or agency with experience in providing infusion-related nursing services or nursing services for bleeding disorder patients if such services are not provided by the pharmacy.

(10) If requested by the patient or the patient's authorized designee, the pharmacist shall explain any known insurance copayments, deductibles, coinsurance payments, or lifetime maximum insurance payment limits. For purposes of complying with this paragraph, the pharmacy may rely on information supplied by the patient's insurer.

(11) The pharmacy shall register with the National Patient Notification System, or its successor, to receive

recall notification for all products included in the National Patient Notification System. The pharmacy shall maintain current and accurate contact information with the National Patient Notification System.

(e) Pharmacies that provide legend blood clotting products to treat or prevent symptoms of established bleeding disorder patients, or that offer or advertise to provide blood clotting products specifically for bleeding disorder patients, shall develop and follow written policies and procedures to ensure compliance with this Section. The pharmacy shall review the policies and procedures on an annual basis and document such review. The pharmacy's written policies and procedures shall include procedures for:

(1) processing prescriptions for blood clotting products by pharmacy staff to ensure the timely handling and dispensing of blood clotting products;

(2) processing partial fill requests by patients to reduce or eliminate excessive dispensing;

(3) providing and documenting recall notifications in accordance with this Section;

(4) transferring, dispensing, refilling, or delivering blood clotting products to established patients in the event of an emergency or disaster;

(5) notifying patients prior to terminating business or terminating the dispensing of any blood clotting product or prior to a known or anticipated termination of pharmacy

services for a bleeding disorder patient; such notification shall be provided in writing and, when reasonably possible, shall be provided at least 7 days prior to any such termination;

(6) shipping or providing blood clotting products to the patient within the time frames required in this Section;

(7) receiving, processing, and dispensing prescription or dispensing requests for a blood clotting product to bleeding disorder patients, including procedures for handling and processing physician requests indicating a patient's emergent need for a blood clotting product;

(8) ensuring appropriate cold chain management and packaging practices are used to ensure proper drug temperature, stability, integrity, and efficacy are maintained during shipment in accordance with manufacturer requirements; and

(9) handling and processing preauthorization notifications and requests and communicating preauthorization requirements to the patient and applicable prescriber.

(f) This Section shall not be construed to require dispensing without appropriate payment or payment arrangements. If the pharmacy is waiting for authorization, certification, or other action from a third-party payor prior to dispensing, the pharmacy shall notify the patient that the

prescription is available for dispensing and explain any alternative payment options. Notification shall be provided as soon as reasonably practicable. Notification shall be provided to the patient prior to the expiration of the shipping and delivery time frames required by subsection (d).