



New Missouri Standards for Pharmacies Dispensing Blood-Clotting Therapies

In 2011, the Missouri legislature enacted [§ 338.400](#), RSMo, which required the Board to promulgate standards of care for pharmacies dispensing blood-clotting therapies. The Board recently promulgated rule [20 CSR 2220-6.100](#) to implement the provisions of [§ 338.400](#). Rule [20 CSR 2220-6.100](#) became effective on [May 30, 2013](#). The following FAQ is being provided to assist licenses in complying with the new standards.

Who Does The New Rule Apply To?

Rule [20 CSR 2220-6.100](#) applies to:

- Pharmacies dispensing blood-clotting factor concentrates;
- Pharmacies dispensing blood-clotting products to established bleeding disorder patients; and
- Pharmacies that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients.

Requirements for Pharmacies Dispensing “Blood-Clotting Factor Concentrates”?

[20 CSR 2220-6.100\(2\)](#) generally details the requirements applicable to pharmacies dispensing blood-clotting factor concentrates. Examples of blood-clotting factor concentrates include, but may not be limited to:

- Recombinant Factor VII & Recombinant-activated Factor VIIa;
- Recombinant Factor VIII & plasma-derived Factor VIII;
- Recombinant Factor IX & plasma-derived Factor IX;
- von Willebrand factor products;
- Bypass products for patients with inhibitors;
- Prothrombin complex concentrates; and
- Activated prothrombin complex concentrates.

As currently approved by the U.S. Food and Drug Administration (FDA), blood-clotting factor concentrates do not include:

- Aminocaproic Acid;
- Desmopressin Acetate;
- Warfarin; and
- Heparin.

This document is provided for informational purposes only and does not constitute a summary of all compliance requirements. Licensees should review the full text of the rule and § 338.400 to ensure compliance. This document does not constitute a rule statement of general applicability or binding law. In the event of a conflict or inconsistency, duly promulgated or enacted state or federal law shall control. The Board expressly reserves the right to revise the contents as deemed appropriate or necessary.

Under the rule, pharmacies dispensing blood-clotting factor concentrates must comply with the following:

1. **Preferred Contact Method:** The patient or the patient's designee must be asked to designate a preferred contact method for receiving notifications in the event of a recall or withdrawal of the concentrate dispensed or any related ancillary infusion equipment and supplies. [20 CSR 2220-6.010(2)(A)]. The preferred contact method must be documented with the patient information required by 20 CSR 2220.2.190(2). If the patient/designee refuses to provide a preferred contact method, the Board recommends documenting the refusal in the patient's prescription record.
2. **Substitutions:** As with current law, prescriptions for blood-clotting factor concentrates must be dispensed as written or as authorized by the prescriber. [20 CSR 2220-6.010(2)(H)]. If the prescriber authorizes the pharmacy to change or substitute the blood-clotting factor concentrate originally prescribed, the patient/patient's designee must be notified and counseled regarding the change or substitution prior to dispensing via the patient's identified preferred contact method. Documentation is not required if substitution was authorized on the original prescription (i.e.- substitution permitted signature line signed). Counseling is mandatory unless refused by the patient/designee.
3. **Pharmacy Contact:** The pharmacy must provide **a toll free number** for patients to contact the pharmacy to report problems with a delivery or product. The toll free number must be provided each time a prescription is dispensed (both new and refill). [20 CSR 2220-6.010(2)(C)].
4. **Delivery Requirements:** If requested by the patient/patient's designee, blood-clotting factor concentrates must be shipped and delivered to the patient within two (2) business days for established patients in non-emergency situations and three (3) business days for new patients. Non-emergencies include, but may not be limited to, routine prophylaxis requests. Appropriate cold chain management and packaging practices must be used to ensure proper drug temperature, stability, integrity, and efficacy are maintained during shipment in accordance with manufacturer requirements. [20 CSR 2220-6.010(2)(B)].
5. **Automatic Refills:** Unless previously authorized by the patient or the patient's designee, the pharmacy must contact the patient for authorization to dispense prior to shipping a refill of any blood-clotting product to the patient. Authorization may be given verbally or in writing. The authorization date must be documented in the pharmacy's prescription records. The Board also recommends documenting the method/manner of patient authorization. [20 CSR 2220-6.010(2)(D)].
6. Barring extenuating circumstances, blood clotting factor concentrates must be dispensed within plus or minus ten percent (+/- 10%) of prescribed assays, or as otherwise authorized or directed by the prescriber. [20 CSR 2220-6.010(2)(E)].
7. **Recall/Withdrawal Notifications:** Licensees must notify the patient and the prescriber within twenty-four (24) hours after notification from the manufacturer or any state/federal entity of a recall or withdrawal of a concentrate or any ancillary infusion equipment/supplies. Notification is required only if the manufacturer or state/federal entity requires or recommends patient notification. The pharmacy must also obtain a

This document is provided for informational purposes only and does not constitute a summary of all compliance requirements. Licensees should review the full text of the rule and § 338.400 to ensure compliance. This document does not constitute a rule statement of general applicability or binding law. In the event of a conflict or inconsistency, duly promulgated or enacted state or federal law shall control. The Board expressly reserves the right to revise the contents as deemed appropriate or necessary.

prescription for an alternative product if a new or amended prescription is required to dispense or deemed necessary and appropriate by the prescriber. [[20 CSR 2220-6.010\(2\)\(B\)](#)].

If attempts to contact the patient via the preferred contact method are unsuccessful, the pharmacy must mail notification to the patient/patient's designee within the required twenty-four (24) hours or the next business day. The time, date, and method(s) of notification must be documented in the pharmacy's records and maintained for two (2) years from the date of recall or withdrawal. [[20 CSR 2220-6.010\(2\)\(B\)](#)].

Requirements for Pharmacies Dispensing Blood-Clotting Products To Established Patients?

In addition to the requirements for pharmacies dispensing blood-clotting factor concentrates, [20 CSR 2220-6.100](#) contains additional requirements for pharmacies dispensing blood clotting products to established patients, or who offer or advertise to dispense blood clotting products specifically for bleeding disorder patients.

Section [338.400](#), RSMo, defines a “blood-clotting product” as:

(4) Blood-Clotting Product- A medicine approved for distribution by the federal Food and Drug Administration that is used for the treatment and prevention of symptoms associated with bleeding disorders, including but not limited to recombinant Factor VII, recombinant-activated Factor VIIa, recombinant Factor VIII, plasma-derived Factor VIII, recombinant Factor IX, plasma-derived Factor IX, von Willebrand factor products, bypass products for patients with inhibitors, prothrombin complex concentrates; and activated prothrombin complex concentrates;

Except as otherwise provided by [§ 338.400](#), RSMo, a “blood clotting product” does not include medical products approved solely for the treatment or prevention of side effects of a blood-clotting drug or medication. [[20 CSR 2220-6.100\(1\)\(B\)](#)].

An established bleeding disorder patient is defined as a bleeding disorder patient that has been dispensed a legend blood-clotting product by the pharmacy on more than three (3) occasions in a single calendar year. [[20 CSR 2220-6.100\(1\)\(C\)](#)]. A “bleeding disorder” is defined as:

(A) “Bleeding disorder,” a medical condition characterized by a deficiency or absence of one (1) or more essential blood-clotting components in the human blood, including all forms of hemophilia, acquired hemophilia, von Willebrand’s disease, and other bleeding

disorders that result in uncontrollable bleeding or abnormal blood-clotting. [[20 CSR 2220-6.100\(1\)\(A\)](#)]

A “bleeding disorder” does not include bleeding conditions secondary to another medical condition or diagnosis, except for acquired hemophilia. [[20 CSR 2220-6.010\(1\)\(A\)](#)].

Under the rule, pharmacies dispensing blood clotting products to established patients, or who offer or advertise to dispense blood clotting products specifically for bleeding disorder patients must comply with the following:

- ✓ **Board Notification:** Written notification must be annually provided to the Board if the pharmacy intends on providing legend blood-clotting products to bleeding disorder patients. Notification must be made on or before January 31st of each year. The Board anticipates establishing a pharmacy permit class specifically for pharmacies dispensing blood clotting products. Until that time, notifications may be e-mailed to the Board at pharmacy@pr.mo.gov or faxed to (573) 526-3464. [[20 CSR 2220-6.010\(3\)\(A\)](#)].
- ✓ **Pharmacist Availability:** A pharmacist must be available twenty-four (24) hours a day, seven (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 required by [§ 338.400](#) and 20 CSR 2220-6.100. [[20 CSR 2220-6.010\(3\)\(C\)](#)].
- ✓ **Pharmacist Training/Continuing Education:** Pharmacists engaged in dispensing or filling blood-clotting factor concentrates or who provide patient counseling on blood clotting factor concentrates to bleeding disorder patients must have sufficient knowledge, experience and training to perform the duties assigned. Additionally, pharmacists engaged in counseling bleeding disorder patients shall complete four (4) continuing education hours (0.40 CEU) related to blood-clotting factor concentrates, infusion treatment/ therapy or blood-clotting disorders or diseases each biennial renewal period. [[20 CSR 2220-6.010\(3\)\(D\)](#)].
- ✓ **Hazardous Waste:** Hazardous waste disposal containers must be provided or available for purchase at the pharmacy (i.e.- sharp or equivalent biohazard waste containers). [[20 CSR 2220-6.010\(3\)\(G\)](#)].
- ✓ **National Register:** The pharmacy must register with the National Patient Notification System, or its successor, to receive recall notifications for all products included in the National Patient Notification System. Registration is free and may be completed online at <http://www.patientnotificationsystem.org/>. The pharmacy must maintain current and accurate contact information with the National Patient Notification System. [[20 CSR 2220-6.010\(3\)\(K\)](#)].
- ✓ **Supply Requirements:** The pharmacy must identify, or make arrangements with, a supplier(s) who can provide all brands, assays and vial sizes of FDA approved blood-clotting products, including both, plasma and recombinant products. A list of identified suppliers must be maintained at the pharmacy and available during inspection. Pharmacies are not required to purchase products before receiving a prescription.

Instead, the pharmacy must have an identified supplier if a product is needed. [[20 CSR 2220-6.010\(3\)\(B\)](#)].

- ✓ **Ancillary Supplies:** Ancillary equipment and supplies required to infuse blood-clotting products intravenously must be available for purchase. Ancillary equipment/supplies include, but are not limited to, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, and cold compression packs. Items must be restocked in a reasonable amount of time but in no event later than seven (7) calendar days. [[20 CSR 2220-6.010\(3\)\(H\)](#)].
- ✓ **Nursing Services:** The pharmacy must have contact information available for a nurse or nursing service/agency with experience in providing infusion related nursing services or nursing services for bleeding disorder patients, if the nursing services are not provided by the pharmacy. [[20 CSR 2220-6.010\(3\)\(I\)](#)].
- ✓ **Shipment/Delivery Requirements:** [20 CSR 2220-6.100\(3\)\(E\) and \(F\)](#) establish the following delivery requirements:
 - **Non-emergencies:** If requested by an established patient, the pharmacy must provide for the shipment and delivery of blood-clotting products to the patient within two (2) business days after receiving a prescription or refill request. For new patients, shipment/delivery must be made within three (3) business days. Non-emergencies include, but may not be limited to, routine prophylaxis requests. [[20 CSR 2220-6.010\(3\)\(E\)](#)].
 - **Emergencies:** Established patients must be provided access to blood-clotting products within twelve (12) hours after being notified by the prescriber of a patient's emergent need for the product. Emergency requests must be documented in the pharmacy's records. Determination of an emergency is within the professional medical judgment of the physician. [[20 CSR 2220-6.010\(3\)\(F\)](#)].

If the pharmacy is waiting for action from a third-party payor prior to dispensing (i.e. authorization, certification, etc.), the pharmacy must notify the patient that the prescription is ready and explain any alternate payment options. Notification must be made as soon as reasonably practicable but in no event later than the required delivery timeframe. Pharmacies are not required to dispense before payment is confirmed.

- ✓ **Insurance Information:** If requested, the pharmacy must explain any known insurance copayments, deductibles, coinsurance payments or lifetime maximum insurance payment limits. [[20 CSR 2220-6.010\(3\)\(J\)](#)]. The Board recognizes that licensees may have limited access to or knowledge of benefit information. [20 CSR 2220-6.010\(3\)\(J\)](#) provides the pharmacy may rely on information supplied by the patient's insurer.
- ✓ **Policy & Procedure Manual:** The pharmacy must establish a written policy & procedure manual to ensure compliance with [§ 338.400](#) and [20 CSR 2220-6.100](#). Detailed policy & procedure requirements are listed in [20 CSR 2220-6.100\(4\)](#). Examples of required policy & procedure provisions include policies/procedures for:
 - Processing prescriptions
 - Handling partial fills

- Providing & documenting recall notifications
- Procedures for dispensing in the event of an emergency/disaster
- Cold chain management and packaging

Policies and procedures must be reviewed annually. Documentation of the annual review must be maintained in the pharmacy's records. [[20 CSR 2220-6.010\(4\)](#)].

Once again, licensees should read [§ 338.400](#) and [20 CSR 2220-6.100](#) in their entirety to ensure compliance with Missouri law. Compliance questions regarding [§ 338.400](#) or [20 CSR 2220-6.100](#) should be sent to MissouriBOP@pr.mo.gov. Licensees may also call the Board office at (573) 751-0091.