For level IV STEMI centers, it is likely the hospital requesting to be a level IV STEMI center will already have an emergency department and a radiology department. Further this emergency department will already have the required resuscitation equipment.

For level I and II STEMI centers, it is very likely the hospitals requesting to be a level I, or II STEMI center will already have a Computerized Tomography (CT) scan so this will not be a new cost to these STEMI centers.

For level I, II and III STEMI centers, it is very likely the hospitals requesting to be a level I, II or III STEMI center will already have X-ray capability in the radiology department and the operating room so this will not be a new cost to these STEMI centers.

For level I STEMI centers, it is very likely the hospitals will already have a functioning cardiac catheterization laboratory and therefore the resuscitation equipment and other equipment required to be in the laboratory will already have been purchased by level I STEMI centers.

For levels I, II, III and IV STEMI centers, it is very likely the hospitals requesting to be said STEMI centers will already have the equipment and ability to conduct laboratory analyses required for these STEMI centers so this should not be a new cost to these STEMI centers.

For level I, II, III and IV STEMI centers, it is likely that these hospitals already have a social worker providing support services in place, so this will not be a new cost for the STEMI centers.

For level I and II STEMI centers, it is likely that these hospitals already have a rehabilitation program in place, so this will not be a new cost for the STEMI centers.

For level I and II STEMI centers, it is likely the hospitals already have the required operating room equipment, so this will not be a new cost to the STEMI centers.

It is very likely members on the STEMI call roster are already going to be carrying electronic communications devices (a cell phone and beeper). Thus, it is likely these charges in Levels I, II, III and IV STEMI centers won't be a new cost to the STEMI centers.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Regulation and Licensure
Chapter 40—Comprehensive Emergency Medical Services Systems Regulations

PROPOSED RULE

19 CSR 30-40.770 Community-based or Regional Plan for Emergency Medical Services for Trauma, ST-Segment Elevation Myocardial Infarction (STEMI), or Stroke

PURPOSE: This rule establishes the procedures for the submission of a community-based or regional plan for the transportation of patients to stroke, STEMI, or trauma centers.

(1) A community or region developing its own transportation plan for stroke, STEMI, and trauma patients may submit a plan at any time and shall ensure that it complies with section 190.200.3., RSMo. Such a plan shall also—

(A) Identify the geographic boundaries of the area covered by the plan;

(B) Designate, and provide contact information for, an individual, plan's designee who will serve as the plan's point of contact throughout the plan's approval and administration process; and

(C) Identify individuals involved in the drafting, planning, and/or consultation of the plan, who shall collectively be known as the "planning committee."

(2) Upon completion of a community-based or regional plan, the plan shall be submitted to the chair of the regional emergency medical services advisory committee defined by section 190.102, RSMo, and the regional emergency medical services medical director defined by section 190.103, RSMo, for the geographic area covered by the plan. Upon receipt of a plan submitted pursuant to the provisions of section 190.200, RSMo, the chair and medical director shall forward the plan to the emergency medical services medical director's advisory committee (the committee) as defined by section 190.103, RSMo, for consideration. Within forty-five (45) days of receipt of a community-based or regional plan, the committee shall meet and complete its review of the plan. Upon a finding of good cause, the chair of the committee may grant the committee a reasonable extension of time for review of the plan.

(3) In reviewing a community-based or regional plan, the committee shall determine whether the plan meets the requirements of section 190.200.3., RSMo, and this rule.

(4) At the conclusion of its review, the committee shall vote on the question of whether to recommend or not recommend the plan for approval. If a majority of the committee votes to recommend the plan for approval, said recommendation shall constitute *prima facie* evidence that the plan meets the requirements of section 190.200.3., RSMo, and should be approved. The committee shall attach such conditions (such as regular analysis and reporting of medical outcomes to the committee) to its recommendation for approval as it deems appropriate to ensure that the plan continues to meet the requirements of Chapter 190, RSMo. If a majority of the committee votes to not recommend the plan, that decision, with an explanation of the reason(s) for the decision, shall be provided in writing to the plan's designee. A community or region receiving a non-recommendation by the committee may modify its plan according to the committee's reason(s) for non-recommendation and resubmit the plan within thirty (30) days directly to the committee.

(5) Following recommendation of a community-based or regional plan, the committee shall forward the plan to the Director of the Department of Health and Senior Services (director) for approval. The director shall have thirty (30) days to review the plan for its compliance with section 190.200.3., RSMo. At the conclusion of the review, the director shall approve or disapprove the plan. If the director disapproves the plan, the reason(s) for disapproval shall be provided in writing to the plan's designee. The director's decision shall be the final agency action. A community or region whose plan is not approved by the director may modify its plan according to the director's reason(s) for disapproval and resubmit the plan within thirty (30) days directly to the committee and follow the approval process as outlined herein.

(6) Once a plan is approved by the director, the planning committee shall—

(A) Notify all agencies impacted by the plan of the manner in which emergency medical care is modified within the region based on the plan;

(B) Monitor per the plan the related medical and system outcomes and regional resources and capacity;

(C) Revise the plan when indicated based on medical and system outcomes, emerging clinical research or guidelines, or when revision is indicated based on changes in capacity or other related issues and submit through the approval process as outlined herein; and

(D) Notify the committee and department at least thirty (30) days before ceasing to use the plan.

AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with Teresa Generous, Director, Department of Health and Senior Services, Division of Regulation and Licensure, PO Box 570, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Regulation and Licensure
Chapter 40—Comprehensive Emergency Medical Services Systems Regulations

PROPOSED RULE

19 CSR 30-40.780 Definitions and Abbreviations Relating to the Transport Protocol for Stroke and the Transport Protocol for ST-Segment Elevation Myocardial Infarction (STEMI) Patients

PURPOSE: This rule defines terminology related to the state transport protocol for stroke and the state transport protocol for STEMI.

(1) The following definitions and abbreviations shall be used in the interpretation of the rule in 19 CSR 30-40.790:

(A) Field is the specific area or location, outside of the hospital, where an injury, accident, or medical emergency occurs requiring immediate assistance of medical personnel for the purpose of treating or transporting the sick or injured to another location for treatment;

(B) Local and regional process is the process that has been established and agreed upon specifically pertaining to a local city, town,

or small district, or a combination of localities forming a regional area. This is not the community-based or regional plan;

(C) Lytics are thrombolytic drugs, including recombinant tissue plasminogen activator, used to dissolve clots blocking flow in a blood vessel. These lytic/thrombolytic drugs are used in the treatment of acute ischemic stroke and acute myocardial infarction;

(D) Lytic/therapeutic window is the period of time during which lytics can be administered following the onset of symptoms in order to reduce brain or heart injury;

(E) Lytic therapy (fibrinolysis/thrombolysis) is drug therapy used to dissolve clots blocking flow in a blood vessel. It refers to drugs used for that purpose, including recombinant tissue plasminogen activator. This type of therapy can be used in the treatment of acute ischemic stroke and acute myocardial infarction;

(F) Lytic/thrombolytic ineligible patients are those patients identified as ineligible for lytic/thrombolytic therapy due to specific contraindications. An appropriate course of treatment will be utilized when lytic/thrombolytic therapy is contraindicated;

(G) Out of the lytic/therapeutic or potential therapeutic window is the period of time following the accepted time (lytic/therapeutic window and potential therapeutic window) frames for specific therapies for a patient suffering an ischemic stroke;

(H) Outside of the percutaneous coronary intervention (PCI) window is the period of time following the accepted time frame in which PCI is most advantageous and recommended;

(I) Percutaneous coronary intervention (PCI) is a procedure used to open or widen narrowed or blocked blood vessels to restore blood flow supplying the heart;

(J) Percutaneous coronary intervention (PCI) window is a time frame in which PCI is most advantageous and recommended;

(K) Potential therapeutic window is the period of time after the accepted window for lytic therapy has expired in which interventional therapy may be beneficial in restoring blood flow during an ischemic stroke; and

(L) Recombinant tissue plasminogen activator (t-PA also known as rt-PA) is a thrombolytic (clot-dissolving) agent, the goal of which is to destroy the thrombus (clot) within the blood vessel by stimulating fibrinolysis (clot breakdown) to allow restoration of blood flow.

AUTHORITY: sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with Teresa Generous, Director, Department of Health and Senior Services, Division of Regulation and Licensure, PO Box 570, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Regulation and Licensure
Chapter 40—Comprehensive Emergency Medical Services Systems Regulations

PROPOSED RULE

19 CSR 30-40.790 Transport Protocol for Stroke and ST-Segment Elevation Myocardial Infarction (STEMI) Patients

PURPOSE: This rule establishes protocols for transporting suspected STEMI patients by severity and time of onset to the STEMI center where resources exist to provide appropriate care and suspected stroke patients by severity and time of onset to the stroke center where resources exist to provide appropriate care.

(1) All ground and air ambulances shall use the following state transport protocol for suspected stroke patients except in those circumstances listed in sections (3), (4), and (5) of this rule:

(A) Step 1—Assess for life threatening conditions (serious airway or respiratory compromise or immediate life threatening conditions that cannot be managed in the field).

1. If there are life threatening conditions, transport the patient to the nearest appropriate facility for stabilization prior to transport to a stroke center. Consider air/ground/facility options for timely and medically appropriate care (particularly in non-urban areas).

2. If there are no life threatening conditions, go to step 2 below in subsection (1)(B); and

(B) Step 2—Assess the duration of onset of symptoms (time last known well).

1. Group 1—If the patient is within the lytic/therapeutic window then transport to a level I, II, or III stroke center according to local and regional process. Consider the time for transport, the patient's condition, air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas), and the treatment windows. Continue to reassess the patient. If the patient's condition changes, then start back with subsection (1)(A) and follow the state stroke protocol outlined in section (1) starting from subsection (1)(A) and on according to the patient's condition. Consider out-of-state transport based on local and regional process for bi-state regions.

2. Group 2—If the patient is within the potential therapeutic window then transport to a level I stroke center or transport to a level I, II, or III stroke center according to local and regional process. Consider the time for transport, the patient's condition, air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas), and the treatment windows. Continue to reassess the patient. If the patient's condition changes then start back with subsection (1)(A) and follow the state stroke protocol outlined in section (1) starting from subsection (1)(A) and on according to the patient's condition. Consider out-of-state transport based on local and regional process for bi-state regions.

3. Group 3—If the patient is out of the lytic/therapeutic and potential therapeutic windows, then transport to a level I, II, III or IV stroke center according to local and regional process. Consider the time for transport, the patient's condition, air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas), and the treatment windows. Continue to reassess the patient. If the patient's condition changes, then start back with subsection (1)(A) and follow the state stroke protocol outlined in section (1) starting from subsection (1)(A) and on according to the patient's condition. Consider out-of-state transport based on local and regional process for bi-state regions.

(2) All ground and air ambulances shall use the following state transport protocol for suspected STEMI patients except in those circumstances listed in sections (3), (4), and (5) of this rule:

(A) Step 1—Assess for life threatening conditions (serious airway or respiratory compromise or immediate life threatening conditions that cannot be managed in the field).

1. If there are life threatening conditions, then transport the patient to the nearest appropriate facility for stabilization prior to transport to a STEMI center. Consider air/ground/facility options for timely and medically appropriate care (particularly in non-urban areas).

2. If there are no life threatening conditions, then go on to step 2 below in subsection (2)(B) and assess vital signs and perform an electrocardiogram (ECG) if the ground or air ambulance has that

capability. An electrocardiogram and electrocardiogram equipment are recommended;

(B) Step 2—Determine if the patient's vital signs and the electrocardiogram identifies the following:

1. ST-elevation in two (2) contiguous leads or new or presumed new left bundle branch block; and

2. The patient has two (2) of the following three (3) signs of cardiogenic shock:

A. Hypotension where systolic blood pressure is less than ninety millimeters of mercury (90 mmHG);

B. Respiratory distress where respirations are less than ten (10) or greater than twenty-nine (29) per minute; or

C. Tachycardia where the heart rate is greater than one hundred beats per minute (100 BPM);

3. If the patient has an electrocardiogram with ST-elevation in two (2) contiguous leads or new or presumed new left bundle branch block and two (2) of the three (3) signs of cardiogenic shock then transport to a level I STEMI center according to local and regional process. Consider the time for transport, the patient's condition, and the air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas);

4. If initial transport from the scene to a level I STEMI center is prolonged, then consider transporting to the nearest appropriate facility for stabilization prior to transport to a level I STEMI center;

5. Continue to reassess the patient. If the patient's condition changes, then start back at subsection (2)(A) above and follow the state STEMI protocol outlined in section (2) starting from subsection (2)(A) and on according to the patient's condition;

6. Consider out-of-state transport based on local and regional process for the bi-state region;

7. Communicate electrocardiogram findings to the hospital;

8. If the patient has a positive electrocardiogram but is negative for signs of cardiogenic shock, then go to step 3 in subsection (2)(C) below; and

(C) Step 3—Calculate the estimated time from STEMI identification with the patient to expected percutaneous coronary intervention (PCI) with the patient in order to determine whether the patient is within the percutaneous cornary intervention window. Communicate electrocardiogram findings to the hospital. If no ST-elevation or new or presumed new left bundle branch block then consider a fifteen-(15-) lead electrocardiogram, if available.

1. Group 1—If the patient is within the PCI window or the patient has had chest pain longer than twelve (12) hours or the patient is lytic/thrombolytic ineligible then transport to a level I or level II STEMI center according to local and regional process. Consider the time for transport, the air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas), the patient's condition, and all treatment windows. Consider the ischemic time and the potential role for lytics (within the lytic window) at an intervening STEMI center in route to the percutaneous coronary intervention center if approaching longer times within the percutaneous coronary intervention window. Continue to reassess the patient. If the patient's condition changes, then start back at subsection (2)(A) and follow the state STEMI protocol outlined in section (2) starting from subsection (2)(A) and on according to the patient's condition. Consider out-of-state transport based on local and regional process for bi-state regions.

2. Group 2—If the patient is outside the percutaneous coronary intervention window and within the lytic/therapeutic window, or outside both windows and the patient has no other known complications, then transport to the STEMI center (level I, II, III, or IV) according to local and regional process. Consider the time for transport, air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas), the patient's condition, and all the treatment windows. Consider the lytic window and the potential for STEMI center lytic administration when determining the destination(s). Continue to reassess the patient. If the patient's condition changes, then start back at subsection (2)(A) above and follow the state STEMI protocol outlined in section (2) starting from subsection (2)(A) and on according to the patient's condition. Consider out-of-state transport based on local and regional process for bi-state regions.

(3) When initial transport from the scene of illness or injury to a STEMI or stroke center would be prolonged, the STEMI or stroke patient may be transported to the nearest appropriate facility for stabilization prior to transport to a STEMI or stroke center.

(4) Nothing in this rule shall restrict an individual patient's right to refuse transport to a recommended destination. All ground and air ambulances shall have a written process in place to address patient competency and refusal of transport to the recommended destination.

(5) Ground and air ambulances are not required to use the state transport protocols in this rule when the ambulance is using a community-based or regional plan that has been approved by the department pursuant to section 190.200.3., RSMo, that waives the requirements of this rule. Copies of flow charts of an algorithm depicting the stroke and STEMI state transport protocols are available at the Health Standards and Licensure (HSL) office, online at the department's website www.health.mo.gov, or may be obtained by mailing a written request to the Missouri Department of Health and Senior Services, HSL, PO Box 570, Jefferson City, MO 65102-0570 or by calling (573) 751-6400.

AUTHORITY: sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with Teresa Generous, Director, Department of Health and Senior Services, Division of Regulation and Licensure, PO Box 570, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 6—Pharmaceutical Care Standards

PROPOSED RULE

20 CSR 2220-6.100 Pharmacy Standards for Dispensing Blood-Clotting Products

PURPOSE: This rule implements the provisions of section 338.400, RSMo, and establishes pharmacy standards for dispensing blood clotting products.

(1) Definitions. The following definitions are hereby adopted and applicable to this rule:

(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. As defined by section 338.400, RSMo, "bleeding disorder" does not include a bleeding condition secondary to another medical condition or diagnosis, except for acquired hemophilia;

(B) "Blood-clotting product," a medicine approved for distribution by the federal Food and Drug Administration (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. Except as otherwise provided by section 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;

(C) "Established patient," For purposes of section 338.400, RSMo, and this rule, an "established patient" shall be defined as a bleeding disorder patient that has been dispensed a legend blood clotting product by the pharmacy on more than three (3) occassions in a single calendar year; and

(D) "Pharmacy," an entity engaged in the practice of pharmacy as defined in section 338.100, RSMo, that provides blood-clotting products and ancillary infusion equipment or supplies to patients with bleeding disorders.

(2) General Requirements. All Missouri licensed pharmacists and pharmacy permit holders shall comply with the following requirements when dispensing blood-clotting factor concentrates:

(A) Prescriptions for blood-clotting factor concentrates shall be dispensed as written or authorized by the prescribing physician, 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 factor concentrate originally prescribed, the patient or the patient's designee shall be notified and counseled regarding the change or substitution prior to dispensing via the preferred contact method identified by the patient or designee pursuant to subsection (2)(E);

(B) If requested by the patient or the patient's designee, the pharmacy shall ship and deliver blood-clotting factor concentrates to the patient or the patient's designee as prescribed within two (2) business days of receiving a prescription or refill request for established patients and three (3) business days for new patients in nonemergency situations. Nonemergency situations shall 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;

(C) Patients must 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;

(D) 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;

(E) Barring extenuating circumstances, prescriptions for blood clotting factor concentrates shall be dispensed within plus or minus ten percent (10%) of prescribed assays, or as otherwise authorized or directed by the prescriber; and

(F) Recalls or Withdrawals. Prior to dispensing any blood clotting factor concentrate, 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 concentrate dispensed or any related ancillary infusion equipment and supplies dispensed by the pharmacy. The preferred contact method shall be documented with the patient information required by 20 CSR 2220-2.190(2).

1. Notice of concentrate or ancillary infusion equipment and supplies recalls and withdrawals shall be provided to the patient via the patient's preferred contact method within twenty-four (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 twenty-four (24) hours of such recall or withdrawal and shall obtain a prescription for an alternative product if a new or amended prescription is required to dispense or deemed necessary and appropriate by the prescriber.

2. If attempts to contact the patient via the preferred contact method are unsuccessful, the pharmacy shall mail notification to the patient or the patient's authorized designee within the required twenty-four (24) hours or the next business day.

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

(3) In addition to the provisions of section (2), 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:

(A) 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 calendar year in a manner and form approved by the board;

(B) 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 federal 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;

(C) A pharmacist shall 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 designated by section 338.400, RSMo, and the provisions of this rule;

(D) Pharmacists engaged in dispensing or filling blood-clotting factor concentrates or who provide patient counseling regarding blood-clotting factor concentrates 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 four (4) continuing education hours (0.40 CEU) related to blood-clotting factor concentrates, infusion treatment or therapy, or blood-clotting disorders or diseases each biennial renewal period. The continuing education required by this rule may be used to satisfy the pharmacist's continuing education requirements. Proof of compliance with this section shall be maintained at the pharmacy for a minimum of four (4) calendar years and shall be made available during inspection or at the request of the board;

(E) 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 two (2) business days of receiving a prescription or refill request for established patients and three (3) business days for new patients in nonemergency situations;

(F) Established patients shall be provided access to blood-clotting products within twelve (12) hours of notification from a physician of the patient's emergent need for a blood-clotting product. For purposes of this section, 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;

(G) 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;

(H) At a minimum, the pharmacy shall provide or have available for purchase ancillary equipment 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. If supplies are depleted, the pharmacy shall restock the required ancillary equipment and supplies in a reasonable amount of time which shall not exceed seven (7) calendar days;

(I) 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;

(J) 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 section, the pharmacy may rely on information supplied by the patient's insurer; and

(K) 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.

(4) 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 section 338.440, RSMo, and the provisions of this rule. The pharmacy shall review the policies and procedures on an annual basis and document such review. At a minimum, the pharmacy's written policies and procedures must include procedures for:

(A) Processing prescriptions for blood-clotting products by pharmacy staff to ensure the timely handling and dispensing of blood-clotting products;

(B) Processing partial fill requests by patients to reduce or eliminate excessive dispensing;

(C) Providing and documenting recall notifications in accordance with this rule;

(D) Transferring, dispensing, refilling, or delivering blood-clotting factor concentrates to established patients in the event of an emergency or disaster;

(E) Notifying patients prior to terminating business or terminating the dispensing of any blood-clotting factor concentrate or prior to a known or an anticipated termination of pharmacy services for a bleeding disorder patient. Notification shall be provided in writing and, when reasonably possible, shall be provided a minimum of seven (7) days prior to any such termination;

(F) Shipping or providing blood-clotting products to the patient within the time frames required herein;

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

(H) 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

(I) Handling and processing preauthorization notifications and requests and communicating preauthorization requirements to the patient and applicable prescriber.

(5) This rule 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 payer 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. At a minimum, however, notification shall be provided to the patient prior to the expiration of the shipping and delivery time frames required by subsection (2)(E), (3)(B), or (3)(F) of this rule.

AUTHORITY: section 338.280, RSMo 2000, and sections 338.140 and 338.400, RSMo Supp. 2012. Original rule filed Nov. 13, 2012.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule will cost private entities approximately ten thousand two hundred thirty-two dollars ($10,232) during the first year of implementation of the rule and twenty-six thousand seven hundred twenty-three dollars and twenty-five cents ($26,723.25) recurring annually after the first year of implementation and annually thereafter for the life of the rule. It is anticipated that the costs will recur for the life of the rule, may vary with inflation, and are expected to increase at the rate projected by the Legislative Oversight Committee.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Missouri State Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*

PRIVATE ENTITY FISCAL NOTE

I. RULE NUMBER

Title 20 -Department of Insurance, Financial Institutions and Professional Registration
Division 2220 - State Board of Pharmacy
Chapter 6 - Pharmaceutical Care Standards
Proposed Rule 20 CSR 2220-6.100 Pharmacy Standards for Dispensing Blood Clotting Products
Prepared November 7, 2012 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
25	Pharmacies dispensing blood clotting factors to bleeding disorder patients	$10,232.00 During First Year of Implementation of the Rule
25	Pharmacies dispensing blood clotting factors to bleeding disorder patients	$26,723.25 Recurring Annually After the First Year of Implementation and Annually Thereafter for the Life of the Rule

III. WORKSHEET

ESTIMATE OF LICENSEE COSTS

During First Year of Implementation of the Rule

Estimated # of Participating Pharmacies	Calculation of Estimates	TOTAL COSTS
25	Establishing written policies and procedures ($ 51.16 pharmacist hourly wage x 8 hours x 25 pharmacies)	$10,232.00
		$10,232.00

Recurring Annually After the First Year of Implementation and Annually Thereafter for the Life of the Rule

Estimated # of Participating Pharmacies	Calculation of Estimates	TOTAL COSTS
25	Toll free phone number ($50 per month x 12 months)	$15,000.00
25	Annual board notification of intent to provide services (mailing costs @ $.65)	$16.25
25	Notification of prescriber authorized medication changes/substitues ($ .65 mailing costs x 820 bleeding disorder patients x 4 notifications per year)	$2,132.00
25	Refill notification for automatic shipment ($ .65 mailing costs x 820 bleeding disorder patients x 4 notifications per year)	$2,132.00
25	Patient notification of product recalls ($ .65 mailing costs x 820 bleeding disorder patients x 2 notifications per year)	$1,066.00
3	Notification of termination of business ($ .65 mailing costs x 100 patients x 3 pharmacies)	$195.00
25	Notification of third party payer delays ($ .65 mailing costs x 410 patients x 4 notifications)	$1,066.00
25	Annual review of policies and procedures ($ 51.16 pharmacist hourly wage x 4 hours x 25 pharmacies)	$5,116.00
		$26,723.25

IV. ASSUMPTION

General Assumptions:

1. The board anticipates the recurring costs will continue annually for the life of the rule. Estimated costs may vary with inflation.
2. Based on information from the Midwest Hemophilia Association and pharmacy representatives specializing in dispensing bleeding clotting products, the board estimates fewer than 25 Missouri pharmacies will be engaged in dispensing products identified in the rule. The board was informed its estimation may be higher than the number of pharmacies currently dispensing blood clotting products for bleeding disorder patients. However, the estimate has been used to ensure full compliance with Chapter 536, RSMo and to account for future fluctuations.
3. Based on information from the Midwest Hemophilia Association, approximately 820 bleeding disorder patients currently exist in Missouri. As a result, an estimated statewide total of 820 patients was used to estimate costs. The board understands many of the current 820 patients receive blood clotting products from non-pharmacy sources which could significantly reduce the number of patients referenced in the rule. However, 820 patients were estimated to ensure full compliance with Chapter 536, RSMo, and to account for population growth.

4. Based on internet research, the board estimates a monthly cost of approximately $50 per month to maintain a basic commercial toll-free telephone number. Significantly, several pharmacies currently maintain toll-free numbers and will not experience additional costs. However, the costs to all estimated pharmacies have been included to ensure compliance with Chapter 536, RSMo.
5. Registration with the National Patient Notification system is free and can be completed electronically. Accordingly, no registration costs have been estimated.
6. The rule requires documentation of dispensing and notification activities in the pharmacy's prescription record. Pharmacies are currently required to maintain a prescription record system and to document dispensing activities by 20 CSR 2220-2.010 and 20 CSR 2220-2.018. The proposed rule would allow use of the prescription record system currently mandated. Accordingly, no additional costs have been estimated for maintaining/documenting required records or activities.
7. The proposed rule requires affected pharmacies to adopt policies and procedures. An estimated total of 8 hours would be required for a pharmacist to compile the required documents. The United States Bureau of Labor Statistics estimates the median annual pharmacist wage/salary to be approximately $ 106,410 in the *Occupational Outlook Handbook, 2010-2011 Edition*. Based on the estimated annual salary, an hourly pharmacist wage of $ 51.16 was utilized to estimate costs. Notably, model policies and procedures may be available from industry organizations.
8. A pharmacist would spend an estimated maximum of 4-hours each year conducting the proposed annual policy and procedure review. Costs were estimated utilizing the previously mentioned estimated pharmacist hourly wage ($51.16 per hour x 4-hours annually x 25 pharmacies).
9. The board anticipates establishing a free electronic process for providing all required board notifications. However, estimated mailing costs have been included herein to ensure compliance with Chapter 536.

Notifications

10. Many of the notifications required by the proposed rule may be provided electronically or by phone, if authorized by the patient. The potential number of patients requesting electronic or phone notification is unknown. As a result, mailing costs have been included herein to ensure compliance with Chapter 536. Mailing costs include costs of postage, envelopes and letterhead.
11. Based on information from parent and pharmacy representatives, the board understands many insurance plans authorize a 90-day supply of medications/supplies referenced by the proposed rule. Accordingly, the board estimates notification of medication changes/substitutes, automatic shipments and third party payer delays will only be required approximately 4 times per year per patient.
12. The number of potential third party payer delays is unknown. The board estimates approximately half of the affected patients may experience a payment delay at each estimated 90-day dispensing cycle that would require notification by the pharmacy.
13. Based on historical data from the National Patient Notification System, less than 2 recalls of the products/items designated in the rule are issued each year that require patient notification. This number has remained historically consistent. Accordingly, recall notification costs were estimated based on an estimated 2 applicable recalls per year. *Note: In the years that exceeded 2 recalls, the recalls were generally issued by the same manufacturer on the same date for similar products. Notification of these multiple recalls can be included in a single notification.*
14. The number of pharmacies required to notify patients of a termination of business or discontinuation of services is unknown. According to the board's FY12 licensing statistics, less than 10% of total licensed pharmacies notified the board of a business closing. The board estimates a similar total would be applicable to pharmacies subject to the proposed rule. Accordingly, the board estimates approximately 3 pharmacies would be required to provide patient notification of a closing or discontinuation of services.

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Periodical
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THIS ISSUE CONTAINS THREE PARTS

END OF PART II