



**NATIONAL HEMOPHILIA FOUNDATION**  
*for all bleeding and clotting disorders*

MASAC Document #188  
(Replaces #181)

**MASAC RECOMMENDATIONS REGARDING STANDARDS OF SERVICE FOR  
PHARMACY PROVIDERS OF CLOTTING FACTOR CONCENTRATES FOR HOME  
USE TO PATIENTS WITH BLEEDING DISORDERS**

*The following recommendation was approved by the Medical and Scientific Advisory Council (MASAC) on November 15, 2008, and adopted by the NHF Board of Directors on November 16, 2008.*

Bleeding disorders such as hemophilia are chronic disorders characterized by bleeding episodes that may occur spontaneously or after mild to severe trauma. The timing and severity of bleeding episodes are unpredictable, even for patients on regularly scheduled treatment; thus providers of clotting factor concentrates must be able to effectively respond to varying frequency and dosing needs.

There are a number of pharmacy providers who supply clotting factor concentrates to patients with bleeding disorders treated at home. When patients do not receive optimal service from these providers, there is potential for adverse health events that lead to poor outcomes and/or increased costs.

MASAC acknowledges the necessity of cost efficiency in the provision of health care, yet cost efficiency should not occur at the expense of quality patient care. The purpose of this document is to establish minimum standards of service for pharmacy providers to meet the specific needs of individuals with bleeding disorders.

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**STANDARDS OF SERVICE FOR PHARMACY PROVIDERS OF  
CLOTTING FACTOR CONCENTRATES FOR HOME USE TO PATIENTS WITH  
BLEEDING DISORDERS**

Patients with bleeding disorders require clotting factor concentrates for prevention and treatment of bleeding episodes. It is essential that any pharmacy provider dispensing clotting factor concentrates for home use provide services that meet the minimal standards delineated below.

**A. Pharmacy Provider Staff Knowledge of Clotting Factor Concentrates and Ancillary Supplies**

1. Pharmacy provider staff shall have sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and assure high quality service for the patient.
2. Pharmacy provider staff shall be experienced with filling and handling prescriptions for the full range of clotting factor concentrates.
3. Pharmacy provider staff shall be knowledgeable about necessary ancillary supplies.
4. Pharmacy provider staff shall be knowledgeable about containers for the disposal of hazardous waste.
5. Pharmacy provider staff shall direct patients to contact their established treating physicians for all medical and therapeutic questions.
6. Pharmacy provider staff shall direct staff medical questions and concerns to the treating physician.

**B. Clotting Factor Concentrates and Ancillaries**

1. Pharmacy providers shall be able to provide the full range of available concentrates, including all available assays and vial sizes.
2. Pharmacy providers shall be able to provide all necessary ancillary supplies for administration of clotting factor concentrates. Examples of ancillary supplies include, but are not limited to: needles; syringes; gauze; anesthetic creams; sterile field pads; sterile gloves.
3. Pharmacy providers shall provide containers for the disposal of hazardous waste, and the collection of such containers shall be arranged pursuant to state and federal law.
4. Some consumers of clotting factor concentrates require additional services, such as nursing services. If the pharmacy providers do not offer these services directly, they shall coordinate with the nursing agencies to ensure that all of the patient's needs are adequately met.

**C. Processing of Prescription Orders**

1. Pharmacy provider staff shall work with prescribing physicians to ensure that prescription orders are filled within 48 hours.
2. Prescriptions of clotting factor concentrates shall be dispensed as written by the prescribing physician. No changes or substitutions shall be made unless approved by the physician.
3. If the prescription does not indicate a specific brand name of product, the pharmacist shall ask the prescribing physician which product should be dispensed.
4. Filling of all prescription orders shall be within plus or minus 5-10 % of prescribed assays, barring extenuating circumstances. This standard shall not be violated by dispensing a number of vials so excessive that it would compromise compliance or so low a dose that it would compromise medical outcome.
5. Clotting factor concentrates shall have acceptable outdates based on diagnosis and frequency of treatment. Short-dated product (outdate within 6 months) shall only be dispensed after consultation with the prescribing physician.

6. Pharmacy provider staff shall supply any ancillary supplies required by the patients and prescribed by their physicians.

#### **D. Hours of Operation / Access to Staff**

1. Pharmacy providers shall be open, at a minimum, Monday through Friday, excluding holidays, during regular business hours (9:00 am to 5:00 pm) in their service area time zones. If a pharmacy serves all 48 contiguous states, it will need to be open from 9:00 am until 8:00 pm Eastern Time, Monday through Friday, not including holidays.
2. Pharmacy staff shall provide 24-hour emergency access including multilingual interpreters in case of emergency.
3. If the pharmacy receives a call about an emergency situation, the treating physician shall be notified immediately. Pharmacy provider in consultation with the treating physician shall have plan in place to ensure that, in case of emergent need, patient shall have access to factor concentrate within 12 hours of expressed need, with a goal of 3 hours where logistically possible.

#### **E. Delivery**

1. Routine orders from established patients shall be correctly filled and delivered within 48 hours from the time the order is placed.
2. If the pharmacy receives a call about an emergency situation, the treating physician shall be notified immediately. Pharmacy provider in consultation with the treating physician shall have plan in place to ensure that, in case of emergent need, patient shall have access to factor concentrate within 12 hours of expressed need, with a goal of 3 hours where logistically possible.
3. Pharmacy providers shall have a plan in place to meet delivery requirements in the event of a natural disaster.
4. Product shall be delivered to the location requested by the patient that has been determined by the pharmacy provider to be appropriate and safe.
5. Shipping of all clotting factor concentrates shall meet all federally mandated standards, including those for temperature control.
6. Pharmacy providers shall adhere to all HIPAA confidentiality guidelines.
7. Pharmacy providers shall have an emergency contact number for customers to report problems with deliveries.

#### **F. Recordkeeping, Billing and Product Recall**

1. Pharmacy providers shall have an accurate record-keeping system that meets state and federal requirements. In addition, pharmacy providers shall have treatment prescription information available for patients and prescribing physicians.
2. Pharmacy providers shall explain patient copay, deductible and coinsurance payment responsibilities, and lifetime cap limits clearly at the time the first order is placed and annually when updating insurance information, or sooner if there has been a change in insurance.
3. Pharmacy providers shall provide a statement of factor cost per unit dispensed to the consumer.
4. Pharmacy providers must be able to trace the path any bottle of clotting factor concentrate has taken and the way it has been handled from the time it left the manufacturer until the time it is delivered to the consumer.
5. Pharmacy providers shall participate in the National Patient Notification System for clotting factor concentrate recalls.

## **GLOSSARY**

**EMERGENCY:** a situation in which the patient's condition requires immediate medical attention and/or treatment.

**HOME USE:** use of clotting factor concentrate in the home or another outpatient setting.

**PHARMACY PROVIDER:** an entity that dispenses clotting factor concentrates to patients for home use.