Oklahoma Health Care Authority (OHCA)
Pharmacy Provider Attestation
Hemophilia and Other Rare Bleeding Disorders Standards of Care

In order to be reimbursed for providing factor replacement products to SoonerCare members, _____, NPI _____, (the "Provider/Pharmacy") hereby agrees to abide by the following standards of care and to provide, at a minimum, the following clinically appropriate items and services to patients with hemophilia and other related blood clotting disorders:

1. The Provider/Pharmacy shall be licensed as a pharmacy by the Oklahoma State Board of Pharmacy. The Pharmacist-in-Charge must be licensed as a pharmacist in Oklahoma.
2. The Provider/Pharmacy agrees that it will provide the following services:
    a. The Provider/Pharmacy shall be capable of providing a full range of factor products including all available vial sizes.
    b. The Provider/Pharmacy shall provide support services to patients on a "24/7" basis in order to assure availability of appropriate support in the event of an after-hours emergency.
    c. The Provider/Pharmacy staff shall deliver factor within 24 hours (with a delivery goal of four hours) of notification of a need due to a current bleeding episode. If the patient is not having an emergency/current bleeding episode, the Provider/Pharmacy shall deliver factor within three days of notification of need.
    d. The Provider/Pharmacy shall provide all necessary supplies for the appropriate preparation and administration of the factor product as well as appropriate sharps and bio-hazardous disposal unit (to include retrieval and destruction of the disposal unit). If the items are SoonerCare compensable, such items must be billed as durable medical equipment (DME) via a DME contract.
    e. The Provider/Pharmacy must provide access to multilingual interpreters for those patients and families for whom English is not their primary language. Interpreters must be available on a "24/7" basis, in order to assure availability in the event of an after-hours emergency.
    f. Case Management
        i. Case Management can be performed by a pharmacist, nurse, social worker, or case manager.
        ii. An in-home patient assessment must be performed upon initiation of services and at least yearly thereafter.
            1. An assessment must include, at a minimum:
                a. Verification of appropriate and adequate storage;
                b. A current inventory of factor product and supplies;
                c. Verification of access to a bio-hazardous waste disposal unit;
                d. A review of current treatment records/logs;
                e. A assessment of educational opportunities to be performed by appropriately trained staff (please refer to 3 (b)(ii) below); and

f. Identification of any adverse events.

2. In the event a patient or caregiver refuses entry to the home, the pharmacy must re-attempt the in-home assessment within three months. If the patient or caregiver continues to deny access, the pharmacy must discuss this issue with the prescribing provider and develop an action plan to verify items set forth in subparagraph 2(f)(ii)(1) above. Documentation must be kept of any refusal, re-attempt, and action plan.
3. The in-home assessment must be completed annually and must be documented and signed by patient or caregiver and pharmacy personnel acknowledging the availability of patient and/or caregiver training and the patient/caregiver's understanding of the items set forth in subparagraph 2(f)(ii)(1) above, together with any additional information discussed.

iii. Regular follow up with the patient via telephone, video call, or in-person. This contact should be at least quarterly and must address, at a minimum:
1. All recent bleeding episodes reported should be forwarded to the prescribing practitioner immediately.
2. Current inventory
   a. Number of factor doses on hand;
   b. Expiration dates of vials on hand.
3. Confirmation of factor storage.
4. Adverse events
   a. If adverse events are reported to a non-clinical case manager, a clinician should become involved immediately.

iv. Coordination of care including nursing, DME, treating practitioner, and all medications, regardless of source.

3. Educational requirements
   a. Staff Education
      i. Staff having contact with the patient via telephone, video calling, or in-person, must be appropriately trained and knowledgeable about hemophilia and other bleeding disorders.
      ii. Two hours of Continuing Education (CE) on hemophilia or other related bleeding disorders must be completed annually. Licensed staff must use accredited CE based on their license type. Non-licensed staff may use non-accredited CE provided by a licensed professional.
         1. Staff members, whether employed or contracted by the pharmacy, who are required to complete CE include but are not limited to the following:
            a. Pharmacist in Charge;
            b. Nurse manager;
            c. Nurse performing direct patient care;
            d. Social worker; and
            e. Case Manager (including customer service representatives).

2. Documentation of educational activity completed must be maintained by the pharmacy and must include the CE certificate or date of activity, staff in attendance, and name and license of professional providing activity.

b. Member and Caregiver Education
   i. Pharmacy staff shall encourage engagement with a Comprehensive Hemophilia Treatment Center. Studies have shown better clinical outcomes for those patients engaged with a Comprehensive Hemophilia Treatment Center.
   ii. Pharmacy staff must discuss educational needs of the patient with the treating practitioner. Once educational opportunities are identified, the pharmacy staff must provide training for the patients and family members in accordance with the treating physician's or mid-level practitioner's recommendations. All patient efforts must be documented. Areas of education may include but are not limited to the following:
      1. Proper storage for factor products and ancillary supplies;
      2. Proper disposal of bio-hazardous waste;
      3. Preparation of factor and supplies;
      4. Training on self-infusion
         a. Prescriber to provide order
            i. Professional licensed nurse (LPN or RN) to train patients or caregivers for peripheral venous access.
            ii. Licensed RN to train patients or caregivers on central line care (e.g. PICC line, InfusaPort, etc.) which includes but is not limited to access, flushing, infusions, and dressing changes.
         b. Training must be in accordance with the MASAC guidelines.
      5. Treatment record keeping; and
      6. Factor and supply management.

4. Factor Product Dispensing and Delivery
   a. Prescriptions cannot be filled without an expressed need from the patient, caregiver or prescribing practitioner. Auto-filling is not allowed. If prescription is written for prophylaxis with additional doses for breakthrough bleeding, then the monthly prophylaxis dispensing should not include further additional doses absent documented use of doses for breakthrough bleeding.
   b. Factor products must be packaged in such a way that a patient or caregiver can easily determine what is to be used for each dose:
      i. If the factor dose to be infused only consists of one vial/box, the vial/box should be labeled as such;
      ii. If the factor dose to be infused consists of two or more vials/boxes then each dose should be packaged as a group of appropriate vials/boxes and labeled as an individual dose.
   c. Factor dose must be within 5% of the prescribed dose.

i. If unable to provide factor dosing within 5% of prescribed dose, then pharmacy must provide proof of all available vial sizes from the manufacturer at the time dispensing occurred.
ii. Any dose requiring more than 3 vials/boxes to be used must be approved by the prescribing practitioner and documented.
iii. Pharmacy staff must, by the 10th of every month , fax or email to the OHCA a copy of the prescription, units per vial dispensed, quantity of each vial size, how the doses were packaged if more than one vial was to be used per dose, and delivery confirmation with member's or caregiver's signature.

d. Any factor product which is short-dated (expiring within 6 months) may only be dispensed after approval from the prescribing practitioner and must be documented.
e. The pharmacy staff must assure appropriate storage of the factor products and supplies including cold chain supply shipping and delivery. The pharmacy must be able to trace the supply chain from manufacturer to patient delivery.
f. The pharmacy must keep records of all lots of factor products dispensed to each patient and notify patient and treating practitioner of any recalls of dispensed factor products. The pharmacy must participate in the National Patient Notification System for clotting factor recalls.
g. The pharmacy provider must have a plan in place for delivery of factor products to the patient in the event of a natural disaster.

5. OHCA Auditing
   a. The OHCA has the right to audit records of the blood clotting factor providers to assure all requirements are being met. The OHCA will audit these records which include but is not limited to the following:
      i. In-home assessment records;
      ii. Educational information and training provided;
      iii. Adverse Event records including reports to other state and federal agencies;
      iv. Sharps and bio-hazardous waste disposal units delivery proof and education on proper disposal in patient record; and
      v. Patient records, including:
         1. Original Prescriptions;
         2. Dispensing records (including lot numbers and expiration dates).
   b. The pharmacy will be excluded from providing blood factor products if OHCA finds that the pharmacy is out of compliance with the requirements as outlined.

Please review, sign and return by **December 27 of each year**. Failure to return by this date may result in denial of factor replacement product claims beginning January 1st. This attestation will be valid from January 1st to December 31st of each year. Re-attestations will be required by January 1st.

Done this _____day of _____ _____.
(month) (year)

I,_____ hereby certify that I have the authority
(Name of Representative of Pharmacy Provider)

to bind _____ to this attestation.
(Pharmacy Provider)

_____
(Signature)

Title of above representative:
_____

Pharmacist in Charge (PIC) as listed with the Oklahoma State Board of Pharmacy:
_____

Address (pharmacy provider service location):_____

_____

_____

Phone (pharmacy provider service location): _____

Phone of PIC (if different):_____

Email address: _____

Email address of PIC (if different):_____

National Provider Identifier (NPI): _____

Notary Public: _____

Commission Expires: _____

Please return to:
The OHCA
C/O Pharmacy Department
4345 N. Lincoln Blvd
Oklahoma City, OK 73105