

APA-1

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control No: 560 . Department or Agency: Alabama Medicaid Agency

Rule No: 560-X-16-.31(5), (8), (11), and (14).

Rule Title: Hemophilia Management Standards of Care
_____ New Rule; X Amend; _____ Repeal; _____ Adoption by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? _____ no

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? _____ yes

Is there another, less restrictive method of regulation available that could adequately protect the public? _____ no

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? _____ no

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? _____ no

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? _____ yes

Does the proposed rule have any economic impact? _____ no

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975 and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of certifying officer: Stephanie Lindsay

Date: 1/21/2014

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EDITED AND APPROVED BY _____ DOCUMENT NO. _____

ALABAMA MEDICAID AGENCY

NOTICE OF INTENDED ACTION

RULE NO. & TITLE: 560-X-16-.31 Hemophilia Management Standards of Care

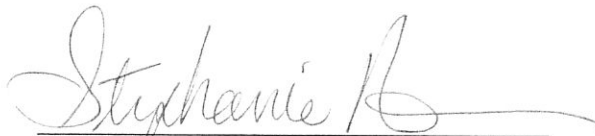
INTENDED ACTION: Amend 560-X-16-.31

SUBSTANCE OF PROPOSED ACTION: The above referenced rule is being amended to clarify the type of continuing education credits needed by providers, address assay variance percentage policy and include possible Agency action when providers are noncompliant with the established Hemophilia Standards of Care.

TIME, PLACE, MANNER OF PRESENTING VIEWS: Written or oral comments may be submitted to the Alabama Medicaid Agency, 501 Dexter Avenue, Post Office Box 5624, Montgomery, Alabama 36103-5624. Agency business hours are 8:00 a.m. to 5:00 p.m. Monday through Friday.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: Written/Oral comments concerning this change must be received by the Alabama Medicaid Agency no later than March 7, 2014.

CONTACT PERSON AT AGENCY: Stephanie Lindsay, Administrative Secretary, Alabama Medicaid Agency, 501 Dexter Avenue, Post Office Box 5624, Montgomery, Alabama 36103-5624.



Stephanie McGee Azar
Acting Commissioner

Rule No. 560-X-16-.31 Hemophilia Management Standards of Care.

In order to be paid for providing blood clotting factor to Alabama Medicaid recipients, the provider must agree to provide, at the minimum, the following clinically appropriate items and services to their patients with hemophilia and blood clotting factor-related diseases:

(1) Home or office delivery of blood clotting factor and supplies. All shipments/delivery of clotting factor, including overnight deliveries, must use appropriate cold chain management and packaging practices to ensure proper temperature, drug stability, integrity, and efficacy are maintained during shipment.

(2) Educational materials and programs.

(a) The provider shall develop a training library at each enrolled provider location with materials for patient use, to include but not limited to, audio, video, electronic, and written materials.

(b) The provider shall offer educational materials to patient or family/caregiver at minimum at initiation of participation with the provider, yearly during the in-home assessment, and upon the request of Medicaid, the prescribing physician, or patient or family/caregiver.

(c) Topics of education shall include, but not be limited to, specific patient and family/caregiver education aimed at preventing injury that would result in a bleed, self-administration and reconstitution of blood clotting products.

(3) Medically necessary ancillary supplies required to perform the actual IV administration of clotting factor. Supplies may be billed to Medicaid through the Durable Medical Equipment (DME) program. In addition, sharps containers and any other necessary biohazardous waste containers shall be provided, as well as pickup and disposal of waste containers according to national, state and local biohazardous waste ordinances.

(4) Emergency telephone support 24 hours a day, 7 days a week to ensure patients are directed appropriately for care in emergent situations.

(5) For the purposes of this Rule and the Alabama Medicaid Agency hemophilia management standards of care, "clinical staff trained in hemophilia and related blood clotting factor related diseases" is defined as follows:

(a) Pharmacists are required to obtain a minimum of 2 Continuing Education (CE, CME or CEU) credit hours per year that are specific to hemophilia or related blood clotting factor-related diseases.

(b) Nurses and social workers are required to obtain a minimum of 4 Continuing Education (CEU) hours per year (~~8 hours every 2 years~~) that are specific to hemophilia or related blood clotting factor-related diseases.

Continuing education must be specific to hemophilia or related blood clotting factor-related diseases and must be recognized by a state or national health care professional accrediting body. ~~hemophilia or bleeding disorder education/support group~~

(for example: Hemophilia Federation of America or the National Hemophilia Association).

(6) Emergency delivery of blood clotting factor within 24 (with a target of less than 12) hours of the receipt of a prescription for a covered person's emergent situation, or notification of the patient with an existing valid prescription. Emphasis should be placed during patient education of the importance of keeping an adequate supply on hand and self-administration for emergent situations.

(7) A pharmacist, nurse, and/or a case representative assigned to each patient. A case representative shall maintain and document, at a minimum, monthly telephone contact with the patient or family/caregiver to include, but not limited to:

- Inquiry regarding patient's current state of well-being
- Assessment of patient/family compliance/adherence, and persistence with the medical treatment plan
- Incidence of adverse events
- Incidences of supply or equipment malfunctions
- Home inventory check of factor and supplies
- Confirmation of next delivery date

Case representatives may include administrative support staff, but must coordinate with clinical staff (as described in (5) above) in the event a clinical issue should arise.

(8) Compliance programs.

(a) The provider must assess patient adherence on monthly telephone contact (see (7) above) and on all in-home visits by a pharmacist, nurse, or case manager.

(b) The provider must verify and document the amount of clotting factor the patient has on hand prior to each dispense. Blood clotting factor and related products are not to be sent to the patient on an auto-ship basis. The provider shall discourage "stockpiling" of product.

(c) The number of bleeds and infusions from the prior shipment shall be tracked to validate the need for additional product or non-compliance with the medical treatment plan.

(9) Notification of product recalls or withdrawals.

(a) Any stock of recalled medications/equipment/supplies shall be removed from stock and quarantined immediately.

(b) Any recalled items dispensed to patients shall be retrieved and quarantined; notification to patients must occur within 24 hours of the recall receipt.

(c) The prescribing physician shall be notified of a medication recall. A prescription for an alternative product shall be obtained, if necessary.

(10) Visiting clinical services.

(a) At minimum, an initial and subsequent yearly in-home assessment of the patient, family/caregiver, and environment shall be conducted by a nurse or pharmacist trained in blood clotting factor related diseases.

(b) Additional in-home assessments of the patient, family/caregiver, and environment deemed necessary by the physician or patient situation shall be conducted.

(c) Visits may be provided directly by the provider or by arrangement with a qualified local home health care agency. All hemophilia-related clinical staff must be trained in hemophilia and bleeding disorder related diseases.

(11) A registered pharmacist trained in blood clotting factor related diseases to perform assay to prescription management. Providers should attempt to achieve the lowest assay percentage in each case. Variance in assay to prescription/target dose should not exceed +/- 10%.

(12) Adverse drug reaction and drug interaction monitoring and reporting.

(a) Pharmacists shall counsel the patient or family/caregiver in accordance with the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) to encourage appropriate medication use, promote realistic therapy expectations, help recipients manage or minimize expected adverse effects and encourage compliance.

(b) Pharmacists shall report any issues or concerns related to the patient's medications to the physician. For significant events, utilization of the FDA 3500 MedWatch voluntary reporting form is encouraged.

(13) Continuation of Care. The provider shall not present any bill to or collect any monies from a covered Medicaid recipient with whom the provider has agreed to the provision of services and supplies for the home treatment of bleeding episodes associated with hemophilia, except as follows:

(a) to collect the copayments/coinsurance amounts the covered person is required to pay under the terms defined by Medicaid, or

(b) if the service/product has been deemed "non-covered" and the recipient has been notified in advance as outlined in the Alabama Medicaid Agency Administrative Code and Provider Billing Manual.

Upon discontinuation of services by the provider, the provider shall, at a minimum, coordinate for another designated health care provider to provide services to covered persons, prior to withdrawal of any hemophilia-related services from the home of any covered person. The provider shall continue to provide services and supplies to a covered individual until the individual obtains an alternate source of services and supplies. Every effort shall be made by the provider (including notification to the Medicaid Director of Pharmacy) to find an alternative provider to ensure that the coordination of care/transition follows the minimum standards of care as set forth in this document.

(14) The Alabama Medicaid Agency (or its designated representative), to ensure clinically appropriate services are being given to hemophilia patients, shall monitor providers of blood clotting factor by prospective and retrospective audits, as well as administer a patient/family/caregiver satisfaction survey to include, but not limited to, measurement of:

- (a) staff availability
- (b) staff knowledge
- (c) timeliness of deliveries
- (d) accuracy of supplies and equipment
- (e) overall satisfaction

If a provider does not meet one or more of the standards for care, as outlined in this Rule, the Alabama Medicaid Agency shall provide a written notice of that determination, with an explanation therefore, to the provider. The provider will not be reimbursed for blood clotting factor or hemophilia related services until the provider meets the standards as approved by the Agency and/or the Agency may seek recoupment. Providers are to attest each year of their understanding and willingness to follow the standards by signing a new Standard of Care agreement each year.

Author: Kelli D. Littlejohn, RPh, Pharm D, Director, Pharmacy Services

Statutory Authority: State Plan, Attachment 3.1-A and Attachment 4.19-B; Title XIX, Social Security Act; 42 CFR Section 430.0, et seq.

History: New Rule: Filed September 20, 2007; effective December 14, 2007. **Amended:** Filed January 21, 2014.