

APA-1

TRANSMITTAL SHEET FOR  
NOTICE OF INTENDED ACTION

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

Rule No: 560-X-16-.06

Rule Title: Reimbursement for Covered Drugs and Services

\_\_\_\_\_ 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

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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.

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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: 10/22/12

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PUBLISHED IN VOLUME \_\_\_\_\_ ISSUE NO. \_\_\_\_\_

EDITED AND APPROVED BY \_\_\_\_\_ DOCUMENT NO. \_\_\_\_\_

**ALABAMA MEDICAID AGENCY**

**NOTICE OF INTENDED ACTION**

**RULE NO. & TITLE:** 560-X-16-.06 Reimbursement for Covered Drugs and Services.

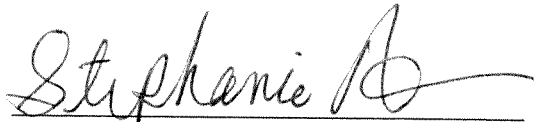
**INTENDED ACTION:** Amend Rule: 560-X-16-.06 (8) (9)

**SUBSTANCE OF PROPOSED ACTION:** The above-referenced rule is being amended to comply with Act No. 2011-615, amending Alabama Code (1975) , §40-26B-70, et seq. The above referenced rule of the Administrative Code is being amended to delete items (8) and (9) since 340 B entities apply to several different provider types other than pharmacy. All 340 B Entity information will be included in Chapter 1, the General Chapter of the Administrative Code.

**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 December 5, 2012.

**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-.06. Reimbursement for Covered Drugs and Services.**

(1) Medicaid pays for certain legend and non-legend drugs prescribed by practitioners legally licensed by the state of Alabama to prescribe the drugs authorized under the program and dispensed and/or administered by a licensed pharmacist or licensed authorized physician in accordance with state and federal laws as stated in Rule 560-X-16-.01.

(2) Multiple Source Drugs. Reimbursement for covered multiple source drugs in the Medicaid Program shall not exceed the lowest of:

(a) The federally mandated upper limit (FUL) for certain multiple source drugs as established and published by CMS plus a reasonable dispensing fee as discussed in paragraph (6) below; or

(b) The Alabama Estimated Acquisition Cost (AEAC) for the drug plus a reasonable dispensing fee. AEAC is defined by Medicaid as the Average Acquisition Cost (AAC) of the drug or, in cases where no AAC is available, the Wholesale Acquisition Cost (WAC) + 9.2%; or

(c) The provider's Usual and Customary charge to the general public for the drug; or

(d) The Alabama State Maximum Allowable Cost (State MAC) plus a reasonable dispensing fee. The State MAC is defined as the AAC of a drug multiplied by at least 1.0 that will apply to all multiple source drugs within a particular grouping. The State MAC reimbursement will apply to certain multiple source drug products that meet therapeutic equivalency, market availability, and other criteria deemed appropriate by the Alabama Medicaid Agency. Reimbursement methodology for the State MAC shall be as follows:

- Drugs are subject to a State MAC if there is at least one non-innovator multiple source alternative product available.
- The Alabama Medicaid Agency or its designated representative will collect and review pharmacy invoices and other information deemed necessary by the Alabama Medicaid Agency in an effort to determine AAC in accordance with applicable State and Federal law.
- This information will be collected from Medicaid-participating pharmacies via surveys. The AAC is multiplied by at least 1.0 to derive the State MAC rate that will apply to all multiple source drugs within the particular grouping.
- The Alabama Medicaid Agency will periodically review the rates and adjust them as necessary to reflect the Alabama Medicaid Agency's understanding of prevailing market conditions.

EXCEPTION: The FUL and/or State MAC may be waived for a brand innovator multiple-source drug. For these cases the prescriber must provide documentation of the medical necessity for the brand name rather than the available generic equivalent and receive an override.

(3) Other Drugs. Reimbursement for covered drugs other than multiple source drugs shall not exceed the lower of:

(a) The Alabama Estimated Acquisition Cost (AEAC) for the drug plus a reasonable dispensing fee. AEAC is defined by Medicaid as the Average Acquisition Cost

(AAC) of the drug or, in cases where no AAC is available, the Wholesale Acquisition Cost (WAC) + 9.2%; or

(b) The provider's Usual and Customary charge to the general public for the drug; or

(c) For blood clotting factor products, Medicare Part B Drug pricing plus a reasonable dispensing fee.

(4) Blood clotting factor products. In addition to providing blood clotting factor, providers of the Alabama Medicaid Agency are required to provide, at the minimum, clinically appropriate items and services to their hemophilia patients as outlined in Rule No. 560-X-16-.31.

(5) The pharmacist shall submit claims in the units specified on the prescription by the prescribing physician up to a 34-day supply. A 90-day supply is permitted for certain maintenance therapies. Payment for units greater than 34 days, unless otherwise permitted, may be recouped by Medicaid unless the pharmacist can provide documentation to support the units dispensed. Medications supplied in a dosage form that would prevent the dispensing of an exact 30 up to a 34-day supply for chronic medications, such as insulin, may require quantities that exceed the 34-day maximum and would not be subject to recoupment as long as the pharmacist can provide appropriate documentation.

(6) Dispensing Fees. A reasonable dispensing fee is set by the Agency. This fee is reviewed periodically for reasonableness and, when deemed appropriate by Medicaid, may be adjusted.

(7) Unless the designated amount of the original days' supply has been utilized or there is a documented consultation with the prescribing physician, only one dispensing fee is allowed for a 30 up to a 34-day supply of the same drug per month. For quantities up to a 34-day supply, the designated amount is 75% of the original days' supply. For quantities greater than a 34-day supply, the designated amount is 90% of the original days' supply.

~~(8) The Veterans Health Care Act of 1992 enacted section 340 B of the Public Health Services Act. "Limitation on Prices of Drugs Purchased by Covered Entities". This Section provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge to Medicaid a price for covered outpatient drugs that will not exceed the average manufacturer price decreased by a rebate percentage.~~

~~(a) Eligible entities are as follows:~~

~~1. Federally qualified health centers.~~

~~2. Health centers for residents of public housing funded under section 340A of the Public Health Services Act, (42 U.S.C. 256a.)~~

~~3. Family planning projects received grants or contracts under section 1001 of the Public Health Services Act, (42 U.S.C. 300.)~~

- ~~4. An entity receiving a grant for outpatient early intervention services for HIV disease under subpart II of part C of title XXVI of the Public Health Services Act, (42 U.S.C. 300ff-51 et seq.)~~
- ~~5. A State-operated AIDS drug purchasing assistance program receiving financial assistance.~~
- ~~6. A black lung clinic receiving funds.~~
- ~~7. A comprehensive hemophilia diagnostic treatment center receiving a grant.~~
- ~~8. A native Hawaiian Health Center receiving funds.~~
- ~~9. An urban Indian organization receiving funds.~~
- ~~10. Any entity, certified by the Secretary, receiving assistance under title XXVI of the Public Health Services Act, (42 U.S.C. 300ff et seq.)~~
- ~~11. Any entity, certified by the Secretary, receiving funds relating in the treatment of sexually transmitted disease.~~
- ~~12. A "disproportionate share" hospital as defined in section 1886 (d)(1)(B) of the Social Security Act.~~

~~(b) When an eligible entity submits a bill to the Medicaid Agency for a drug purchase by or on behalf of a Medicaid recipient, the amount billed shall not exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with the Veterans Health Care Act of 1992, plus the dispensing fee established by the Medicaid Agency. Covered entities are identified to Medicaid by the Department of Health and Human Service. These entities will be notified by Medicaid of their designation as a Veteran's Health Care Act provider. These providers are required to bill at actual invoice cost plus dispensing fee. As manufacturer price changes occur, providers must ensure that their billings are updated accordingly.~~

~~(c) Audits of the eligible entities' claims submissions and invoices will be conducted by the Medicaid Agency. Providers must be able to verify acquisition costs through review of actual invoices for the time frame specified. Charges to Medicaid in excess of the actual invoice costs will be subject to recoupment by the Medicaid Agency.~~

(98) Medicaid may reimburse for professional services provided by licensed pharmacists. Professional services may include vaccine administration, medication maintenance therapy adherence and other clinical services as designated by the Agency.

**Author:** Kelli D. Littlejohn, R.Ph., Pharm. D., Director, Clinical Services and Support.

**Statutory Authority:** State Plan, Attachment 3.1-A and 4.19-B; Title XIX, Social Security Act; 42 CFR Section 447.205 & Section 447.331; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508); Veterans Health Care Act of 1992 (Public Law 102-585).

**History:** Rule effective October 1, 1982. **Amended:** October 29, 1987; December 10, 1987; April 14, 1992; November 12, 1993; April 12, 1996; November 12, 1997; and February 10, 1998. **Amended:** Filed March 19, 1999; Effective June 10, 1999. **Amended:** Filed March 20, 2002; effective June 14, 2002. **Amended:** Filed April 20, 2005; effective July 15, 2005.

**Amended:** Filed July 20, 2007; effective December 14, 2007. **Amended:** Filed January 22,

2008; effective May 1, 2008. **Amended:** Emergency Rule filed and effective November 2, 2009. **Amended:** Filed November 18, 2009; effective February 15, 2010. **Amended:** Filed May 20, 2010; effective August 13, 2010. **Amended:** Filed November 19, 2010; effective March 1, 2011. **Emergency Rule:** Filed and Effective October 1, 2012. **Amended:** Filed October 22, 2012;