

APA-1

TRANSMITTAL SHEET FOR  
NOTICE OF INTENDED ACTION

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

Rule No: 560-X-1-.30

Rule Title: 340 B Entities

X New Rule; \_\_\_\_\_ 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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**ALABAMA MEDICAID AGENCY**

**NOTICE OF INTENDED ACTION**

**RULE NO. & TITLE:** 560-X-1-.30 340 B Entities

**INTENDED ACTION:** Add New Rule: 560-X-1-.30

**SUBSTANCE OF PROPOSED ACTION:** The above-referenced rule is being added to comply with Act No. 2011-615, amending Alabama Code (1975), §40-26B-70, et seq. This new rule has been added to Chapter 1 which will address 340 B Entities. Since this information applies to several different provider types other than pharmacy, it was appropriate to remove this section from Chapter 16, Pharmacy, and include it in the general chapter. It has also been amended with other provider types based on the most current Social Security Act. 340 B entities that are hospitals will now be allowed to bill 'total charges' instead of acquisition cost on their claims.

**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.



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Stephanie McGee Azar  
Acting Commissioner

**Rule No. 560-X-1-30. 340 B Entities.**

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 340B 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 340B entities are defined in 42 U.S.C. § 256b(a)(4).

(b) When an eligible 340B entity, other than a disproportionate share hospital, a children's hospital excluded from the Medicare prospective payment system, a free-standing cancer hospital exempt from the Medicare prospective payment system, sole community hospital, rural referral center, or critical access hospital, submits a bill to the Medicaid Agency for a drug purchased 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. A disproportionate share hospital, children's hospital excluded from the Medicare prospective payment system, free-standing cancer hospital exempt from the Medicare prospective payment system, sole community hospital, rural referral center, or critical access hospital may bill Medicaid the total charges for the drug. As manufacturer price changes occur, the entities must ensure that their billings are updated accordingly.

(c) Eligible 340B entities are identified on the Department of Health and Human Service's website. These entities shall notify Medicaid of their designation as a 340B provider.

(d) Audits of the eligible 340B entities' (claims submissions and invoices) will be conducted by the Medicaid Agency. Eligible 340B entities, other than the providers listed above in paragraph (b), 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 in accordance with Chapter 33 of the Administrative Code.

**Author:** Jerri R. Jackson, Associate Director, Institutional Services Unit.

**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); 42U.S.C. § 256b.

**Emergency Rule:** Filed and effective October 1, 2012. Amended: Filed October 22, 2012.