

APA-1

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

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

Rule No: 560-X-16-.01

Rule Title: Pharmacy Services - General
 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

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: 10/21/13

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ALABAMA MEDICAID AGENCY

NOTICE OF INTENDED ACTION

RULE NO. & TITLE: 560- X-16-.01-Pharmacy General Services

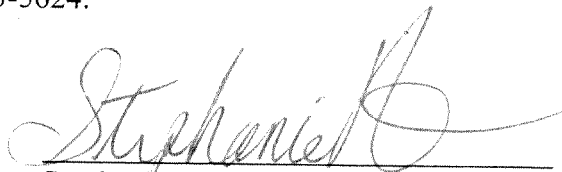
INTENDED ACTION: Amend 560- X-16-.01-Pharmacy General Services

SUBSTANCE OF PROPOSED ACTION: The above referenced rule is being amended to remove barbiturates, benzodiazepines, and agents used to promote smoking cessation from the list of drugs the Medicaid program may exclude or restrict from coverage. These changes are being made in accordance with Centers for Medicare and Medicaid Services (CMS) Program Notices.

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, 2013.

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

Chapter 16 - Pharmaceutical Services

Rule No. 560-X-16-.01 Pharmacy Services - General.

(1) The State Plan provides for the payment of certain legend and non-legend drugs prescribed by Doctors of Medicine, and other practitioners including, but not limited to nurse practitioners, dentists, and physician assistants who are legally authorized to prescribe these drugs and when dispensed and/or administered by a licensed pharmacist or licensed authorized physician in accordance with state and federal laws.

(2) In accordance with the Medicaid Drug Amendments contained in the Omnibus Budget Reconciliation Act of 1990, (Public Law 101-508), the following shall apply: with the exception of allowable published exclusions, only those drugs manufactured by companies having signed rebate agreements with the Secretary of Health and Human Services are compensable. The exclusions are:

(a) DESI and IRS drugs which may be restricted in accordance with Section 1927(d)(2) of the Social Security Act

(b) Agents when used for anorexia, weight loss, or weight gain except for those specified by the Alabama Medicaid Agency

(c) Agents when used to promote fertility except for those specified by the Alabama Medicaid Agency

(d) Agents when used for cosmetic purposes or hair growth except for those specified by the Alabama Medicaid Agency

(e) Agents when used for the symptomatic relief of cough and cold except for those specified by the Alabama Medicaid Agency

~~(f) Agents when used to promote smoking cessation, unless authorized for pregnant females~~

~~(g) Prescription vitamin and mineral products, except prenatal vitamins and fluoride preparations and others as specified by the Alabama Medicaid Agency~~

~~(h) Nonprescription drugs except for those specified by the Alabama Medicaid Agency~~

~~(i) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated test or monitoring services be purchased exclusively from the manufacturer or its designee~~

~~(j) Barbiturates except for those specified by the Alabama Medicaid Agency and for dual eligible individuals effective January 1, 2013 when used for treatment of epilepsy, cancer or a chronic mental health disorder as Part D will cover those indications~~

~~(k) Benzodiazepines except for those specified by the Alabama Medicaid Agency and dual eligible individuals effective January 1, 2013 as Part D will cover all indications~~

~~(l) Agents when used for the treatment of sexual or erectile dysfunction, unless authorized for medical necessity~~

(3) Medicaid will pay for approved drug items when they are properly prescribed for eligible Medicaid recipients.

(4) Telephone prescriptions are not allowed for Schedule II controlled substances. The pharmacist must obtain an original prescription and maintain that documentation on file.

EXCEPTION: In accordance with Alabama pharmacy law, Controlled Substances Act, §20-2-58(c), a prescription written for Schedule II substances for a resident of a long-term care facility may be transmitted by the practitioner or the agent of the practitioner to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription.

(5) The pharmacist initiates a two part Medicaid Pharmacy Claim. The original part of the claim must be retained by the pharmacy for State and audit purposes, and the duplicate is submitted to the fiscal agent for payment. Claims for services may be filed electronically if the provider has signed an electronic claim agreement with the Alabama Medicaid Agency.

(6) Eligible recipients have freedom of choice in the selection of a pharmacy that has a current Pharmacy Vendor Agreement, and must be accorded the same courtesies and services rendered to all other patrons of the pharmacy.

(7) Title XIX (Medicaid) prescriptions should be written and dated for either legend or over-the-counter drugs. Signatures by the prescribing physician are required on all prescriptions for Schedule II drugs. Stamped or typewritten signatures are not acceptable. Schedule II drugs may not be dispensed to Medicaid recipients without an original prescription. Therefore, call-in prescriptions are not acceptable for Schedule II drugs. Telephone prescriptions for non-controlled drugs and drugs other than Schedule II drugs are acceptable without subsequent signature of the practitioner. EXCEPTION: In accordance with Alabama pharmacy law, Controlled Substances Act, §20-2-58(c), a prescription written for Schedule II substances for a resident of a long-term care facility may be transmitted by the practitioner or the agent of the practitioner to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription.

(a) Effective April 1, 2008, all prescriptions for outpatient drugs for Medicaid recipients which are executed in written (and non-electronic) form must be executed on tamper-resistant prescription pads. The term "written prescription" does not include e-prescriptions transmitted to the pharmacy, prescriptions faxed to the pharmacy, or prescriptions communicated to the pharmacy by telephone by a prescriber. This requirement does not apply to refills of written prescriptions which were executed before April 1, 2008. It also does not apply to drugs provided in nursing facilities, intermediate care facilities for the mentally retarded, and other institutional and clinical settings to the extent the drugs are reimbursed as part of a per diem amount, or where the order for a drug is written into the medical record and the order is given directly to the pharmacy by the facility medical staff.

1. If a written prescription is received which is not on a tamper-resistant prescription blank, the pharmacy must contact the prescribing provider and either have the prescription re-submitted in compliant written form or convert the prescription, where otherwise allowable, into verbal, faxed or electronic form.

2. In an emergency situation where the pharmacy is unable to contact the prescribing provider, the pharmacy may choose to fill the prescription from the non-compliant form and subsequently obtain a prescription in compliant form. If a compliant prescription cannot be obtained within 72 hours, the pharmacy must withdraw the claim.

3. To be considered tamper-resistant on or after April 1, 2008, a prescription pad must contain at least one of the following three characteristics:

(i) one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form; or
(ii) one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber; or
(iii) one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

4. To be considered tamper-resistant on or after October 1, 2008, a prescription pad must contain all of the foregoing three characteristics.

(8) Pharmacies shall use the correct physician license number when submitting a pharmacy claim to Medicaid.

(9) Pharmacies should not dispense refill medication to recipients until such time that the designated amount of the original prescription has been utilized. 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. Pharmacists must have documentation on the original prescription that the prescribing physician was consulted and the physician approved. Payments for early refills may be recouped by the Medicaid Agency.

(10) Pharmacies receiving hard denials such as early refill, therapeutic duplication and excessive quantity must receive an override from Medicaid or its designated agent before payment will be made.

(11) Any changes to the original prescription, such as physician approved changes in dosage, should be documented on the original prescription.

(12) A provider agrees to accept as payment in full the amount paid by the State, plus any cost-sharing amount to be paid by the recipient, for covered items, and further agrees to make no additional charge or charges for covered item to the recipient, sponsor, or family of the recipient. However, a provider may bill the recipient for the appropriate allowable copayment amount.

(13) The provider may refuse to accept Medicaid for a Medicaid-covered item and bill the recipient as a regular paying patron if the recipient is informed prior to dispensing the prescription. The recipient has the right to have the prescription filled by any other authorized Medicaid provider.

Author: Tiffany D. Minnifield, Associate Director, Pharmacy Administrative Services.

Statutory Authority: State Plan Attachment 3.1-A and 4.18-B; Title XIX, Social Security Act; 42 CFR Section 447.15, 447.331 & Section 401, et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508), and Public Law 110-28 (SSA Sec. 1903(i)).

History: Rule effective October 1, 1982. Amended July 8, 1983; March 12, 1984; July 9, 1984; June 8, 1985; April 11, 1986; November 10, 1987; April 14, 1992; March 13, 1993; January 1, 1994; March 15, 1994; April 12, 1996; February 11, 1997; November 12, 1997; February 10, 1998; and June 10, 1999. **Amended:** Filed December 19, 2005; effective March 17, 2006.

Amended: Filed March 20, 2006; effective June 16, 2006. **Amended:** Emergency Rule filed and effective April 1, 2008. **Amended:** Filed April 21, 2008; effective July 16, 2008. **Amended:** Filed October 20, 2009; effective January 15, 2010. **Amended:** Emergency Rule filed and effective November 2, 2009. **Amended:** Filed November 18, 2009; effective February 15, 2010. **Amended:** Filed November 19, 2010; effective March 1, 2011. **Amended:** Filed December 11, 2012; effective January 15, 2013. **Amended:** Filed October 21, 2013;