APA-1

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control:	560	
control.	500	
Department or Agency:	Alabama Medicaid Agency	
Rule No.:	560-X-1601	
Rule Title:	Pharmacy Services - General	
Intended Action	Amend	
Would the absence of the proposed rule significantly harm or No No		
Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? $\hfill -$		Yes
Is there another, less restrictive method of regulation available No		
Does the proposed rule have the effect of directly or indirectly No		
To what degree?: N/A		
Is the increase in cost more harmful to the public than the harm		
Are all facets of the rule-making process designed solely for the purpose of, and so they have, as their primary effect, the Yes protection of the public?		
Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject		No
Does the proposed rule have a	an 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, <u>Code of Alabama 1975</u> .		
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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, <u>Code of Alabama 1975</u> , and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.		
Signature of certifying offi	cer Stephanie Lindsay	

\underline{St}	ephanie Lindsay
St	ephanie Lindsay iday, November REC'D & FILED
Fr	iday, November 11 E D Q I ILLE
	NOV 17, 2023
	LEGISLATIVE SVC AGENCY

Date

ALABAMA MEDICAID AGENCY

NOTICE OF INTENDED ACTION

AGENCY NAME:

Alabama Medicaid Agency

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

INTENDED ACTION: Amend

SUBSTANCE OF PROPOSED ACTION:

The above referenced rule is being amended to clarify drug coverage through outpatient pharmacy. EO 735 protect public health, safety, or welfare exception and state law exception.

TIME, PLACE AND 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:

Thursday, January 4, 2024

CONTACT PERSON AT AGENCY:

Stephanie Lindsay Administrative Secretary Alabama Medicaid Agency 501 Dexter Avenue Post Office Box 5624 Montgomery, Alabama 36103-5624 Phone: (334) 353-3781

Stephanie Azar

Stephanie McGee Azar

(Signature of officer authorized to promulgate and adopt rules or his or her deputy)

APA-2

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 the anorexia, weight loss, or weight gain except for those specified by the Alabama Medicaid Agencyanorexia, weight loss, or weight gain except for those specified by the Alabama Medicaid Agency. Selective covered outpatient drugs for all eligible beneficiaries will be covered as listed on the state's website.

(c) Agents when used to promote fertility except for those specified by the Alabama Medicaid Agency. Selective covered outpatient drugs for all eligible beneficiaries will be covered as listed on the state's website.

(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 Agents when used for the symptomatic relief of cough and cold.

(f) (e) Prescription vitamin and mineral products, except prenatal vitamins and fluoride preparations and others as specified by the Alabama Medicaid Agency. Selective covered outpatient drugs for all eligible beneficiaries will be covered as listed on the state's website.

(f) Selective non-prescription covered outpatient drugs for all eligible beneficiaries will be covered as listed on the state's website. (g) Nonprescription drugs except for those specified by the Alabama Medicaid Agency

(h) 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

(i) 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 intellectually disabled, 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 noncompliant 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 physicianNational Provider Identifier (NPI) provider ID or the state license number in the prescriber ID field 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 85% of the original days' supply for opioids (both agonists and partial agonists) and 75% for all other drugs. For quantities greater than a 34day 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 Medicaidcovered 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 Heather Vega, Director, Director, Pharmacy Administrative Clinical Services and Support

Statutory Authority: State Plan Attachment 3.1A and 4.18B; Title XIX, Social Security Act; 42 C.F.R. Section 447.15, 447.331 & Section 401, et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508). History: Rule effective October 1, 1982. Amended: Effective July 8, 1983. Emergency rule : Effective January 1, 1984. Amended: Effective March 12, 1984, July 9, 1984; June 8, 1985; April 11, 1986; November 10, 1987; April 14, 1992; March 13, 1993. Emergency rule : Effective June 1, 1993. Amended: Filed July 7, 1993. Effective: August 12, 1993. Emergency rule : Effective January 1, 1994. Amended: Filed February 7, 1994; effective March 15, 1994. Amended: Filed March 7, 1996; effective April 12, 1996. Amended: Filed January 7, 1997; effective February 11, 1997. Amended: Filed January 6, 1998; effective February 10, 1998. Amended: Filed May 6, 1999; effective June 10, 1999. Amended: Filed February 10, 2006; effective March 17, 2006. Amended: Filed May 12, 2006; effective June 16, 2006. Amended: Filed June 11, 2008; effective July 16, 2008. Amended: Filed December 11, 2009; effective January 15, 2010. Amended: Filed January 11, 2010; effective February 15, 2010. Amended: Filed January 25, 2011; effective March 1, 2011. Amended: Filed December 11, 2012; effective January 15, 2013. Amended: Filed December 12, 2013; effective January 16, 2014. Amended: Filed October 12, 2018; effective November 26, 2018. Amended: Filed: November 30, 2023;

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