APA-1

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control No: 560 Department or Agency: Alabama Medicaid Agency

Rule No: 560-X-16-.27

Rule Title: Preferred Drug List.

_____ 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? yes

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: 2/18/2015

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FOR APD USE ONLY

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EDITED AND APPROVED BY _____ DOCUMENT NO. _____

APA-2

ALABAMA MEDICAID AGENCY

NOTICE OF INTENDED ACTION

RULE NO. & TITLE: 560-X-16-.27 Preferred Drug List

INTENDED ACTION: Amend 560-X-16-.27

SUBSTANCE OF PROPOSED ACTION: The above referenced rule is being amended to clarify the scope of the preferred drug list and product review process within the Medicaid pharmacy program.

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 April 3, 2015.

CONTACT PERSON AT AGENCY: Stephanie Lindsay, Administrative Secretary, Alabama Medicaid Agency, 501 Dexter Avenue, Post Office Box 5624, Montgomery, Alabama 36103-5624. Phone: (334) 242-5833.

Stephanie McGee Azar
Acting Commissioner

APA-6

ECONOMIC IMPACT STATEMENT

FOR APA RULE

(Section 41-22-23 (f))

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

Rule No.: 560-X-16-.27 .

Rule Title: Preferred Drug List .

_____New __X__Amend _____Repeal _____Adopt by Reference

_____This rule has no economic impact.

__X__This rule has an economic impact, as explained below:

1. NEED/EXPECTED BENEFIT OF RULE:

   This amendment is to clarify the scope of the preferred drug list and product review process within the Medicaid pharmacy program. This change will allow the Medicaid Agency to negotiate and accept additional supplemental rebates on certain drug/drug classes. Efficacy and safety considerations override all other considerations in the preferred drug decision making process.

2. COSTS/BENEFITS OF RULE AND WHY RULE IS THE MOST EFFECTIVE, EFFICIENT, AND FEASIBLE MEANS FOR ALLOCATING RESOURCES AND ACHIEVING THE STATED PURPOSE:

   Modifying the scope of the preferred drug list may allow the Medicaid Agency to potentially accept additional supplemental rebates of approximately $3 million state and federal funds annually.

3. EFFECT OF THIS RULE ON COMPETITION:

   This rule will allow additional opportunities for drug manufacturers to compete for preferred drug status.

4. EFFECT OF THIS RULE ON COST-OF-LIVING AND DOING BUSINESS IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:

N/A

5. EFFECT OF THIS RULE ON EMPLOYMENT IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:

N/A

6. SOURCE OF REVENUE TO BE USED FOR IMPLEMENTING AND ENFORCING THIS RULE:

State and federal funds.

7. THE SHORT-TERM/LONG-TERM ECONOMIC IMPACT OF THIS RULE ON AFFECTED PERSONS, INCLUDING ANALYSIS OF PERSONS WHO WILL BEAR THE COSTS AND THOSE WHO WILL BENEFIT FROM THE RULE:

Modifying the scope of the preferred drug list may allow the Medicaid Agency to potentially accept additional supplemental rebates of approximately $3 million state and federal funds annually.

8. UNCERTAINTIES ASSOCIATED WITH THE ESTIMATED BENEFITS AND BURDENS OF THE RULE, INCLUDING QUALITATIVE/QUANTITATIVE BENEFITS AND BURDEN COMPARISON:

Any uncertainty related to the economic impact is due to the constant release of new pharmaceutical products.

9. THE EFFECT OF THIS RULE ON THE ENVIRONMENT AND PUBLIC HEALTH:

N/A

10. DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE RULE IS NOT IMPLEMENTED:

N/A

Rule No.560-X-16-.27 Preferred Drug List

(1) The Alabama Medicaid Agency will utilize a preferred drug list for determination of drugs available for reimbursement under the Medicaid Program ~~without prior authorization~~. For reimbursement under the Medicaid Program, use of the Preferred Drug list is mandatory. Drugs not included on the list may be available through the prior authorization process. Medicaid shall strive to ensure any restriction on pharmaceutical use does not increase overall health care costs to Medicaid.

(2) Over the counter drugs covered by Medicaid will be considered preferred drugs for purposes of this rule. Over the counter drugs will not appear on the preferred drug list.

(3) The Alabama Medicaid Agency will utilize the Pharmacy and Therapeutics Committee to review and recommend drugs for the Preferred Drug List. The Committee will consist of three clinical pharmacists licensed to practice in the state of Alabama including at least one independent pharmacist and one long term care pharmacist, and at least five physicians licensed to practice medicine in the state of Alabama. Physician members will be appointed by the Medicaid Commissioner from a list of at least two nominees for each position submitted by Medical Association of the State of Alabama. Clinical pharmacist members will be nominated by the Alabama Pharmacy Association and appointed by the Medicaid Commissioner; pursuant to state law governing professional services. Members will serve staggered two year terms and may be reappointed to the Pharmacy and Therapeutics Committee for additional terms.

(4) Drugs will be considered for the preferred drug list based on the following:
- (a) clinical efficacy
- (b) side effect profiles
- (c) appropriate usage
- (d) cost

(5) Meetings of the Pharmacy and Therapeutics Committee shall meet the requirements of the State open meetings law, and documents relating to a recommendation by the Committee shall be available under the State's public records law.

(6) Pharmaceutical manufacturers may request a product review by the Medicaid Pharmacy and Therapeutics Committee of any new pharmaceutical product falling within the scope of the Medicaid preferred drug list. The request must be in writing and directed to the Pharmacy Program Director. Reviews will be placed on the agenda for review in the order in which they are received.

(7) Medicaid will maintain a database of industry representatives for correspondence and notice regarding the Preferred Drug Program. Manufacturers are responsible for providing accurate contact information to Medicaid. Medicaid will update the information bi-annually. If no contact information is provided, Medicaid will utilize contact information on file with the Medicaid Drug Rebate Program.

(8) Medicaid will send written notice not less than thirty (30) calendar days prior to a meeting of the Pharmacy and Therapeutics Committee to manufacturers whose brand name drug(s) will be considered for preferred status at the meeting.

(9) A product or a product with a new indication must have been on the market for a minimum of six (6) months before a review can be requested by a pharmaceutical manufacturer. Requests must be in writing and clearly labeled as a request for product review. Evidence supporting inclusion of the product may be submitted in writing and clearly labeled as part of the request for product review.

(10) Pharmaceutical manufacturers may submit evidence supportive of inclusion of a product on the Medicaid Preferred Drug List to be reviewed by the Pharmacy and Therapeutics Committee. Written comments must meet the following requirements:

(a) Must be received by Medicaid at least twenty-one (21) calendar days prior to the Pharmacy and Therapeutics Committee meeting. Deadlines falling on weekends or holidays must be received by noon CST of the next business day.

(b) Must be clinically based.

(c) Must not contain cost information. Submissions with cost information will be rejected in its entirety.

(d) Must be clearly labeled and indicate the class of products represented.

(e) Must provide to Medicaid twenty (20) copies by the deadline.

(11) Pharmaceutical manufacturers may make oral presentations to the Pharmacy and Therapeutics Committee on products being reviewed for preferred status. Oral presentations must meet the following requirements:

(a) Limited to five (5) minutes per drug class.

(b) Limited to one (1) representative and one (1) presentation per product.

(c) Limited to branded products within the class being considered.

(d) No cost information can be addressed. Inclusion of cost information will terminate the presentation.

(e) Must submit a one (1) page summary of the presentation twenty-one (21) calendar days prior to the meeting. See 10(a) above.

(f) Must provide twenty (20) copies if summary is to be distributed to Committee members at meeting. Copies must be submitted to Medicaid at sign-in.

(g) Presenters must sign-in at the registration table a minimum of ten (10) minutes prior to the scheduled start time of meeting. Failure to sign-in will result in elimination of the oral presentation.

(h) No visual aids other than designated handouts are allowed.

(12) Manufacturers may request a reconsideration of a clinical recommendation of the Pharmacy and Therapeutics Committee. Written requests should be submitted to the Medicaid Pharmacy Director and received no later than thirty (30) calendar days following the posting of the final Preferred Drug List to the Medicaid website. Requests must include clinical documentation including references to justify a reconsideration. Manufacturer contact information should be included with the submission. Medicaid will respond to requests for reconsideration within ninety (90) calendar days of receipt.

Author: Allison Scott, Preferred Drug List Administrator
Statutory Authority: State Plan Attachment 3.1-A and 4.18-B; Title XIX, Social Security Act; 42 CFR Section 447.331 & Section 401, et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508).
History: New Rule Filed June 21, 2004; Effective September 17, 2004. **Amended:** Filed February 19, 2015.