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 September 4, 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

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~~. Prescriptions for drugs within the scope of the Medicaid preferred drug list that are not included on the preferred drug list require prior authorization before being reimbursed. Notwithstanding the preceding sentence, Medicaid may, to the extent permitted under 42 U.S.C. § 1396r-8(d), enter into an agreement with a manufacturer to designate a drug that is subject to prior authorization as a preferred drug. 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 July 20, 2015.