APA-1

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

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

Rule No: 560-X- 16-.20 (7) .

Rule Title: Quantity Limitations .

_____ 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? Yes

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? Yes

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? 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.

****

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: _____

****

FOR APD USE ONLY

PUBLISHED IN VOLUME _____ ISSUE NO. _____

EDITED AND APPROVED BY _____ DOCUMENT NO. _____

APA-2

ALABAMA MEDICAID AGENCY

NOTICE OF INTENDED ACTION

RULE NO. & TITLE: 560-X- 16-.20 (7) Quantity Limitations

INTENDED ACTION: Amend 560-X -16-.20 (7)

SUBSTANCE OF PROPOSED ACTION: The above-referenced rule is being amended to limit the number of brand name outpatient pharmacy prescriptions for adult recipients to one brand name per month per recipient. Prescriptions for Medicaid eligible recipients under age 21 in the Child Health Services/EPSDT Program and Medicaid eligible nursing facility residents are excluded from these limitations. Existing allowances for up to 10 brand name antiretrovirals, antipsychotics, and switchovers per adult recipient will remain intact.

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 July 5, 2012.

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

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-.20 (7).

Rule Title: Quantity Limitations.

_____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:
The limitation of the number of outpatient pharmacy prescriptions for adult recipients (prescriptions for Medicaid eligible recipients under age 21 in the Child Health Services/EPSDT Program and Medicaid eligible nursing facility residents are excluded) to one brand maximum per recipient per month would have an estimated total budget savings of $14,000,000 for the remainder of FY 12 and $42,000,000 for FY13. This amendment would be effective June 1, 2012.

2. COSTS/BENEFITS OF RULE AND WHY RULE IS THE MOST EFFECTIVE, EFFICIENT, AND FEASIBLE MEANS FOR ALLOCATING RESOURCES AND ACHIEVING THE STATED PURPOSE:
This rule change will allow Medicaid to preserve pharmacy benefits while still providing access to medically necessary medications.

3. EFFECT OF THIS RULE ON COMPETITION:
N/A

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:
A source of revenue will not be required for implementing and enforcing this rule.

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:
The reduction in covered prescriptions will increase the costs incurred by Medicaid recipients to obtain prescriptions above the monthly total brand name limit of one.

8. UNCERTAINTIES ASSOCIATED WITH THE ESTIMATED BENEFITS AND BURDENS OF THE RULE, INCLUDING QUALITATIVE/QUANTITATIVE BENEFITS AND BURDEN COMPARISON:
It is estimated that 19.1% of all adult Alabama Medicaid pharmacy program recipients would be impacted by this rule change during any given month. There will likely be uncertain costs that are difficult to measure. Some savings generated by the reduction in the prescription limit may be offset by increased health care costs in other areas, such as more Medicaid claims for doctor visits and hospital and nursing home admissions. Also, pharmacy tax and rebate revenues generated will be reduced as the number of filled prescriptions decreases.

9. THE EFFECT OF THIS RULE ON THE ENVIRONMENT AND PUBLIC HEALTH:
No impact is expected on the environment. Public health may be adversely impacted by Medicaid recipients not receiving all of their medically necessary medications.

10. DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE RULE IS NOT IMPLEMENTED:
If this rule is not implemented, it is probable that the Agency will not be able to provide medically necessary medications to all recipients due to budgetary shortfalls.

**Additional pages may be used if needed.

Rule No. 560-X-16-.20 Quantity Limitations.

(1) Prescriptions should be written to provide a sufficient amount of medication necessary for the duration of the illness or an amount sufficient to cover the interval between physician's visits. A 34-day supply shall not be split into small units and submitted as separate claims.

(2) The quantity for which a prescription is written should not exceed a maximum of eleven refills for non controlled prescriptions or five refills for Control III-V prescriptions. Claims for prescription refills beyond eleven refills for non controlled prescriptions or five refills for Control III-V prescriptions shall be denied.

(3) Quantities (units) of drugs prescribed by a physician shall not be arbitrarily changed by a pharmacist except by authorization of the physician.

(a) The pharmacist must contact the prescribing physician for authorization to reduce the quantity of any Medicaid prescription.

(b) Authorization to reduce the units of a prescription must be noted on the prescription form by the pharmacist.

(4) If the full quantity prescribed is not available at the time of dispensing, the pharmacist may dispense the quantity available. In this case the pharmacist is required to note on the prescription the number of units dispensed and retain the claim until the balance of medication is dispensed. The claim is then submitted with one dispensing fee. If more than one dispensing fee is received, recoupments may be initiated if the dispensing pharmacy cannot provide documentation to support why multiple dispensing fees were received within the same month.

(5) Medicaid patients regulated on long-term or maintenance drugs which require a systematic and routine dosage of thirty to thirty-four days or more should receive their drugs in quantities greater than the thirty to thirty-four-day supply.

(6) Maintenance medications are those generally used to treat chronic conditions or illnesses and are ordered/prescribed and taken regularly and continuously. Medicaid recipients can obtain a 90-day supply of maintenance medications as designated by the Agency. The patient must first have demonstrated stability for at least 60 days (same strength and dose) on a given maintenance medication. Only one co-pay is collected and only one dispensing fee is paid for the 90-day supply. A list of maintenance medications is available on the Medicaid website.

(7) Effective ~~October 1, 2011~~ June 1, 2012, the number of outpatient pharmacy prescriptions for all recipients except as specified below is limited to ~~four~~ one brand name drugs per month per recipient. ~~In no case can total brand name prescriptions exceed ten per month per recipient.~~ There is no limit on generic and covered over-the-counter prescriptions. Prescriptions for Medicaid eligible recipients under age 21 in the Child Health Services/Early and Periodic Screening, Diagnosis and Treatment (EPSDT)

Program and prescriptions for Medicaid eligible nursing facility residents are excluded from these limitations.

(a) Brand name anti-psychotic and anti-retroviral agents may be paid up to ten prescriptions per month but in no case can total brand name prescriptions exceed ten per month per recipient.

(b) Effective November 22, 2004, coverage of up to ten brand name prescriptions per month may be allowed through overrides for drugs classified by American Hospital Formulary Services (AHFS) or First DataBank (FDB) Therapeutic Class as Antineoplastic Agents, Antiarrhythmic Agents, Cardiotonic Agents, Miscellaneous Vasodilating Agents, Miscellaneous Cardiac Agents, Nitrates and Nitrites, Alpha Adrenergic Blocking Agents, Beta Adrenergic Blocking Agents, Dihydropyridines, Miscellaneous Calcium Channel Blocking Agents, Diuretics, Angiotensin-Converting Enzyme Inhibitors, Angiotensin II Receptor Antagonists, Mineralocorticoid (Aldosterone) Receptor Antagonists, Central Alpha Agonists, Direct Vasodilators, Peripheral Adrenergic Inhibitors, Miscellaneous Hypotensive Agents, Hemostatics, Calcium Replacements, Electrolyte Depleters, Immunosuppresives, Alpha Glucosidase Inhibitors, Amylinomimetics, Biguanides, Dipeptidyl Peptidase-4 Inhibitors, Incretin Mimetics, Insulins, Meglitinides, Sulfonylureas, Thiazolidinediones, and Miscellaneous Diabetic Agents. Overrides will be granted only in cases in which the prescribing physician documents medical necessity for the recipient to be switched from a product in one of the above named classes to a brand name product within the same therapeutic class in the same calendar month. The first product must have been covered by Medicaid.

Author: Bakeba R. Thomas, Associate Director, Pharmacy Clinical Support.
Statutory Authority: State Plan, Attachment 3.1-A; Title XIX, Social Security Act; 42 CFR Section 401, et seq.
History: Rule effective October 1, 1982: Amended December 6, 1984; November 10, 1987; April 14, 1992; November 12, 1997; and February 10, 1998. **Amended:** Filed March 22, 2004; effective June 18, 2004. **Amended:** Filed August 20, 2004; effective November 22, 2004. **Amended**: Filed August 22, 2005; effective November 16, 2005. **Amended:** Filed August 20, 2007; effective November 16, 2007. **Amended:** Filed November 19, 2010; effective March 1, 2011. **Amended**: Filed June 20, 2011; effective September 15, 2011. Emergency Rule filed and effective June 1, 2012. **Amended:** Filed May 21, 2012.