TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control No: 560 . De	epartment or Agency:	Alabama Medicaid	Agency	
Rule No: <u>560-X-16</u>	20 (6), (7)			
Rule Title: Quantity L	imitations			****
New Rule;	X Amend;	Repeal;	Adoption by Refe	erence
Would the absence of the health, welfare, or safe	he proposed rule signi	ficantly harm or endan	ger the public	no
Is there a reasonable re of the public health, sai	lationship between the ety, or welfare?	state's police power ar	nd the protection	yes
Is there another, less re protect the public?	strictive method of reg	gulation available that o	could adequately	no
Does the proposed rule of any goods or service	have the effect of direct involved and, if so,	ectly or indirectly incre to what degree?	asing the costs	no
Is the increase in cost, result from the absence			rm that might	no
Are all facets of the rul they have, as their prim ************************************	ary effect, the protecti	on of the public?		<u>yes</u> ******
Does the proposed rule	have any economic in	npact? <u>yes</u>		
If the proposed rule has note prepared in accord ************************************	ance with subsection (f) of Section 41-22-23	. Code of Alabama	1975
Certification of Author	zed Official			
I certify that the attache Chapter 22, Title 41, Co the Administrative Proc	ode of Alabama 1975 and sedure Division of the	and that it conforms to Legislative Reference	all applicable filir	requirements of ag requirements of
Signature of certifying		ruie Linda	Xy	
Date: <u>U 20 3</u> ***********************************	 *********	*******	C' ************	*****
FOR APD USE ONLY				
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ALABAMA MEDICAID AGENCY

NOTICE OF INTENDED ACTION

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

INTENDED ACTION: Amend 560-X-16-.20

SUBSTANCE OF PROPOSED ACTION: The above referenced rule is being amended to limit the number of outpatient pharmacy prescriptions for all recipients, except as specified below, to four brand name and five total drugs per month per recipient effective October 1, 2013. 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. 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. Allowances will be made for a 3 month supply in certain chronic drug classes to override the prescription limit. This amendment is also to change the maintenance supply language from 90 day supply to three month supply.

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 August 2, 2013.

<u>CONTACT PERSON AT AGENCY:</u> Stephanie Lindsay, Administrative Secretary, Alabama Medicaid Agency, 501 Dexter Avenue, Post Office Box 5624, Montgomery, Alabama 36103-5624.

Stephanie McGee Azar Acting Commissioner

ECONOMIC IMPACT STATEMENT

FOR APA RULE

(Section 41-22-23 (f))

Control No.	560. Department or Agency <u>Alabama Medicaid Agency</u> .
Rule No.: 5	60-X-1620
Rule Title: <u>(</u>	Quantity Limitations
Nev	w X Amend Repeal Adopt by Reference
Thi	s rule has no economic impact.
X_This	s rule has an economic impact, as explained below:
The language (pressure street)	D/EXPECTED BENEFIT OF RULE: limitation of the number of outpatient pharmacy prescriptions for adult recipients scriptions for Medicaid eligible recipients under age 21 in the Child Health ices/EPSDT Program and Medicaid eligible nursing facility residents are excluded) we drugs, four brands maximum, per recipient per month would have an estimated annual budget savings of \$12 million. This amendment would be effective October 113. Drugs used for HIV/AIDS and antipsychotics are allowed up to 10 brand criptions per month, and allowances will be made for a 3 month supply in certain nic drug classes to override the prescription limit.
EFFI ACH This	TS/BENEFITS OF RULE AND WHY RULE IS THE MOST EFFECTIVE, CIENT, AND FEASIBLE MEANS FOR ALLOCATING RESOURCES AND ILEVING THE STATED PURPOSE: rule change will allow Medicaid to preserve pharmacy benefits while still providing st to medically necessary medications.
	ECT OF THIS RULE ON COMPETITION: This rule will not have an effect on petition.
	ECT OF THIS RULE ON COST-OF-LIVING AND DOING BUSINESS IN THE GRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:

The reduction in covered prescriptions may have an adverse effect on pharmacies that are enrolled as Medicaid providers.

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

 An adverse impact on pharmacies as stated in Item 4 could result in a corresponding adverse impact on the number of pharmacists and support personnel employed by pharmacies.
- 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 may increase the costs incurred by Medicaid recipients to obtain prescriptions above the monthly total limit of five that fall outside of the exclusions. Pharmacies and their employees may be adversely affected as stated in Items 4 and 5.
- 8. UNCERTAINTIES ASSOCIATED WITH THE ESTIMATED BENEFITS AND BURDENS OF THE RULE, INCLUDING QUALITATIVE/QUANTITATIVE BENEFITS AND BURDEN COMPARISON:

 It is estimated that 26% of all Alabama Medicaid pharmacy program recipients may be impacted by this rule change during a fiscal year. 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, tax revenues generated by the pharmacy prescription tax 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-three month 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-three month supply. A list of maintenance medications is available on the Medicaid website.
- (7) Effective October 1, 2011, the number of outpatient pharmacy prescriptions for all recipients except as specified below is limited to four brand name drugs per month per recipient. Effective October 1, 2013, the number of outpatient pharmacy prescriptions for all recipients except as specified below is limited to four brand name and five total 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. Amended: Filed June 20, 2013.