# TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control No: <u>560</u> . Departmen	t or Agency: _	Alabama Medicaid	Agency	
Rule No: <u>560-X-1620 (7)</u>				
Rule Title: <u>Quantity Limitation</u> New Rule; <u>X</u>		Repeal;	Adoption by	Reference
Would the absence of the propo health, welfare, or safety?	sed rule signif	icantly harm or endar	nger the public	no
Is there a reasonable relationship of the public health, safety, or w	p between the velfare?	state's police power a	and the protection	yes
Is there another, less restrictive protect the public?	method of reg	ulation available that	could adequately	no
Does the proposed rule have the of any goods or services involv			easing the costs	no
Is the increase in cost, if any, more result from the absence of the p		the public than the h	arm that might	no
Are all facets of the rulemaking they have, as their primary effectives ************************************	t the protection	on of the public?		yes *******
Does the proposed rule have any				
If the proposed rule has an econ note prepared in accordance wit ************************************	h subsection (	f) of Section 41-22-23	3. Code of Alabar	na 1975
Certification of Authorized Offi	cial			
I certify that the attached propose Chapter 22, Title 41, <u>Code of A</u> the Administrative Procedure D	labama 1975 a ivision of the	and that it conforms to	o all applicable fil Service.	e requirements of ing requirements of
Signature of certifying officer:	DIN	hans A		
FOR APD USE ONLY	The second secon		ጉ · · · ጥ ጥ ጥ ጥ ጥ ጥ ጥ ጥ ጥ ች ቾ ቾ	ጥጥጥጥጥሞሞ
PUBLISHED IN VOLUME		ISSUE N	O	
EDITED AND APPROVED BY	(	DOC	CUMENT NO.	

#### 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)

<u>SUBSTANCE OF PROPOSED ACTION</u>: The above-referenced rule is being amended to limit the number of outpatient pharmacy brand prescriptions for adult recipients to four drugs, 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. This amendment will be effective October 1, 2011.

**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, 334-242-5833. 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 4, 2011.

**CONTACT PERSON AT AGENCY:** Stephanie McGee Azar, Administrative Secretary, Alabama Medicaid Agency, 501 Dexter Avenue, Post Office Box 5624, Montgomery, Alabama 36103-5624.

R. Bob Mullins, Jr., MD

Commissioner

## ECONOMIC IMPACT STATEMENT

## FOR APA RULE

(Section 41-22-23 (f))

Contro	l No. <u>560</u> .	Department or Agency _	Alabama Medicaid Agency .		
Rule N	o.: <u>560-X-1620</u>	(7)			
Rule T	itle: Quantity Lin	<u>nitations</u>			
	New X	AmendRepeal	Adopt by Reference		
	_ This rule has	no economic impact.			
X	This rule has	an economic impact, as e	xplained below:		
8					
1.	The limitation or recipients (presc Services/ EPSD' to five drugs, pe	riptions for Medicaid elig Γ Program and Medicaid ε r month per recipient will ollars annually for both F	pharmacy brand prescriptions for adult able recipients under age 21 in the Child Health bligible nursing facility residents are excluded) have a total budget impact of savings of Y 2012 and FY 2013. This amendment would		
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 providing access to medically necessary medications.				
3.	EFFECT OF TH N/A	IIS RULE ON COMPETI	ΓΙΟΝ:		
4.			LIVING AND DOING BUSINESS IN THE RULE IS TO BE IMPLEMENTED:		

- 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: N/A
- 8. UNCERTAINTIES ASSOCIATED WITH THE ESTIMATED BENEFITS AND BURDENS OF THE RULE, INCLUDING QUALITATIVE/QUANTITATIVE BENEFITS AND BURDEN COMPARISON:
  It is estimated that less than 1% of all Alabama Medicaid pharmacy program recipients would be impacted by this rule change during a fiscal year.
- 9. THE EFFECT OF THIS RULE ON THE ENVIRONMENT AND PUBLIC HEALTH:  $\rm N/A$
- 10. DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE RULE IS NOT IMPLEMENTED:

  If this rule change is not implemented it is probable that the Agency will not be able to provide medically necessary medications to all recipients due to budgetary shortfall.

<sup>\*\*</sup>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 January October 1, 2008 2011, the number of outpatient pharmacy prescriptions for all recipients except as specified below is limited to five four 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.