



## Fast Track Proposed Regulation Agency Background Document

<b>Agency name</b>	DEPT. OF MEDICAL ASSISTANCE SERVICES
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC 30-50-35 and 12 VAC 30-50-75
<b>Regulation title</b>	12 VAC 30-50-35 "Requirements relating to payment for covered outpatient drugs for the categorically needy" and 12 VAC 30-50-75 "Requirements relating to payment for covered outpatient drugs for the medically needy"
<b>Action title</b>	Discontinue Coverage of Benzodiazepines and Barbiturates for Dual Eligible Individuals
<b>Date this document prepared</b>	July 1, 2013

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

This regulatory change proposes to eliminate coverage for both benzodiazepines and barbiturates for full benefit dual eligibles (eligible for both Medicare and Medicaid), who may now obtain both these drugs under Medicare Part D drug coverage.

Currently, the Medicaid State Plan provides drug coverage for certain drug classes not provided for under Medicare Part D, including the drug classes of benzodiazepines and barbiturates. This regulatory action eliminates Medicaid coverage of benzodiazepines and barbiturates for approximately 109,000 categorically needy and medically needy full benefit dual eligibles. These drug categories will be covered by these individuals' chosen Medicare Part D pharmacy benefit plan effective January 1, 2014.

### Statement of final agency action

I hereby approve the foregoing Regulatory Review Summary with the attached amended regulations, 12 VAC 30-50-35 "Requirements relating to payment for outpatient drugs for the categorically needy" and 12 VAC 30-50-75 "Requirements relating to payment for covered

drugs for the medically needy” and adopt the action stated therein. I certify that this final regulatory action has completed all the requirements of the Code of Virginia § 2.2-4012.1, of the Administrative Process Act.

\_\_\_\_\_  
Date

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Cynthia B. Jones, Director  
Dept. of Medical Assistance Services

**Legal basis**

The *Code of Virginia* (1950) as amended, § 32.1-325, grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance. The *Code of Virginia* (1950) as amended, § 32.1-324, authorizes the Director of DMAS to administer and amend the Plan for Medical Assistance according to the Board's requirements. The Medicaid authority as established by § 1902 (a) of the *Social Security Act* [42 U.S.C. 1396a] provides governing authority for payments for services.

**Purpose**

This amendment to the State Medicaid regulations eliminates redundant coverage of benzodiazepines and barbiturates between Medicare and Medicaid. This amendment will not prevent full benefit dual eligibles from receiving these drugs. With this change full benefit dual eligibles will obtain these two drugs from their Medicare Part D pharmacy benefit provider, rather than through the Medicaid fee-for-service program. In accordance with existing Medicaid policy, DMAS will continue to provide coverage for all other Virginia Medicaid-covered drugs that are not covered under Medicare Part D coverage.

**Rationale for using fast track process**

DMAS is utilizing the fast track process because the agency does not anticipate any objections to these changes. Full benefit dual eligibles will continue to have the same access to all of the classes of drugs they previously had under Medicaid. This change is anticipated by the provider community because the expanded Medicare Part D drug coverage for benzodiazepines and barbiturates, regardless of medical condition, will be a national change that all Medicare Part D pharmacy benefit plans shall implement. These plans are required by CMS to inform their enrollees of these changes.

## Substance

The sections of the State Plan for Medical Assistance that will be affected by this action are:

12 VAC 30-50-35 – Requirements relating to payment for covered outpatient drugs for the categorically needy and 12 VAC 30-50-75 – Requirements relating to payment for covered outpatient drugs for the medically needy.

Prior to the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA), federal law restricted coverage of these two drugs under Medicare Part D, but they were available through Medicaid. Effective January 1, 2014, benzodiazepines and barbiturates will be covered for full benefit dual eligibles under Medicare Part D for all health conditions.

This change resulted from the passage of both Section 175 of MIPPA and the Affordable Care Act of 2010. MIPPA amended section 1860D-2(e)(2)(A) of the Social Security Act to remove the blanket exclusion of these two drugs from Part D coverage. The Affordable Care Act amended section §1927(d)(2) of the Social Security Act, to require Medicare Part D coverage of benzodiazepines and barbiturates for any health condition, effective January 1, 2014.

Because of this additional Part D drug coverage, DMAS no longer needs to provide this class of drugs to full benefit dual eligible individuals. Therefore, DMAS terminates coverage of benzodiazepines and barbiturates for full benefit dual eligibles in order to eliminate redundant coverage of these two drugs.

## Issues

- 1) The primary advantage to the general public and private citizens with this proposed regulatory amendment is the cost savings associated with the implementation of this change. DMAS will no longer need to provide benzodiazepines and barbiturates and barbiturate drugs. With the implementation of this change, the cost of these drugs will be borne by the Medicare Part D plan of the enrollee, not by the Virginia Medicaid program. There are no disadvantages to the general public or private citizens.
- 2) The primary advantage to the agency and the Commonwealth is the transfer of coverage for barbiturates to the federally funded Medicare Part D plans, which will save money for the Commonwealth.
- 3) Medicaid enrolled pharmacies that provide coverage to full benefit dual eligibles also participate in the Medicare Part D plans that will be providing this additional coverage. It is anticipated that the transition to a different payor for these classes of drugs from the Virginia Medicaid program to Medicare Part D plans should cause no disruption in coverage. There are no perceived disadvantages to the Commonwealth for this proposed regulatory change.

**Requirements more restrictive than federal**

These regulatory changes are not more restrictive than Federal regulations and are, in fact, less restrictive because DMAS elects to continue to cover additional classes of drugs not covered by Part D plans.

**Localities particularly affected**

There will be no localities that are more affected than others as these requirements will apply statewide.

**Regulatory flexibility analysis**

This regulatory action is not expected to affect small businesses as it does not impose compliance or reporting requirements, nor deadlines for reporting, nor does it establish performance standards to replace design or operational standards.

**Economic impact**

<b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</b>	\$0
<b>Projected cost of the <i>new regulations or changes to existing regulations</i> on localities.</b>	\$0
<b>Description of the individuals, businesses or other entities likely to be affected by the <i>new regulations or changes to existing regulations</i>.</b>	Categorically Needy and Medically Needy Full Benefit Dual Eligibles will be impacted by the proposed regulations. Medicaid enrolled pharmacies serving Full Benefit Dual Eligibles in Virginia
<b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	Approximately 109,000 Full Benefit Dual Eligibles Approximately 1000 Medicaid Enrolled Pharmacies
<b>All projected costs of the <i>new regulations or changes to existing regulations</i> for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of</b>	\$0

<b>real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</b>	
<b>Beneficial impact the regulation is designed to produce.</b>	Cost savings associated with no longer providing benzodiazepines and barbiturates for conditions other than epilepsy, cancer and chronic mental health disorders for dual eligibles

**Alternatives**

DMAS was not allowed to consider any policy alternatives as the Centers for Medicare and Medicaid Services issued State Plan preprinted pages for states' implementation and written policy clarifications.

**Family impact**

These changes do not strengthen or erode the authority or rights of parents in the education, nurturing, and supervision of their children; or encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents. It does not strengthen or erode the marital commitment, but may decrease disposable family income depending upon which provider the recipient chooses for the item or service prescribed.

**Detail of changes**

This amendment to the regulations is proposed to eliminate redundant coverage of benzodiazepines and barbiturates that were previously excluded for Medicare beneficiaries under their Medicare Part D drug. This amendment will not prevent full benefit dual eligibles from receiving these drugs when medically necessary; however, the coverage will be provided by their Medicare Part D pharmacy benefit providers, not the fee for service Medicaid program. DMAS will continue to provide coverage for all other drugs enumerated in 12 VAC 30-50-35 and 12 VAC 30-50-75 that will continue to be excluded from Medicare Part D coverage in accordance with existing Medicaid policy.

DMAS will modify its pharmacy claims processing system to deny coverage of benzodiazepines and barbiturates for full benefit dual eligibles.

<b>Current section number</b>	<b>Proposed new section number, if applicable</b>	<b>Current requirement</b>	<b>Proposed change, intent, rationale, and likely impact of proposed requirements</b>
12 VAC 30-50-35		Benzodiazepines and barbiturate coverage for Categorically Needy full benefit dual eligibles.	No benzodiazepines and barbiturate coverage for any condition for Categorically Needy full benefit dual eligible individuals.

12 VAC 30-50-75		Benzodiazepines and barbiturate coverage for Medically Needy full benefit dual eligibles	No benzodiazepines and barbiturate coverage for any condition for Medically Needy full benefit dual eligible individuals.
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