Virginia Regulatory Town Hall

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Fast Track Proposed Regulation
Agency Background Document

Agency name	DEPT. OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation	12 VAC 30-50-35 and 12 VAC 30-50-75
Regulation title	Amount, Duration, and Scope of Medical and Remedial Services Provided to the Categorically Needy; Amount, Duration, and Scope of Medical and Remedial Services Provided to the Medically Needy
Action title	Part D Coverage of Benzodiazepines and Barbiturates
Date this document prepared	October 3, 2012

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 proposed regulatory change proposes to eliminate Medicaid coverage for two classes of drugs, benzodiazepines for all conditions and barbiturates, for patients with a diagnosis of epilepsy, cancer or a chronic mental health disorder for full benefit dual eligibles (eligible for both Medicare and Medicaid). Effective January 1, 2013, these drugs will be covered for full benefit dual eligibles under their Medicare Part D drug benefit. This additional Medicare Part D coverage is being provided as a result of the passage of Section 175 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA), which amended section 1860D-2(e)(2)(A) of the Act to include barbiturates "used in the treatment of epilepsy, cancer, or a chronic mental health disorder" and benzodiazepines for all conditions in their existing Medicare Part D coverage.

Because of this additional Part D drug coverage, DMAS will no longer need to provide these classes of drugs to full benefit dual eligibles. DMAS will continue to cover barbiturates for full benefit dual eligibles for diagnoses other than epilepsy, cancer and chronic mental health disorders. These recipients will need to obtain a prior authorization for barbiturates from their prescribing provider indicating a medical condition other than the three specified in the amended section of the MIPPA.

Statement of final agency action

I hereby approve the foregoing Agency Background Summary with the attached amended regulations, Requirements relating to payment for outpatient drugs for the categorically needy (12 VAC 30-50-35) and Requirements relating to payment for covered drugs for the medically needy (12 VAC 30-50-75) and adopt the action stated therein. I certify that this fast track regulatory action has completed all the requirements of the Code of Virginia § 2.2-4012.1, of the Administrative Process Act.

Date

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.

Section 175 of the Medicare Improvement for Patients and Providers Act of 2008 (PL 110-275) amended § 1869D-2(e)(2)(A) of the *Social Security Act* to include barbiturates (when used for the treatment of epilepsy, cancer, or a chronic mental health disorder) and benzodiazepines in Part D drug coverage as of January 1, 2013. With this new coverage under Medicare Part D for these dual eligible persons, Medicaid no longer needs to offer this benefit.

Purpose

This amendment to the regulations is proposed to eliminate redundant coverage of two classes of drugs that were previously excluded for Medicare beneficiaries, including full benefit dual eligibles, under their Medicare Part D drug benefit. This amendment will not prevent full benefit dual eligibles from receiving these drugs, however the coverage will be provided by their Medicare Part D pharmacy benefit provider, 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.

An analysis of benzodiazepine and barbiturate drug utilization by full benefit dual eligibles in fiscal year 2012 indicated that the elimination of these two classes of drugs will significantly reduce current non Medicare Part D covered drug expenditures for approximately 109,000 full benefit dual eligibles by approximately $ 2.2 million per year (state and federal funds). Pursuant to Code of Virginia § 2.2-4007.05, DMAS does not anticipate any impact upon the public health, safety or welfare.

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 and for the same conditions. This change is anticipated by the provider community because the expanded Medicare Part drug coverage for benzodiazepines and barbiturates will be a national change that all Medicare Part D pharmacy benefit plans are implementing. 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
12 VAC 30-50-75 – Requirements relating to payment for covered outpatient drugs for the medically needy

Currently, the State Plan for Medical Assistance 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 discontinues Medicaid coverage of benzodiazepines for all conditions and barbiturates for epilepsy, cancer and chronic mental health disorders for approximately 109,000 categorically needy and medically needy full benefit dual eligibles. These categories of drugs will be covered by their chosen Medicare Part D pharmacy benefit plan effective January 1, 2013.

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. Recent analysis of benzodiazepine and barbiturate utilization by full benefit dual eligibles suggests that DMAS will save approximately $ 2.2 million annually in total dollars. 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 benzodiazepines and barbiturates to the Federally funded Medicare Part D plans, which will save the Commonwealth approximately $ 1.1 million in general funds.
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 and will cover barbiturates for conditions 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

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	$0
Projected cost of the *new regulations or changes to existing regulations* on localities.	$0
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	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

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. 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
All projected costs of the *new regulations or changes to existing regulations* 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 real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	$0
Beneficial impact the regulation is designed to produce.	Approximately $ 2.2 million in total state and federal dollars will be saved annually by the implementation of this regulation

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.

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 two classes of drugs that were previously excluded for Medicare beneficiaries under their Medicare Part D drug benefit. 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 provider, 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.

An analysis of benzodiazepine and barbiturate drug utilization by full benefit dual eligibles in fiscal year 2012 indicated that the elimination of these two classes of drugs will significantly reduce current non Medicare Part D covered drug expenditures for approximately 109,000 full benefit dual eligibles by approximately $ 2.2 million per year (state and federal funds).

DMAS will utilize its existing pharmacy preferred drug list contractor, Magellan Health, to process the service authorization requests for full benefit dual eligibles to receive barbiturates for conditions other than epilepsy, cancer or chronic mental health disorders. The existing contract does not need to be revised to accommodate this additional prior authorization requirement as it is based on volume of service authorizations, which has declined during the contract period due to the expansion of managed care to other regions in the state in July of 2012.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12 VAC 30-50-35		Benzodiazepine and barbiturate coverage for Categorically Needy full benefit dual eligibles	No benzodiazepine coverage and no barbiturate coverage for conditions other than epilepsy, cancer and chronic mental health disorders for Categorically Needy full benefit dual eligibles
12 VAC 30-50-75		Benzodiazepine and barbiturate coverage for Medically Needy full benefit dual eligibles	No benzodiazepine coverage and no barbiturate coverage for conditions other than epilepsy, cancer and chronic mental health disorders for Medically Needy full benefit dual eligibles