Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	Department of Medical Assistance Services
Virginia Administrative Code (VAC) citation	12 VAC 30, Chapters 30, 40 and 50
Regulation title	Groups Covered, and Agencies Responsible for Eligibility Determinations; Eligibility Conditions and Requirements; Amount, Duration and Scope of Medical and Remedial Services
Action title	Medicare Prescription Drug Program (Part D)
Document preparation date	

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style, and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) established the Medicare Prescription Drug Program, also known as Medicare Part D, making prescription drug coverage available to individuals who are entitled to receive Medicare benefits under Part A or Part B, beginning on January 1, 2006. In response to this federal mandate the 2005 General Assembly mandated that the Medicaid Agency promulgate "necessary regulations to implement the provisions of the Medicare Part D prescription drug benefit" and required DMAS to promulgate such regulations within 280 days of the enactment of Chapters 24 and 56 of the 2005 session.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

I hereby approve the foregoing Agency Background Document with the attached amended State Plan pages, Groups Covered, and Agencies Responsible for Eligibility Determinations (12 VAC 30-30-60); Eligibility Conditions and Requirements (12 VAC 30-40-10); Amount, Duration and Scope of Medical and Remedial Services (12 VAC 30-50-35, --75 and --530) 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, of the Administrative Process Act and is full, true, and correctly dated.

_____ _____

Date

Patrick W. Finnerty, Director

Dept. of Medical Assistance Services

Legal basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly bill and chapter numbers, if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

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

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) established the Medicare Prescription Drug Program, also known as Medicare Part D, making prescription drug coverage available to individuals who are entitled to receive Medicare benefits under Part A or Part B, which began on January 1, 2006. Previously, Virginia's Medicaid Program provided outpatient drugs for its Medicaid recipients, both the categorically needy and medically needy. As of January 1, 2006, Medicaid recipients who are enrolled in Medicare Part A, or eligible for Medicare Part B, were no longer eligible to receive their pharmacy benefits

under the State's Medicaid Program, except for drugs that are excluded under the Medicare Prescription Drug Program. Virginia was required to submit State Plan Amendments to ensure that its State Medicaid Program pharmacy benefits are consistent with the requirements under Part D. DMAS also made a change to continue transportation necessary to obtain Part D drugs.

The MMA also established the Low-Income Subsidy (LIS) to assist individuals who have low income and resources with payment of the premiums, deductibles, and co-payments required under Part D. The MMA requires both the Social Security Administration and the State Medicaid agency to accept and process applications for LIS. States had to have in place the capacity to accept and provide assistance with such applications by July 1, 2005 for individuals who requested such a determination by the State. In addition, the MMA required the State to provide for screening of individuals who may be eligible for Medicare cost-sharing as Qualified Medicare Beneficiaries (QMBs), Specified Low-Income Medicare Beneficiaries (SLMBs), or Qualified Individuals (QIs), and to offer enrollment to eligible individuals. These requirements appear both in the statute (Section 1935(a) of the Social Security Act) and in federal regulations at 42 CFR 423.774 and 423.904.

Virginia had in place these provisions via an emergency regulation on January 1, 2006, which reflected its compliance with the MMA and met the criteria for receipt of any federal financial assistance claimed in conjunction with Virginia's compliance with the MMA. DMAS must continue to cover the drugs and services described below in order to maintain comparability of services. This present action is the next step in making these changes permanent. This action will not in any genuine sense help assure the safety and welfare of the citizens of the Commonwealth; DMAS is making this change to comply with federal law.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The sections of the State Plan for Medical Assistance that are affected by this change are as follows:

12 VAC 30-30-60: Groups Covered and Agencies Responsible for Eligibility Determinations -- Requirements Relating to Determining Eligibility for Medicare Prescription Drug Low-Income Subsidies. This is a new provision requiring the Medicaid agency to determine eligibility for premium and cost-sharing subsidies under Part D for Medicare beneficiaries and report subsidy eligible individuals to the Centers for Medicare and Medicaid services. This provision also mandates that the Medicaid agency screen individuals for Medicare cost-sharing and offer enrollment to eligible individuals.

12 VAC 30-40-10: Eligibility Conditions and Requirements – This regulation requires beneficiaries that may be eligible for Medicare Parts A, B and/or D to enroll in those programs as a condition of eligibility for Medicaid. Application for Medicare is a condition of eligibility

unless the State does not pay the applicable Medicare premiums and cost-sharing, except those applicable under Part D, for persons covered by the Medicaid eligibility group under which the individual is applying.

12 VAC 30-50-35: Amount, Duration and Scope of Medical and Remedial Services – Requirements Relating to Payment for Covered Outpatient Drugs for the Categorically Needy. This provision provides assurance that the Medicaid agency will not cover any Part D drug for a full-benefit Medicaid recipient who is entitled to receive Medicare benefits. It also requires the Medicaid agency to provide to the Centers for Medicare and Medicaid Services information regarding which drugs excluded for payment under Medicare Part D will be covered by Medicaid for categorically needy individuals.

12 VAC 30-50-75: Amount, Duration and Scope of Medical and Remedial Services – Requirements Relating to Payment for Covered Outpatient Drugs for the Medically Needy. This provision provides assurance that the Medicaid agency will not cover any Part D drug for a full-benefit Medicaid recipient who is entitled to receive Medicare benefits. It also requires the Medicaid agency to provide to the Centers for Medicare and Medicaid Services information regarding which drugs excluded for payment under Medicare Part D will be covered by Medicaid for medically needy individuals.

12 VAC 30-50-530: Amount, Duration and Scope of Medical and Remedial Services – Methods of providing transportation. This provision provides assurances that the Medicaid agency will provide necessary transportation for dual-eligible recipients to obtain medically necessary, non-covered Medicare Part D prescription drugs.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.

If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

Medicare beneficiaries who do not have access to prescription drug coverage may benefit from the Medicare Part D program and the Commonwealth will benefit where it currently pays with General Funds for prescription drugs through various agencies (e.g., DMHMRSAS, VDH). These regulations will ensure that the Commonwealth is the payer of last resort for Medicaid eligible individuals who also qualify for Medicare.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandates that State Medicaid enrollees who are also Medicare eligible ("dual eligibles") receive their prescription drug benefits through Medicare not Medicaid beginning January 1, 2006. There are no advantages to the Medicaid population or the agency as a result of these regulations

which were necessary to comply with the MMA. There are disadvantages for the dual eligibles in that they must select from a confusing array of Medicare-approved private prescription drug plans, or be auto-assigned to one, which may or may not include all of their needed medications in the plan's formulary. There are minimum required co-payments for prescriptions, where as under Medicaid an individual could not be compelled to make co-payments if the individual could not afford it. Disadvantages for the agency and Commonwealth include substantial administrative activities/costs in order to discontinue drug coverage under Medicaid and implement coverage under Medicare. The MMA also requires States to help finance Medicare Part D by paying the federal government the State share of the cost of prescription drug coverage for the dual eligibles. The Phased-Down State Contribution, or "Clawback," is set at 90% of costs for 2006 and decreases to 75% by 2015. However, Virginia has implemented a number of pharmacy savings initiatives that are not reflected in the federal government's calculation of the State's Clawback amount. Therefore, the Clawback amount far exceeds what the cost would be for Virginia if the State were to continue to provide drug coverage to dual eligibles through Medicaid as in previous years.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

There were no substantive changes between the emergency regulation, the proposed regulation and the final regulation.

Public comment

Please summarize all comment received during the public comment period following the publication of the proposed stage, and provide the agency response. If no public comment was received, please so indicate.

DMAS' proposed regulations were published in the August 21, 2006, *Virginia Register* (VAR 22:25) for their public comment period from August 21, 2006 through October 20, 2006. The Agency received no public comments.

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

There were no substantive changes between the emergency regulation, the proposed regulation and the final regulation.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

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 and is not expected to affect disposable family income.