Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	DEPT 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 branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

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.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly

chapter number(s), 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. As noted above, Chapters 24 and 56 of the 2005 Acts of the Assembly required these regulatory changes.

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 entitled to receive Medicare benefits under Part A or 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 must ensure a continuum of coverage for medically necessary drugs, and the transportation necessary to obtain those 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.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

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

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.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

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	The estimated net state fund cost to DMAS from the Medicare Part D program is $16.5 million (GF) in FY 2007 and $19.3 million (GF) in FY 2008.
Projected cost of the regulation on localities	Minimal impact anticipated for local departments of social services (LDSS) except for staff time in responding to inquiries and assisting in applications for the Part D Low Income Subsidy and drug plan selection.
Description of the individuals, businesses or other entities likely to be affected by the regulation	Local departments of social services and state DSS; local Area Agencies on Aging, or VICAP, and state DOA; Dept. of Mental Health, Mental Retardation and Substance Abuse Services (DMHMRSAS) and its inpatient and outpatient facilities, including the Hiram Davis Community Resource Pharmacy; VACSB and local CSBs; Virginia Dept. of Health and local health departments; and all pharmacies throughout the state.
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.	120 local departments of social services; 25 local Area Agencies on Aging, or VICAP; 16 inpatient and outpatient operations of DMHMRSAS ; 40 Community Services Boards / Behavioral Health Authorities; 35 local health districts comprised of 227 administrative and health department offices; 1,594 licensed pharmacies (as of 3/06).
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	Local departments of social services will have to retain LIS applications and maintain any LIS cases determined by staff; however, no LIS case determinations have been made as of 3/06. These Virginia regulations do not require reporting, recordkeeping or other administrative activities for compliance by small businesses.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

Because DMAS must maintain continuity of services and comparability of services for all Medicaid recipients, there were no viable alternatives concerning drug coverage. Concerning the processing of applications for Medicare Part D coverage, the Agency used the application provided by the Social Security Administration and integrated this new application into DMAS' pre-existing eligibility process. With regard to transportation, although the federal government allowed DMAS to decide whether to cover transportation for Part D drugs, the Agency had no other workable alternatives to covering this service, as transportation providers have no way of determining whether a given prescription is paid for by Part D or by Medicaid. The federal government also permitted states the option of making Medicare enrollment a condition of Medicaid eligibility, stating that federal financial participation would no longer be available for Medicare Part D prescription drugs for full-benefit, dual eligible Medicare/Medicaid beneficiaries. DMAS chose to require Medicare enrollment to ensure that Virginia does not pay for health care services that may be covered under the Medicare program. Federal law requires that Medicaid be the payor of last resort, and this provision ensures that DMAS remains the payor of last resort for Medicare eligibles.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

No comments were received during the NOIRA public comment period.

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, but may decrease disposable family income depending upon which provider the recipient chooses for the item or service prescribed.

Detail of changes

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

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

No changes were made between the publication of the Emergency Regulation/NOIRA and this Proposed regulation.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
	12 VAC 30-30-60	None	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 – no current requirement for Medicare enrollment.	Inserts a new condition of eligibility requiring enrollment in Medicare Parts A, B and/or D in order to qualify for Medicaid.
	12 VAC 30-50-35	None	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	None	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		Methods of providing transportation – no reference to Part D	This provision requires the Medicaid agency to provide necessary transportation for dual-eligible recipients to obtain medically necessary drugs that are not covered under Medicaid, but are covered under Medicare Part D.