Virginia Regulatory Town Hall

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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) 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 form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

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).

Preamble

The APA (Section 2.2-4011) states that an "emergency situation" is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date.

1) Please explain why this is an "emergency situation" as described above.
2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.

The Administrative Process Act (Section 2.2-4011) states that an "emergency situation" is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation

shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date. This suggested emergency regulation meets the standard at *COV* 2.2-4011(i) as discussed below.

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.

The Governor is hereby requested to approve this agency's adoption of the emergency regulations entitled Groups Covered, and Agencies Responsible for Eligibility Determinations; Eligibility Conditions and Requirements; Amount, Duration and Scope of Medical and Remedial Services (12 VAC 30-30-60, 30-40-10, 30-50-35, 30-50-75, and 30-50-530) and also authorize the initiation of the promulgation process provided for in § 2.2-4007.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

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. Currently, Virginia's Medicaid Program provides outpatient drugs for its Medicaid recipients, both the categorically needy and medically needy. Effective January 1, 2006, Medicaid recipients who are entitled to receive Medicare benefits under Part A or Part B will no longer 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 must have the capacity to accept and provide assistance with such applications by July 1, 2005 for individuals who request such a determination by the State. In addition, the MMA requires 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 regulations at 42 CFR 423.774 and 423.904.

Virginia is required to ensure that these provisions are in place no later than January 1, 2006 to reflect its compliance with the MMA and to meet 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.

Legal basis

Other than the emergency authority described above, 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., 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.

Substance

Please detail any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons why the regulation is essential to protect the health, safety, or welfare of Virginians. Delineate any potential issues that may need to be addressed as a permanent final regulation is developed.

The section(s) of the State Plan for Medical Assistance that is (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.

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.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet 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.

Family impact

Please assess the impact of the emergency 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.