



Proposed Regulation Agency Background Document

Agency name	DEPT OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation	12VAC30, Chapter 50
Regulation title	Drugs or drug categories which are not covered
Action title	Discontinue Coverage of Erectile Dysfunction Drugs for Sex Offenders
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 Department of Medical Assistance Services shall not provide reimbursement for drugs used for treatment of erectile dysfunction, for persons who have been convicted of a sex offense or a crime against a minor and are listed in the State Police Sex Offender and Crimes Against Minors Registry established under the Code of Virginia §9.1-900, *et. seq.* as amended.

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. Further, in a May 23, 2005 letter to State Medicaid Directors, the Centers for Medicare and Medicaid Services (CMS) states that "the use of these drugs in the case of a sex offender is not appropriate and Medicaid should not pay for the cost of such drugs in such circumstances."

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 purpose of this regulatory action is to halt Medicaid reimbursement for erectile dysfunction drugs for convicted sex offenders. This action is accomplished by adding to the list of non-covered drugs described in 12 VAC 30-50-520 erectile dysfunction drugs for convicted sex offenders.

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 section of the State Plan for Medical Assistance that is affected by this change is the Amount, Duration and Scope of Services: Drugs or drug categories which are not covered [(Attachment 3.1-A & B, Supplement 5 (12VAC30-50-520)].

This regulation is being promulgated to address the health and safety issues presented by Medicaid coverage of erectile dysfunction drugs for convicted sex offenders. In addition to concern for the citizens of the Commonwealth, DMAS has received direction from the federal Medicaid authority concerning the coverage of erectile dysfunction drugs for sex offenders. In a May 23, 2005 letter to State Medicaid Directors, the Centers for Medicare and Medicaid Services (CMS) advised states that "the use of these drugs in the case of a sex offender is not appropriate and Medicaid should not pay for the cost of such drugs in such circumstances." The letter further advised that CMS would no longer provide federal financial participation for erectile dysfunction drugs dispensed to convicted sex offenders.

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.

This is a public safety issue that has the added virtue of being the right thing to do. The public benefits because convicted violent sex offenders will no longer be able to use public money to purchase medication that treats their erectile dysfunction and possibly facilitates the commission of additional sexual offenses.

There are no major disadvantages or other matters of public interest to the public, the agency, government officials, the regulated community, or the Commonwealth.

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	Projected costs to the State is minimal and can be absorbed by the current administrative budgets for the Department of Medical Assistance Services and the Virginia State Police.
Projected cost of the regulation on localities	-0-
Description of the individuals, businesses or other entities likely to be affected by the regulation	Currently, 434 convicted sex offenders were identified as Medicaid recipients. However, only 52 of them were receiving erectile dysfunction drugs.
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 20 sexual offenders annually. There are no small businesses affected.
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.	. -0-

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.

The Agency considered accomplishing this limitation through its Drug Utilization Review (DUR) program, however it was determined that the scope of the DUR program, being limited to clinical or medical decisions, was not the appropriate vehicle to effect this policy change.

Public comment

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

Commenter	Comment	Agency response

The public comment period was from June 13, 2005 through July 13, 2005. No public comments were received.

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 disposable elderly parents. It does not strengthen or erode the marital commitment, but may decrease 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.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12 VAC 30-50-520		No limit for erectile dysfunction drugs	Limits reimbursement for erectile dysfunction drugs for convicted sex offenders. Since the emergency regulation, the following was added to the end of the first sentence of § G: “for sexual offenders.

Enter any other statement here