townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	Department of Medical Assistance Services
Virginia Administrative Code (VAC) citation(s)	12 VAC 30 – 50–210
Regulation title(s)	Prescribed Drugs, Dentures, and Prosthetic Devices, and Eyeglasses Prescribed by a Physician Skilled in Diseases of the Eye or by an Optometrist
Action title	Coverage of Insect Repellant to Prevent Zika Infections
Date this document prepared	10/27/2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

This fast track regulation provides Medicaid coverage for insect repellants when they are prescribed by an authorized health professional for individuals of childbearing age, in order to prevent the transmission of the Zika virus. This fast track action follows an emergency regulation that went into effect on 8/22/2016.

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 Regulatory Review Summary entitled Coverage of Insect Repellant to Prevent Zika Infections (12 VAC 30– 50–210) 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.

10/27/2016
Date

/signature/
Cynthia B. Jones, Director

Dept. of Medical Assistance Services

Legal Basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

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. Describe the rationale or justification of the proposed regulatory action. ***Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens.*** *Discuss the goals of the proposal and the problems the proposal is intended to solve.*

This regulatory action will permit DMAS to cover insect repellant for Medicaid enrollees of childbearing age if it is prescribed by an authorized health professional. Covering insect repellant could prevent Zika transmission and avert babies being born with microcephaly and other severe brain defects who could eventually need expensive waiver services.

Individuals of childbearing age have been defined as women and men aged 14-44, based on Virginia Department of Health guidelines.

Rationale for Using Fast-Track Process

*Please **explain the rationale for using the fast-track process** in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?*

The fast track process is being utilized to promulgate this change in regulatory language as it is expected to be a non-controversial amendment to existing regulations. This regulatory action will represent a significant public health benefit, at a relatively low cost. Increasing access to repellant for the Fee-for-Service (FFS) population will help prevent infection by the Zika virus during the early stages of pregnancy when Zika has the most catastrophic impact on fetal development. Covering repellant in FFS will represent a cost savings because pregnant women are often in FFS during their first and second trimester.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

An informational bulletin issued by the Centers for Medicare and Medicaid Services entitled "Medicaid Benefits Available for the Prevention, Detection, and Response to the Zika Virus" which was issued on June 1, 2016, permits coverage of insect repellant with a prescription and specifies that repellants would be eligible for federal matching funds.

Ohio currently covers insect repellants as durable medical equipment. Louisiana covers insect repellants under the pharmacy benefit if local mosquito-borne transmission has occurred. Before the emergency regulation took effect, Virginia Premier was the only Medicaid health plan in Virginia that currently covers insect repellants with a prescription for all of their Medicaid members.

There are approximately 4,700 pregnant women in Fee-for-Service Medicaid and FAMIS in any given month, and additional women are covered by Medicaid managed care. Many of these women are in the early stages of pregnancy. Covering insect repellant has significant public health benefits and downstream cost savings in that insect repellant can prevent infection during the early stages of pregnancy when Zika has the most catastrophic impact on fetal development.

These regulations will cover insect repellants that have been evaluated and registered by the EPA for effectiveness. More specifically, these include EPA-registered insect repellants with one of the following active ingredients: DEET, picaridin, IR3535, oil of lemon eucalyptus, or para-menthane-diol.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, and likely impact of proposed requirements
12VAC30-50-210		Coverage of nonlegend (otherwise known as "over the counter") drugs and supplies is permitted in certain circumstances.	EPA-registered insect repellants are added to the list of nonlegend drugs and items covered with a prescription for individuals of childbearing age.

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 there are no disadvantages to the public or the Commonwealth, please indicate.*

CMS has encouraged state Medicaid programs to cover insect repellants when prescribed by an authorized health professional. The primary advantage to the public and to the Commonwealth from covering insect repellant for pregnant women in Fee-for-Service and the Medicaid Managed care plans is that this coverage could prevent Zika transmission and prevent children born with microcephaly and other severe brain defects. Investing in the coverage of insect repellant now could prevent a child from being born with microcephaly who could eventually need expensive *ID/D* Waiver or other waiver services.

It is evidenced that mosquito-borne Zika infections are now originating in the United States, and there is a threat that Virginia residents may soon be subject to locally-based Zika infection. The lack of access to insect repellant for Medicaid enrollees in Virginia has created an urgent situation that necessitates the implementation of regulations in order to address this emerging public health threat. Infection by the Zika virus during the early stages of pregnancy can have a catastrophic impact on fetal development, thereby positioning insect repellant as a critical need for Medicaid enrollees of childbearing age. Further regulatory action is needed for DMAS to speedily address the increased likelihood of Zika virus transmission in Virginia and specifically for Medicaid and F AMIS enrollees.

There are no disadvantages to the public or the Commonwealth related to this regulatory action.

Requirements More Restrictive Than Federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no requirements more restrictive than federal, contained in these recommendations.

Localities Particularly Affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There will be no localities that are more affected than others as these requirements will apply statewide.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

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

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated 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**	For DMAS' coverage of insect repellants for Medicaid members of child-bearing age, the estimated total cost to the Commonwealth for this FFS program is $69,601, beginning August, 2016 through December 31, 2016. From a Pharmacy program perspective, there are no costs associated with the implementation.
Projected cost of the new regulations or changes to existing regulations on localities.	None
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	**Coverage is limited to members:** 1) currently pregnant; or 2) of childbearing years (women and men age 14-44) who are trying to conceive
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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	No businesses, small or large, will be affected by this action.

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 including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) 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.	No impact on businesses.
Beneficial impact the regulation is designed to produce.	Prevention of the spread of the Zika virus in pregnant women may prevent the birth of children with microcephaly or other birth defects.

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. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

No other alternatives would address this developing public health situation.

Public Participation Notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

No comments were submitted during the NOIRA comment period.

Family Impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) 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; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

These changes do not strengthen or erode the authority or rights of parents in the education, nurturing, and supervision of their children; nor 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 list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre**-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, and likely impact of proposed requirements
12VAC30-50-210		Coverage of nonlegend (otherwise known as "over the counter") drugs and supplies is permitted in certain circumstances.	EPA-registered insect repellants are added to the list of nonlegend drugs and items covered with a prescription for individuals of childbearing age.

There are no differences between the emergency regulation text and the current text.