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## Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

<b>Agency name</b>	DEPT. OF MEDICAL ASSISTANCE SERVICES
<b>Virginia Administrative Code (VAC) citation(s)</b>	12 VAC 30-50-210
<b>Regulation title(s)</b>	Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.
<b>Action title</b>	Coverage of Mosquito Repellant to Prevent Zika Virus
<b>Date this document prepared</b>	

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to eighteen months), 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 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 of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 emergency regulation provides Medicaid coverage for mosquito 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.

## Acronyms and Definitions

*Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.*

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DMAS = Department of Medical Assistance Services

EPA = Environmental Protection Agency

FAMIS = Family Access to Medical Insurance Security Plan

## Emergency Authority

*The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006. Please explain why this is an emergency situation as described above, and provide specific citations to the Code of Virginia or the Appropriation Act, if applicable.*

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Section 2.2-4011(A) of the *Code of Virginia* states that agencies may adopt regulations in emergency situations after the agency submits a written request stating the nature of the emergency and the Governor approves the action.

This action qualifies as an emergency regulation pursuant to Code of Virginia § 2.2-4011(A) because the Agency has determined that these changes "are necessitated by an emergency situation." On August 3, 2016, DMAS submitted a request to the Governor stating the nature of this emergency and specifically requesting his authority pursuant to Virginia Code § 2.2-4011(A) to promulgate emergency regulations to address the emergency. In the letter, DMAS Director Cynthia B. Jones stated the following:

"There are currently 48 confirmed cases of Zika virus infection in Virginia, almost all of which arise from mosquito bites, and are travel related. However, the state of Florida is now reporting 14 Zika cases in which the infection was caused by local mosquitos. It is clear 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. It has come to our attention that the lack of access to mosquito repellent for Medicaid enrollees in Virginia has created an urgent situation that necessitates the implementation of emergency 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. The Virginia Health Commissioner and I have identified insect repellent as a critical need for Medicaid enrollees of childbearing age. Emergency regulations are needed for DMAS to speedily address the increased likelihood of Zika virus transmission in Virginia and specifically for Medicaid and FAMIS enrollees."

In light of this situation the Governor has approved DMAS' promulgation of this emergency regulation effective August 12, 2016. This emergency regulation is DMAS' response to that directive.

The Governor is hereby requested to approve this agency’s adoption of the emergency regulations entitled Coverage of Mosquito Repellant to Prevent Zika Virus (12 VAC 30-50-210) and also authorize the initiation of the regulation promulgation process provided for in § 2.2-4007 of the *Code*.

**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) the promulgating entity, i.e., agency, board, or person.*

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 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.*

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

**Need**

*Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.*

DMAS has determined that this regulatory action is needed to protect the health, safety, and welfare of Medicaid enrollees of childbearing age by covering insect repellant to prevent the transmission of Zika virus.

**Substance**

*Please describe 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 the agency has determined that the proposed regulatory action is essential to protect the healthy, safety, or welfare of Virginians.*

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 repellent with a prescription and specifies that repellents would be eligible for federal matching funds.

Ohio currently covers insect repellents as durable medical equipment. Louisiana covers insect repellents under the pharmacy benefit if local mosquito-borne transmission has occurred. Virginia Premier is the only Medicaid health plan in Virginia that currently covers insect repellents 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 repellent has significant public health benefits and downstream cost savings in that insect repellent can prevent infection during the early stages of pregnancy when Zika has the most catastrophic impact on fetal development.

These regulations will cover insect repellents that have been evaluated and registered by the EPA for effectiveness. More specifically, these include EPA-registered insect repellents 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 repellents are added to the list of nonlegend drugs and items covered with a prescription for individuals of childbearing age.

### 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. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.*

No other alternatives would address the emergency nature of this developing public health situation.

## Public participation

*Please indicate whether the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments. Please also indicate whether a Regulatory Advisory Panel or a Negotiated Rulemaking Panel has been used in the development of the emergency regulation and whether it will also be used in the development of the permanent regulation.*

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>), or by mail, email, or fax to Karen Thomas ((804) 225-2874) or Donna Proffitt ((804) 371-0428), Div. of Program Operations, DMAS, 600 East Broad Street, Suite 1300, Richmond, VA 23219; fax (804) 786-1680; [Karen.Thomas@dmas.virginia.gov](mailto:Karen.Thomas@dmas.virginia.gov) or [Donna.Proffitt@dmas.virginia.gov](mailto:Donna.Proffitt@dmas.virginia.gov) . Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.

## 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.