COMMONWEALTH of VIRGINIA

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MEMORANDUM

TO: **EMILY MCCLELLAN**
Regulatory Supervisor
Virginia Department of Medical Assistance Services

FROM: **KIM F. PINER** KFP
Senior Assistant Attorney General

DATE: **February 9, 2017**

SUBJECT: **12 VAC 30-50-210 Fast-Track Regulation for Coverage of Insect Repellenat to Prevent Zika Infections**

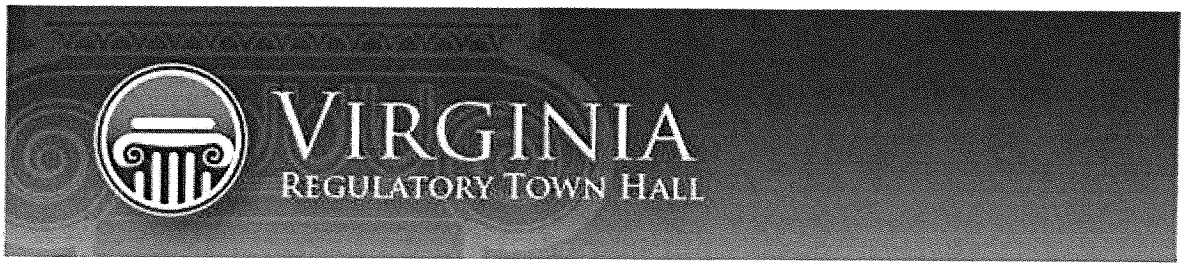
I am in receipt of the attached regulation to provide Medicaid coverage of insect repellant to prevent Zika infections. You have asked the Office of the Attorney General to review and determine if DMAS has the legal authority to promulgate this regulation and if the regulation comports with state and federal law.

Based on my review, the Director, acting on behalf of the Board of Medical Assistance Services pursuant to Virginia Code §§ 32.1-324 and 325, has the authority to promulgate this regulation subject to compliance with the provisions of Article 2 of the Administrative Process Act and has not exceeded that authority. This regulation will amend the State Plan; therefore, approval by the Centers for Medicare and Medicaid Services also will be required.

Pursuant to Virginia Code § 2.2-4012.1, if an objection to the use of the fast-track process is received within the 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, DMAS shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process set out in this article with the initial publication of the Fast-Track regulation serving as the Notice of Intended Regulatory Action.

If you have any questions or need additional information about this regulation, please contact me at 786-3524.

Attachment



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.

Proposed Text

Action: Coverage of Mosquito Repellant to Prevent Zika Virus
Stage: Fast-Track 10/27/16 2:07 PM

12VAC30-50-210. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

A. Prescribed drugs.

1. Drugs for which Federal Financial Participation is not available, pursuant to the requirements of § 1927 of the Social Security Act (OBRA 90 § 4401), shall not be covered.

2. Nonlegend drugs shall be covered by Medicaid in the following situations:

a. Insulin, syringes, and needles for diabetic patients;

b. Diabetic test strips for Medicaid recipients under 21 years of age;

c. Family planning supplies;

d. Designated categories of nonlegend drugs for Medicaid recipients in nursing homes; ~~and~~

e. Designated drugs prescribed by a licensed prescriber to be used as less expensive therapeutic alternatives to covered legend drugs; and

f. U.S. Environmental Protection Agency-registered insect repellents with one of the following active ingredients: DEET, picaridin, IR3535, oil of lemon eucalyptus, or p-Menthane-3,8-diol for all Medicaid members of reproductive age (ages 14 through 44 years) and all pregnant women, when prescribed by an authorized health professional.

3. Legend drugs are covered for a maximum of a 34-day supply per prescription per patient with the exception of the drugs or classes of drugs identified in 12VAC30-50-520. FDA-approved drug therapies and agents for weight loss, when preauthorized, will be covered for recipients who meet the strict disability standards for obesity established by the Social Security Administration in effect on April 7, 1999, and whose condition is certified as life threatening, consistent with Department of Medical Assistance Services' medical necessity requirements, by the treating physician. For prescription orders for which quantity exceeds a 34-day supply, refills may be dispensed in sufficient quantity to fulfill the prescription order within the limits of federal and state laws and regulations.

4. Prescriptions for Medicaid recipients for multiple source drugs subject to 42 CFR 447.332 shall be filled with generic drug products unless the physician or other practitioners so licensed and certified to prescribe drugs certifies in his own handwriting "brand necessary" for the prescription to be dispensed as written or unless the drug class is subject to the Preferred Drug List.

5. New drugs shall be covered in accordance with the Social Security Act § 1927 (d) (OBRA 90 § 4401).

6. The number of refills shall be limited pursuant to § 54.1-3411 of the Drug Control Act.

7. Drug prior authorization.

a. Definitions. The following words and terms used in these regulations shall have the following meanings unless the context clearly indicates otherwise:

"Clinical data" means drug monographs as well as any pertinent clinical studies, including peer review literature.

"Complex drug regimen" means treatment or course of therapy that typically includes multiple medications, co-morbidities ~~and/or~~, or caregivers.

"Department" or "DMAS" means the Department of Medical Assistance Services.

"Drug" shall have the same meaning, unless the context otherwise dictates or the board otherwise provides by regulation, as provided in the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia).

"Emergency supply" means 72-hour supplies of the prescribed medication that may be dispensed if the prescriber cannot readily obtain authorization, or if the physician is not available to consult with the pharmacist, including after hours, weekends, holidays and the pharmacist, in his professional judgment consistent with current standards of practice, feels that the patient's health would be compromised without the benefit of the drug, or other criteria defined by the Pharmacy and Therapeutics Committee and DMAS.

"Nonpreferred drugs" means those drugs that were reviewed by the Pharmacy and Therapeutics Committee and not included on the preferred drug list. Nonpreferred drugs may be prescribed but require authorization prior to dispensing to the patient.

"Pharmacy and Therapeutics Committee," "P&T Committee" or "committee" means the committee formulated to review therapeutic classes, conduct clinical reviews of specific drugs, recommend additions or deletions to the preferred drug list, and perform other functions as required by the department.

"Preferred drug list" or "PDL" means the list of drugs that meet the safety, clinical efficacy, and pricing standards employed by the P&T Committee and adopted by the department for the Virginia Medicaid fee-for-service program. Most drugs on the PDL may be prescribed and dispensed in the Virginia Medicaid fee-for-service program without prior authorization; however, some drugs as recommended by the Pharmacy and Therapeutics Committee may require authorization prior to dispensing to the patient.

"Prior authorization," as it relates to the PDL, means the process of review by a clinical pharmacist of legend drugs that are not on the preferred drug list, or other drugs as recommended by the Pharmacy and Therapeutics Committee, to determine if medically justified.

"State supplemental rebate" means any cash rebate that offsets Virginia Medicaid expenditure and that supplements the federal rebate. State supplemental rebate amounts shall be calculated in accordance with the Virginia Supplemental Drug Rebate Agreement Contract and Addenda.

"Therapeutic class" means a grouping of medications sharing the same Specific Therapeutic Class Code (GC3) within the Federal Drug Data File published by First Data Bank, Inc.

"Utilization review" means the prospective and retrospective processes employed by the agency to evaluate the medical necessity of reimbursing for certain covered services.

b. Medicaid Pharmacy and Therapeutics Committee.

(1) The department shall utilize a Pharmacy and Therapeutics Committee to assist in the development and ongoing administration of the preferred drug list and other pharmacy program issues. The committee may adopt bylaws that set out its make-up and functioning. A quorum for action of the committee shall consist of seven members.

(2) Vacancies on the committee shall be filled in the same manner as original appointments. DMAS shall appoint individuals for the committee that assures a cross-section of the physician and pharmacy community and remains compliant with General Assembly membership guidelines.

(3) Duties of the committee. The committee shall receive and review clinical and pricing data related to the drug classes. The committee's medical and pharmacy experts shall make recommendations to DMAS regarding various aspects of the pharmacy program. For the preferred drug list program, the committee shall select those drugs to be deemed preferred that are safe, clinically effective, as supported by available clinical data, and meet pricing standards. Cost effectiveness or any pricing standard shall be considered only after a drug is determined to be safe and clinically effective.

(4) As the ~~United States~~ U.S. Food and Drug Administration (FDA) approves new drug products, the department shall ensure that the Pharmacy and Therapeutics Committee will evaluate the drug for clinical effectiveness and safety. Based on clinical information and pricing standards, the P&T Committee will determine if the drug will be included in the PDL or require prior authorization.

(a) If the new drug product falls within a drug class previously reviewed by the P&T Committee, until the review of the new drug is completed, it will be classified as nonpreferred, requiring prior authorization in order to be dispensed. The new drug will be evaluated for inclusion in the PDL no later than at the next review of the drug class.

(b) If the new drug product does not fall within a drug class previously reviewed by the P&T Committee, the new drug shall be treated in the same manner as the other drugs in its class.

(5) To the extent feasible, the Pharmacy and Therapeutics Committee shall review all drug classes included in the preferred drug list at least every 12 months and may recommend additions to and deletions from the PDL.

(6) In formulating its recommendations to the department, the committee shall not be deemed to be formulating regulations for the purposes of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

(7) Immunity. The members of the committee and the staff of the department and the contractor shall be immune, individually and jointly, from civil liability for any act, decision, or omission done or made in performance of their duties pursuant to this subsection while serving as a member of such board, committee, or staff provided that such act, decision, or omission is not done or made in bad faith or with malicious intent.

c. Pharmacy prior authorization program. Pursuant to § 1927 of the Act and 42 CFR 440.230, the department shall require the prior authorization of certain specified legend drugs. For those therapeutic classes of drugs subject to the PDL program, drugs with nonpreferred status included in the DMAS drug list shall be subject to prior authorization. The department also may require prior authorization of other drugs only if recommended by the P&T Committee. Providers who are licensed to prescribe legend drugs shall be required to obtain prior authorization for all nonpreferred drugs or other drugs as recommended by the P&T Committee.

(1) Prior authorization shall consist of prescription review by a licensed pharmacist or pharmacy technician to ensure that all predetermined clinically appropriate criteria, as established by the P&T Committee relative to each therapeutic class, have been met before the prescription may be dispensed. Prior authorization shall be obtained through a call center staffed with appropriate clinicians, or through written or electronic communications (e.g., faxes, mail). Responses by telephone or other telecommunications device within 24 hours of a request for prior authorization shall be provided. The dispensing of 72-hour emergency supplies of the prescribed drug may be permitted and dispensing fees shall be paid to the pharmacy for such emergency supply.

(2) The preferred drug list program shall include: (i) provisions for an expedited review process of denials of requested prior authorization by the department; (ii) consumer and provider education; (iii) training and information regarding the preferred drug list both prior to implementation as well as ongoing communications, to include computer and website access to information and multilingual material.

(3) Exclusion of protected groups from pharmacy preferred drug list prior authorization requirements. The following groups of Medicaid eligibles shall be excluded from pharmacy prior authorization requirements: individuals enrolled in hospice care, services through PACE or pre-PACE programs; persons having comprehensive third party insurance coverage; minor children who are the responsibility of the juvenile justice system; and refugees who are not otherwise eligible in a Medicaid covered group.

d. State supplemental rebates. The department has the authority to seek supplemental rebates from pharmaceutical manufacturers. The contract regarding supplemental rebates shall exist between the manufacturer and the Commonwealth. Rebate agreements between the Commonwealth and a pharmaceutical manufacturer shall be separate from the federal rebates and in compliance with federal law, §§ 1927(a)(1) and 1927(a)(4) of the Social Security Act. All rebates collected on behalf of the Commonwealth shall be collected for the sole benefit of the state share of costs. One hundred percent of the supplemental rebates collected on behalf of the state shall be remitted to the state. Supplemental drug rebates received by the Commonwealth in excess of those required under the national drug rebate agreement will be shared with the federal government on the same percentage basis as applied under the national drug rebate agreement.

e. Pursuant to 42 USC § 1396r-8(b)(3)(D), information disclosed to the department or to the committee by a pharmaceutical manufacturer or wholesaler which discloses the identity of a specific manufacturer or wholesaler and the pricing information regarding the drugs by such manufacturer or wholesaler is confidential and shall not be subject to the disclosure requirements of the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia).

f. Appeals for denials of prior authorization shall be addressed pursuant to 12VAC30-110, Part I, Client Appeals.

8. Coverage of home infusion therapy. This service shall be covered consistent with the limits and requirements set out within home health services (12VAC30-50-160). Multiple applications of the same therapy (e.g., two antibiotics on the same day) shall be covered under one service day rate of reimbursement. Multiple applications of different therapies (e.g., chemotherapy, hydration, and pain management on the same day) shall be a full service day rate methodology as provided in pharmacy services reimbursement.

B. Dentures. Dentures are provided only as a result of EPSDT and subject to medical necessity and preauthorization requirements specified under Dental Services.

C. Prosthetic devices.

1. Prosthetic services shall mean the replacement of missing arms, legs, eyes, and breasts and the provision of any internal (implant) body part. Nothing in this regulation shall be construed to refer to orthotic services or devices or organ transplantation services.

2. Artificial arms and legs, and their necessary supportive attachments, implants and breasts are provided when prescribed by a physician or other licensed practitioner of the healing arts within the scope of their professional licenses as defined by state law. This service, when provided by an authorized vendor, must be medically necessary and preauthorized for the minimum applicable component necessary for the activities of daily living.

3. Eye prostheses are provided when eyeballs are missing regardless of the age of the recipient or the cause of the loss of the eyeball. Eye prostheses are provided regardless of the function of the eye.

D. Eyeglasses. Eyeglasses shall be reimbursed for all recipients younger than 21 years of age according to medical necessity when provided by practitioners as licensed under the Code of Virginia.