COMMONWEALTH of VIRGINIA
Office of the Attorney General

202 North 9th Street
Richmond, Virginia 23219
804-786-2071
FAX 804-786-1991
Virginia Relay Services
800-828-1120

Mark R. Herring
Attorney General

MEMORANDUM

TO: **EMILY McCLELLAN**
Regulatory Supervisor
Department of Medical Assistance Services

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

DATE: **AUGUST 15, 2016**

SUBJECT: **Emergency Regulations – Coverage of Mosquito Repellant to Prevent Zika Virus**

I have reviewed the attached emergency regulations that would provide Medicaid coverage for mosquito repellants when they are prescribed by an authorized health professional for all Medicaid members of reproductive age (ages 14-44) and pregnant women, subject to approval by the Centers for Medicare and Medicaid Services ("CMS"). These emergency regulations are promulgated to prevent the transmission of the Zika virus.

Based on my review, it is this Office's view that the Director of the Department of Medical Assistance Services ("DMAS"), acting on behalf of the Board of Medical Assistance Services pursuant to Virginia Code § 32.1-324, has the authority to promulgate these regulations, subject to compliance with the provisions of Article 2 of the Virginia Administrative Process Act ("APA"), and has not exceeded that authority. The attached emergency regulations will enable the Director to cover mosquito repellents to this group consistent with the authority set forth in Virginia Code § 32.1-324.

The authority for this emergency action is found in Virginia Code § 2.2-4011(A), which provides that regulations that an agency finds are necessitated by an emergency situation may be adopted by an agency upon consultation with the Attorney General, which approval shall be granted only after the agency has submitted a request stating in writing the nature of the emergency, and the necessity for such action shall be at the sole discretion of the Governor. The Department's statement of the nature of the emergency and necessity for such action is set forth in the "Agency Background Document." The Agency Background Document also indicates that

the Department submitted a written request to the Governor stating the nature of such emergency. The Governor determined that there is a public health emergency posed by the Zika virus and authorized the Board to promulgate emergency regulations by letter dated August 12, 2016.

Pursuant to § 2.2-4012, the attached emergency regulations shall become effective upon approval by the Governor and filing with the Registrar of Regulations. In addition, the emergency regulations shall be effective for no more than 18 months. If the Department intends to continue regulating the subject matter governed by these emergency regulations beyond 18 months, it will be necessary to replace these emergency regulations with regulations duly promulgated under Article 2 of the APA. A Notice of Intended Regulatory Action relating to the proposed replacement regulations must be filed with the Registrar within 60 days of the effective date of the emergency regulations. The proposed regulations must be filed with the Registrar within 180 days after the effective date of the emergency regulations. Va. Code § 2.2-4011(C).

If you have any questions or need any additional information, please feel free to contact me at 786-3524.

8/15/16 10:27 AM [latest]

12VAC30-50-210

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. Environmental Protection Agency-registered insect repellents with one of the following active ingredients: DEET, picaridin, IR3535, oil of lemon eucalyptus, or para-menthane-diol for all Medicaid members of reproductive age (ages 14-44) 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 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 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.