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.

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. ~~Notwithstanding the provisions of §32.1-87 of the Code of Virginia, and in compliance with the provision of §4401 of the Omnibus Reconciliation Act of 1990, §1927(e) of the Social Security Act as amended by OBRA 90, and pursuant to the authority provided for under §32.1-325 A of the Code of Virginia, prescriptions~~ Prescriptions for Medicaid recipients for multiple source drugs subject to 42 CFR 447.332 shall be filled with generic drug products (i) 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 (ii) 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 meaning unless the context clearly indicates otherwise:

~~"Board" means the Board for Medical Assistance Services.~~

~~"Committee" means the Medicaid Prior Authorization Advisory Committee.~~

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

~~"Director" means the Director 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 a 72-hour supply 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, or other criteria defined by the P & T Committee and DMAS.

"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 (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 that may be prescribed and dispensed in the Virginia Medicaid fee-for-service program.

"Prior authorization", as it relates to the threshold program, means the process of reviewing drugs with respect to established limits or criteria to determine the appropriateness of all existing prescriptions and newly prescribed medications to help ensure appropriate, quality, and cost-effective prescription drug treatments. The process is also designed to prevent waste and abuse of the pharmacy program by assisting providers and the department in identifying clients who may be accessing multiple physicians and pharmacies.

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

"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.

~~b. Medicaid Prior Authorization Advisory Committee; membership. The Medicaid Prior Authorization Committee shall consist of 11 members to be appointed by the board. Five members shall be physicians, at least three of whom shall care for a significant number of Medicaid patients; four shall be pharmacists, two of whom shall be community pharmacists; one member shall be a consumer of mental health services; and one shall be a Medicaid recipient.~~

~~(1) A quorum for action of the committee shall consist of six members.~~

~~(2) The members shall serve at the pleasure of the board; vacancies shall be filled in the same manner as the original appointment.~~

~~(3) The board shall consider nominations made by the Medical Society of Virginia, the Old Dominion Medical Society, the Psychiatric Society of Virginia, the Virginia Pharmaceutical Association, the Virginia Alliance for the Mentally Ill, and the Virginia Mental Health Consumers Association when making appointments to the committee.~~

~~(4) The committee shall elect its own officers, establish its own procedural rules, and meet as needed or as called by the board, the director, or any two members of the committee. The department shall provide appropriate staffing to the committee.~~

~~c. Duties of the committee.~~

~~(1) The committee shall make recommendations to the board regarding drugs or categories of drugs to be subject to prior authorization, prior authorization requirements for prescription drug coverage and any subsequent amendments to or revisions of the prior authorization requirements. The board may accept or reject the recommendations in~~

~~whole or in part, and may amend or add to the recommendations, except that the board may not add to the recommendation of drugs and categories of drugs to be subject to prior authorization.~~

~~(2) In formulating its recommendations to the board, 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). The committee shall, however, conduct public hearings prior to making recommendations to the board. The committee shall give 30 days' written notice by mail of the time and place of its hearings and meetings to any manufacturer whose product is being reviewed by the committee and to those manufacturers who request of the committee in writing that they be informed of such hearings and meetings. These persons shall be afforded a reasonable opportunity to be heard and present information. The committee shall give 30 days' notice of such public hearings to the public by publishing its intention to conduct hearings and meetings in the Calendar of Events of The Virginia Register of Regulations and a newspaper of general circulation located in Richmond.~~

~~(3) In acting on the recommendations of the committee, the board shall conduct further proceedings under the Administrative Process Act.~~

~~d. Prior authorization of prescription drug products; coverage.~~

~~(1) The committee shall review prescription drug products to recommend prior authorization under the state plan. This review may be initiated by the director, the committee itself, or by written request of the board. The committee shall complete its recommendations to the board within no more than six months from receipt of any such request.~~

~~(2) Coverage for any drug requiring prior authorization shall not be approved unless a prescribing physician obtains prior approval of the use in accordance with regulations promulgated by the board and procedures established by the department.~~

~~(3) In formulating its recommendations to the board, the committee shall consider the potential impact on patient care and the potential fiscal impact of prior authorization on pharmacy, physician, hospitalization and outpatient costs. Any proposed regulation making a drug or category of drugs subject to prior authorization shall be accompanied by a statement of the estimated impact of this action on pharmacy, physician, hospitalization and outpatient costs.~~

~~(4) The committee shall not review any drug for which it has recommended or the board has required prior authorization within the previous 12 months, unless new or previously unavailable relevant and objective information is presented.~~

~~(5) Confidential proprietary information identified as such by a manufacturer or supplier in writing in advance and furnished to the committee or the board according to this subsection 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). The board shall establish by regulation the means by which such confidential proprietary information shall be protected.~~

~~e. Immunity. The members of the committee and the board and the staff of the department 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.~~

~~f. Annual report to joint commission. The committee shall report annually to the Joint Commission on Health Care regarding its recommendations for prior authorization of drug products.~~

Pharmacy prior authorization and preferred drug list. RESERVED (b-g).

h. Pharmacy prior authorization program and threshold limits. Pursuant to § 1927 of the Act and 42 CFR § 440.230, the Department shall require the prior authorization of legend drugs when both institutionalized and non-institutionalized recipients are prescribed high numbers of legend drugs. Over-the-counter drugs and legend drug refills shall not count as a unique prescription for the purposes of prior authorization as it relates to the threshold program.

(1) Prior authorization shall be required for non-institutionalized Medicaid recipients whose current volume of prescriptions exceeds 9 unique prescriptions within 180 days and as may be further defined by the agency's guidance documents for pharmacy utilization review, limitations, and the prior authorization program. This prior authorization shall be required regardless of whether or not the prescribed drug appears on the preferred drug list of legend drugs. All recipients subject to these prior authorization limits shall be given advance notice of such limits and shall be advised of their rights to appeal. Such appeals shall be considered and responded to pursuant to 12 VAC 30-110-10 et. seq.

(2) Prior authorization shall be required for institutionalized Medicaid recipients whose current volume of prescriptions exceeds 9 unique prescriptions within 30 days and as may be further defined by the agency's guidance documents for pharmacy utilization review, limitations, and prior authorization program. The prior authorization shall be required regardless of whether or not the drug

is listed on the PDL of legend drugs. All recipients subject to these prior authorization limits shall be given advance notice of such limits and shall be advised of their rights to appeal. Such appeals shall be considered and responded to pursuant to 12 VAC 30-110-10 et. seq.

(3) Prior authorization shall consist of prospective and retrospective drug therapy review by a licensed pharmacist or pharmacy technician to ensure that all predetermined clinically appropriate criteria, as established by the department, 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 a 72-hour emergency supply of the prescribed drug shall be permitted and dispensing fees shall be paid to the pharmacy for such emergency supply.

(4) Exclusion of protected groups from pharmacy prior authorization requirements. The following groups of Medicaid eligibles shall be excluded from all pharmacy prior authorization requirements: individuals enrolled in hospice, services through PACE or pre-PACE programs; minor children who are the responsibility of the juvenile justice system; refugees who are not otherwise eligible in a Medicaid covered group; persons who are receiving services through the Medicaid Family Planning waiver.

(5) Exclusion of protected institutions from pharmacy threshold prior authorization. For the purposes of threshold prior authorization, nursing

facility residents do not include residents of the Commonwealth's mental retardation training centers. For the purposes of threshold prior authorization, non-institutionalized recipients do not include recipients of services at Hiram Davis Medical Center.

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.