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;
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 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.

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 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.
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" 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).

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 (§9-6.14:1 et seq.). 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.

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 (§2.1-340 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.
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 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. Prosthetic devices (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.
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.

12VAC30-50-520. Drugs or drug categories which are not covered.

1. A. Agents when used for anorexia or weight gain. Coverage of anorexiants for other than weight loss requires medical justification. 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.

B. Agents when used for cosmetic purposes or hair growth.

1. Minoxidil shall not be covered when prescribed for hair growth or other cosmetic purposes.

2. Agents containing hydroquinone or its derivatives which are used solely for depigmentation of the skin.

C. Agents used to promote fertility.

D. Expired drugs. Drugs dispensed past the labeled expiration date.

E. DESI Drugs. The Program shall not provide reimbursement for drugs determined by the Food and Drug Administration (FDA) to lack substantial evidence of effectiveness.

F. Nonlegend drugs. Nonlegend drugs, with those exceptions shown in 12VAC30-50-100 et seq., shall not be covered.