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. 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 meaning 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 a 72-hour supply of the prescribed medication that ~~is~~ 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.

“Non-preferred drugs” means those drugs that were reviewed by the Pharmacy and Therapeutics Committee and not included on the preferred drug list. Non-preferred drugs may be prescribed but require prior 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 (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 PDL, means the process of reviewing drugs, which 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 Virginia Supplemental Rebate Agreement 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.

b. Medicaid Pharmacy and Therapeutics Committee.

1. The Department shall utilize a Pharmacy and Therapeutics Committee (the "P & T 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. The Department shall appoint individuals for the Committee that assures a cross-section of the physician and pharmacy community.

c. 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.

d. As the United States Food and Drug Administration (FDA) approves new drug products, the Department shall ensure that the Pharmacy and Therapeutics (P&T) 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.

1. 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 non-preferred, 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.

2. 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.

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

~~d~~ f. 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).

~~e~~ g. Pursuant to 42 U.S.C. § 1396r-8(b)(3)(D), information disclosed to the Department or to the Committee by a 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~~ h. 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.

~~g~~ i. 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 preferred drug list program, drugs not included in the DMAS preferred 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 non-preferred drugs or other drugs as recommended by the P&T Committee.

~~h~~ j. 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 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.

~~i~~ k. 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.

~~j~~ l. Appeals for denials of prior authorization shall be addressed pursuant to 12 VAC 30-110-10 Part I Client Appeals.

~~k~~ m. 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.

~~l~~ n. State supplemental rebates. The Department has the authority to seek supplemental rebates from drug 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 (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 (100%) 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.

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.

Pharmacy services prior authorization.

Definitions. The following words and terms used in these regulations shall have the following meaning 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.

“Contractor” means an independent contractor that implements, and administers, pursuant to its contract, the Department’s pharmacy prior authorization programs as set out in the Title XIX State Plan.

"Department" or “DMAS” means the Virginia 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 a 72-hour supply of the prescribed medication that ~~is~~ 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.

“Grandfather clause” means procedure by which selected therapeutic classes or drugs as designated by the P & T Committee may be automatically approved if the patient is currently and appropriately receiving the drug.

“Non-preferred drugs” means those drugs that were reviewed by the Pharmacy and Therapeutics Committee and not included on the preferred drug list. Non-preferred drugs may be prescribed but require prior 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. The Pharmacy and Therapeutics Committee

shall be composed of 8 to 12 members, including the Commissioner of the Department of Mental Health, Mental Retardation and Substance Abuse Services, or his designee. Other members shall be selected or approved by the Department. The membership shall include a ratio of physicians to pharmacists of 2:1. Physicians on the Committee shall be licensed in Virginia, one of whom shall be a psychiatrist, and one of whom specializes in care for the aging. Pharmacists on the Committee shall be licensed in Virginia, one of whom shall have clinical expertise in mental health drugs, and one of whom has clinical expertise in community-based mental health treatment.

“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 PDL, means the process of reviewing drugs, which 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 Virginia Supplemental Drug Rebate Agreement 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.

A. DMAS shall operate, in conjunction with the Title XIX State Plan for Medical Assistance (12 VAC 30-50-210 et seq.) a program of prior authorization of pharmacy services. This program shall include, but not necessarily be limited to, the use of a preferred drug list.

B. Medicaid Pharmacy and Therapeutics Committee.

1. The Department shall utilize a Pharmacy and Therapeutics Committee (the “P&T 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. The Department shall appoint individuals for the Committee that assures a cross-section of the physician and pharmacy community.

3. Duties of the Committee.

a. 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. The Committee shall recommend to the Department:

(i) Which therapeutic classes of drugs should be subject to the preferred drug list program and prior authorization requirements;
(ii) Specific drugs within each therapeutic class to be included on the preferred drug list;
(iii) Appropriate exclusions for medications, including atypical anti-psychotics, used for the treatment of serious mental illnesses such as bi-polar disorders, schizophrenia, and depression;
(iv) Appropriate exclusions for medications used for the treatment of brain disorders, cancer and HIV-related conditions;
(v) Appropriate exclusions for therapeutic classes in which there is only one drug in the therapeutic class or there is very low utilization, or for which it is not cost-effective to include in the preferred drug list program;
(vi) Appropriate grandfather clauses when prior authorization would interfere with established complex drug regimens that have proven to be clinically effective;
(vii) Other clinical criteria that may be included in the pharmacy program; and
(viii) Guidance and recommendations regarding the Department's pharmacy programs.

(ix) As the United States Food and Drug Administration (FDA) approves new drug products, the Department shall ensure that the Pharmacy and Therapeutics (P&T) 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 non-preferred, 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.

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

C. 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).

D. Pursuant to 42 U.S.C. § 1396r-8(b)(3)(D), information disclosed to the Department or to the Committee by a 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).

E. 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.

F. 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 preferred drug list program, drugs not included in the DMAS preferred 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 non-preferred drugs or other drugs as recommended by the P&T Committee.

G. 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 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.

H. 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.

I. Appeals for denials of prior authorization shall be addressed pursuant to 12 VAC 30-110-10 Part I Client Appeals.

J. Pharmacy contractor. The Department may contract for pharmaceutical benefit management services to manage, implement and administer the Medicaid pharmacy benefits preferred drug list, as directed, authorized, and as may be amended from time to time, by DMAS.

1. The Department, as the sole Title XIX authority for the Commonwealth, shall retain final administrative authority over all pharmacy services.

2. The Department shall not offer or pay directly or indirectly any material inducement, bonus, or other financial incentive to a program contractor based on the denial or administrative delay of medically appropriate prescription drug therapy, or on the decreased use of a particular drug or class of drugs, or a reduction in the proportion of beneficiaries who receive prescription drug therapy under the Medicaid program. Bonuses shall not be based on the percentage of cost savings generated under the benefit management of services.

K. Supplemental rebates.
The Department shall have the authority to seek supplemental rebates from drug 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 (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 (100%) 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.

L. Appeals. The Department shall provide an expedient reconsideration process and initiate and fully participate in the DMAS' appeal process pursuant to 12 VAC 30-110 Part I Client Appeals for providers and recipients.

M. Annual report The Department shall report to the Governor and the Chairmen of the House Appropriations and Senate Finance Committees on an annual basis.