12 VAC 30-50-210. 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 12 VAC 30-50-520. 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 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~~ *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:

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

"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.

~~"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 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 (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.

"Prior authorization," as it relates to the threshold program, means the process of review by a clinical pharmacist of legend 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.

"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 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.~~

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. Other pharmacy prior authorization programs. 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 noninstitutionalized 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 noninstitutionalized Medicaid recipients whose current volume of prescriptions of legend drugs exceeds nine 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 the prescribed drug appears on the preferred drug list of legend drugs. All recipients subject to these prior authorization limits shall be advised of their rights to appeal. Such appeals shall be considered and responded to pursuant to 12 VAC 30-110.

(2) Prior authorization shall be required for institutionalized Medicaid recipients whose current volume of prescriptions of legend drugs exceeds nine 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 the drug is listed on the PDL of legend drugs. All recipients subject to these prior authorization limits shall be advised of their rights to appeal. Such appeals shall be considered and responded to pursuant to 12 VAC 30-110.

(3) Prior authorization shall consist of prospective and retrospective drug therapy review by a licensed pharmacist 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 72-hour emergency supplies of the prescribed drug may be permitted and dispensing fees shall be paid to the pharmacy for such emergency supply.

(4) 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, noninstitutionalized recipients do not include recipients of services at Hiram Davis Medical Center.

e. 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.

f. 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).

g. Appeals for denials of prior authorization shall be addressed pursuant to 12 VAC 30-110, 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 (12 VAC 30-50-160). 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.

CERTIFIED: I hereby certify that these regulations are full, true, and correctly dated.

10/8/2004
Date

/s/ P. W. Finnerty
Patrick W. Finnerty, Director
Dept. of Medical Assistance Services

12 VAC 30-80-40. Fee-for-service providers: pharmacy.

Payment for pharmacy services shall be the lowest of items 1 through 5 (except that items 1 and 2 will not apply when prescriptions are certified as brand necessary by the prescribing physician in accordance with the procedures set forth in 42 CFR 447.331 (c) if the brand cost is greater than the Centers for Medicare and Medicaid Services (CMS) upper limit ~~or~~ *of* VMAC cost) subject to the conditions, where applicable, set forth in subdivisions 6 and 7 of this section:

1. The upper limit established by the CMS for multiple source drugs pursuant to 42 CFR 447.331 and 447.332, as determined by the CMS Upper Limit List plus a dispensing fee. If the agency provides payment for any drugs on the HCFA Upper Limit List, the payment shall be subject to the aggregate upper limit payment test.

2. The Virginia ~~Medicaid~~ Maximum Allowable Cost (VMAC) established by the Virginia Department of Medical Assistance Services to be inclusive of appropriate multiple source and specific high cost drugs plus a dispensing fee. *The VMAC methodology shall be defined as the 75th percentile cost level, or the 60th percentile cost level for unit dose drugs, of the aggregate for each generic manufacturer's drug for each Generic Code Number (GCN). Manufacturers' costs are supplied by the most current First Data Bank file.* Multiple source drugs may include but are not limited to Food and Drug Administration-rated products such as drugs established by a Virginia Voluntary Formulary (VVF) drugs, Federal Upper Limit Drugs and any other state or federally approved listing. "Multisource drugs" means covered outpatient drugs for which there are two or more drug products that:

a. Are included in the Centers for Medicare and Medicaid Services' state drug rebate program;

b. Have been approved by the Federal Food and Drug Administration (FDA);

c. Are included in the Approved Products with Therapeutic Equivalence Evaluations as generically equivalent; and

d. Are sold or marketed in Virginia.

3. The provider's usual and customary charge to the public, as identified by the claim charge.

~~3.~~ *4.* The Estimated Acquisition Cost (EAC), which shall be based on the published Average Wholesale Price (AWP) minus a percentage discount established by the General Assembly (as set forth in subdivision 8 of this section) or, in the absence thereof, by the following methodology set out in subdivisions a through c below.

a. Percentage discount shall be determined by a statewide survey of providers' acquisition cost.

b. The survey shall reflect statistical analysis of actual provider purchase invoices.

c. The agency will conduct surveys at intervals deemed necessary by DMAS.

~~4. (Reserved.)~~

~~5. The provider's usual and customary charge to the public, as identified by the claim charge.~~

~~6.~~ *5.* Payment for pharmacy services will be as described above; however, payment for legend drugs will include the allowed cost of the drug plus only one dispensing fee per month for each specific drug. Exceptions to the monthly dispensing fees shall be allowed for drugs determined by the department to have unique dispensing requirements. The dispensing fee of $3.75 (effective July 1, 2003) shall remain in effect.

~~7.~~ *6.* The Program pays additional reimbursement for unit dose dispensing ~~system~~ *systems* of dispensing drugs. DMAS defines its unit dose dispensing system coverage consistent with that of the Board of Pharmacy of the Department of Health Professions (18 VAC 110-20-420). This service is paid only for patients residing in nursing facilities. Reimbursements are based on the allowed payments described above plus the unit dose per capita fee to be ~~submitted by the pharmacy for unit dose dispensing services to a nursing home resident~~ *calculated by DMAS' fiscal agent based on monthly per nursing home resident service per pharmacy provider*. Only one service fee per month may be ~~submitted by~~ *paid to* the pharmacy for each patient receiving unit dose dispensing services. The maximum allowed drug cost for specific multiple source drugs will be the lesser of~~: either the VMAC, based on the 60th percentile or maximum cost level, as identified by the state agency or CMS' upper limits~~ *subdivisions 1 through 4 of this section* as applicable. All other drugs will be reimbursed at drug costs not to exceed the estimated acquisition cost determined by the state agency. The original per capita fee shall be determined by a DMAS analysis of costs related to such dispensing, and shall be reevaluated at periodic intervals for appropriate adjustment. *The unit dose dispensing fee is $5.00 per recipient per month per pharmacy provider.*

~~8.~~ *7.* Determination of EAC was the result of a report by the Office of the Inspector General that focused on appropriate Medicaid marketplace pricing of pharmaceuticals based on the documented costs to the pharmacy. An EAC of AWP minus 10.25% shall become effective July 1, 2002.

The dispensing fee of $3.75 (effective July 1, 2003) shall remain in effect, creating a payment methodology based on the previous algorithm (least of 1 through 5 of this subsection above) plus a dispensing fee where applicable.

~~9.~~ *8.* Home infusion therapy.

a. The following therapy categories shall have a pharmacy service day rate payment allowable: hydration therapy, chemotherapy, pain management therapy, drug therapy, total parenteral nutrition (TPN). The service day rate payment for the pharmacy component shall apply to the basic components and services intrinsic to the therapy category. Submission of claims for the per diem rate shall be accomplished by use of the [~~HCFA~~ CMS] 1500 claim form.

b. The cost of the active ingredient or ingredients for chemotherapy, pain management and drug therapies shall be submitted as a separate claim through the pharmacy program, using standard pharmacy format. Payment for this component shall be consistent with the current reimbursement for pharmacy services. Multiple applications of the same therapy shall be reimbursed one service day rate for the pharmacy services. Multiple applications of different therapies shall be reimbursed at 100% of standard pharmacy reimbursement for each active ingredient.

9. Supplemental rebate agreement. Based on the requirements in § 1927 of the Social Security Act, the Commonwealth of Virginia has the following policies for the supplemental drug rebate program for Medicaid recipients:

a. The model supplemental rebate agreement between the Commonwealth and pharmaceutical manufacturers for legend drugs provided to Medicaid recipients, submitted to CMS on February 5, 2004, and entitled Virginia Supplemental Drug Rebate Agreement Contract A and Amendment #2 to Contract A has been authorized by CMS.

b. The model supplemental rebate agreement between the Commonwealth and pharmaceutical manufacturers for drugs provided to Medicaid recipients, submitted to CMS on February 5, 2004, and entitled Virginia Supplemental Drug Rebate Agreement Contract B and Amendment #2 to Contract B has been authorized by CMS.

c. The model supplemental rebate agreement between the Commonwealth and pharmaceutical manufacturers for drugs provided to Medicaid recipients, submitted to CMS on February 5, 2004, and entitled Virginia Supplemental Drug Rebate Agreement Contract C, and Amendments #1 and #2 to Contract C has been authorized by CMS.

d. Supplemental drug rebates received by the state 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. Prior authorization requirements found in § 1927(d)(5) of the Social Security Act have been met.

f. Nonpreferred drugs are those that were reviewed by the Pharmacy and Therapeutics Committee and not included on the preferred drug list. Nonpreferred drugs will be made available to Medicaid beneficiaries through prior authorization.

g. Payment of supplemental rebates may result in a product's inclusion on the PDL.

CERTIFIED: I hereby certify that these regulations are full, true, and correctly dated.

10/8/2004
Date

_/s/ P. W. Finnerty
Patrick W. Finnerty, Director
Dept. of Medical Assistance Services

PART XVI.
PHARMACY SERVICES PRIOR AUTHORIZATION.

12 VAC 30-130-1000. Pharmacy services prior authorization.

A. Definitions. The following words and terms used in this part shall have the following meanings unless the context clearly indicates otherwise:

"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.

"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.

"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 eight 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.

B. 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.

C. 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. 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 PDL program, the committee shall select those drugs to be deemed preferred that are safe and clinically effective, as supported by available clinical data, and meet pricing standards.

b. 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:

(1) Which therapeutic classes of drugs should be subject to the preferred drug list program and prior authorization requirements;

(2) Specific drugs within each therapeutic class to be included on the preferred drug list;

(3) Appropriate exclusions for medications, including atypical anti-psychotics, used for the treatment of serious mental illnesses such as bi-polar disorders, schizophrenia, and depression;

(4) Appropriate exclusions for medications used for the treatment of certain brain disorders, cancer and HIV-related conditions;

(5) 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;

(6) Appropriate grandfather clauses when prior authorization would interfere with established complex drug regimens that have proven to be clinically effective;

(7) Other clinical criteria that may be included in the pharmacy program; and

(8) Guidance and recommendations regarding the department's pharmacy programs.

c. 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.

(1) If the new drug product falls within a drug class previously reviewed by the P&T Committee, until the review of the new legend drug is completed, it will be classified as nonpreferred, requiring prior authorization in order to be dispensed. The new legend 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.

d. To the extent feasible, the P&T Committee shall review all drug classes included in the PDL at least every 12 months and may recommend additions to and deletions from the PDL.

D. 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.

E. 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. 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.

F. 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.

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

CERTIFIED: I hereby certify that these regulations are full, true, and correctly dated.

10/8/2004
Date

_/s/ P. W. Finnerty
Patrick W. Finnerty, Director
Dept. of Medical Assistance Services