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Final Regulation
Agency Background Document

Agency name	DEPT OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation	12 VAC 30 –50, 30-80, 30-130
Regulation title	Amount, Duration, and Scope of Services; Methods and Standards for Establishing Payment Rates—Other Types of Services; Amount, Duration, and Scope of Selected Services
Action title	Preferred Drug List, Pharmacy and Therapeutics Committee, State Supplemental Rebates, Utilization Control of High Drug Thresholds
Document preparation date	10/8/2004; NEED GOV APPROVAL BY NOV. 9, 2004

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style, and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

This action proposes to modify Medicaid's coverage of prescription pharmacy services in two ways: (i) implementation of the Preferred Drug List (PDL) and prior authorization requirements for those prescription (legend) and covered over-the-counter (nonlegend) drugs that are not approved for the agency's Preferred Drug List (PDL) and prior authorization requirements for preferred drugs or other drugs, including new drugs, due to clinical considerations as determined by the Pharmacy & Therapeutics Committee; (ii) implementation of utilization review requirements in cases where recipients use high numbers of prescription drugs (high drug threshold), and; (iii) modification, consistent with federal requirements, to Virginia's methodology for its reimbursement of generic drugs, known as the Virginia Maximum Allowable Cost (VMAC), in order to conform the VMAC with the federally approved State Plan. As part of the PDL program, this action also proposes to institute state supplemental rebates (12 VAC 30-80-40) between the Commonwealth and pharmaceutical manufacturers.

Preferred Drug List, Pharmacy and Therapeutics Committee, and State Supplemental Rebates

Drugs that are approved for inclusion in the PDL will not require prior authorization. The determination of which legend and non-legend drugs are to be included in the PDL will be based on the safety, clinical efficacy and pricing standards employed by the Pharmacy and Therapeutics Committee (P&T Committee). DMAS and the P&T Committee will review the best prices, along with other pharmacological information, including information from pharmaceutical manufacturers, as part of its considerations of which drugs to include in the PDL. The P&T Committee will also review drug classes or the PDL annually and also new drugs to determine if they may be included in the PDL or will require prior authorization.

It is the intent of this regulation that the Commonwealth will receive Supplemental Rebates, in addition to the rebates received under the Manufacturer's CMS Agreement, pursuant to Section 1927 of the *Social Security Act* (42 U.S.C. §1396r-8), for the Manufacturer's Supplemental Covered Product(s). The decision on payment of supplemental rebates is a separate consideration made after all clinical considerations are reviewed by the P&T Committee and do not guarantee inclusion on the PDL. The payments of supplemental rebates by the pharmaceutical manufacturers to the Commonwealth will not affect DMAS' payment methodology for pharmacy services in spite of this new language's placement in 12 VAC 30-80-40.

VMAC

The VMAC methodology provides for reimbursing for certain generic drugs. The Centers for Medicare and Medicaid Services (CMS), relative to an unrelated Title XIX State Plan Amendment, required DMAS to include the current methodology in the Plan, thereby causing this VAC change. This language addition is merely the inclusion of existing policy and represents no change in current policy. The VMAC methodology is being significantly changed in a separate regulatory action.

Utilization Review of High Drug Threshold

DMAS also proposes to amend coverage of pharmacy services to provide that institutionalized and non-institutionalized recipients, who are prescribed very high numbers of prescribed drugs, receive additional scrutiny of their drug profiles. Such recipients are often elderly and infirm and utilize high numbers of prescription drugs that can pose hazards to their health and safety. This additional level of scrutiny will likely benefit those recipients who obtain prescription or pharmacy services from multiple providers and/or pharmacies, respectively. Currently, in such situations, the different pharmacies have no way to confer with each other concerning individual recipients' prescription activities. These changes will improve the quality of care as Medicaid recipients make use of their pharmacy services benefit under Medicaid.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

I hereby approve the foregoing Agency Background Document with the attached amended State Plan pages titled the Preferred Drug List, with the Pharmacy and Therapeutics Committee, State Supplemental Rebates, and High Drug Utilization Review (12 VAC 30-50-210, 12 VAC 30-80-40, 12 VAC 30-130-1000) and adopt the action stated therein. I certify that this final regulatory action has completed all the requirements of the Code of Virginia § 2.2-4012, of the Administrative Process Act and is full, true, and correctly dated.

Date

Patrick W. Finnerty, Director

Dept. of Medical Assistance Services

Legal basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly bill and chapter numbers, if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The Code of Virginia (1950) as amended, § 32.1-325, grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance. The Code of Virginia (1950) as amended, § 32.1-324, authorizes the Director of the Department of Medical Assistance Services (DMAS) to administer and amend the Plan for Medical Assistance according to the Board's requirements.

The Medicaid authority as established by § 1902 (a) of the Social Security Act [42 U.S.C. 1396a] provides governing authority for payments for services.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

The purpose of this action is to implement two significant changes: (i) a preferred drug list (PDL) and prior authorization program for pharmacy services, including the coverage of newly approved legend and non-legend drugs, provided to Medicaid fee-for-service clients, state supplemental rebates, and a specified methodology for reimbursing for generic drugs; and (ii) utilization review of high drug thresholds for non-institutionalized and institutionalized (e.g., nursing facility) recipients who are prescribed large numbers of different prescription (legend) drugs within specific time periods. The preferred drug list, prior authorization and utilization review changes will protect the health and welfare of Medicaid recipients as they make use of their pharmacy services benefits under Medicaid. The state supplemental rebates, one of many considerations reviewed in a product's potential inclusion on the PDL, will not affect the health, safety, and welfare of Medicaid recipients. The addition of the VMAC methodology language does not establish a new policy or cause new expenditures as this policy has long been in effect. This VMAC change will have no impact on the health, safety, or welfare of Medicaid recipients or the citizens of the Commonwealth.

Preferred Drug List, Pharmacy and Therapeutics Committee, State Supplemental Rebates, and VMAC

For those therapeutic classes of drugs subject to the PDL program, a preferred drug is one meeting the safety, clinical efficacy, and pricing standards employed by the P&T Committee. Non-preferred drugs are those that were reviewed by the P&T Committee and not included on the preferred drug list. The non-preferred drugs will require prior authorization prior to dispensing. The P&T Committee may also recommend prior authorization requirements or clinical guidance regarding preferred drugs or other drugs, including legend and non-legend drugs newly approved by the Food and Drug Administration (FDA). This action also establishes the parameters for action by the P&T Committee as well as the Department's contractor for pharmacy services benefits management. The goals of the program are to improve the quality of pharmaceutical services and to reduce the significant increases in the cost of drugs prescribed to the Medicaid fee-for-service program beneficiaries without reducing the quality of rendered services.

Pharmaceutical manufacturers already calculate and provide the Department a federal rebate for their covered product or products, as appropriate. The Department has the authority to seek state supplemental rebates from pharmaceutical manufacturers. The contract regarding supplemental rebates shall exist between the pharmaceutical manufacturers 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 Commonwealth and are not permitted by federal law to be shared with contractors. 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.

The addition of the VMAC methodology was required by the CMS. The requirement was made in the context of a federal review of an unrelated State Plan Amendment. The new language for the VAC does not represent any new reimbursement policies or methodologies but merely states in the VAC the existing policy.

Utilization Review of High Drug Thresholds

The purpose of this action is to implement a program of prospective and retrospective utilization review and prior authorization of pharmacy services for non-institutionalized and institutionalized (e.g., nursing facility) recipients who are prescribed large numbers of different legend drugs within specific time periods. Such utilization review of covered pharmacy services is permitted by 42 CFR § 440.230 (d) "[t]he agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures." These changes are necessary to protect the health and safety of Medicaid recipients who are prescribed very high numbers of legend drugs by having trained professionals evaluate their drug profiles for safety and necessity.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The sections of the State Plan for Medical Assistance that are affected by this regulatory action are the Amount, Duration, and Scope of Services: Pharmacy Services (Attachment 3.1-A&B, Supplement 1 (12 VAC 30-50-210)); Methods and Standards for Establishing Payment Rates-Other Types of Care Pharmacy Services (Attachment 4.19-B (12 VAC 30-80-40)). The state-only regulations affected by this action are the Pharmacy and Therapeutics Committee (12 VAC 30-130-1000).

Preferred Drug List, Pharmacy and Therapeutics Committee, State Supplemental Rebates, and VMAC

This action proposes to implement a PDL and prior authorization program for pharmacy services provided to Medicaid fee-for-service clients. For those therapeutic classes of drugs subject to the PDL program, a preferred drug is one that meets the safety, clinical efficacy, and pricing standards employed by the Pharmacy and Therapeutics (P&T) Committee. Non-preferred drugs are those that were reviewed by the P&T Committee and not included on the PDL. The non-preferred drugs require prior authorization prior to dispensing. The P&T Committee may also recommend prior authorization requirements for preferred drugs or other drugs, including new drugs, due to clinical considerations. New drugs are those legend and non-legend drugs which are newly approved for use by the FDA. This action also establishes the parameters for action by the P&T Committee as well as the Department's contractor for pharmacy services benefits management.

Pharmaceutical manufacturers will calculate and provide the Department a federal rebate for the covered product or products as appropriate. The Department has the authority to seek state supplemental rebates from pharmaceutical manufacturers. The contract regarding state supplemental rebates shall exist between the pharmaceutical 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 Medicaid costs and is not permitted, by federal law, to be shared with contractors. One hundred percent (100%) of the supplemental rebates collected on behalf of the state shall be remitted to the Commonwealth. 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.

Text corrections have been made concerning the VMAC methodology pursuant, for generic drug reimbursement, to requirements from the Centers for Medicare and Medicaid Services (CMS). During federal review of another unrelated State Plan Amendment that affects 12 VAC 30-80-40, CMS required DMAS to add text to this regulation detailing the methodology for arriving at the VMAC. The changes indicated here as new text merely conform this Virginia Administrative Code section to the parallel section in the State Plan for Medical Assistance. This new text does not represent a change in methodology, policy, or expenditures.

Utilization Review of High Drug Thresholds

Other than the existing emergency regulation concerning this issue, the State Plan for Medical Assistance does not presently contain any limitations or utilization review requirements for either institutionalized or non-institutionalized persons who receive high numbers of prescriptions for legend drugs. This modification to the State Plan's coverage of Medicaid pharmacy services was proposed to the 2003 General Assembly by the pharmacy industry. The General Assembly approved the industry's recommendation and directed DMAS to implement this modification.

For non-institutionalized recipients, DMAS intends to implement utilization review requirements when such recipients require more than nine prescriptions for legend drugs. For institutionalized recipients, DMAS intends to implement utilization review requirements when such recipients require more than nine prescriptions for legend drugs. Due to the ever-increasing complexity of prescription medications, it will benefit recipients to have additional pharmaceutical and medical professionals reviewing their drug profiles to prevent drug-to-drug interactions, overdoses, and inappropriate dosages.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and

3) other pertinent matters of interest to the regulated community, government officials, and the public.

If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

Preferred Drug List, Pharmacy and Therapeutics Committee, State Supplemental Rebates, and VMAC

There are no disadvantages to the public for the approval of these proposed regulations. The advantages to the public and the Commonwealth are that reductions in Medicaid expenditures may be realized for pharmacy services. Medicaid recipients will still have ready access to less costly, but no less therapeutically beneficial, drugs. The disadvantage to the agency is the difficulty in implementing such a prior authorization program. The pharmaceutical manufacturers whose drugs are not selected for inclusion in the PDL may experience a market shift and therefore a loss of revenues previously experienced from Virginia Medicaid.

The Department has the authority to seek supplemental rebates from pharmaceutical manufacturers in addition to the rebates received under Manufacturer's CMS Agreement, pursuant to Section 1927 of the Social Security Act (42 U.S.C. §1396r-8), for the Manufacturer's Supplemental Covered Product(s). The advantages are a cost savings to the Commonwealth and a reduction in Medicaid prescription expenditures. Such rebates to the Commonwealth will not affect the reimbursement to pharmacy providers for rendered services.

There are no issues associated with the inclusion of the VMAC language since this is effecting no policy or methodology changes. These text corrections were required by the CMS in the context of approving an unrelated State Plan Amendment. The changes indicated here as new text merely conforms this VAC section to the parallel section of the Title XIX State Plan. This new text does not represent a change in methodology, policy, or expenditures.

UR of High Drug Thresholds

There are no disadvantages to the public in this change. An advantage to the public is that small Medicaid expenditure savings might be obtained. Medicaid recipients can be expected to benefit the most from this change because the higher level of scrutiny of their drug profiles will better ensure their health and safety. The program is a process of reviewing drug usage by Medicaid fee-for-service recipients to determine the appropriateness of all existing prescriptions and newly prescribed medications to ensure appropriate, quality, and cost-effective prescription drug treatments. The process also is designed to improve the health and safety of the patient and 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.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

There are no changes in these final regulations over those which were initially proposed for public comment.

Public comment

Please summarize all comment received during the public comment period following the publication of the proposed stage, and provide the agency response. If no public comment was received, please so indicate.

DMAS' proposed regulations were published in the July 26, 2004, *Virginia Register* for their public comment period from July 26 through September 24, 2004. Comments were received from the National Association of Chain Drug Stores (NACDS), the Tidewater Pediatric Consultants, and the Pediatric/Adolescent Gastroesphogeal Reflux Association, Inc. (PAGER). A summary of the comments received and the agency's response follows.

Commenter	Comment	Agency response
NACDS	DMAS should follow the statutory mandates in constituting the P&T Committee	The Pharmacy and Therapeutics Committee currently consists of 12 members, which is within the range of 8-12 stated in regulations. In addition, all requirements for the composition of the Committee have been met. The actual size of the Committee may fluctuate at any time within these guidelines; therefore, the Agency will maintain the current regulations to allow flexibility in the membership of the Committee.
Tidewater Ped. Consultants	While recognizing the expense of a particular asthma drug, the commenters stated that the improved efficacy and compliance should be considered. Patients should not be required to fail on less expensive medicines in order for the more expensive to approved especially if the patient had already demonstrated successful compliance.	The Pharmacy and Therapeutics Committee has thoroughly reviewed the relevant drug classes for asthma management. A comprehensive selection of asthma medications is available, without prior authorization requirements, through the current preferred drug list. In addition, there are no “fail first” requirements for these medications.
PAGER	Commenter recommended a pediatric carve-out for patients with Gastroesophageal Reflux Disease (GERD) so that prior authorization and other barriers to services would not impede children receiving this needed medical care.	The Pharmacy and Therapeutics Committee has thoroughly reviewed the relevant drug classes for GERD management. Prior authorization requirements have been eliminated for children under age 12 for the most highly utilized medications in the pediatric population.

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

These final adopted regulations are identical to the previous emergency and proposed regulations.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC30-50-210		Definitions, requirements related to the Medicaid Prior Authorization Advisory Committee	Repeals definitions and all requirements related to the Medicaid Prior Authorization Advisory Committee.
		Former regulation permitted pharmacist to dispense brand name only if "brand necessary" written on prescription by prescriber.	Emergency and proposed regulations allow brand name drugs to be dispensed if they are on the PDL without special notation by the prescriber.
		Former regulation contained definitions for "Board," "Committee," and "Director."	The emergency and proposed regulation strikes these definitions.
		Former regulation contained no definitions for "Clinical data," "Complex drug regimen," "Emergency supply," "Non-preferred drugs," "P&T committee," "PDL," Prior authorization," "Utilization review," "State supplemental rebate," or "Therapeutic class."	The emergency and proposed regulation adds definitions for these terms. The emergency regulation for the PDL contained a different definition of the term "Emergency supply" than was found in the emergency regulation for Threshold. The proposed regulation contains the definition of "Emergency supply" used in the Threshold emergency regulation.
		Former regulation contained an extensive description of the Medicaid Prior Authorization Advisory Committee structure and function.	Emergency and proposed both strike this section and replace it with a section describing the Medicaid Pharmacy and Therapeutics Committee structure and function, the Preferred Drug List and other pharmacy prior authorization programs (including High Drug Threshold), and the

			state supplemental rebate program. New language was added describing how the P&T Committee will review new drugs approved by the FDA and will perform annual reviews on the PDL. Adds language describing the agency's purview of pharmacy benefits contract, and annual reporting requirements.
12VAC 30-80-40		Reference to VMAC exists in payment methodology Section contains the reimbursement methodology for pharmacy services. No prior reference to state supplemental rebates	In an unrelated State Plan Amendment, CMS required DMAS to specify how the VMAC is derived. The VMAC methodology is clarified that 60% is used for generic unit dose drugs and 75% is used for other non-unit dose generic drugs. This provision was not in the previous emergency regulations. New state supplemental rebate language that the State will receive Supplemental Rebates, in addition to the rebates received under Manufacturer's CMS Agreement, pursuant to Section 1927 of the Social Security Act (42 U.S.C. §1396r-8), for the Manufacturer's Supplemental Covered Product(s).
12VAC 30-130-1000		New regulation.	Contains a definition section comparable to that found in 12VAC30-50-210. Establishes additional parameters for the make up, responsibilities, and limits for the P&T Committee, preferred drug list and contracts for state supplemental rebates. The emergency regulation contained definitions for Clinical data, Complex drug regimen, DMAS, drug, emergency supply, "non-preferred drugs, PDL, prior authorization, state supplemental rebate and therapeutic class, which were removed from the proposed regulation. Because the sections (12 VAC 30-130) of the emergency regulation addressing FOIA and immunity for the P&T Committee, pharmacy prior authorization program and appeals are addressed in the State Plan (12 VAC 30-50-210), these sections were removed from this state-only regulation in this proposed regulation stage. New language was added describing how the P&T Committee will review new drugs approved by the FDA and will perform annual reviews on the PDL.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

Only to the extent that this PDL and prior authorization requirements provide improved quality of care will this regulatory action have any impact on the institution of the family and family stability including strengthening or eroding the authority and rights of parents in the education, nurturing, and supervision of their children; encouraging or discouraging economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents, strengthening or eroding the marital commitment; and increasing or decreasing disposable family income.