Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency Name:	Dept. of Medical Assistance Services
VAC Chapter Number:	12 VAC 30-50; 30-80; 30-130
Regulation Title:	Amount, Duration, and Scope of Services: Prior Authorization (PA) of Pharmacy Services, Preferred Drug List (PDL), and Utilization Review (UR) of High Drug Thresholds; Methods and Standards for Establishing Payment Rates-Other Types of Care Pharmacy Services
Action Title:	PA of Pharmacy Services, PDL, UR of High Drug Thresholds, State Supplemental Rebates
Document preparation date	**NEED GOV APPROVAL BY 07/01/2004**

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

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Do ***not*** *state each provision or amendment or restate the purpose and intent of the regulation.*

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) drugs that are not approved for the agency's Preferred Drug List (PDL) or prior authorization requirements for preferred drugs or other drugs, including new drugs, due to clinical considerations as determined by the Pharmacy & Therapeutics Committee; and (ii) implementation of utilization review requirements in cases where recipients use high numbers of prescription drugs (high drug threshold). 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. Furthermore, language is also being added, consistent with federal requirements, that sets out Virginia's methodology for its reimbursement of generic drugs, known as the Virginia Maximum Allowable Cost (VMAC), in order to conform the VAC with the federally approved State Plan.

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

Drugs that are approved for inclusion in the PDL will not require prior authorization. The determination of which 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, from pharmaceutical manufacturers as part of its considerations of 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). Payment of supplemental rebates may result in a product's 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.

The VMAC methodology provides for reimbursing for certain generic drugs. The Centers for Medicare and Medicaid Services, relative to an unrelated Title XIX State Plan Amendment, required DMAS to include this methodology in the Plan. This change is merely the inclusion of existing policy and represents no change in current policy.

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 prescription drugs, receive additional scrutiny of their drug profiles. Such recipients are often elderly and infirmed and high numbers of prescription drugs 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 benefits under Medicaid.

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. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss 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 drugs, provided to Medicaid fee-for-service clients, including state supplemental rebates for manufacturer's covered product(s) for which the manufacturer has agreed to pay 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 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 prescription drugs in the Medicaid fee-for-service program 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 state 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 Centers for Medicare and Medicaid Services. 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 briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.)

The section of the State Plan for Medical Assistance that is affected by this regulatory action is 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 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 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.

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 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 within 180 day time period. For institutionalized recipients, DMAS intends to implement utilization review requirements when such recipients require more than nine prescriptions for legend drugs within 30 day time period. 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 there are no disadvantages to the public or the Commonwealth, please 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.

Financial impact

Please identify the anticipated financial impact of the proposed regulation and at a minimum provide the following information:

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	PDL (includes State Supplemental Rebates): $1,447,600 GF for 2004. High Drug Threshold: $1,237,242 GF for 2004.
Projected cost of the regulation on localities	There is no cost to localities to implement this regulation.
Description of the individuals, businesses or other entities likely to be affected by the regulation	PDL/Threshold: Medicaid recipients, medical providers (prescribers), pharmacists, and pharmaceutical companies.
Agency's best estimate of the number of such entities that will be affected	Up to approximately 100,000 Medicaid recipients per month, 27,000 medical providers, prescribers, 1600 pharmacy providers may be affected, and 43 Pharmaceutical companies.
Projected cost of the regulation for affected individuals, businesses, or other entities	No cost to Medicaid recipients, medical providers (prescribers), pharmacists. Cost to pharmaceutical companies to date is approximately 13 million dollars.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

There are no alternatives to consider as the agency was directed by the 2003 General Assembly to implement a pharmacy prior authorization program that used a PDL. The Assembly also directed the agency to convene its P&T Committee and dictated the professional make-up. The Assembly also directed DMAS to implement utilization review of high prescription drug thresholds, and the change to VMAC is the current method used, set forth in the State Plan.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

DMAS published the content of this proposed regulation as two separate emergency regulations. The Preferred Drug List component was published in the *Virginia Register* on December 29, 2003, (VR 20:8) along with the Notice of Intended Regulatory Action (NOIRA). The High Drug Threshold emergency regulation and NOIRA was published on January 26, 2004 (VR 20:10). The only comment received was from the National Association of Chain Drug Stores. This comment only re-iterated the provisions of 12 VAC 30-50-210 that would provide the most cost savings to DMAS while maintaining high quality of services and operational efficiency for DMAS and community pharmacies. The items listed were:

- Prescriptions for recipients for multiple source drugs shall be filled with generic drugs unless identified as 'dispense as written';
- Use of a P&T Committee, consisting of physicians, pharmacists, agency staff, to develop and maintain the preferred drug list;
- Providers licensed to prescribe drugs are to be the parties who are required to secure the prior authorization;
- Requests for prior authorization will be responded to within 24 hours;
- The prior authorization center will be appropriately staffed with medical and pharmaceutical professionals, and;
- All collected rebates will be remitted only to the Commonwealth.

This commenter also recommended to DMAS' consideration the use of a disease state management program. The commenter stated that numerous chronic diagnoses had successfully leant themselves to such health care management and had resulted in cost savings. The commenter offered their Association's assistance in creating the best programs.

Agency response: DMAS appreciates the comments of the National Association of Chain Drug Stores and other interested parties in the development of this new program. The Department, in addressing these issues in order to create greater safeguards for Medicaid recipients and hold down the increasing costs of the prescription drug program, will include this Association as well as other provider groups in its deliberations.

Impact on family

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.

Detail of changes

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

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

Current section number	Proposed new section number	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,"	The emergency and proposed regulation adds definitions for these terms.
		"Emergency supply," "Non-preferred drugs," "P&T committee," "PDL," Prior	The emergency regulation for the PDL contained a different definition of the term "Emergency supply" than was found in the

		authorization," "Utilization review," "State supplemental rebate," or "Therapeutic class." Former regulation contained an extensive description of the Medicaid Prior Authorization Advisory Committee structure and function. No similar requirements for PDL, high drug thresholds exist in current regulation.	emergency regulation for Threshold. The proposed regulation contains the definition of "Emergency supply" used in the Threshold emergency regulation. 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.