Virginia Regulatory Town Hall

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Fast Track Proposed Regulation
Agency Background Document

Agency name	DEPT. OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation	12 VAC_30-80 and 12 VAC 30-50
Regulation title	Methods and Standards for Establishing Payment Rates—Other Types of Care: Fee for Service Pharmacy Services Reimbursement; Amount, Duration, and Scope of Services
Action title	Supplemental Drug Rebate Agreements; NF Unit Dose Dispensing Fee, and; Drug Threshold Program
Date this document prepared	May 7, 2012

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

The proposed amendments affect DMAS' regulatory language for three issues: (i) the Pharmacy program's use of Supplemental Rebate Agreements; (ii) discontinuing the payment of dispensing fees for unit dose drugs, and; (iii) removing the limits on the use of large numbers of prescription drugs.

Supplemental Rebates

This action modifies the existing model supplemental rebate agreement(s) for pharmaceutical products and the model supplemental rebate amendment(s) as set out in regulation. The Medicaid model supplemental rebate agreement between the Commonwealth of Virginia and pharmaceutical manufacturers for legend drugs provided to fee-for-service Medicaid recipients was originally effective January 1, 2004. The suggested changes to the supplemental rebate agreement(s) and amendment(s) streamline the contract and renewal process between DMAS and pharmaceu-

tical manufacturers while maintaining all of the existing contract terms and conditions between the two parties to the contract. These proposed changes reduce the amount of paperwork and time necessary to review and execute new contracts and modifications to existing contracts.

Unit Dose Drugs Dispensing Fee

This action also conforms 12 VAC 30-80-40 to the requirements of the 2011 *Acts of the Assembly* Chapter 890 Item 297 NNNN which discontinued the payment of a $5 per individual per month dispensing fee for unit dose drugs which are dispensed by nursing facilities' pharmacies to their residents.

Drug Threshold Program

This action also proposes to remove the service limit requirements applied to persons who require high numbers of prescription drugs. The elimination of the pharmacy threshold program is proposed in this regulatory change because this function has been assumed by the Virginia Drug Utilization Review Board (DUR Board), and therefore these regulations (12 VAC30-50-210(A)(7)(d)(1)-(4)) are no longer needed.

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 entitled Supplemental Drug Rebate Agreements and NF Unit Dose Drug Dispensing Fee (12 VAC 30-80-40) and Remove Drug Threshold Limits (12 VAC 30-50-210) 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.

___5/16/12_____ /s/ Cynthia B. Jones/sc_____

Date Cynthia B. Jones, Director

Dept. of Medical Assistance Services

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

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 and 325, authorizes the Director of 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.

Supplemental Rebates

The federal Omnibus Budget Reconciliation Act of 1990, section 4401 added § 1927 to the *Social Security Act* (42 U.S.C. §1396r-8). This provided for the Commonwealth to receive supplemental rebates on pharmaceutical products purchased by Medicaid for fee-for-service recipients, in addition to the rebates received under the Manufacturers' CMS Agreement. The payments of supplemental rebates by the pharmaceutical manufacturers to the Commonwealth does not affect DMAS' payment methodology for pharmacy services.

Unit Dose Drugs Dispensing Fee

The *2011 Acts of the Assembly*, Chapter 890, Item 297 NNNN directed DMAS to discontinue paying the dispensing fee of $5 to nursing facilities for drugs dispensed to residents via unit dose systems.

Drug Threshold Program

The need for the regulations controlling the use of high numbers of prescription drugs no longer exists. DMAS' authority for this change derives from its general authority set out in the *Code of Virginia* § 32.1-325 which provides for administering and amending the State Plan for Medical Assistance.

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.

This suggested regulatory action will not affect the health, safety, or welfare of the citizens of the Commonwealth. The federally mandated drug rebate program does benefit the Commonwealth by permitting DMAS to recover some of its expenditures for legend drugs.

Supplemental Rebates

The supplemental rebate program, which was implemented by DMAS in 2004, saves the Commonwealth of Virginia millions of dollars per year in the cost of legend drugs provided to fee-

for-service Medicaid recipients. This rebate program helps DMAS offset some of its expenditures while at the same time assuring that fee-for-service Medicaid recipients have access to clinically appropriate medications in all covered therapeutic drug classes.

The proposed changes to the supplemental rebate agreement described in 12 VAC 30-80-40(A)(9) reduces the time necessary to execute new contracts, renew existing contracts and increases the flexibility of DMAS and its pharmaceutical manufacturing partners in the contracting process, thereby enhancing a cost effective and clinically appropriate pharmacy program that saves the Commonwealth money.

Unit Dose Drugs Dispensing Fee
The discontinuing of the dispensing fee for unit dose drugs which are dispensed by nursing facility pharmacies will save DMAS a small expenditure.

Drug Threshold Program
The need for the provisions establishing prior authorization requirements when high numbers of prescription drugs are required has been replaced by the Drug Utilization Review Board functions.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

Please note: If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

This proposed regulatory change is being promulgated through the fast track process because it is non-controversial: (i) it reduces the time and effort needed to execute contracts and revisions to these contracts without reducing or modifying existing terms or conditions of the supplemental rebate agreements between DMAS and pharmaceutical manufacturers; (ii) it eliminates a dispensing fee that is no longer necessary, and; (iii) it removes prior authorization requirements for using high numbers of prescription drugs because it has been replaced with the Drug Utilization Review program. No opposition is expected as a result of this suggested fast track regulatory action.

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.) Please be sure to define any acronyms.

The sections of the State Plan that are affected by this action are the Methods and Standards for Establishing Payment Rates—Other Types of Care: Fee for Services Reimbursement for Pharmacy Services (12 VAC 30-80-40) and the Amount, Duration, and Scope of Services: Pharmacy Services (12 VAC 30-50-210).

Supplemental Rebates

Prior to 2004, DMAS did not collect rebates for expenditures for legend drugs and spent almost $499 million for this service. In 2005, DMAS' gross expenditures for prescribed drugs were almost $612 million with almost $11 million in manufacturers' rebates. In 2007, with the implementation of the federal Medicare Part D program (which reimburses for a significant amount of the legend drugs required by Virginia Medicaid individuals), DMAS saw its gross expenditures for prescribed drugs decrease to almost $228 million with a decrease in concomitant the manufacturers' rebates to slightly more than $2 million.

The current supplemental rebate contracting policy requires DMAS and pharmaceutical manufacturers to execute an 18-to-20 pages contract each time there is a change in the types of supplemental drugs to be included in the supplemental rebate program by a specific pharmaceutical manufacturer. The supplemental rebate contracts and amendments in current regulation are the model supplemental rebate contracts A, B and C and amendments #1 and #2.

DMAS proposes to develop one Supplemental Drug Rebate Agreement and one Supplemental Drug Rebate Amendment. Additional changes to these documents by either the manufacturer or DMAS would be made through addenda to the original agreement. Renewals to the agreement would be made through an amendment to the original agreement.

Unit Dose Drugs Dispensing Fee

In 2003, DMAS implemented a unit dose dispensing fee of $5 per member per month as a means of reimbursing nursing home pharmacies for the packaging of individual doses of medication for their Medicaid residents. This dispensing fee compensated nursing facility pharmacies for the time/materials to perform in-house packaging as was the practice at the time.

Community pharmacies are also paid a dispensing fee for their pharmacy services for individuals who live in their communities. Community pharmacies do not use unit dose packaging systems for drugs dispensed to non-institutionalized individuals.

With the implementation of the Medicare Part D prescription drug program in 2006, the vast majority of Medicaid recipients residing in nursing facilities became eligible for Medicare Part D prescription drug benefits. As a result, the payment of the dispensing fee for unit dose prescription drugs covered by DMAS was no longer necessary. Although DMAS still covers drugs not covered by Medicare Part D (benzodiazepines, barbiturates, and over the counter medications) and prescription drugs for nursing facility residents enrolled in the Medicaid program but not eligible for Medicare Part D, the vast majority by volume of unit dose prescriptions are provided by Medicare Part D plans.

Additionally, DMAS determined in a recent analysis of pharmacy reimbursement that nursing facility pharmacies are no longer packaging unit dose prescriptions in-house but are receiving pre-packaged unit dose prescriptions directly from external pharmacies thereby making the unit dose dispensing fee no longer necessary. DMAS estimates that the elimination of this unnecessary unit dose dispensing fee will save the agency approximately $323,708 in General Fund dollars for the 2012 state fiscal year.

Drug Threshold Program

DMAS is proposing the removal of the pharmacy threshold program. This program, adopted by DMAS in 2004, required prior authorization for fee-for-service non-institutionalized Medicaid patients whose volume of prescriptions for legend drugs exceeded nine unique prescriptions within 180 days and institutionalized Medicaid patients whose volume of legend drugs exceeded nine unique prescriptions within 30 days. The definition of "prior authorization" as it relates to the pharmacy threshold program is eliminated as is the description of the program in 12 VAC 30-50-210(A)(7)(d)(1) through (4).

The elimination of the pharmacy threshold program in current state regulation is proposed in this regulatory change because this function has been assumed by the Virginia Drug Utilization Review Board (DUR Board), and therefore is no longer needed. The DUR Board carries out reviews at least semi-annually of high prescription use by patients and targets prescribers of these patients through individual notifications that includes relevant peer-reviewed clinical standards specific to these patients' diagnoses.

In addition, pharmacists are informed at the point of sale through prospective DUR (Pro-DUR) edits if prescriptions have exceeded 9 unique prescriptions within 180 days or 30 days, depending on the non-institutional/institutional status of patients. This DUR Board function achieves the objectives of the pharmacy threshold program by reducing over-prescribing without clinical justification and informs prescribers and pharmacists about patients who have received excessive, clinically questionable prescriptions.

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.

Supplemental Rebates

The primary advantages to this regulatory change is to decrease the time and paperwork and increase the flexibility of DMAS and its pharmaceutical manufacturing partners by modifying the supplemental rebate agreement and amendment. There are no known disadvantages to this regulatory change.

Unit Dose Drugs Dispensing Fee

This change has a small advantage for the agency in that it will save slightly more than $300,000 in expenditures. It would be a slight disadvantage to the nursing facilities that have been receiving these dispensing fees.

Drug Threshold Program

There are no advantages nor disadvantages to anyone regarding the removal of this text. This function has been assumed by the Drug Utilization Review Board so this additional service limit text is not necessary.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no requirements in this proposal which are more restrictive than applicable Federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities within the Commonwealth of Virginia that are particularly impacted by this regulatory change.

Regulatory flexibility analysis

Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

Supplemental Rebates

DMAS was required by Federal regulation to submit its supplemental rebate agreement and amendment to the agreement for approval prior to its use. There are no alternatives to this requirement. This requirement and the changes to the supplemental rebate documents proposed in

this proposed regulatory change does not impact the health, safety, environmental and economic welfare of the constituents impacted by this change. These proposed changes reduce the bureaucracy and paperwork involved in the supplemental rebate contracting process for both the agency and its pharmaceutical manufacturing partners. This proposed regulatory change maintains compliance and reporting requirements required in Federal regulation.

Unit Dose Drugs Dispensing Fee
This change does not require small businesses to make any changes in how they interact with DMAS. It does not impose any new deadlines nor reporting requirements.

Drug Threshold Program
This change simply removes unnecessary text from the VAC without making any programmatic changes in DMAS' pharmacy services.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

This proposed regulatory change does not have any anticipated negative economic impacts on the constituents impacted by this regulation. The reduction in paperwork and process is anticipated to reduce the time and effort associated with entering into contracts, contract renewals and contract changes with the supplemental rebate program.

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	$0
Projected cost of the *new regulations or changes to existing regulations* on localities.	$0
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	Existing pharmaceutical manufacturers who have supplemental rebate agreements and any new pharmaceutical manufacturers who wish to participate in the supplemental drug rebate program and meet the regulatory requirements. Nursing facility pharmacies (76) will lose small dispensing fee payments formerly received for unit dose drugs. Neither Medicaid pharmacy providers nor recipients will be affected by the removal of the drug threshold program text.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently	Approximately 20 pharmaceutical manufacturers are required to provide rebates to DMAS. As of the beginning of 2012, DMAS had 1,857

owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	pharmacies enrolled in the Medicaid program of which 76 are NF pharmacies. Since the DUR program carries out drug utilization review activities, the removal of this unneeded text will have no impact. DMAS does not retain information on which or how many of its business partners would meet the definition of a small business.
All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	$0
Beneficial impact the regulation is designed to produce.	The contract signing, change, and renewal process will be streamlined, less bureaucratic and will reduce paperwork

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. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no viable alternatives to the proposal considered other than maintaining the existing, paperwork intensive process. The current supplemental rebate contracts are identified specifically in the state plan and state regulation. Any changes to these contracts require an amendment to the state plan and state regulation.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

These changes do not strengthen or erode the authority or rights of parents in the education, nurturing, and supervision of their children; or encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents. It does not strengthen or erode the marital commitment.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12 VAC 30-80-40	Not Applicable	Model Supplemental Rebate Agreement Contracts A, B and C and Model Supplemental Rebate Amendments #1 and #2	New Supplemental Rebate Agreement Replaces Contracts A, B and C. This new agreement reduces redundancy in the two existing agreements A&B. New Supplemental Rebate Amendment replaces Amendments #1 and #2. This new amendment reduces redundancy in the two existing amendments #1 and #2
12 VAC 30-80-40	Not Applicable	Provides for a dispensing fee to be paid to nursing facilities' pharmacies when they are distributing unit dose drugs.	NF pharmacies will lose small payments are a result of the removal of this provision.
12 VAC 30-50-210 (A)(7)(d)		Requires prior authorization when either non-institutionalized or institutionalized persons require high numbers of prescription drugs in a specific time period.	Change has no operational impact because this function has been assumed by the Drug Utilization Review Board.