Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Dept. of Medical Assistance Services 12 VAC 30
VAC Chapter Number:	Chapter 20
Regulation Title:	Recipient Cost Sharing and Similar Charges
Action Title:	Increase Co-pays for Brand-Name Prescription Drugs
Date:	7/19/2000

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form, Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

This proposed regulation intends to increase the amount of the co-payment that Medicaid recipients are required to pay when their precriptions are filled with brand-name drugs instead of appropriate generics.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

The Code of Virginia (1950) as amended, §32.1-325, grants to the Board of Medical Assistance Services (BMAS) the authority to administer and amend the Plan for Medical Assistance. The Code of Virginia (1950) as amended, §32.1-324, grants to the Director of the Department of Medical Assistance Services (DMAS) the authority to administer and amend the Plan for Medical Assistance in lieu of Board action pursuant to the Board's requirements. The Code also provides, in the Administrative Process Act (APA) §§9-6.14:7.1 and 9-6.14:9.1, for this agency's promulgation of proposed regulations subject to the Governor's review.

42 CFR §§ 447.50 through 447.59, inclusive, are based on § 1902(a)(14) of the Social Security Act, which permits states to require certain recipients to share some of the costs of Medicaid by imposing upon them payments such as enrollment fees, premiums, deductibles, co-insurance, co-payments, or similar cost sharing charges.

The Notice of Intended Regulatory Action was filed with the Registrar of Regulations on January 19, 2000, and published in the February 14, 2000, Virginia Register for comment period from February 14 through March 15, 2000.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

The purpose of this proposal is to update the prescription co-payment amount for brand-name drugs from the current $1 to $2. This regulatory action is not expected to affect the health, safety, or welfare of Medicaid recipients because, pursuant to federal law, they cannot be denied this important prescription drug service if they cannot pay the co-payment amount.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

The sections of the State Plan affected by this action are Co-payments and Deductibles for Categorically Needy and QMBs for Services other than under 42 CFR § 447.53 (12 VAC 30-20-150) and Co-payments and Deductibles for Medically Needy and QMBs for Services other than under 42 CFR § 447.53 (12 VAC 30-20-160).

Federal Medicaid regulations permit State plans to impose "nominal" cost sharing on certain recipients. Federal regulations also protect special groups of Title XIX eligibles from being required to pay copays: children, pregnant women, institutionalized individuals, persons receiving emergency and family planning services, and individuals enrolled in health maintenance organizations (42 CFR § 447.53). For non-institutional services, such as pharmacy services, the maximum amount of the co-payment varies with the cost of the service. 42 CFR § 447.54 provides:

State payment for the service	Maximum copayment
$10 or less	$0.50
$10.01 to $25	$1.00
$25.01 to $50	$2.00
$50.01 or more	$3.00

The State Plan currently imposes a co-payment for different services for the Categorically and Medically Needy recipients and Qualified Medicare Beneficiaries (QMBs) subject to federally-specified exclusions. In 1989, there were many fewer generically equivalent drug products available in the marketplace than are available now. When the State Plan first imposed a co-payment for pharmacy services in 1975, the co-payment amount was $0.50. This was increased in 1989 to the current amount of $1.00. At that time, the average cost per prescription was $14.47. Also during this time period, the Cost of Living Adjustment (COLA) index was 2.305, making the $0.50 increase less than a COLA increase.

The COLA index from 1989 to 1999 was 1.34. Based on this rate of increase, it would make the $14.47 average pharmaceutical price in 1989 be equivalent to $19.44 in 1999. Instead, the average pharmaceutical price actually increased to $38.00 (almost a 263% increase over 1989). In 1999, generic products averaged $18.00 in cost (somewhat less than COLA index), but brand name pharmaceutical products' prices actually increased to $70 (or 484% the average drug cost in '89). Differing the co-payment amount between brand-name drugs and generic drugs recognizes that brand drugs are more expensive than generic drugs. This regulatory action proposes to update the co-payment amount for brand-name drugs, as permitted by 42 CFR § 447.54.

Co-payments require recipients to share a small part of the cost of services and possibly make recipients and providers more cost conscious when deciding between appropriate therapies, thereby reducing costs to taxpayers. In the early 1990's, the private sector established in commercial insurance the use of the variable co-pay as a standard of practice, using the

differential payment to cause physicians and patients to be aware of the variance in costs between branded products and multi-source generics. At least five other State Medicaid programs have two tier co-payments for generic and brand drugs and eight states have variable co-payments for drugs (depending on the cost of the drug). At least five State Medicaid programs have a maximum pharmacy co-payment of $3. This differential has promoted the choice of generic drug products as an effective and efficient means of therapeutic decision-making.

Based on the cost of living indexes shown above, DMAS would be within its authority to increase the co-pay to $3.00 according to the guidelines set in the CFR. The current proposal is modest in its fiscal impact when considered against that possibility. As in the previous increase, the amount requested does not reflect the total inflationary increase in program costs.

DMAS is experiencing a large and growing demand for "single source" brand products for which a designated generic substitute is not available. While brand products represented only 38 percent of drug claims in 1999, they accounted for more than 70% of Medicaid pharmacy spending representing a 10 percent increase from 60% just two years ago.

Even if there is no generic substitute, in many instances there are therapeutic alternatives to using generic products. The therapeutic choice will be the decision of the prescriber. If the prescriber prescribes a brand product, however, the higher copayment will still apply to reflect the higher cost of the service, as permitted by federal law.

The only feasible alternatives which are permitted by federal law, rather than a co-payment change, to direct recipients away from the more expensive, branded products are prior authorization and education. Prior authorization would be more intrusive for both recipients and physicians and considerably more expensive and difficult for DMAS to implement and administer. Current state law would also require a lengthy process after which one would expect few products, if any, to be prior authorized, based on past experience. The agency already intends to educate prescribers and recipients to discourage the unnecessary use of brand drugs, but the agency does not believe that education alone is likely to have much impact.

This regulation may increase recipients' feelings of responsibility for their own health care but it will also increase out-of-pocket health care costs for poor Virginia families. Under the State Plan, however, co-payments are not imposed on children under the age of 21, recipients in nursing homes, or recipients receiving emergency services, pregnancy-related services and family planning services. Also pharmacies cannot deny services if the recipients cannot pay the co-payments. If prescribers change their prescribing patterns, the increase in out-of-pocket costs would be less.

DMAS has consulted with its standing Pharmacy Liaison Committee on this issue. This Committee is comprised of representatives of various aspects of the pharmaceutical industry: chain drug stores, independents, long-term care pharmacies, manufacturers (Pharmaceutical Research and Manufacturers Association), and the state pharmaceutical association (Virginia Pharmacists Association). The Committee's advice on this issue has been that few pharmacists are unable to collect the pharmacy co-pays from recipients, meaning that recipients have been

honoring their debt. In addition, if a pharmacist does incur numerous uncollected co-payments, he may attempt to collect the debt at a later time or, failing this, accumulate these debts and write them off against federal taxes as bad debts.

DMAS recognizes that new science, better medical practice and direct-to-consumer (DTC) advertising all contribute to the documented increases in pharmaceutical expenditures. Drug expenditure increases are not unique to Title XIX programs but are occurring across the nation in all private health insurance and other public health care programs. Factors contributing to these increases include: the aging population who are requiring higher numbers of various drugs, a growing prevalence of identified and treated diseases, the introduction and use of new therapeutic agents, and inflationary increases.

DMAS also recognizes that all new brand name drugs are not necessarily better than older, more established compounds. Just because the Food and Drug Administration determines that a new drug is safe and effective, does not mean it affords any therapeutic advantages over existing compounds in the marketplace. In fact, new compounds do not carry with them the safety profile that more established compounds will have accumulated. Two examples of such newer drugs that have been found, in their first few years of use, to not be as safe as the FDA testing indicated are Rezulin and Duract. Both of these compounds have been taken off the market due to safety concerns that did not surface during the FDA testing and approval processes prior to marketing.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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 include a sentence to that effect.

The primary advantage of this regulation would be savings to the taxpayer. The direct savings from higher co-payments for brand drugs is relatively minor, an estimated $2 million annually. The potential savings, if successful in changing prescribing patterns and reducing unnecessary prescriptions for brand drugs, could be substantially more.

A secondary advantage to Medicaid recipients in this proposed change is in directing them to established pharmaceutical compounds, which have a proven safety record, rather than potentially risking their health, or perhaps lives, with new compounds.

The primary disadvantage is the increased cost for recipients. However, if the pharmacy does not collect the copayment from the recipient, the pharmacy bears the cost because Medicaid payments will not make up the loss to the pharmacy.

Some studies indicate that co-payments can result in the reduction in both necessary and unnecessary treatment. That is why federal Medicaid regulations stipulate that only "nominal"

co-payments are permitted. The agency does not anticipate that a $1 differential on the copayment for brand drugs would have any impact on a recipient receiving appropriate treatment. However, both the physician and recipient would have some incentive to try traditional, less expensive therapy first, when appropriate.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

DMAS estimates that increasing the copayment from $1 to $2 on brand drugs will save Medicaid at least $2 million annually. Recipients who must make co-payments will pay an additional $13 in co-payments on average annually based on current prescribing patterns. Medicaid will save additional money to the extent that the copayment (and additional provider and recipient education efforts) leads to switches from brand drugs to generic drugs. The potential savings from switching all prescribed brand drugs that physicians authorized as "brand necessary" in 1999 to an available generic would have been $6 million. Prescribers may also consider prescribing generics with the same therapeutic impact rather than brand drugs in appropriate circumstances.

There are no localities that are uniquely affected by these regulations as they apply statewide.

The Department of Medical Assistance Services is established and receives federal financial participation pursuant ot Title XIX of the Social Security Act (42 U.S.C. §§ 1396 through 1396v); and Title 32.1, Chapter 10, of the Code of Virginia. The Virginia Medicaid Program is funded with both federal and state funds. The current federal funding participation (FFP) for medical assistance expenditures is 51.67%, which became effective October 1, 1999. This rate will increase to 51.85% on October 1, 2000. There would be no ongoing cost to the State. There would be no administrative impact on localities or other entities.

This program is not expected to have any impact on local departments of social services as it does not affect eligible groups or the eligibility determination process.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by

the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

The changes are located in item A of both 12 VAC 30-20-150 and 12 VAC 30-20-160 and provide for the differentiation of co-payment amounts between generic and brand-name drugs. Also, sections 150 and 160 have two new sections, labeled G and H added to establish a definition of a generic drug.

Alternatives

Please describe the specific 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.

Because DMAS operates an 'open formulary' drug program, it covers all drugs that the Food and Drug Administration authorizes. For DMAS to have a 'closed formulary' (cover only certain drugs), it would require legislative action.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

DMAS received comments and questions from The Purdue Frederick Company during the comment period for the Notice of Intended Regulatory Action. The comments concerned whether DMAS intended to adhere to the higher co-payment amount for brand name drugs where no generic substitute was available or had been approved by the Virginia Voluntary Formulary. The commenter also asked if DMAS would permit therapeutic substitution if the generic version of a brand name drug were not available. DMAS has no mechanism for authorizing routine therapeutic substitution.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

DMAS has examined these regulations and, in so far as is possible, has ensured that they are clearly written and easily understandable by the individuals and entities affected.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

DMAS, as part of its ongoing monitoring of Plan activities, will monitor the effect of this change.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which 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.

Other than a possible reduction in disposable income, this regulatory action will not have any negative effects on the institution of the family or family stability. It will not erode the marital commitment and will not discourage economic self-sufficiency, self-pride, or the assumption of family responsibilities.