Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency Name:	Dept. of Medical Assistance Services
VAC Chapter Number:	12VAC 10-650 and 130-280 through 130-410
Regulation Title:	Drug Utilization Review
Action Title:	2003 Drug Utilization Review
Document preparation date	NEED GOV APPROVAL BY **date**

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.*

The purpose of this regulation is to propose to modify the drug utilization review program that was implemented in 1993. DMAS' voluntary drug utilization review program focused on educational and advisory interventions with prescribing physicians and dispensing pharmacists but has not been as effective as is necessary. Such programs are intended to protect Medicaid recipients from adverse drug reactions, over- and under-utilization of drug therapies, situations of therapeutic duplication (which can seriously endanger life and health depending on the medications' side effects), drug-disease contraindications, drug interactions, drug allergy interactions, and incorrect drug dosage or duration. To enable DMAS to better respond to this unmet need, the agency proposes to modify its claims processing and provider requirements.

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 Medicaid Prospective Drug Utilization Review (ProDUR) system was designed to identify potential drug conflicts or contraindications, at the time that drugs are dispensed to recipients, so that appropriate review and modification of the drug therapy could be performed before recipients' health and safety are endangered. This system functions in conjunction with the point-of-sale (POS) program (a computerized claims processing mechanism available to pharmacists) as a pharmacy claim is electronically reviewed for patient eligibility and claims adjudication. The purpose of this regulatory action is to modify the ProDUR system to enable DMAS to reject or deny claims for drugs which conflict with or are contraindicated by criteria established by the DUR board until reviews of recipients' drug therapies are performed by the pharmacist and/or prescribing medical provider.

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 Drug Utilization Review [section 4.26 (12 VAC 30-10-650)]. The state-only regulations that are also affected are the Drug Utilization Review regulations at 12 VAC 30-130-280 through 130-410.

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) tied a state's claiming of federal financial participation (FFP) to its implementation of drug use review (DUR) program pursuant to § 1927 of the *Social Security Act*. DMAS complied with this federal mandate with the implementation of its prospective drug utilization review for non-institutionalized recipients, and retrospective drug utilization review for nursing facility residents. DMAS' DUR program met all federal requirements and therefore received federal approval in 1993.

At the outset of the DUR program, DMAS focused on the development of medical provider (prescriber) and pharmacist educational interventions and programs pursuant to federal law. Prospective DUR (ProDUR), that is review of utilization prior to the dispensing of the prescription medicine, recognizes and utilizes the dispensing pharmacist's ability to maximize therapeutic outcomes. The dispensing pharmacist is required to review each patient's drug therapy profile before each prescription is filled. During the review of drug therapy profiles, pharmacists are responsible for screening for potential drug therapy problems, using their knowledge as trained health care professionals and supported by computer-assisted databases of clinical manuals approved by the Commonwealth's DUR Board.

The 1990 federal law also required the states to create professional boards that would conduct that state Medicaid program's drug utilization review activities, such as developing therapeutic criteria and educational intervention programs. Educational interventions, primarily through the use of electronic reminder messages, were expected to result in a reduction of situations of drug-to-drug interactions, over- and under-utilization, incorrect drug dosages and duration of therapies, therapeutic duplication, adverse drug reactions, drug allergy interactions, and drug-disease contraindications, to name a few.

To date, the expected reductions envisioned by the 1990 DUR mandates have not been observed in DMAS' covered pharmacy services. Two of the areas of concern are situations when recipients obtain multiple prescriptions that are therapeutically duplicative of each other and prescriptions that are refilled within less than 30 days. The first example is referred to as 'therapeutic duplication' while the second is referred to as 'early refill'. DMAS has observed in these two instances, that dispensing pharmacists appear to be frequently using available override and intervention codes, with the limited clinical information available to them, in order to process their claims.

However, in order for this prospective drug utilization review process to be as effective as envisioned by Congress in 1990, the dispensing pharmacist should have access to the recipient's complete drug profile. For this to occur without further programmatic changes, the Medicaid recipient would have to secure all pharmacy services from only one pharmacy. This is not typically the case, however, since recipients tend to use multiple pharmacies depending on various factors, such as their immediate medical needs, their transportation capabilities, and other life circumstances. In this situation, DMAS (in its claims history and processing systems) is the sole location for recipients' complete drug profiles.

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.

There are no disadvantages to the public for the approval of these proposed regulations. The advantages to the public are that some Medicaid dollars will not be spent on inappropriate, perhaps fraudulent, pharmacy services. Advantages to Medicaid recipients are that these changes will better protect their health and safety when fully implemented. Pharmacy providers may find these new requirements to be frustrating because they will have additional processes to follow in order to secure payment of their claims, but they may also find this system helpful in alerting them to situations that require their intervention. This is an advantage to prescribers and pharmacists, since the system will alert them to other drugs the recipient may be taking that do not otherwise appear in the medical records of each separate medical professional in the prescription drug regimen of the recipient. Finally, by more readily identifying harmful drug contra-indications, Medicaid recipients who try to fraudulently use their Medicaid pharmacy benefits will likely be detected quicker and stopped from further pursuing these activities.

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	This regulation is projected to save the Commonwealth $296,255 per year.
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	Medicaid-enrolled pharmacists and medical providers (prescribers), and Medicaid recipients.
Agency's best estimate of the number of such entities that will be affected	Up to approximately 100,000 recipients per month, 1600 pharmacy providers and 27,000 medical providers may be affected.
Projected cost of the regulation for affected individuals, businesses, or other entities	There are no costs projected for the affected groups.

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.

Educational interventions have not been effective for a variety of reasons. When the pharmacist encounters a ProDUR alert message, the point-of-sale electronic system's notice has consisted of either a message-only (the pharmacist is not required to administer any intervention in order to process their claims) or the claim has rejected (the pharmacist enters an override intervention code so his claim is authorized for payment). Currently, DMAS believes that the use of available override codes is occurring with less than complete information as recipients are using multiple pharmacy outlets. DMAS' claims processing and claims history systems are the only single depository of recipients' complete pharmacy information. In the absence of the revised ProDUR edits, the health and safety of Medicaid recipients may possibly be at risk because inappropriate drug utilization may continue without prescribers' or pharmacists' knowledge.

Public comment

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

DMAS' emergency regulations were published in the January 26, 2004, *Virginia Register* (VR20:10) along with the Notice of Intended Regulatory Action (NOIRA). No comments were received on either the emergency regulations or on the NOIRA notice.

Impact on family

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

This regulation has no impact on recipients or their families. These changes do not strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 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; strengthen or erode the marital commitment; or increase or decrease 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.

There are no changes between the emergency regulation and the proposed regulation.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12 VAC 30-10-650		Describes the ProDUR Program: how the Program assesses data on drug use to set standards for drug use, and that it involves intervention via the counseling and education of recipients and physicians.	The proposed regulations update the compendia used to obtain data, both by referencing later editions of the standards, and by removing outdated sources and adding MICROMEDICS, Facts and Comparisons, and the Drug Information Handbook.
		The DUR process screens for therapeutic complications, drug disease contraindications, drug-drug interactions (both prescription and over the counter), incorrect dosage, drug allergy interactions and clinical abuse/misuse.	Adds new language that ProDUR interventions may include electronic messages as well as rejection of claims at point of sale pending intervention. In addition, DMAS will reject/deny claims that conflict with the criteria and require the pharmacist to intervene as specified through the electronic message at the point of sale. In addition to face-to-face interventions, telephonic discussions are added. Language is added stating that DMAS will seek to educate pharmacists as well as physicians via the ProDUR program.
		Predetermined criteria and standards for the Program are recommended by the DUR Board and approved by the BMAS.	The DMAS director is given authority to approve the predetermined criteria and standards for the Program.
		The point-of-sale system includes verifications, claims data capture and adjudication.	Adjudication may now include rejection/denial of claims that conflict with the DUR criteria.
12 VAC 30-130-290		Sets forth scope and purpose of DUR Program, to ensure that prescriptions are appropriate and medically necessary, providing education to practitioners.	Adds language specifying that the Program will now include rejecting or denying claims that conflict with DUR criteria.

12 VAC 30-130-310		Describes the patient medication profile, pharmacists' responsibilities, patient counseling and compliance monitoring. Pharmacies are required to have DMAS DUR criteria on hand for use by their pharmacists.	Includes new requirement that the pharmacist include prescriber information in the patient profile, including prescriber's name, Medicaid and DEA provider numbers. DMAS' designated agent is added in to have authorized access to patient information for compliance monitoring purposes. Requirement for having criteria on hand is stricken and replaced with statement that if the system identifies a conflict with one or more ProDUR criteria, a message will be transmitted to the pharmacist; claims may be rejected or pharmacists may be required to obtain prior authorization before dispensing the medication. Compliance monitoring may include electronic messages, or claim rejection/denial until the conflict is resolved.
12VAC30-130-320		Criteria and Standards for DUR, which states that the criteria will be consistent with the American Hospital Formulary Service Drug Information, the U.S Pharmacopeia-Drug Information, and the AMA Drug Evaluations.	New language strikes the AMA Drug Evaluations and inserts MICROMEDICS, Facts and Comparisons, and the Drug Information Handbook.
12VAC30-130-330		Educational program description, including means by which information is disseminated. DMAS will establish the educational program through accredited health care institutions and organizations; programs will be based upon the compendia and literature mentioned above, as well as data obtained from retrospective DUR process.	Means by which information and reminders are disseminated may now include via telephone. Adds pharmacy benefits manager to the list of health care institutions/organizations that may provide DUR education. Programs may now be based upon data obtained from both the prospective DUR process and from the retrospective process.
	12VAC30-130-335		New section that provides for DMAS electronic messaging at point-of-sale for rejecting or denying those claims that conflict with certain ProDur edits until conflicts are resolved (conflict resolution may include calling DMAS' pharmacy contractor for more complete information).