Virginia Regulatory Town Hall

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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	DEPT. OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation	12VAC 10-650 and 130-280 through 130-410
Regulation title	Drug Utilization Review
Action title	2003 Drug Utilization Review
Document preparation date	11/17/2003; **NEED GOV APPROVAL BY DEC 30TH**

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

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).

Preamble

The APA (Section 2.2-4011) states that an "emergency situation" is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date.

1) Please explain why this is an "emergency situation" as described above.
2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.

The Administrative Process Act (Section 2.2-4011) states that an "emergency situation" is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date. This suggested emergency regulation meets the standard at *COV* 2.2-4011(i) as discussed below.

DMAS' voluntary drug utilization review program, implemented in 1993, 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. The health and safety of Medicaid recipients is being endangered because the previously implemented interventions have not deterred or stopped these situations. To enable DMAS to better respond to this unmet need, the agency must have the authority to modify its claims processing and provider requirements.

The Governor is hereby requested to approve this agency's adoption of the emergency regulations entitled Drug Utilization Review (12 VAC 30-10-650 and 130-280 through 130-410) and also authorize the initiation of the promulgation process provided for in § 2.2-4007.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

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 modification of the drug therapy could be performed before recipients' health and safety were 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 action is to modify the ProDUR system to enable DMAS to reject 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 prescribers.

Legal basis

1) Please confirm that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the emergency regulation and that it comports with applicable state and/or federal law.
2) Please indicate that the regulation is not otherwise exempt under the provisions of subdivision A.4 of Section 2.2-4006 of the APA.

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 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.

The Office of the Attorney General has certified that this agency has the authority to promulgate emergency regulations and that such emergency regulations comport with applicable state and federal laws and regulations. Additionally, these emergency regulations are not otherwise exempt under the COV § 2.2-4006.

Substance

Please detail any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons why the regulation is essential to protect the health, safety, or welfare of Virginians. Delineate any potential issues that may need to be addressed as a permanent final regulation is developed.

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 review for non-institutionalized recipients, and retrospective review for nursing facility residents, drug utilization review program. 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 physician 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. This is done by requiring the dispensing pharmacist 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 data bases 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.

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.

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.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12 VAC 30-10-650		Sets out standard federally required language (from 1990)	Adds reference to rejecting or denying claims that conflict with DUR criteria.
12 VAC 30-130-290 thru 410		Sets out standard federally required language (from 1990)	Adds reference to rejecting or denying claims that conflict with DUR criteria.
	12VAC30-130-325		New section to provide for rejecting those claims that conflict with certain ProDur edits until conflicts are resolved (conflict resolution may include calling DMAS' pharmacy contractor for more complete information).

Finally, the previously discussed federal law exempted certain hospitals from the federal drug utilization review requirements that are discussed herein. Therefore, DMAS is not permitted to apply any of these requirements to hospitals that use a drug formulary system and bill Medicaid no more than the hospital's purchasing cost for covered drugs.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet 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 impacted as inappropriate drug utilization will continue without prescribers' knowledge.

Family impact

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

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 nor affect a family's disposable income.