

## **COMMONWEALTH of VIRGINIA**

Office of the Attorney General Richmond 23219

**Jerry W. Kilgore** Attorney General 900 East Main Street Richmond, Virginia 23219 804-786-2071 804-371-8947 TDD

## **MEMORANDUM**

TO: VICTORIA P. SIMMONS

Regulatory Coordinator

Department of Medical Assistance Services

FROM: PAIGE S. FITZGERALD

Special Counsel to DMAS

**DATE:** April 23, 2004

**SUBJECT:** Proposed Regulations concerning Prior Authorization of Pharmacy Services,

Preferred Drug List, Utilization Review of High Drug Thresholds, and

**State Supplemental Rebates** 

I am in receipt of the proposed regulations concerning changes to the regulations governing the provision of pharmacy services. You have asked the Office of the Attorney General to review and determine if the Department of Medical Assistance Services has the legal authority to promulgate the above-referenced proposed regulations and to identify any federal or state mandates regarding this regulation.

Based on that review, it is my view that the Director, acting on behalf of the Board pursuant to Va. Code § 32.1-324, has the authority to promulgate these amendments to the State Plan, subject to compliance with the provisions of Article 2 of the Administrative Process Act and has not exceeded that authority. These regulations will enable the Director, in lieu of the Board of Medical Assistance Services, to make permanent the regulations concerning the pharmacy program, specifically the regulations concerning the preferred drug list, utilization review of high drug thresholds, and state supplemental rebates. Many of the changes were made by the promulgation of emergency regulations, and were approved by this Office in three separate memoranda, dated

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October 24, 2003, November 26, 2003, and April 9, 2004.

Pursuant to 42 U.S.C. § 1396r-8, DMAS has the authority to seek supplemental rebates from pharmaceutical manufacturers. Further, the authority for prior authorization of drugs and the utilization of high drug thresholds is 42 C.F.R. § 440.230(d), which states that "[t]he agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures." In addition, the 2003 Appropriation Act (2003 Acts of Assembly chapter 1042), Item 325(ZZ), requires that DMAS "shall amend the State Plan for Medical Assistance Services to modify the delivery system of pharmaceutical products to include a Preferred Drug List program no later than January 1, 2004."

The 2003 Appropriation Act, Item 325(UU), also mandated that DMAS "shall amend the State Plan for Medical Assistance to require prior authorization of prescription drugs for non-institutionalized recipients when more than nine unique prescriptions have been prescribed within a 180-day period. Over-the-counter prescriptions shall not count as a unique prescription for the purposes of prior authorization. For the purposes of prior authorization, non-institutionalized recipients do not include recipients of services at Hiram Davis Medical Center." Similarly, Item 325(VV) provides that DMAS "shall amend the State Plan for Medical Assistance to require prior authorization of prescription drugs for nursing facility residents when more than nine unique prescriptions have been prescribed within a 30-day period. Over-the-counter prescriptions shall not count as a unique prescription for the purposes of prior authorization. For the purposes of prior authorization, nursing facility residents do not include residents of the Commonwealth's mental retardation training centers." The foregoing provisions provide DMAS with the necessary authority to promulgate these regulations.

If you have any questions or need any additional information, please feel free to call me at 786-0095.

cc: Kim F. Piner, Esquire