REGULATORY REVIEW SUMMARY

Amendment to the Plan for Medical Assistance

I. IDENTIFICATION INFORMATION

Title of Final Regulation: Amount, Duration, and Scope of Services Pharmacy Services: Coverage of Weight Loss Drugs

Director's Adoption: July 2, 1999

Effective Date: September 1, 1999

Agency Contact: William J. Lessard, Jr.
Division of Program Operations
Dept. of Medical Assistance Services
600 E. Broad St., Suite 1300
Richmond, Virginia 23219
(804) 371-8852

II. SYNOPSIS

Basis and Authority: 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. Section 9-6.14:4.1 C contains agency exemptions otherwise subject to the public notice and comment requirements of Article 2 of the APA. The *Code* also provides, in the Administrative Process Act (APA) §9-6.14:1 et seq., for the exemption of certain regulatory actions by state agencies. This action was mandated by the General Assembly in Chapter 935 of the *1999 Acts of Assembly* Item 335 KK and is therefore exempt from Article 2 of the APA.

Purpose: The purpose of this action is to amend the State Plan for Medical Assistance concerning the coverage of weight loss drugs due to action taken by the 1999 General Assembly in Chapter 935 of the *1999 Acts of Assembly* Item 335 KK. Coverage of new

drugs now available or available in the future for treating weight loss is expected to improve the health of Medicaid recipients.

Substance and Analysis: The sections of the State Plan affected by this action are Attachment 3.1 A&B, Supplement 1 Narrative for the Amount, Duration, and Scope of Services (12VAC30-50-210) and Supplement 5 Drugs or Drug Categories Which are Not Covered (VAC30-50-520).

Prior to July 1, 1997, the State Plan for Medical Assistance did not cover drugs prescribed for weight loss. The 1997 General Assembly mandated coverage of anorexiants when prescribed for weight loss for recipients who met the specific Social Security Administration (SSA) criteria for obesity. These affected individuals' conditions had to be certified as life-threatening by their treating physicians.

The SSA criteria for obesity are a weight in excess of 100 percent of the SSA defined desired level and a concurrent medical condition (such as high blood pressure, history of pain and limitation of motion in a weight-bearing joint or the spine, congestive heart failure, chronic venous insufficiency in either leg with pain on weight bearing and persistent edema, or respiratory disease) that the attending physician determines to be life-threatening.

The 1997 General Assembly also directed that anorexiant drugs which are prescribed for weight loss must be prior authorized.

At the time this action was originally taken to cover anorexiant drugs for weight loss, these types of chemical compounds were the only drug therapy available for weight loss. Recently, the FDA has approved lipase inhibitors for weight loss. Other drug therapies for weight loss may be available in the near future. This regulatory action will provide Medicaid coverage for any FDA-approved drug therapies and agents for weight loss on the same terms as anorexiant drugs being covered for weight loss. This means that recipients still must meet the strict disability standards for obesity established by the SSA and their conditions must be certified as life-threatening by the treating physicians. It also means that drugs for weight loss must be prior authorized.

The General Assembly specified that recipients requesting this covered service must meet the strict disability standards for obesity established by SSA. Since the SSA revises its disability standards from time to time, it may also eliminate the listing in the future. However, since it was the intent of the General Assembly to use the standards in effect when the 1999 Appropriations Act became effective, it is specified that the disability standard to be used shall be the ones in effect on April 7, 1999.

This regulation will have a limited impact on the agency because the eligibility criteria are very stringent. In 1998 and 1999 to date, DMAS received 23 and 37, respectively, requests for coverage of anorexiants for weight loss of which 13 and 18, respectively, were approved. A 30-day supply of the anorexiant drug currently available

and at the generally recommended dosage costs $83.42. While DMAS may expect a slight increase in coverage requests because of the publicity about the new drug's FDA approval, a significant increase is not expected in total approvals for this drug therapy treatment of morbid obesity. A 30-day supply of the lipase inhibitor recently approved by the FDA will cost $108.11. This change makes available to recipients new potentially more effective drugs, as they become available for treating morbid obesity.

An alternative treatment for morbid obesity is gastric bypass surgery which also must be prior authorized. In 1998 and 1999 to date, DMAS received 47 and 60 requests for gastric bypass surgery, of which 31 and 32, respectively, were approved.

Issues: The primary advantage of this regulatory action is to cover new, potentially more effective drugs as they become available to treat Medicaid recipients with morbid obesity. The agency projects no negative issues involved in implementing this regulatory change.

Impact: Prescribers will have additional agents available for treating morbid obesity, but they will have to request prior authorization from DMAS. Pharmacy providers will have to submit the claim on paper with the prior authorization attached.

Recipients with morbid obesity will have new, potentially more effective therapies available for treating their condition. Some of the new therapies, however, would commit a recipient to extended maintenance therapy, but Medicaid would no longer pay for the drugs when a recipient no longer meets the morbid obesity criteria. These drug therapies will not be available to the many recipients with moderate obesity.

Since the State Plan for Medical Assistance already covers anorexiants and gastric bypass surgery for treating weight loss, the agency anticipates a negligible budget impact to cover additional drugs for treating weight loss.

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

Forms: No new forms will be required for implementation of this regulation.

Evaluation: DMAS will incorporate the monitoring of this State Plan amendment in its ongoing Plan monitoring and management activities.

III. STATEMENT OF AGENCY FINAL ACTION

I hereby approve the foregoing Regulatory Review Summary and take the adoption action stated therein. Because this final regulation is exempt from the public notice and comment requirements of the Administrative Process Act (Code 9-6.14:4.1 C), the Department of Medical Assistance Services will receive, consider and respond to petitions by any interested person at any time with respect to reconsideration or revision.

07/02/1999
Date

/s/ Dennis G. Smith
Dennis G. Smith, Director
Dept. of Medical Assistance Services

REGULATORY REVIEW CHECKLIST

To accompany Regulatory Review Package

Agency Department of Medical Assistance Services

Regulation title Amount, Duration, and Scope of Services: Pharmacy Services

Purpose of the regulation Coverage of new weight loss drugs will make available a new treatment methodology for persons having morbid obesity as defined by the SSA.

Summary of items attached:

☒ **Item 1:** A copy of the proposed new regulation or revision to existing regulation.

☒ **Item 2:** A copy of the proposed regulation submission package required by the Virginia Administrative Process Act (Virginia Code Section 9-6.14:7.l.G [redesignated Section 9-6.14:7. l.H after January 1, 1995]). These requirements are:

- ☒ (i) the basis of the regulation, defined as the statutory authority for promulgating the regulations, including the identification of the section number and a brief statement relating the content of the statutory authority to the specific regulation proposed.
- ☒ (ii) the purpose of the regulation, defined as the rationale or justification for the new provisions of the regulation, from the standpoint of the public's health, safety and welfare.
- ☒ (iii) the substance of the regulation, defined as the identification and explanation of the key provisions of the regulation that make changes to the current status of the law.
- ☒ (iv) the issues of the regulation, defined as the primary advantages and disadvantages for the public, and as applicable for the agency or the state, of implementing the new regulatory provisions.
- ☒ (v) the estimated impact, defined as the projected number of persons affected, the projected costs, expressed as a dollar figure or range, for the implementation and compliance thereof, and the identity of any localities particularly affected by that regulation.

☒ **Item 3:** A statement from the Attorney General that the agency possesses, and has not exceeded, its statutory authority to promulgate the proposed regulation.

Regulatory Review Checklist
Page Two

☒ **Item 4:** A statement disclosing whether the contemplated regulation is mandated by state law or federal law or regulation, and, if mandated in whole or in part, a succinct statement of the source (including legal citation) and scope of the mandate, together **with an attached copy of all cited legal provisions.**

☒ **Item 5:** For any proposed regulation that exceeds the specific minimum requirements of a legally binding state or federal mandate, a specific rather than conclusory statement setting forth the reasoning by which the agency has concluded that the proposed regulation is essential to protect the health, safety or welfare of citizens or for the efficient and economical performance of an important governmental function.

☒ **Item 6:** For any proposed regulation that exceeds the specific minimum requirements of a legally binding state or federal mandate, a specific rather than conclusory statement describing the process by which the agency has considered less burdensome and less intrusive alternatives for achieving the essential purpose, the alternatives considered, and the reasoning by which the agency has rejected such alternatives.

☒ **Item 7:** A schedule setting forth when, no later than three (3) years after the proposed regulation is effective, the agency will initiate a review and reevaluation of the regulation to determine if it should be continued, amended, or terminated. Include a description of the specific and measurable goals the proposed regulation is intended to achieve, if practical.

☒ **Item 8:** A detailed fiscal impact analysis prepared in coordination with DPB that includes: (a) the projected cost to the state to implement and enforce the proposed regulation and (b) the source of funds to meet this projected cost.

/s/ Dennis G. Smith	07/02/1999	VPS 7/8/99
Signature of Agency head	Date	Date forwarded to DPB & Secretary