

REGULATORY REVIEW CHECKLIST

To accompany Regulatory Review Package

Agency Department of Medical Assistance Services

Regulation title Standards for the Coverage of Organ Transplant Services

Purpose of the regulation To expand coverage of certain transplants to persons with leukemia.

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.I.G [redesignated Section 9-6.14:7. I.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.

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- 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.

Dennis G. Smith
Signature of Agency head

4/29/99
Date

VPS 5/4/99
Date forwarded

to

DPB & Secretary

REGULATORY REVIEW SUMMARY

Amendment to the Plan for Medical Assistance

I. IDENTIFICATION INFORMATION

Title of Final Regulation: Expansion of Bone Marrow Transplantation:
Coverage of Leukemia Diagnoses

Director's Adoption: April 29, 1999

Effective Date: July 1, 1999

Agency Contact: Moses N. Adiele, M.D.
Program Operations
Dept. of Medical Assistance Services
600 E. Broad St., Suite 1300
Richmond, Virginia 23219
(804) 786-8056

II. SYNOPSIS

Basis and Authority: 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 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 due to conformance to General Assembly mandates (§9-6.14:1 (C)(4)(a)).

This action was mandated, permitting no agency discretion, by the 1999 General Assembly in Chapter 935 of the 1999 Acts of Assembly Item 335 DD and is therefore exempt from Article 2 of the APA.

The General Assembly, in this referenced Appropriations Act language, directed DMAS to adopt an emergency regulation to be effective by July 1, 1999.

DMAS has not ignored this directive but has attained the desired effective date via the more expedient mechanism of adopting an exempt final regulation.

Purpose: The purpose of this Plan amending action is to incorporate the diagnosis of leukemia under the coverage policy on high-dose chemotherapy and bone marrow transplants. This will benefit the health of Medicaid recipients because this action represents the coverage of medical procedures for persons with leukemia that have not heretofore been covered by Medicaid.

Substance and Analysis: The section of the State Plan affected by this action is the Standards for Coverage of Organ Transplant Services: High Dose Chemotherapy and Bone Marrow/Stem Cell Transplantation Coverage for Persons over 21 Years of Age (Attachment 3.1-E (12 VAC 30-50-570)).

Currently, DMAS only covers high dose chemotherapy and bone marrow/stem cell transplantation procedures for individuals older than 21 years of age who have diagnoses of lymphoma and breast cancer.

This Plan amendment requires Virginia Medicaid to cover high-dose chemotherapy and bone marrow/stem cell transplants, when this treatment is the appropriate treatment for individuals over the age of 21 who have been diagnosed with leukemia. For this new coverage, the patient must have a performance status, as determined by the attending physician, sufficient to proceed with the high-dose chemotherapy and bone marrow transplant.

Incorporating these policies into the State Plan for Medical Assistance is intended to clarify these policies' coverages for providers and recipients and set out specific parameters within which the services will be paid and outside of which the services will be denied. Incorporating these policies into the State Plan is required in order for DMAS to claim Federal matching dollars.

Issues: The primary advantage of this change for the public is the coverage of these transplant services for individuals who have leukemia. Previously, persons with such diagnosis have had to rely on conventional chemotherapy treatments. The agency expects no disadvantages to accrue to either itself or the Commonwealth as a result of this change. The agency projects no negative issues involved in implementing this regulatory change.

Impact: The 1999 Appropriations Act provided \$241,000 (GF) and \$256,000 (NGF) in FY 2000 for these transplants based on an estimated five transplant recipients per year. There are no localities that are uniquely affected by these regulations as they apply statewide.

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

Evaluation: The Department of Medical Assistance Services routinely evaluates its State Plan amendments as part of its ongoing Plan management activities. This change will become part of those Plan monitoring activities..

III. STATEMENT OF AGENCY FINAL ACTION

I hereby approve the foregoing Regulatory Review Summary and take the adoption action stated herein. 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.

4/29/99
Date

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