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 To promulgate a uniform payment methodology for pharmacy infusion services regardless of the patient's location.

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.

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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.

/s/ Dennis G. Smith	October 19, 1999	10/19/99 VPS
Signature of Agency head	Date	Date forwarded to DPB & Secretary

REGULATORY REVIEW SUMMARY

Amendment to the Plan for Medical Assistance

I. IDENTIFICATION INFORMATION

Title of Proposed Regulation: Amount, Duration, and Scope of Services: Pharmacy Services: Pharmacy Infusion Services

Director's Approval: October 19, 1999

Public Comment Period: January - March, 2000

Proposed Effective Date: June 1, 2000

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II. SYNOPSIS

Basis and Authority: The Code of Virginia (1950) as amended, §32.1-325, grants to the Board of Medical Assistance Services (BMAS) the authority to administer and amend the Plan for Medical Assistance. The Code of Virginia (1950) as amended, §32.1-324, grants to the Director of the Department of Medical Assistance Services (DMAS) the authority to administer and amend the Plan for Medical Assistance in lieu of Board action pursuant to the Board's

requirements. The Code also provides, in the Administrative Process Act (APA) §§9-6.14:7.1 and 9-6.14:9.1, for this agency's promulgation of proposed regulations subject to the Governor's review.

The Notice of Intended Regulatory Action for this regulation was filed with the Virginia Register on August 27, 1999, for publication on September 13, 1999.

Purpose: This proposed action to modify these existing regulations is intended to provide a consistent payment methodology for all pharmacy intravenous infusion therapy services, provided in a fee-for-service program regardless of the patient's place of residence. By simplifying their billing and documentation procedures, this consistent payment methodology will benefit pharmacists who are asked to render specialized and highly technical pharmacological services to patients who require medicinal and nutritional intravenous therapies, thereby protecting the patients' health and safety.

Substance and Analysis: The sections of the State Plan affected by this action are the Narrative for Amount, Duration, and Scope of Services: Pharmacy Services (12 VAC 30-50-210) and Methods and Standards for Establishing Payment Rates-Other Types of Care (12 VAC 30-80-40).

The Virginia Medicaid program began covering pharmacy services in 1969, with the program's origination. As medical technology and pharmacological advances have been made by the medical community and the pharmaceutical industry, Medicaid has modified its pharmacy policy coverage in keeping with the changes. This is the essence of this proposed State Plan change. The Health Care Financing Administration (HCFA) requires that payment methodologies be set out in the State Plan for purposes of supporting states' claims of Federal Financial Participation.

These two regulations (the Amount, Duration, and Scope of Services and the Methods and Standards for Establishing Payment Rates-Other Types of Care) are federally required to be in the State Plan for Medical Assistance. This proposed action to modify these existing regulations provides a consistent payment methodology for all pharmacy intravenous infusion therapy services, provided in a fee-for-service program, regardless of the patient's place of residence (either at home or in a nursing facility). By simplifying their billing and documentation procedures, this consistent payment methodology will provide administrative relief to pharmacists who are asked to render specialized and highly technical pharmacological services to patients who require medicinal and nutritional intravenous therapies. This change will make no difference in reimbursement amounts paid to pharmacists.

Issues: Provision of pharmacy services in the Medicaid program provides for treatment of patients needing medication, thereby providing for their health, safety, and well-being and for other citizens of the Commonwealth. The streamlined process provided will increase the efficient and economical performance of the program for both providers and the

Commonwealth. The only disadvantage is that if this change is not implemented, pharmacists will continue to be burdened with a highly detailed, cumbersome billing process when they have rendered intravenous infusion therapy services.

Fiscal/Budget Impact: DMAS expects this regulatory change to be budget neutral. This amendment will not result in any additional funds being paid to pharmacists. It will only make easier their process of completing claims and submitting them to Medicaid for payment. There are no localities that are uniquely affected by these regulations as they apply statewide.

Funding Source/Cost to Localities/Affected Entities: This change in payment methodology should prove budget neutral to the state for implementation and enforcement. Funds will be provided through the Medicaid Pharmacy Program at a level equivalent to current expenditures. There will be no cost increase to localities. Entities to be affected will be providers of long term care facility pharmacy services, estimated to be about 25 pharmacies out of a total of 1700 enrolled pharmacy providers. That provider group was instrumental in designing the new methodology and supports this expedited payment process.

There will be no impact on local departments of social services from this regulatory action.

Forms: No new forms are required to implement this proposed regulation. The existing forms that are used for billing pharmacy services are: the Daily Pharmacy Drug Claim Ledger (DMAS-173) and the HCFA 1500 claim form.

Evaluation: The Department of Medical Assistance Services routinely monitors the implementation of Plan changes as part of its ongoing management monitoring activities.

III. STATEMENT OF AGENCY ACTION

I hereby approve the foregoing Regulatory Review Summary and the attached amended pages to the State Plan for Medical Assistance for publication for public comment period in conformance to the public notice and comment requirements of the Administrative Process Act, Code of Virginia §9-6.14:7.1., Article 2.

October 19, 1999
Date

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

JUSTIFICATION FOR PROPOSED REGULATORY CHANGE
Under Executive Order Twentyfive (98)

I. IDENTIFICATION INFORMATION

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

Issue Name: Pharmacy Infusion Services

II. JUSTIFICATION

Federal/State Mandate/Scope

The legal authority of the Agency to administer the Medicaid Program is as stated above (II.). Although requirements for this initiative are not present in state or federal law, the proposed changes will provide for consistency in payment methodology, a reduced burden on providers and the agency in documentation of multiple ingredients, and simplification of the attendant manual adjudication process necessary in claims payment.

Essential Nature of Regulation

Provision of pharmacy services in the Medicaid program exists for treatment of patients needing medication, thereby providing for their health, safety, and well being and for other citizens of the Commonwealth. The streamlined process set forth in the regulations will increase the efficient and economical performance of the program for both providers and the Commonwealth.

This initiative is anticipated to be budget-neutral.

Agency Consideration of Alternatives

The issue of billing for I.V. pharmacy services has been discussed in-house and with a panel of providers. At the request of the affected providers, this new method of payment will replace a system requiring each component be itemized. Review of the previous process showed that

procedure to be burdensome to providers and difficult to adjudicate claims. The new process is the less burdensome, less intrusive alternative.

Family Impact Assessment (Code of Virginia §2.1-7.2)

This proposed regulation will not have any impact on families. This change will be transparent to families. It will only ease the billing process of pharmacists when they are providing complex and highly technical pharmaceutical services to individuals who are receiving infusion therapy services, whether the patients are in their home or in a nursing facility.

Regulation Review Schedule

The regular review of this regulation will occur in conjunction with the review of all agency regulations according to the schedule approved by the Secretary of Health and Human Resources under Executive Order Twentyfive (98).