REGULATORY REVIEW CHECKLIST

To accompany Preliminary Determination Package

Agency Department of Medical Assistance Services

Regulation title Recipient Cost Sharing and Similar Charges

Purpose of the regulation To increase copay for brand-name drug prescriptions.

Summary of items attached:

☒ **Item 1:** An explanation of the specific reason for the proposed regulation.

☒ **Item 2:** A statement identifying the source of the agency legal authority to promulgate the contemplated regulations and a statement as to 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. **(Be sure to attach a copy of all cited legal provisions).**

☒ **Item 3:** A statement setting forth the reasoning by which the agency has concluded that the contemplated 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 4:** A statement describing the process by which the agency has considered, or will consider, less burdensome and less intrusive alternatives for achieving the essential purpose, the alternatives considered or to be considered (to the extent known), and the reasoning by which the agency has rejected any of the alternatives considered.

/s/ Dennis G. Smith, Director	11/1/99	11/2/99 VPS
Signature of Agency Head	Date	Date forwarded to DPB & Secretary

PRELIMINARY JUSTIFICATION FOR REGULATORY ACTION
UNDER EXECUTIVE ORDER TWENTYFIVE (98)

I. IDENTIFICATION INFORMATION

Regulation Name: Recipient Cost Sharing and Similar Charges

Issue Name: Increase of Brand-Name Drug Copayments

VAC Numbers: 12 VAC 30-20-150 and 12 VAC 30-20-160.

Registrar's Filing Deadline: _____

II. LEGAL AUTHORITY

Agency Legal Authority: Code of Virginia §§32.1-324 and 32.1-325; 42 U.S.C. §1396.

Director Approval of Action: /s/ Dennis G. Smith Nov. 1. 1999
Dennis G. Smith Date

III. JUSTIFICATION

1. Statement of Reason for Regulation

The regulation updates the prescription copayment amount. The current prescription copay of $1 was promulgated in 1989 when the average cost per prescription was only $14.47. The average cost per prescription (combining generic and brand-name drugs) now is $38, varying depending on whether the prescription is filled with a generic or brand-name drug. The average cost per prescription for a generic drug is now $18 while the average cost per prescription for a brand-name drug is $70. Therefore, the regulation proposes to update the pharmacy copayment amount, for all groups (except those specifically exempted from co-pay requirements) of Medicaid eligible individuals, for brand-name drugs from the current $1 to $2.

2. Federal/State Mandate and Scope

The legal authority of the Agency to administer the Medicaid Program is as stated above (II.). This regulation has not been mandated by state or federal law. The State Plan currently

imposes a $1 copay per prescription for the categorically and medically needy subject to certain exclusions. The regulation proposes to update the copayment amount for brand-name drugs, as permitted by 42 CFR § 447.54.

3. Essential Nature of Regulation

This regulation is essential for the efficient and economical performance of an important governmental function. Copayments, helps make recipients and providers more cost conscious in deciding between appropriate therapies, thereby reducing costs to taxpayers. Differing the copayment amount between brand-name and generic drugs recognizes that brand-name drugs are more expensive than generic drugs.

DMAS estimates that increasing the copay from $1 to $2 only on brand-name drugs will save Medicaid at least $2 million annually. Medicaid will save additional money to the extent that the copayment (and additional provider and recipient educational efforts) leads to switches from brand-name drugs to generic drugs. The potential savings from switching from the prescribed brand-name drug, which the physician has authorized as "brand necessary," to an available generic is an additional $6 million a year. Prescribers may also consider prescribing generics with the same therapeutic impact rather the brand-name drugs.

There is no impact on local social service agencies.

4. Agency Consideration of Alternatives

The State Plan already imposes a copayment amount on prescription drug services. This regulatory action only updates the copayment amount for increased costs of brand-name drugs.

Higher copayments for brand-name drugs are typical in the current health insurance market place, including the state employees' Key Advantage plan. The intent of this proposal is to reduce the use of brand-name drugs, if possible. The agency can further discourage the use of brand-name drugs, by educating prescribers, which it plans to do.

The Agency will consider any alternatives identified through the public comment process.

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

The increase of the copay on brand-name drugs from $1 to $2 will increase out-of-pocket health care costs for Virginia families on Medicaid. Under the State Plan, however, copays are not imposed on children under the age of 21 and recipients in nursing homes nor on emergency services, pregnancy-related services and family planning services. Recipients of pharmacy services could face an average additional $13 in copayments annually based on current prescribing patterns. If prescribers change their prescribing habits and recipients request generic drugs and pharmacists advise recipients on generics, this increased cost could be reduced.