REGULATORY REVIEW CHECKLIST

To accompany Regulatory Review Package

Agency Department of Medical Assistance Services

Regulation title Program of All-Inclusive Care for the Elderly (PACE)

Purpose of the regulation To implement permanent regulations for PACE.

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	11/10/99	11/10/99 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: Program of All-Inclusive Care for the Elderly (PACE)

Director's Approval: November 10, 1999

Public Comment Period:

Proposed Effective Date: July 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.

Subsequent to an emergency adoption action, the agency initiated the public notice and comment process as contained in Article 2 of the APA. The emergency regulation became

effective on July 1, 1999. The *Code*, at §9-6.14:4.1(C) required the agency to file the Notice of Intended Regulatory Action within 60 days of the effective date of the emergency regulation if it intended to promulgate a permanent replacement regulation. The Notice of Intended Regulatory Action for this regulation was filed with the Virginia Register on May 6, 1999.

DMAS' statutory authority for a PACE program derives from both state and Federal authority. In Chapter 853 of the 1995 of the *Virginia Acts of Assembly* Item 396 Q, the General Assembly directed DMAS to seek an § 1115 (a) (to the *Social Security Act*) demonstration waiver from HCFA to implement one or more Programs of All-Inclusive Care for the Elderly (PACE), to be effective July 1, 1995. The *Balanced Budget Act of 1997* §§ 4802 and 4803 established and defined the PACE program by creating the new § 1934 of the *Social Security Act*, to be an optional Title XIX service.

Purpose: The purpose of this proposal is to promulgate permanent regulations for the provision of PACE services for frail, elderly Medicaid recipients. These regulations will link all types of medical care that such individuals might need, through a system of care management to the benefit of the individuals' health, safety, and welfare.

Substance and Analysis: The sections of the State Plan affected by this action are Services Provided to the Categorically Needy (12 VAC 30-50-10), Services Provided to the Medically Needy (12 VAC 30-50-50), and Amount, Duration, and Scope of Services for Categorically and Medically Needy (12 VAC 30-50-140 and 12 VAC 30-50-150). The regulations affected by this regulatory action are Program of All-Inclusive Care for the Elderly (12 VAC 30-120-61 through 12 VAC 30-120-68).

The Program of All-Inclusive Care for the Elderly (PACE) is a nationwide replication of the comprehensive service delivery and financing model of long term care for the frail elderly pioneered by On Lok Senior Health services in San Francisco in the 1970s. The various states have been allowed in the past to operate PACE programming through waiver authority from HCFA. The *Balanced Budget Act of 1997* (BBA '97) gave states the option of providing PACE services as an optional Title XIX State Plan service which granted provider status to authorized PACE programs. Prior to BBA '97, DMAS had authority to provide pre-PACE services in a long-term care prepaid health plan which offered Medicaid services under Medicaid capitation while Medicare fee-for-service services were coordinated by the pre-PACE site.

PACE provides a community-based health care plan as an alternative to nursing home care, unless that is the appropriate level of care. PACE integrates all aspects of care to include primary, medical and specialty care, nursing, social services, personal care, in-home supportive services, rehabilitative therapies, meals and nutritional care, transportation, hospitalization, and nursing home care.

The mission of the PACE model is to:

- Enhance the quality of life and autonomy of frail, older adults;
- Maximize the dignity and respect of older adults;
- Enable frail, older adults to live in their homes and in the community as long as medically and socially feasible;
- Preserve and support the older adult's family unit.

PACE programs achieve this mission by using a multidisciplinary team approach to manage care while providing a comprehensive range of acute care services and preventive care at a cost that is lower, due to its capitation payment mechanism, than the cost of traditional fee-for-service care.

Cost savings result from the pooling of Medicare (Title XVIII) and Medicaid (Title XIX) funding in a care coordination model that allows the PACE provider to manage the care within the program payment limits while providing a full range of services to include long-term care. Such pooling of funds will be permitted by the Health Care Financing Administration (HCFA) in its approval of the Commonwealth's State Plan Amendment upon the completion of the APA promulgation process.

In order for an individual to qualify for PACE services, he must: be age 55 or older; be certified for nursing home care; be residing in the service, or catchment, area; and agree to all the conditions and terms of participation. The services that such PACE individuals will receive are, but may not be limited to:

- Medical services, including the services of a Primary Care Physician (PCP) and other specialists;
- Transportation services;
- Outpatient rehabilitation services, including physical, occupational and speech therapy services;
- Hospital (acute care) services;
- Nursing facility (long-term care) services;
- Prescription drugs;
- Home health services;
- Laboratory services;
- Radiology services;
- Ambulatory surgery services;
- Respite care services;
- Personal care services;
- Hospice services;
- Adult day care services, to include social work services;

- Multi-disciplinary case management services;
- Outpatient mental health and mental retardation services;
- Outpatient psychological services;
- Prosthetics; and
- Durable medical equipment and other medical supplies.

PACE provides needed care in the most appropriate setting for the frail individual. Services are provided in the PACE center, at home, and if needed, in the hospital or other institutional setting. Specialty and ancillary medical services are provided, as are long-term care services. If nursing home placement is needed, PACE provides the service and maintains the continuity of care by regular monitoring of the enrollee's condition. By providing preventive and rehabilitative services, chronic conditions can be stabilized and complications averted or lessened, thereby enhancing quality of life. An interdisciplinary team, consisting of professional and paraprofessional staff, assesses enrollees' needs, develops care plans, and delivers needed services.

This additional service option will provide to Medicaid recipients another cost-effective choice, to operate in conjunction with existing institutional and community based services. PACE providers must provide access to all necessary covered services, on a 24-hour basis, to enrollees without any limitations or conditions. Prior to BBA '97, federal law prevented DMAS from offering PACE services as a State Plan Option.

No policy alternatives were discarded in favor of the options proposed here. The Balanced Budget Act of 1997 allows states to choose whether or not to provide PACE services. The Virginia General Assembly has chosen to provide PACE services as an optional state plan service. This action is to promulgate permanent regulations. The effect of this State Plan Amendment and regulatory action on families will be supportive in that their elderly members will be able to remain in their homes longer without having to be institutionalized in nursing facilities. This action is intended to adopt the emergency regulations into the permanent regulations with minor or no changes.

Issues: PACE programs provide integrated community-based health care as an alternative to nursing home care, unless that is the appropriate level of care. PACE programs achieve integration by using a multidisciplinary team approach to managing care while providing comprehensive services and preventive care at a lower cost. Program savings result from using a capitated payment model for provider reimbursement rather than a traditional fee-for-service payment model. Program participation (enrollment/disenrollment) in a PACE program is strictly voluntary on the part of the client.

The agency projects no negative issues involved in implementing this proposed change as the entity to be regulated by these regulations (the Sentara Senior Community Care program) has worked directly with DMAS and HCFA to develop its program in compliance with state and federal requirements.

Fiscal/Budget Impact: Virginia's Pre-PACE program began under a partially capitated arrangement and subsequently will make a transition to a fully capitated program, pending federal approval. Currently, Virginia has one Pre-PACE under contract with Sentara Senior Community Care. As a Pre-PACE, the capitation rate is initially limited to selected Medicaid covered services, with other Medicaid and Medicare services available under the traditional fee-for-service payment system.

The Pre-PACE program in August, 1999, served 105 individuals. This is an increase from 52 individuals served in January, 1998. The projected costs of the program for FY 1999 are $2,430,088. In the absence of the PACE program, DMAS would incur similar costs for these recipients in Medicaid fee-for-service. This is based on a weighted average of 104 people in the program to date. The average cost per person is $23,256.66. The capitation rate is actuarially based on the cost to DMAS of providing services to recipients in nursing facilities and home and community based care waivers.

This action has no projected costs for localities. Only entities that volunteer and qualify (by meeting all requirements) to be PACE providers, will become PACE providers. This action will affect one entity currently, Sentara Senior Community Care of Virginia Beach, Virginia, a pre-PACE program that will apply for full PACE program status.

There are no localities that are uniquely affected by these regulations as they apply statewide. HCFA has retained the authority to approve PACE providers.

Funding Source/Cost to Localities/Affected Entities: The Department of Medical Assistance Services is established under the authority of Title XIX of the federal Social Security Act, Public Law 89-97, as amended; and Title 32.1, Chapter 10, of the Code of Virginia. The Virginia Medicaid Program is funded with both federal and state funds. The current federal funding participation (FFP) for medical assistance expenditures is 51.60%, which became effective October 1, 1998. It is estimated that this rate will increase to 51.77% on October 1, 1999.

This program is not expected to have any impact on local departments of social services as it does not affect eligible groups nor the eligibility determination process.

Forms: No new forms are required to implement this proposed regulation.

Evaluation: DMAS will include the monitoring of this program in its ongoing Plan monitoring activities.

III. STATEMENT OF AGENCY ACTION

I hereby approve the foregoing Regulatory Review Summary and approve 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.

November 10, 1999
Date

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

JUSTIFICATION FOR PROPOSED REGULATORY CHANGE
Under Executive Order Twenty-five (98)

I. IDENTIFICATION INFORMATION

Regulation Name: Program of All-Inclusive Care for the Elderly

Issue Name: PACE

II. JUSTIFICATION

Federal/State Mandate/Scope

This regulatory action is partially mandated. Chapter 853 of the *1995 Virginia Acts of Assembly*, Item 396 Q directed DMAS to seek a demonstration waiver, under the authority of § 1115 (a) of the *Social Security Act*, in order to implement a Program of All-Inclusive Care for the Elderly. The 1997 Congressional action contained in the Balanced Budget Act (§§ 4802 and 4803) established PACE programs as another optional service under the authority of Title XIX of the *Social Security Act*. However in order for DMAS to secure federal financial participation (federal matching dollars) from the Health Care Financing Administration, it must design and structure its PACE program consistent with federal requirements.

Essential Nature of Regulation

PACE provides needed care in the most appropriate setting for the enrollee. Services are provided in the PACE center, at home, and if needed, in the hospital or other institutional setting. Specialty and ancillary medical services are provided, as are long-term care services. If nursing home placement is needed, PACE provides the service and maintains the continuity of care by regular monitoring of the enrollee's condition. By providing preventive and rehabilitative services, chronic conditions can be stabilized and complications averted or lessened, thereby enhancing quality of life. An interdisciplinary team, consisting of professional and paraprofessional staff, assesses enrollees' needs, develops care plans, and delivers needed services.

Without regulations, DMAS cannot operate its PACE program, approving enrollees, providers, paying claims, and enforcing federal and state requirements.

Agency Consideration of Alternatives

The decision to provide PACE services **is** the least burdensome and least intrusive alternative method to provide necessary services to Medicaid/Medicare eligible citizens, especially since enrollees' participation is voluntary. PACE programs provide community-based health care to the volunteer enrollee as an alternative to nursing home care, unless that is the appropriate level of care. PACE programs integrate all aspects of care to include preventive, primary, medical and specialty care, nursing, social services, personal care, in-home supportive services, rehabilitative therapies, meals and nutritional care, transportation, hospitalization, and nursing home care. The above is provided with an emphasis on community. The alternative for an enrollee is to leave the home environment for institutionalized care sooner rather than later without PACE.

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

Family impact should be positive as care for an elderly family member enrollee is obtained in the community longer, thereby delaying institutionalization.

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 Fifteen (94).