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Exempt Action
Final Regulation
Agency Background Document

Agency name	DEPT OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation(s)	12VAC30-50-335; 12VAC30-50-345
Regulation title(s)	General Pace Plan Requirements; Pace Enrollee Rights
Action title	Federal Changes to Programs of All-Inclusive Care for the Elderly (PACE)
Final agency action date	January 15, 2020
Date this document prepared	January 15, 2020

While a regulatory action may be exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the *Code of Virginia*, the agency is still encouraged to provide information to the public on the Regulatory Town Hall using this form. However, the agency may still be required to comply with the Virginia Register Act, Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

On May 28, 2019, the Centers for Medicare & Medicaid Services (CMS) finalized a rule (84 FR 25610 {June 3, 2019; eff. August 2, 2019}) to update and modernize the Programs of All-Inclusive Care for the Elderly (PACE) program. This rule enforces best practices regarding the care for frail and elderly individuals. The first major proposed update to PACE since 2006, this action allows PACE organizations to operate with greater efficiency, while ensuring they continue to meet the

needs and preferences of participants. More than 45,000 older adults are currently enrolled in more than 100 PACE organizations in 31 states, and enrollment in PACE has increased by over 120 percent since 2011. With the increased demand for PACE services, the federal updates are timely and will provide greater operational flexibility, remove redundancies and outdated information, and codify existing practice.

The majority of participants served by PACE are dually eligible for both Medicare & Medicaid. Catering to populations with varying needs, PACE provides comprehensive medical and social services to certain frail, elderly individuals who qualify for nursing facility care but, at the time of enrollment, can still live safely in the community. With the final rule initiative, members will benefit from strengthened protections and improved care, while PACE providers will be afforded administrative flexibility and regulatory relief.

The purpose of this action is to amend 12VAC30-50-335 (General PACE Plan Requirements) and 12VAC30-50-345 (Pace Enrollee Rights), in order to align the regulations with the federal PACE regulations.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

I hereby approve the foregoing Agency Background Summary with the attached amended regulations entitled "General Pace Plan Requirements" (12 VAC 30-50-335) and "Pace Enrollee Rights" (12VAC30-50-345), and adopt the action stated therein. I certify that this final exempt regulatory action has completed all the requirements of the Code of Virginia § 2.2-4006(A), of the Administrative Process Act.

1/15/2020	/ Karen Kimsey/
Date	Karen Kimsey, Director
	Dept. of Medical Assistance Services

Legal Basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Section 32.1-325 of the Code of Virginia authorizes the Board of Medical Assistance Services to administer and amend the State Plan for Medical Assistance and to promulgate regulations. Section 32.1-324 of the Code of Virginia authorizes the Director of the Department of Medical Assistance Services (DMAS) to administer and amend the State Plan for Medical Assistance and to promulgate regulations according to the Board's requirements. The Medicaid authority as established by § 1902 (a) of the Social Security Act (42 USC § 1396a) provides governing authority for payments for services.

This action is exempt from the Administrative Process Act under 2.2-4006 (A)(4c) of the Code of Virginia, as it is necessary to meet the requirements of federal law or regulations.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

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1. Quality Management and Performance Improvement Program

Current Requirements:
PACE providers are currently required to have an agreement with CMS and DMAS for the operation of a PACE program (42 CFR § 460.32). The agreement must include a description of a quality management and performance improvement program.

CMS replaced all references in 42 CFR Part 460 to "*quality assessment and performance improvement*" with "*quality improvement*." CMS noted that the term "*quality improvement*" is used by PACE organizations, State Administering Agencies, CMS and the industry when referring to quality assessment and performance improvement.

DMAS Recommends:
Amending the section by deleting "*quality management and performance*" and inserting "*the organization's quality"*… (12VAC30-50-335)

2. Content and Terms of Program Agreements

Current Requirements:
PACE providers are currently required to ensure that the program agreement with CMS and DMAS includes the Medicaid capitation rate and the methodology used to calculate Medicare capitation rate.

CMS modified the requirement in §460.32(a)(12) for including the Medicaid capitation rate in the PACE program agreement. This change allows for either the Medicaid capitation rate(s) or the Medicaid payment rate methodology to be included in program agreement. This change addresses challenges with including Medicaid rates resulting from rate-setting methodologies that call for

risk adjustment, performance incentive payments, etc. In these situations, rates may be different for individual participants or dependent on program performance. Removing the requirement for rates in the program agreement addresses operational challenges associated with updating the program agreement.

DMAS Recommends:
Amending the section to include adding the terms "*or Medicaid payment rate methodology*"…

3. Maintenance of Records

Current Requirements:
PACE providers are currently required to retain business and professional records for at least six (6) years from the last date of service.

CMS amended the record retention requirements from six (6) to ten (10) years in §460.200(f)(1)(ii) and (iii) for participant health outcomes data, financial books and records, medical records and personnel records. This change aligns PACE record retention requirements with Medicare Advantage, Part D and other requirements.

DMAS Recommends:
Amending the section by deleting six (6) and inserting ten (10) and replacing "*service*" with "*services*."

4. Change of Ownership

Current Requirements:
PACE providers are currently required to notify CMS and DMAS, in writing, of any change in the organizational structure of a PACE provider organization at least 14 calendar days before the change takes effect.

CMS added a new requirement in §460.60(d) for notification when there is a change of ownership. PACE providers planning a change of ownership must notify CMS and DMAS, in writing, at least 60 days before the anticipated effective date of the change and comply with all requirements in 42 CFR part 422, subpart L (Effect of Change of Ownership or Leasing of Facilities During Term of Contract).

DMAS Recommends:
Amending the section to include, adding the following sentence: *"When planning a change of ownership, CMS and DMAS shall be notified in writing at least 60 calendar days before the anticipated effective date of the change."*

5. PACE Enrollee Rights

Current Requirements:
PACE providers are currently required to inform enrollees of their right to disenroll in PACE at will upon giving 30 days' notice.

CMS revised to 42CFR § 460.112(c)(3) to state that the participant has the right to disenroll from the PACE program at any time and have such disenrollment be effective on the first day of the month following the date the provider organization receives the participant's notice of voluntary disenrollment.

DMAS recommends:
Amending the section by deleting "*will upon giving 30 days' notice*" and inserting *"any time and have such disenrollment be effective the first day of the month following the date the PACE organization receives the participant's notice of voluntary disenrollment."*

Periodic Review
Small Business Impact Review Report of Findings

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the proposed stage, please indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.

In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

This regulatory action is not the result of a periodic review or small business impact review.