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MEMORANDUM

TO: **Emily McClellan**
Regulatory Supervisor
Department of Medical Assistance Services

FROM: **Davis Creef**
Assistant Attorney General
Office of the Attorney General

DATE: **May 24, 2021**

SUBJECT: **2020 Program of All-Inclusive Care for the Elderly (PACE) Changes**

I have reviewed the attached exempt final regulations regarding changes to the Program of All-Inclusive Care for the Elderly (PACE). You have asked the Office of the Attorney General to review and determine if the Department of Medical Assistance Services ("DMAS") has the legal authority to amend the regulations and if the regulations comport with state and federal law.

The changes in these regulations reflect changes in state law and changes in wording or style/corrections of technical errors. Based on my review, it is my view that the Director of DMAS, acting on behalf of the Board of Medical Assistance Services, under Virginia Code §§ 32.1-324 and 325, has the authority to amend these regulations, subject to compliance with the provisions of Article 2 of the Administrative Process Act ("APA") and has not exceeded that authority. Based on the foregoing, it is my view that the amendments to these regulations are exempt from the procedures of Article 2 of the APA under Virginia Code §§ 2.2-4006(A)(4)(a) and 2.2-4006(A)(3).

Please note that Virginia Code § 2.2-4006(B) requires that all changes to the proposed regulation be highlighted in the final regulations. If you have any questions or need additional information about these regulations, please contact me at (804)786-6522.

cc: Kim F. Piner, Esq.

Attachment

Final Text

highlight

Action: 2020 Program of All-Inclusive Care for the Elderly (PACE) Changes
Stage: Final 11/4/20 2:30 PM [latest]

12VAC30-50-330 PACE definitions

For purposes of this part and all contracts establishing the Program of All-Inclusive Care for the Elderly (PACE) programs as defined in 42 CFR Part 460, the following definitions shall apply:

"Adult day health care center" or "ADHC" means a DMAS-enrolled provider that offers a community-based day program providing a variety of health, therapeutic, and social services designed to meet the specialized needs of those elderly and disabled individuals at risk of placement in a nursing facility. ~~The ADHC must be licensed by the Virginia Department of Social Services as an adult day care center (ADC) as defined in 22VAC40-60-10.~~

"Applicant" means an individual seeking enrollment in a PACE plan.

"Capitation rate" means the negotiated Medicaid monthly per capita amount paid to a PACE provider for all services provided to enrollees.

"Catchment area" means the designated service area for a PACE plan.

"Centers for Medicare and Medicaid Services" or "CMS" means the unit of the U.S. Department of Health and Human Services that administers the Medicare and Medicaid programs.

"CFR" means the Code of Federal Regulations.

"Direct marketing" means either (i) conducting directly or indirectly door-to-door, telephonic or other "cold call" marketing of services at residences and provider sites; (ii) mailing directly; (iii) paying "finders' fees;" (iv) offering financial incentives, rewards, gifts or special opportunities to eligible individuals or family/caregivers as inducements to use the providers' services; (v) continuous, periodic marketing activities to the same prospective individual or family/caregiver for example, monthly, quarterly, or annual giveaways as inducements to use the providers' services; or (vi) engaging in marketing activities that offer potential customers rebates or discounts in conjunction with the use of the providers' services or other benefits as a means of influencing the individual's or family/caregiver's use of the providers' services.

"DMAS" means the Department of Medical Assistance Services.

"DSS" means the Department of Social Services.

"Enrollee" means a Medicaid-eligible individual meeting PACE enrollment criteria and receiving services from a PACE plan.

"Full disclosure" means fully informing all PACE enrollees at the time of enrollment that, pursuant to § 32.1-330.3 of the Code of Virginia, PACE plan enrollment can only be guaranteed for a 30-day period.

"Imminent risk of nursing facility placement" means that an individual will require nursing facility care within 30 days if a community-based alternative care program, such as a PACE plan, is not available.

"Long-Term Services and Supports (LTSS) Screening" or "Screening" means the face to face process to (i) evaluate the functional, medical or nursing, and social support needs and at-risk status of individuals referred for certain long-term services requiring nursing facility level of care eligibility; (ii) assist individuals in determining what specific services the individual needs; (iii) evaluate whether a service or a combination of existing community services are available to meet the individual's needs; and (iv) provide a list to individuals of appropriate providers for Medicaid-funded nursing facility, PACE plan services, or the Commonwealth Coordinated Care Plus waiver for those individuals who meet nursing facility level of care.

"Long-Term Services and Supports (LTSS) Screening Team" means the hospital screening team, community-based team (CBT), nursing facility team or DMAS designee contracted to perform screenings pursuant to § 32.1-330 of the Code of Virginia.

"PACE" means a Program of All-Inclusive Care for the Elderly. PACE services are designed to enhance the quality of life and autonomy for frail, older adults; maximize dignity of, and respect for, older adults; enable frail, older adults to live in the community as long as medically and socially feasible; and preserve and support the older adult's family unit.

"PACE plan" means a comprehensive acute and long-term care prepaid health plan, pursuant to § 32.1-330.3 of the Code of Virginia and as defined in 42 CFR 460.6, operating on a capitated payment basis through which the PACE provider assumes full financial risk. PACE plans operate under both Medicare and Medicaid capitation.

"PACE plan contract" means a contract, pursuant to § 32.1-330.3 of the Code of Virginia, under which an entity assumes full financial risk for operation of a comprehensive acute and long-term care prepaid health plan with capitated payments for services provided to Medicaid enrollees being made by DMAS. The parties to a PACE plan contract are the entities operating the PACE plan, DMAS and CMS.

"PACE plan feasibility study" means a study performed by a research entity approved by DMAS to determine a potential PACE plan provider's ability and resources, or lack thereof, to effectively operate a PACE plan. All study costs are the responsibility of the potential PACE provider.

"PACE protocol" means the protocol for the Program of All-Inclusive Care for the Elderly, as published by On Lok, Inc., as of April 14, 1995, or any successor protocol that may be agreed upon by the federal Secretary of Health and Human Services and On Lok, Inc.

"PACE provider" means the entity contracting with the Department of Medical Assistance Services to operate a PACE plan.

"PACE site" means the location, which includes a primary care center, where the PACE provider both operates the PACE plan's adult day health care center and coordinates the provision of core PACE services, including the provision of primary care.

"Plan of care" means the written plan developed by the provider related solely to the specific services required by the individual to ensure optimal health and safety while receiving services from the provider.

~~"Preadmission screening" means the process to: (i) evaluate the functional, nursing, and social supports of individuals referred for preadmission screenings; (ii) assist individuals in determining what specific services individuals need; (iii) evaluate whether a service or a combination of existing community-based services are available to meet the individual's needs; (iv) refer individuals to the appropriate provider for Medicaid-funded nursing facility or home and community-based care for those individuals who meet nursing facility level of care.~~

~~"Preadmission screening team" means the entity contracted with DMAS that is responsible for performing preadmission screening pursuant to § 32.1-330 of the Code of Virginia.~~

"Primary care provider" or "PCP" means the individual responsible for the coordination of medical care provided to an enrollee under a PACE plan.

"Provider" means the individual or other entity registered, licensed, or certified, as appropriate, and enrolled by DMAS to render services to Medicaid recipients eligible for services.

"State Plan for Medical Assistance" or "the Plan" means the Commonwealth's legal document approved by CMS identifying the covered groups, covered services and their limitations, and provider reimbursement methodologies as provided for under Title XIX of the Social Security Act.

"Virginia Uniform Assessment Instrument" or "UAI" means the standardized, multidimensional ~~questionnaire that assesses an individual's social, physical and mental health, and functional abilities~~ assessment instrument that is completed by the LTSS screening team that assesses an individual's physical health, mental health, and psycho/social and functional abilities to determine if the individual meets the nursing facility level of care.

12VAC30-50-335 General PACE plan requirements

A. DMAS, the state agency responsible for administering Virginia's Medicaid program, shall only enter into PACE plan contracts with approved PACE plan providers. The PACE provider must have an agreement with CMS and DMAS for the operation of a PACE program. The agreement must include:

1. Designation of the program's service area;

2. The program's commitment to meet all applicable federal, state, and local requirements;

3. The effective date and term of the agreement;

4. The description of the organizational structure;

5. Participant bill of rights;

6. Description of grievance and appeals processes;

7. Policies on eligibility, enrollment, and disenrollment;

8. Description of services available;

9. Description of the organization's quality improvement program;

10. A statement of levels of performance required on standard quality measures;

11. CMS and DMAS data requirements;

12. The Medicaid capitation rate or Medicaid payment rate methodology and the methodology used to calculate the Medicare capitation rate;

13. Procedures for program termination; and

14. A statement to hold harmless CMS, the state, and PACE participants if the PACE organization does not pay for services performed by the provider in accordance with the contract.

B. A PACE plan feasibility study shall be performed before DMAS enters into any PACE plan contract. DMAS shall contract only with those entities it determines to have the ability and resources to effectively operate a PACE plan. A feasibility plan shall only be submitted in response to a Request for Applications published by DMAS.

C. PACE plans shall offer a voluntary comprehensive alternative to enrollees who would otherwise be placed in a nursing facility. PACE plan services shall be comprehensive and offered as an alternative to nursing facility admission.

D. All Medicaid-enrolled PACE participants shall continue to meet the nonfinancial and financial Medicaid eligibility criteria established by federal law and this chapter. This requirement shall not apply to Medicare only or private pay PACE participants.

E. Each PACE provider shall operate a PACE site that is in continuous compliance with all state licensure requirements for that site.

F. Each PACE provider shall ensure that services are provided by health care providers and institutions that are in continuous compliance with state licensure and certification requirements.

G. Each PACE plan shall meet the requirements of §§ 32.1-330.2 and 32.1-330.3 of the Code of Virginia and 42 CFR Part 460.

H. All PACE providers must meet the general requirements and conditions for participation pursuant to the required contracts by DMAS and CMS. All providers must sign the appropriate participation agreement. All providers must adhere to the conditions of participation outlined in the participation agreement and application to provide PACE services, DMAS regulations, policies and procedures, and CMS requirements pursuant to 42 CFR Part 460.

I. Requests for participation as a PACE provider will be screened by DMAS to determine whether the provider applicant meets these basic requirements for participation and demonstrates the abilities to perform, at a minimum, the following activities:

1. Immediately notify DMAS, in writing, of any change in the information that the provider previously submitted to DMAS.

2. Assure freedom of choice to individuals in seeking services from any institution, pharmacy, practitioner, or other provider qualified to perform the services required and participating in the Medicaid Program at the time the services are performed.

3. Assure the individual's freedom to refuse medical care, treatment, and services.

4. Accept referrals for services only when qualified staff is available to initiate and perform such services on an ongoing basis.

5. Provide services and supplies to individuals in full compliance with Title VI of the Civil Rights Act of 1964, as amended (42 USC § 2000 et seq.), which prohibits

discrimination on the grounds of race, color, religion, sexual orientation, or national origin; the Virginians with Disabilities Act (§ 51.5-1 et seq. of the Code of Virginia); § 504 of the Rehabilitation Act of 1973, as amended (29 USC § 794), which prohibits discrimination on the basis of a disability; and the Americans with Disabilities Act of 1990, as amended (42 USC § 12101 et seq.), which provides comprehensive civil rights protections to individuals with disabilities in the areas of employment, public accommodations, state and local government services, and telecommunications.

6. Provide services and supplies to individuals of the same quality and in the same mode of delivery as is provided to the general public.

7. Use only DMAS-designated forms for service documentation. The provider must not alter the DMAS forms in any manner unless approval from DMAS is obtained prior to using the altered forms.

8. Not perform any type of direct marketing activities to Medicaid individuals.

9. Maintain and retain business and professional records sufficient to document fully and accurately the nature, scope, and details of the services provided.

a. In general, such records shall be retained for at least 10 years from the last date of services or as provided by applicable federal and state laws, whichever period is longer. However, if an audit is initiated within the required retention period, the records shall be retained until the audit is completed and every exception resolved. Records of minors shall be kept for at least six years after such minor has reached the age of 18 years. However, records for Medicare Part D shall be maintained for 10 years in accordance with 42 CFR 423.505(d).

b. Policies regarding retention of records shall apply even if the provider discontinues operation. DMAS shall be notified in writing of the storage location and procedures for obtaining records for review. The location, agent, or trustee shall be within the Commonwealth.

10. Furnish information on request and in the form requested to DMAS, the Attorney General of Virginia or his authorized representatives, federal personnel, and the state Medicaid Fraud Control Unit. The Commonwealth's right of access to provider agencies and records shall survive any termination of the provider agreement.

11. Disclose, as requested by DMAS, all financial, beneficial, ownership, equity, surety, or other interests in any and all firms, corporations, partnerships, associations, business enterprises, joint ventures, agencies, institutions, or other legal entities providing any form of health care services to individuals of Medicaid.

12. Pursuant to 42 CFR 431.300 et seq., 12VAC30-20-90, and any other applicable federal or state law, all providers shall hold confidential and use for authorized DMAS purposes only all medical assistance information regarding individuals served. A provider shall disclose information in the provider's possession only when the information is used in conjunction with a claim for health benefits, or the data are necessary for the functioning of DMAS in conjunction with the cited laws.

13. CMS and DMAS shall be notified in writing of any change in the organizational structure of a PACE provider organization at least 14 calendar days before the change takes effect. 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.

14. In addition to compliance with the general conditions and requirements, all providers enrolled by DMAS shall adhere to the conditions of participation outlined in their individual provider participation agreements and in the applicable DMAS provider manual. DMAS shall conduct ongoing monitoring of compliance with provider participation standards and DMAS policies. A provider's noncompliance with DMAS policies and procedures may result in a retraction of Medicaid payment or termination of the provider agreement, or both.

15. Minimum qualifications of staff.

a. All employees must have a satisfactory work record as evidenced by references from prior job experience, including no evidence of abuse, neglect, or exploitation of vulnerable adults and children. Prior to the beginning of employment, a criminal record check shall be conducted for the provider and each employee and made available for review by DMAS staff. Providers are responsible for complying with the Code of Virginia and state regulations regarding criminal record checks and barrier crimes as they pertain to the licensure and program requirements of their employees' particular practice areas.

b. Staff must meet any certifications, licensure, registration, etc., as required by applicable federal and state law. Staff qualifications must be documented and maintained for review by DMAS or its authorized contractors.

16. At the time of their admission to services, all providers participating in the Medicare and Medicaid programs must provide adult individuals with written information regarding each individual's right to make medical care decisions, including the right to accept or refuse medical treatment and the right to formulate advance directives.

J. Provider's conviction of a felony. The Medicaid provider agreement shall terminate upon conviction of the provider of a felony pursuant to § 32.1-325 of the Code of Virginia. A provider convicted of a felony in Virginia or in any other of the 50 states, the District of Columbia, or the U.S. territories must, within 30 days, notify the Virginia Medicaid Program of this conviction and relinquish the provider agreement. In addition, termination of a provider participation agreement will occur as may be required for federal financial participation.

K. Ongoing quality management review. DMAS shall be responsible for assuring continued adherence to provider participation standards. DMAS shall conduct ongoing monitoring of compliance with provider participation standards and DMAS policies and periodically recertify each provider for participation agreement renewal with DMAS to provide PACE services.

L. Reporting suspected abuse or neglect. Pursuant to §§ 63.2-1508 through 63.2-1513 and 63.2-1606 of the Code of Virginia, if a participating provider entity suspects that a child or vulnerable adult is being abused, neglected, or exploited, the party having knowledge or suspicion of the abuse, neglect, or exploitation shall report this immediately to DSS and to DMAS. In addition, as mandated reporters for vulnerable adults, participating providers must inform their staff that they are mandated reporters and provide education regarding how to report suspected adult abuse, neglect, or exploitation pursuant to § 63.2-1606 F of the Code of Virginia.

M. Documentation requirements. The provider must maintain all records of each individual receiving services. All documentation in the individual's record must be completely signed and dated with name of the person providing the service, title,

and complete date with month, day, and year. This documentation shall contain, up to and including the last date of service, all of the following:

1. The ~~most recently updated~~ Virginia Uniform Assessment Instrument (UAI) and all required forms in the LTSS screening packet pursuant to 12VAC30-60-306, all other assessments and reassessments, plans of care, supporting documentation, and documentation of any inpatient hospital admissions;

2. All correspondence and related communication with the individual and, as appropriate, consultants, providers, DMAS, DSS, or other related parties; and

3. Documentation of the date services were rendered and the amount and type of services rendered.

12VAC30-50-340 Criteria for PACE enrollment

A. Eligibility shall be determined in the manner provided for in the State Plan and these regulations. To the extent these regulations differ from other provisions of the State Plan for purposes of PACE eligibility and enrollment, these regulations shall control.

B. Individuals meeting the following nonfinancial criteria shall be eligible to enroll in PACE plans approved by DMAS:

1. Individuals who are age 55 or older;

2. Individuals who require nursing facility level of care and are at imminent risk of nursing facility placement as determined by a ~~nursing home preadmission~~ LTSSscreening team through a ~~nursing home preadmission~~ long-term services and supports screening performed using the UAI and all required forms in the LTSS screening packet pursuant to 12VAC30-60-306;

3. Individuals for whom PACE plan services are medically appropriate and necessary because without the services the individual is at imminent risk of nursing facility placement;

4. Individuals who reside in a PACE plan catchment area;

5. Individuals who meet other criteria specified in a PACE plan contract;

6. Individuals who participate in the Medicaid or Medicare programs as specified in § 32.1-330.3 E of the Code of Virginia; and

7. Individuals who voluntarily enroll in a PACE plan and agree to the terms and conditions of enrollment.

C. To the extent permitted by federal law and regulation, individuals meeting the following financial criteria shall be eligible to enroll in PACE plans approved by DMAS:

1. Individuals whose income is determined by DMAS under the provision of the State Plan to be equal to or less than 300% of the current Supplemental Security Income payment standard for one person; and

2. Individuals whose resources are determined by DMAS under the provisions of the State Plan to be equal to or less than the current resource allowance established in the State Plan.

D. For purposes of a financial eligibility determination, applicants shall be considered as if they are institutionalized for the purpose of applying institutional deeming rules.

E. DMAS shall not pay for services provided to an applicant by a PACE contractor if such services are provided prior to the PACE plan authorization date set by the ~~nursing home preadmission~~ LTSS screening team.