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TO: **EMILY MCCLELLAN**
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FROM: **MICHELLE A. L'HOMMEDIEU**
Assistant Attorney General

DATE: **July 15, 2020**

SUBJECT: **Final/Exempt Regulations – Federal Changes to Programs of All-Inclusive Care for the Elderly (PACE) (5473/8885)**

I have reviewed the attached exempt final regulations regarding the Programs 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 federal law and changes in wording or style. 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)(c).

It is my understanding that the proposed changes will amend the State Plan. It is my understanding that any approval necessary from CMS has either been obtained or is not needed because the regulatory changes are necessary to reflect the changes made by CMS in federal regulations. If you have any questions, please contact me at 786-6005.

cc: Kim F. Piner, Esq.

Attachment

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Federal Changes to Programs of All-Inclusive Care for the Elderly (PACE)

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 ~~quality management and performance~~ 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 these regulations. 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 service or services required and participating in the Medicaid Program at the time the service or 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 ~~six~~ ten years from the last date of ~~service~~ 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 his 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), 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.

12VAC30-50-345. PACE enrollee rights.

A. PACE providers shall ensure that enrollees are fully informed of their rights and responsibilities in accordance with all state and federal requirements. These rights and responsibilities shall include, but not be limited to:

1. The right to be fully informed at the time of enrollment that PACE plan enrollment can only be guaranteed for a 30-day period pursuant to § 32.1-330.3 F of the Code of Virginia;

2. The right to receive PACE plan services directly from the provider or under arrangements made by the provider; and

3. The right to be fully informed in writing of any action to be taken affecting the receipt of PACE plan services.

B. PACE providers shall notify enrollees of the full scope of services available under a PACE plan, as described in 42 CFR 460.92. The services shall include, but not be limited to:

1. Medical services, including the services of a PCP and other specialists;

2. Transportation services;

3. Outpatient rehabilitation services, including physical, occupational and speech therapy services;

4. Hospital (acute care) services;

5. Nursing facility (long-term care) services;

6. Prescription drugs;

7. Home health services;

8. Laboratory services;

9. Radiology services;

10. Ambulatory surgery services;

11. Respite care services;

12. Personal care services;

13. Dental services;

14. Adult day health care services, to include social work services;

15. Interdisciplinary case management services;

16. Outpatient mental health and mental retardation services;

17. Outpatient psychological services;

18. Prosthetics; and

19. Durable medical equipment and other medical supplies.

C. Services available under a PACE plan shall not include any of the following:

1. Any service not authorized by the interdisciplinary team unless such service is an emergency service (i.e., a service provided in the event of a situation of a serious or urgent nature that endangers the health, safety, or welfare of an individual and demands immediate action);

2. In an inpatient facility, private room and private duty nursing services unless medically necessary, and nonmedical items for personal convenience such as telephones charges and radio or television rental, unless specifically authorized by the interdisciplinary team as part of the participant's plan of care;

3. Cosmetic surgery except as described in agency guidance documents;

4. Any experimental medical, surgical or other health procedure; and

5. Any other service excluded under 42 CFR 460.96.

D. PACE providers shall ensure that PACE plan services are at least as accessible to enrollees as they are to other Medicaid-eligible individuals residing in the applicable catchment area.

E. PACE providers shall provide enrollees with access to services authorized by the interdisciplinary team 24 hours per day every day of the year.

F. PACE providers shall provide enrollees with all information necessary to facilitate easy access to services.

G. PACE providers shall provide enrollees with identification documents approved by DMAS. PACE plan identification documents shall give notice to others of enrollees' coverage under PACE plans.

H. PACE providers shall clearly and fully inform enrollees of their right to disenroll at ~~will upon giving 30 days' notice~~ 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.

I. PACE providers shall make available to enrollees a mechanism whereby disputes relating to enrollment and services can be considered. This mechanism shall be one that is approved by DMAS.

J. PACE providers shall fully inform enrollees of the individual provider's policies regarding accessing care generally and, in particular, accessing urgent or emergency care both within and without the catchment area.

K. PACE providers shall maintain the confidentiality of enrollees and the services provided to them.