Thursday, April 9, 2020

CMS Responses to Questions Asked During the March 24, 2020 Call with the Programs of All-inclusive Care for the Elderly (PACE) Community

This FAQ answers a range of questions from PACE organizations (POs) on the topics of:

- Clinical concerns
- Staffing
- Eligibility, enrollment, and recertification
- Telehealth
- Quality and reporting
- Billing and payment
- CMS communications

This guidance supplements the March 17, 2020 CMS issued guidance to POs on infection control and prevention of Coronavirus Disease 2019 (COVID-19), which we encourage POs to review.

CLINICAL CONCERNS

1. **Where can I find the most up-to-date information from CMS on COVID-19?**

CMS has a Coronavirus (COVID-19) Partner Toolkit to help you stay informed on CMS and HHS materials available on the COVID-19.

2. **Where can I find the most up-to-date information from the Centers for Disease Control and Prevention (CDC) on COVID-19?**

- CDC Resources for Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html
- CDC updates: https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html
- CDC FAQs for COVID-19: https://www.cdc.gov/coronavirus/2019-ncov/faq.html
- Information on affected US locations: https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html

3. **What steps should be taken when a Programs of All-inclusive Care for the Elderly (PACE) participant tests positive?**

If a PACE participant has a laboratory-confirmed COVID-19 diagnosis, immediately contact your local or state health department for consultation and guidance. To find your local health department, use the National Association of County and City Health Officials' Directory of Local Health Departments. There is also a state health department after-hours contact list for healthcare providers to report diseases or conditions of public health importance to state health departments.

Additionally, work with the participant and his/her family to strictly adhere to the CDC Preventing the Spread of Coronavirus Disease 2019 in Homes and Residential Communities guidelines. Individuals with close contact with the participant, including other participants and PO staff, should monitor their health; they should call their healthcare provider right away if they develop symptoms suggestive of COVID-19 (e.g., fever, cough, shortness of breath) (see Public Health Recommendations for Community-Related Exposure).

4. **What steps should be taken when PACE participants have mild upper respiratory symptoms like runny nose, mild cough, and no fever?**

Reported illnesses have ranged from mild symptoms to severe illness and death for confirmed COVID-19 cases. These symptoms may appear 2-14 days after exposure:

- Fever
- Cough
- Shortness of breath

Older adults are at greater risk for severe illness related to COVID-19 but symptoms in older adults may be subtle, so stay observant. Older adults with COVID-19 may not show typical symptoms such as fever or respiratory symptoms. Atypical symptoms may include:

- New or worsening restlessness or uneasiness
- New dizziness
- Diarrhea

POs should separate participants with these symptoms from those participants without such symptoms and continue to evaluate for COVID-19.

Consistent with CDC guidelines, any PACE participants with symptoms that may be attributable to COVID-19 should not attend the PACE center in order to mitigate the risk of infecting other participants and/or personnel. Rapid transmission can occur in communal settings and should be avoided.

If for any reason, a participant **must** leave their home to visit a PACE center, and other options have been exhausted, the participant should wear a facemask during transport and while in the center. If possible, the PO should consider arranging for home-based evaluations for mildly symptomatic residents to reduce potential exposure of others to a person who might end up COVID-19 positive. For more information on telehealth, consult the March 17, 2020 CMS guidance to POs, "Information for PACE Organizations Regarding Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19)."

Regardless of where the participant is located, the PO should provide the participant (and caregiver, as appropriate) with a plan for whom to contact if they develop fever or

respiratory symptoms. This vulnerable population may develop severe symptoms quickly, so a clinical evaluation should be expedient.

CDC has established criteria for determining when a COVID-19 suspected or positive individual can be considered non-infectious to guide discontinuation of transmission-based precautions for hospitalized patients or home isolation.

5. **Many POs, like many health care providers, are experiencing difficulties accessing personal protective equipment (PPE). Do you have any guidance for POs on sources of PPE?**

Your safety is important. Federal actions are underway to:

- Reduce the exhaustion of supplies;
- Encourage deferral of elective procedures so that available PPE can be used for other purposes;
- Produce additional PPE in the US.

Any PO anticipating or experiencing a shortage should engage its local and state health departments. To find your local health department, use the National Association of County and City Health Officials' Directory of Local Health Departments.

The CDC has specific recommendations on strategies to optimize the supply of PPE based on the availability of PPE. POs should also review the Occupational and Health Safety Agency (OSHA) guidance on preparing workplaces for COVID-19, including steps employers can take to reduce workers' risk of exposure.

6. **Is it ever appropriate for staff to re-use personal protective equipment (PPE)?**

Existing CDC guidelines recommend a combination of approaches to conserve supplies while safeguarding health care workers.

The CDC has specific strategies for optimizing the supply of PPE:

- Eye Protection
- Isolation Gowns
- Facemasks
- N95 Respirators

For PPE not covered by the CDC guidance above, consult your local health department. To find your local health department, use the National Association of County and City Health Officials' Directory of Local Health Departments.

7. **What is the recommendation for outside appointments for non-essential medical care?**

CMS recommends postponing adult elective surgeries, and non-essential medical, surgical, and dental procedures during the COVID-19 pandemic. For further guidance,

see the April 7, 2020, CMS Non-Emergent, Elective Medical Services, and Treatment Recommendations.

However, CMS recognizes that at this time many areas have a low, or relatively low and stable incidence of COVID-19, and that it is important to be flexible and allow facilities to provide care for patients needing non-emergent, non-COVID-19 healthcare. For further guidance, see the April 19, 2020 CMS Re-opening Facilities to Provide Non-emergent Non-COVID-19 Healthcare: Phase I.

8. **Are POs required to routinely monitor temperatures of participants and staff?**

Consistent with the March 17, 2020 CMS guidance to POs, in accordance with the infection control requirements at 42 CFR 460.74, POs must follow accepted policies and standard procedures with respect to infection control, including at least the guidelines developed by the CDC.

CMS recommends that POs implement active screening of PACE participants and staff for fever and respiratory symptoms. All staff should be screened at the beginning of their shift for fever and respiratory symptoms. Staff who are ill should not work. In accordance with CDC guidance, every PACE participant should be assessed for symptoms and have their temperature checked every day. Staff should actively monitor participants by taking their temperature and monitoring for shortness of breath, new or change in cough, and sore throat. If they are ill, have them put on a facemask and self-isolate. Arrange for an expedient clinical evaluation.

For further guidance, see the CDC's Preparing for COVID-19: Long-term Care Facilities, Nursing Homes for most up to date guidance. Additionally, consult the April 2, 2020 CMS and CDC COVID-19 Long-Term Care Facility Guidance.

9. **Are POs required to report positive and/or suspected COVID-19 cases to CMS? What type of information should be reported, what is the timeframe for reporting, and to whom should information be reported?**

POs should report all positive or suspected cases immediately to their local health department. To find your local health department, use the National Association of County and City Health Officials' Directory of Local Health Departments. Secondarily, we encourage POs to alert their CMS PACE account manager.

10. **What are CMS's expectations of POs with respect to addressing the needs and preferences of participants residing in SNFs in light of restrictions on access to SNFs?**

CMS recommends that nursing facilities limit access for visitors, except under certain circumstances for compassionate care, such as end-of-life situations. However, the guidance is not intended to reduce access for other health care professionals providing

care to a resident. CMS's March 13, 2020 Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Nursing Homes (REVISED) to state survey agency directors directed "any individuals who entered the facility (e.g., hospice staff), to monitor for signs and symptoms of respiratory infection for at least 14 days after exiting the facility. If symptoms occur, advise them to self-isolate at home, contact their healthcare provider, and immediately notify the facility of the date they were in the facility, the individuals they were in contact with, and the locations within the facility they visited."

CMS and CDC guidance, released April 2, 2020, recommends that for the duration of the state of emergency in their state, all personnel in a long-term care facility should wear a facemask while they are in the facility. Full PPE should be worn per CDC guidelines for the care of any resident with known or suspected COVID-19 per CDC guidance on conservation of PPE. If COVID-19 transmission occurs in the facility, healthcare personnel should wear full PPE for the care of all residents irrespective of COVID-19 diagnosis or symptoms.

Provided that the health care worker is not ill themselves, CMS's guidance should not inhibit their access to the facility for purposes of providing essential care and services. If you feel your PO staff are being inappropriately denied access to a participant residing in a SNF or other long-term care facility, please share your experiences with local, state and federal contacts, including your CMS PACE account manager. POs should also explore the use of remote technology to assess and communicate with PACE participants as appropriate.

STAFFING

11. **When PACE day centers are closed, the POs are required to provide services in the home setting. What should POs do to address the lack of personal care assistants/medical assistants?**

In accordance with their emergency preparedness plans under PACE Regulations at 42 CFR 460.84, POs should have an updated plan for the use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of state or federally designated health care professionals to address surge needs during an emergency. We encourage you to contact your CMS PACE account manager to discuss implementation of your plan should the need arise.

12. **Where there are shelter-in-place orders, please confirm that POs will be able to designate those staff within their organizations that are essential to ensure the organization's continued ability to meet participant needs, such as clinicians, home care workers, drivers, administrators, and all others the PO deems necessary to ensure provision of services.**

We cannot predict the terms of future public health orders and are unable to opine on the legal scope of state laws or executive orders, but CMS understands that a variety of PACE personnel deliver essential services. POs should follow state and local guidelines regarding shelter-in-place rules and essential personnel.

13. **For providers that don't have a contractual agreement with the PACE organization, do they need to be enrolled in Medicare and/or Medicaid, or are PACE organizations allowed to exercise their judgment when potentially bringing in new providers that aren't enrolled in either or both programs?**

Due to the public health emergency posed by COVID-19 and the urgent need to practice social distancing to keep PACE participants safe and healthy, CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with the requirements at 42 CFR 460.70(b)(1)(ii), with respect to physician and non-physician practitioners not enrolled in Medicare and/or Medicaid who provide services to PACE participants. The temporary policy of relaxed enforcement is subject to the following conditions. Such practitioners must have the appropriate state licensure and cannot be on the Medicare preclusion list. This temporary policy will end when the COVID-19 public health emergency, or any extension thereof, ends. We believe that this guidance is a statement of agency policy not subject to the notice and comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. § 553(b)(A). For the same reasons explained above, CMS additionally finds that, even if this guidance were subject to the public participation provisions of the APA, prior notice and comment for this guidance is impracticable, and there is good cause to issue this guidance without prior public comment and without a delayed effective date, 5 U.S.C. § 553(b)(B) & (d)(3).

ELIGIBILITY, ENROLLMENT, RECERTIFICATION

14. **Our state Medicaid program requires an in-person assessment by a third party to determine medical eligibility for PACE. Are these requirements being waived to speed up the application approval process?**

One of the PACE eligibility requirements at 42 CFR 460.150(b)(2) is that the state administering agency determines that the individual requires the level of care under the state plan for coverage of nursing facility services. However, CMS does not prescribe how that assessment occurs. In addition, states have existing flexibility at 42 CFR 460.160(b)(2) to deem PACE participants eligible for continued enrollment in PACE in some circumstances. Confirmation that the individual needs a nursing facility level of care remains a requirement for any new enrollment into PACE.

As articulated in the CMS Families First Coronavirus Response Act – Increased FMAP FAQs, in order to receive the temporary FMAP increase provided under section 6008 of the Families First Coronavirus Response Act (FFRCA), states must provide continuous coverage, through the end of the month in which the emergency period described in

section 6008 ends, to all Medicaid beneficiaries who were enrolled in Medicaid on or after March 18, 2020, regardless of any changes in circumstances or redeterminations at scheduled renewals that otherwise would result in termination. Where an individual no longer meets the eligibility requirements for PACE and the individual is not eligible for a separate plan that provides the same amount, duration and scope of benefits, a state must maintain the individual's enrollment in PACE in order to claim the temporary 6.2% FMAP increase. POs should consult with their state Medicaid agency about the appropriate next steps for any individual whom the state has assessed as no longer meeting the nursing facility level of care.

15. **May verbal enrollments be accepted by both CMS and state agencies? Can a PO have a participant initiate enrollment via a verbal consent without a signature?**

Due to the public health emergency posed by COVID-19 and the urgent need to practice social distancing to keep PACE participants safe and healthy, CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with the signature requirements at 42 CFR 460.152(a)(2), 42 CFR 460.154, 42 CFR 460.156, 42 CFR 460.158 and 42 CFR 460.210(b)(12) of the PACE regulations under the following conditions. In light of COVID-19, a PO may instead obtain a "verbal signature" or verbal concurrence from the participant and/or their designated representative. However, prior to proceeding, we recommend that the PO receive concurrence from its state administering agency. We recommend that the PO maintain a record of the verbal signature or concurrence that clearly documents who took part in the verbal agreement, both at the PO and the participant side (for example, PO enrollment coordinator, participant, their spouse, daughter, etc.). Also, the participant should actually sign all required documents including the enrollment agreement in-person as soon as this becomes possible. This temporary policy will end when the COVID-19 public health emergency, or any extension thereof, ends. We believe that this guidance is a statement of agency policy not subject to the notice and comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. § 553(b)(A). For the same reasons explained above, CMS additionally finds that, even if this guidance were subject to the public participation provisions of the APA, prior notice and comment for this guidance is impracticable, and there is good cause to issue this guidance without prior public comment and without a delayed effective date, 5 U.S.C. § 553(b)(B) & (d)(3).

16. **Can POs suspend processing new enrollments in order to focus staff resources on PACE participant care?**

We recognize that it may be difficult for organizations to take on new enrollments during the emergency. We encourage POs to speak with your state administering agency and CMS PACE account manager if you believe that you cannot safely enroll additional participants. Decisions about stopping or delaying enrollment will be based on the unique circumstances of the PO.

17. **Can we do the assessment of a potential participant's place of residence, or carry out other steps in the intake process described in 460.152(a), remotely?**

Due to the public health emergency posed by COVID-19 and the urgent need to practice social distancing to keep PACE participants safe and healthy, CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with the in-home or and in-person requirements in the PACE regulations at 42 CFR 460.152(a), under the condition that the enrollment activities is are done via non-public-facing two-way real-time audio or video using an acceptable application as described in consistent with the HHS Office for Civil Rights' Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency. This temporary policy will end when the COVID-19 public health emergency, or any extension thereof, ends. We believe that this guidance is a statement of agency policy not subject to the notice and comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. § 553(b)(A). For the same reasons explained above, CMS additionally finds that, even if this guidance were subject to the public participation provisions of the APA, prior notice and comment for this guidance is impracticable, and there is good cause to issue this guidance without prior public comment and without a delayed effective date, 5 U.S.C. § 553(b)(B) & (d)(3).

TELEHEALTH

18. **Can POs offer telehealth as an alternative to in-person or in-center services? Can the Interdisciplinary Team (IDT) do an initial care plan by phone?**

On March 17, 2020, CMS issued guidance to POs, Information for PACE Organizations Regarding Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19). Specifically, in that guidance, we explained that POs may use remote technology as appropriate during the COVID-19 emergency, including for scheduled and unscheduled participant assessments, care planning, monitoring, communication, and other related activities that would normally occur on an in-person basis.

Additionally, we now explain that due to the public health emergency posed by COVID-19 and the urgent need to practice social distancing and prevent the spread of COVID-19, CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with the requirements relating to visits to a potential participant's place of residence and the PACE center pursuant to 42 CFR 460.152 and in connection with in-person assessments required under 42 CFR 460.104, under the condition that the requirements are met via real-time communications and that the platform is a type consistent with one described in the HHS Office for Civil Rights' Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency. This temporary policy will end when the COVID-19 public health emergency, or any extension thereof, ends. We believe that this guidance is a statement of agency policy not subject to the notice and comment

requirements of the Administrative Procedure Act (APA), 5 U.S.C. § 553(b)(A). For the same reasons explained above, CMS additionally finds that, even if this guidance were subject to the public participation provisions of the APA, prior notice and comment for this guidance is impracticable, and there is good cause to issue this guidance without prior public comment and without a delayed effective date, 5 U.S.C. § 553(b)(B) & (d)(3).

Also, on March 27, 2020, CMS issued a long-term care nursing homes telehealth and telemedicine tool kit containing electronic links to reliable sources of information on telehealth and telemedicine.

19. **Do we need an actual signature vs. verbal consent for telehealth?**

There is no federal regulation specific to PACE that requires physical signatures to provide consent for telehealth.

QUALITY & REPORTING

20. **Will the Health Outcomes Survey-Modified (HOS-M) be delayed? We have heard from several POs that they are concerned that response rates will be impacted by the COVID-19 emergency. Responding to participants' requests for assistance with the survey is not top priority at this time. Can steps be taken to ensure that POs' frailty scores in 2021 are not negatively impacted by the COVID-19 emergency?**

As noted in the April 15 guidance, Delay of the 2020 HOS & HOS-M Surveys for 2021 Frailty Score Calculation (HPMS memo), we anticipate fielding the surveys beginning in August. We continue to monitor the situation and will provide PACE organizations and FIDE SNPs with more information in the upcoming months. We will also continue to consider additional ways to support beneficiaries in filling out the surveys.

21. **With the COVID-19 pandemic, is there flexibility around the September 4th, 2020 sweep deadline and the January 31st, 2021 sweep deadlines for 2019 dates of service diagnosis submission?**

Thank you for this suggestion. We are reviewing the request for extending risk adjustment submission deadlines.

22. **Are trial and routine audits being suspended until after the national emergency is over?**

As noted in the March 30 guidance, Reprioritization of PACE, Medicare Parts C and D Program, and Risk Adjustment Data Validation (RADV) Audit Activities (HPMS Memo), CMS is reprioritizing its scheduled program audit activities in order to allow organizations and CMS to focus on the health and safety threats currently faced due to the spread of COVID-19. The suspension of routine audit activities mentioned in this

memorandum will be time-limited. CMS will make an announcement when we resume normal audit activities after the public health emergency has ended.

23. **State survey agencies are unable to complete the Adult Day Health Care (ADHC) licensure surveys at this time. Will CMS waive the requirement of providing proof of an ADHC license for the Site Readiness Review (SRR) for new POs for the upcoming quarterly submission?**

The State Readiness Review (SRR) is required to be completed and submitted as part of the PACE application process referenced at 42 CFR § 460.12(a). However, when an entity or PO initially submits an application to CMS, the SRR is not required at the time of application (and is usually submitted in response to a request for additional information (RAI)). All state required licensure must be in place when the SRR is submitted.

BILLING & PAYMENT

24. **Due to the possibility of catastrophic ramifications for POs during this pandemic crisis, such as an increased number of participants requiring ventilators, will there be additional funding for PACE programs? If we have a significant number of people hospitalized for an extended period of time, we will go under. Will there be any financial relief? Will there be any special, more immediate reimbursement for participants with COVID-19?**

We recognize that many types of risk-bearing entities are understandably concerned right now about the financial and operational impacts of COVID-19, and are monitoring the situation closely. Please continue to update your CMS PACE account manager on any sustainability concerns.

25. **Will there be any leniency on statutory cash requirements for POs?**

There are no federally established reserve limit requirements for POs. In accordance with 42 CFR § 460.80, POs must maintain a fiscally sound operation. In order to maintain a fiscally sound operation the POs must, for example, generally maintain total assets greater than total unsubordinated liabilities (positive net worth). CMS monitors a PACE organization's compliance with fiscal soundness requirements primarily through independently audited annual financial statements for the legal entity. However, there are states that do have reserve limit requirements; therefore, we suggest that POs also check with their respective state administering agency.

26. **If a PO was to have a significant loss of membership, would there be a way to offset the outlay of cash due to the cost of care by having a more rapid risk score true-up for those departing participants?**

Please keep us apprised of your financial situation. We will continue to assess feedback from POs on these issues, and may provide additional guidance.

27. **Could there be a delay in the annual risk score mid-year and final true-ups, currently expected in June and July?**

As of April 6, we are not anticipating a delay.

28. **Could there be a delay in monthly payments or monthly membership reports (MMR)/monthly member data (MBMEMD) files due to resource constraints, work from home environment, etc., at CMS?**

As of April 6, we are not anticipating delays in making monthly payments.

CMS COMMUNICATIONS

29. **Should POs generally assume that CMS guidance and communications to Medicare Advantage organizations also apply to PACE, unless there is a specific communication to PACE that differs from the communication to MA?**

No. Medicare Advantage organizations are different from PACE organizations and are governed by and subject to different federal regulations. We will do our best to specify when guidance applies to PACE. If a PACE organization has questions, please contact your CMS PACE account manager.

30. **Whom can we contact about Part D information and expectations?**

If POs have questions about Part D requirements or policies, please contact your CMS PACE account managers.

31. **Is there a consistent approach/expectation of POs with respect to communications with their CMS PACE account manager? If CMS PACE account managers are not available, what is the expectation?**

The CMS PACE account managers are available in their regular capacity to all POs at this time. All POs should continue to reach out to their assigned CMS PACE account managers for technical assistance and should continue to send all questions to the CMS PACE account managers and the PACE portal as needed. The CMS PACE account managers will continue to respond directly to the questions for which guidance is available and will escalate all other questions for action. The CMS PACE account managers will not be scheduling specific COVID-19 calls with the POs as to prevent any undue burden during this time, but are available to consult as the need arises. If a CMS PACE account manager becomes unavailable due to unforeseen circumstances, we will provide POs and state administering agencies with a designated backup contact for communications.