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Office of Information and Regulatory Affairs
Office of Management and Budget
Submitted electronically via: www.reginfo.gov/public/do/PRAMain

RE: CMS-10630 (OMB control number: 0938-1327)—The PACE Organization (PO) Monitoring and Audit Process in 42 CFR part 460

To Whom it May Concern:

I am writing on behalf of the Providence family of organizations to provide feedback in response to the PACE Organization (PO) Monitoring and Audit Process published in the Federal Register on May 10, 2022.

Providence is one of the largest health systems in the United States, with a seven-state footprint that spans Alaska, California, Montana, New Mexico, Oregon, Texas, and Washington. Our diverse family of organizations employ 120,000 people who serve in 52 hospitals, more than 900 clinics, a health plan, senior services, home health, hospice, PACE, housing, and many other health and educational services. Driven by a belief that health is a human right, we are committed to understanding and responding to the needs of the many communities we serve, and to providing high-quality, equitable health care for all. We have a special focus on serving those who are vulnerable or marginalized, including people who depend on Medicaid coverage for access to care. Each year we work to provide care and services where they are needed most, including investments in community benefit that in 2021 totaled $1.9 billion. Together, we are transforming care with a holistic and deeply compassionate approach to medicine.

Providence operates two of the larger PACE organizations in the country, Providence ElderPlace, in Oregon and Washington. Our Oregon PACE organization currently serves more than 1,691 participants, while our Washington PACE organization serves more than 1,074 participants. PACE programs are well-established and have a strong track record of providing quality comprehensive care to its participants.

Providence would like to express its appreciation for CMS's review of the comments previously submitted on the audit materials in response to the 60-day notice published in the Federal Register on December 21, 2021. In particular, we appreciate CMS's favorable consideration of Providence's and others' comments resulting in the following:

- Reduction in the scope of the requirement for reports detailing the PO's monitoring and tracking of all services across all care settings that were ordered, approved, or care-planned during the data collection period from all participants enrolled in a PO during the data collection period to a sample of 30 participants selected by CMS.
- Elimination of the Observation Participant List from the 2023 PACE audit materials.
- Removal of "Date of Initial Participant Contact" and "Date Individual Began Providing Care Independently" fields from the List of Personnel (LOP) Record Layout.
- Modification of the Contracted Entities and Providers (CEP) Record Layout to recognize practices

as contracted entities, in addition to providers and facilities.

- Removal of the "Call Category" field from the On-Call (OC) Record Layout.
- Modification of the CoordinationofCare1P95 Impact Analysis to focus on residential facilities.
- CMS' commitment to providing updated record layout templates as soon as possible once the audit protocol has been approved by the Office of Management and Budget.

These modifications to the proposed 2023 PACE audit materials will substantially reduce the burden of the audit on POs in ways that we believe will not compromise CMS' ability to identify systemic compliance issues.

PO's Monitoring and Tracking of All Services

Providence is concerned about the requirements for PO's monitoring and tracking of all services across all care settings that were ordered, approved, or care planned during the data collection period for 30 participants selected by CMS. Due to the additional demands placed upon POs resulting from the changes to the List of Participant Medical Records (LOPMR) data universe, the addition of the Contracted Entities and Providers data universe, and the new documentation requirement related to POs' compliance oversight programs, we ask CMS to consider providing additional time to POs to submit the monitoring and tracking reports. Rather than requiring the reports within 20 business days of the audit engagement letter, Providence suggest allowing POs 10 business days to submit the letter, i.e., within 30 business days of the audit engagement letter, or at a time corresponding to submission of the SDAG and/or personnel sample cases. To a significant degree, the same staff work on all these documentation and data submission requirements. Extending the timeframe for submission of the monitoring and tracking reports would be extremely helpful as well.

Although CMS did not adopt the recommendation to impose a sampling methodology for the impact analyses (IAs) involving 50% of participants or personnel, we appreciate CMS's explanation that the 50% threshold is, "an upper limit that is reduced depending on the nature of the issue of noncompliance and in consideration of the PO's enrollment size." We ask that CMS utilize this discretion to the greatest extent possible when IAs are required. Further, we would appreciate it if CMS would clarify that 50% of participants or personnel is an upper limit by modifying the language describing the scope of relevant impact analyses to indicate that their scope is limited to no more than 50% of the participants enrolled or newly enrolled, or no more than 50% of staff. Providence also requests that CMS add additional time to gather documents after receiving engagement letter.

Additionally, Providence requests that CMS implement a much less burdensome approach to auditing POs' compliance with requirements to monitor and track services to ensure ordered, approved, care planned services are provided. More specifically, we strongly recommend that auditors require POs to provide documentation describing their processes, policies, and procedures for monitoring and tracking of all ordered, approved, and care planned services across all care settings.

If CMS is unable to eliminate the reports detailing monitoring and tracking of services from the audit protocol entirely, Providence strongly recommends that the scope of the reports be limited to a probe sample of participants, for example a sample of 10-15 participants chosen randomly by auditors from the PO's participant list.

PO's Electronic Medical Record Tracking

POs should not be expected to be able to retrieve data from their electronic medical record (EMR) systems in the same manner that MAO/Part D plans access their administrative databases. While EMRs

are designed to provide immediate and ongoing access to all information contained in the health record to improve patient care, they are not designed to produce data reports representing all the information documented in the EMR. There is a significant difference between the information entered into the EMR for access by other providers and data that can be extracted for the purposes of auditing. We request that CMS's approach to auditing the provision of services and coordination of care in PACE take this into consideration to a much greater degree. CMS's expectations of insurer-based plans' claims-based data systems are not a sound basis for determining appropriate expectations of PACE organizations' care planning and service delivery data.

As CMS is aware, the scope of services that PACE provides is vast including insurance MA type services, DME, transportation, specialist and primary care services, personal care aides, pharmacy services etc. Nursing facilities have a heightened aversion to risk leading them to allow access to their records on site person by person, but they do not provide electronic remote access to their EMRs. Nor would nursing home EMRs speak to the PACE programs EMR in a way that allows for discrete data element access. Providence ElderPlace has policies and processes in place to coordinate care with nursing facilities to provide participants with the right care at the right time. Audits are expensive, time consuming, and do not improve the quality of care or experience of a PACE participant. In fact, the onerous nature of the data being requested is likely to substantially decrease the time and attention able to be paid to a single PACE participant.

The most significant example of this relates to CMS's newly proposed requirement for the submission of reports detailing the PO's monitoring and tracking of all services across all care settings that were ordered, approved, or care planned during the data collection period. This reporting requirement is of enormous concern to Providence. PACE organizations utilize a variety of systems to monitor, track and ensure the provision of ordered, approved and care planned services. These systems include scheduling systems for multiple types of services. While these and other systems are designed to ensure provision of services, in many cases they are not designed to enable POs to generate the reports that CMS is proposing to require.

Burden on Clinicians

The idea for the Service Determination Request (SDR) universe is valid and reasonable. The actual rule and implementation face some major challenges though. One of the largest reasons that PACE is attractive to clinicians is the chance to avoid the burden of documentation. The details of the SDR process sadly push us beyond the documentation requirements of Fee for Service medicine. This does not serve participants needs better though; however, it may make it easier to audit. Documentation deprives participants of clinician time and energy which is now spent entering hours of documentation.

Participants with cognitive impairment or those who believe that persistence will wear someone down can, and often do, request the same thing over and over. Those with cognition deficits have no recall of having asked for something previously nor of the explanation of why something is provided or not. The need to have an in-person assessment in these cases is burdensome and does not improve the quality of care at all. Therefore, repeat SDR requests for the same thing when there is no change to the participant's status end up depriving other participants (or the same participant on a different topic) of time and attention. It is also the type of practice that drives clinician burnout and turnover. There needs to be a way to address these repeat requests which is less burdensome than the current process.

For those PACE programs such as Providence ElderPlace that have a Part D formulary (which has been approved by CMS), the SDR process for medication requests is a large and unnecessary burden. CMS has already reviewed the formulary including step therapies and prior authorization requirements. If CMS does not require this type of information from Medicare Advantage plans, why does it require it from PACE programs that have a formulary? If a PACE program has a formulary, then we request that CMS exclude Part D medications from the SDR process.

Audit Protocol

Providence believes that CMS has significantly underestimated the burden of the 2023 PACE Audit Protocol on POs, particularly for medium and large size POs with which auditors may have had less experience with in 2020 and 2021. CMS'S use of an audit approach was originally developed for insurer-based plans rather than providers and CMS incorrectly assumed that POs' medical records databases allow for enormously detailed data sets to be retrieved easily.

Providence understands that the 2020 audit protocol was initially implemented at the onset of the COVID- 19 public health emergency and, as a result, opportunities for training may have been limited, we hope that CMS will provide POs an opportunity for training and engagement with CMS staff on the 2023 audit protocol. Further, we encourage CMS to make such training available as soon as possible after the 2023 audit materials are finalized to inform fully POs' preparations for audits in 2023.

Conclusion

Providence appreciates the opportunity to submit these comments and welcomes any questions you may have about them. To do so, please contact Jacquelyn Bombard, executive director of federal relations at Jacquelyn.Bombard@providence.org or 512.569.3105.

Sincerely,

Jacquelyn Bombard
Executive Director, Federal Relations
Providence