Providence St. Joseph Health

May 28, 2019

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10630 (OMB control number: 0938-1327)
http://www.regulations.gov

RE: CMS-10630—Programs of All-Inclusive Care for the Elderly 2020 Audit Protocol

On behalf of Providence St. Joseph Health, thank you for the opportunity to provide feedback to the Centers for Medicare and Medicaid Services (CMS) on the Programs of All-Inclusive Care for the Elderly (PACE) 2020 Audit Protocol. Our comments are based on a detailed review of the 2020 PACE audit protocol materials as well as our experience under the current (2017) version of the protocol which is the basis for the protocol CMS is proposing for 2020.

At Providence St. Joseph Health, we are committed to providing for the needs of the communities we serve, with a special focus on those who are poor and vulnerable. We are dedicated to high-quality, compassionate health care for everyone - regardless of coverage or ability to pay. Together, we are working to improve the health and well-being of entire communities through digital innovation, population health and clinical quality strategies, mental health, specialty institutes, research and education. Our diverse family of organizations employ more than 119,000 people who serve in 51 hospitals, 829 clinics, two health plans, senior services and housing, and many other health and educational services across seven western states. Each year we work to provide care and services where they are needed most, including investments in community benefit that in 2017 totaled more than $1.6 billion.

Providence St. Joseph Health operates two large PACE organizations, Providence ElderPlace, in Oregon and Washington. Our Oregon PACE organization currently serves 1,508 participants, while our Washington PACE organization serves 740. PACE programs are well-established and have a strong track record of providing quality comprehensive care to its participants. We appreciate the opportunity to comment on the important issue of modifying the PACE 2020 Audit Protocol. Our comments focus on several important issues: methods applied to determining access to covered benefits, audit burden, eliminating duplicate information, and the overall cost to Providence St. Joseph Health PACE organizations.

Methods applied to determining access to covered benefits for MAOs are being misapplied to PACE organizations

Providence St. Joseph Health share CMS' commitment to ensuring that all PACE participants receive access to the benefits to which they are entitled through enrollment in PACE and that the care they receive meets the PACE program's high standards. We are very concerned, however, that the methods applied to determining access to covered benefits for Medicare Advantage Organizations (MAOs) are being misapplied to addressing the provision of care by PACE organizations (POs), resulting in an undue burden of data collection and reporting. Consistent with CMS' Patients over Paperwork Initiative, we offer numerous recommendations in this comment for reducing the data collection and reporting burden on PACE providers and their clinical staff related to the PACE audit protocol.

It is our understanding that the audit process being used for PACE was initially developed and implemented for MAOs and Prescription Drug Plans (PDPs). While certain aspects of the protocol evaluate POs compliance with requirements that are analogous to MAO/PDP requirements (e.g., service delivery requests, and grievances and appeals), when implemented in the context of PACE, they can lead to requirements to review 100 percent of participants' medical records; and the burden on POs is enormous. To our understanding, this does not happen when the audit process is applied to MAOs/PDPs. Similarly, the application of this approach to evaluate POs' performance as a provider (vs. health plan) imposes unique and extraordinary burdens on POs. Of greatest concern, requirements for impact analyses involving exhaustive medical record reviews for 100 percent of participants enrolled during the audit review period can consume hundreds of hours of clinical staff time, in some cases for what we believe are not systemic or major issues.

The audit process imposes enormous demands upon POs to provide data that often are only available to POs via manual review of PACE participants' medical records. The demands upon a PO to undertake such reviews significantly impact the ability of clinical staff to address participant needs during the audit period. In reconciling the burden estimates advanced by CMS in this data collection with PACE organizations' actual experience in 2017-2019 and expected experience under the 2020 protocol, we assume that CMS believes that POs can access much more data electronically than is the case. Relative to MAOs, POs are small entities; and although they have invested in and are improving their electronic medical records systems, we are not capable of extracting much of the data that is required by the audit protocol without doing so manually utilizing clinical staff. More specifically, much of the data being requested as part of the List of Participant Medical Records (LOPMR), the Onsite Observation Participant List and numerous of the Impact Analyses (IAs) require exhaustive medical record reviews as we explain in greater detail below. Consequently, much more is required of us than other provider types by their respective audits.

Audit burdens on PACE organizations direct time away from patient care

Providence St. Joseph Health strongly believes that CMS's burden estimates for the PACE audits beginning in 2020 continue to very substantially underestimate the staff and resources required of POs

undergoing audits, particularly for larger POs like ours. We strongly believe that CMS' estimate of 600 hours continues to substantially underestimate the burden associated with the current audit protocol being implemented in 2019 and is even more of an underestimate of the burden associated with the 2020 protocol due to a significant increase in terms of what CMS proposes to require of POs.

The total burden estimates for the four components of the 2020 audit sum to 1,210 hours, more than double CMS' estimate of 600 hours. Using the mean adjusted hourly wage of $68.75 from CMS' Supporting Statement A, the estimated cost for a PO to undergo an audit would be $83,187.50. We believe this is a conservative cost estimate since the staff involved in medical record reviews would be largely clinical with higher adjusted hourly wages. It is important to note that these are estimates for an average size PO, and the burden in terms of both time and cost would be substantially greater for a larger POs like Providence St. Joseph Health's PACE organizations.

Specifically for Providence St. Joseph Health, we anticipate increase in burden in all areas due to additional categories on the universe and IA templates, as well as growth in our PO. As a large PO, the expectation of chart reviews would result in up to as much as 750 staff hours per IA. In the last audit, our Oregon PACE organization had 8 IAs and Washington PACE organization had 11 IAs, which would result in up to a total of **14,250 hours** of staff time. In in order to meet this expectation, we would have to include IDT members, removing them from direct participant care. This could have a significant negative impact on our PACE members.

Participant impact analyses (IAs)

Of greatest concern to Providence St. Joseph Health are the audit demands related to the Impact Analyses (IAs). As proposed, all the IAs require clinical staff to undertake manual medical record reviews. At a minimum, medical record reviews are required to determine if participants experienced any negative outcomes resulting from non-compliance, a question included in all of CMS' proposed IAs. For many of the proposed IAs, the medical record review would be much more extensive, requiring a detailed review of the entire record inclusive of all assessments, care plans, progress notes, etc. for all participants enrolled during the audit review period.

The 2020 protocol increases the number of IA documents from 14 (in 2017) to 25. Taking into account multiple issues within many of these 25 IAs, CMS is proposing IAs related to 46 specific issues of non-compliance in the 2020 protocol. At a minimum, all of the IAs require medical record review to determine negative impact on PACE participants; many require much more in-depth medical record review involving detailed analyses of care plans, assessments, progress notes, service notes, lab reports, etc. for all participants enrolled during the audit review period.

We assume that CMS's burden estimate reflects the expected burden for a PO with an average census of approximately 300. Because of the structure of the audit, these estimates are not close to reflecting the burden imposed on a larger POs like Providence ElderPlace, which may be required to undertake 100 percent medical record reviews for the more than 2,200 participants between both organizations. Because of the detailed nature of the IAs, the information requested may only be accessible by undertaking a manual medical record review which can easily consume hundreds of hours per IA.

We are extremely concerned that the audit process, both as currently implemented and proposed for 2020, places excessive strain on POs' clinical capacity and, in and of itself, jeopardizes participant care.

At a minimum, unless CMS provides instructions to the contrary, we believe that all of the IAs, as currently proposed, would require PO clinicians to undertake a medical record review for purposes of determining whether one or more participants experienced negative outcomes. For many of the IAs (e.g., CarePlanContent1P84, EmergencyCare1P07, MedRecs1P22, PracticeScope1P33, Grievances1P311P751P77, SDRIdentification1P76, MedErrors1P02, ProvisionofServices1P021P81, SrvcRestrict1P90, AlertIDT1P14, Appeals1P651P661P681P73), many more questions/fields require medical record review by clinicians, in some cases involving detailed review of all assessments, care plans, service notes, progress notes, to access the requested information which cannot be electronically abstracted. For a PO of any size this requires many clinical staff to spend many hours combing through medical record documentation. Relative to MAOs, POs are small entities; and although they have invested in and are improving their electronic medical records systems, they are not capable of electronically extracting much of the data that is required by the audit protocol without doing so manually utilizing clinical staff.

While we understand the role of the IAs in determining the scope of non-compliance in MAOs, we believe the burden of the IAs, when imposed on POs and involving exhaustive medical record review, is much too great; and we strongly recommend that CMS reconsider its approach. **Providence St. Joseph Health offers the following overarching recommendations to alleviate the burden that POs have experienced as a result of the IAs and which we anticipate would increase considerably under the proposed 2020 protocol.**

For EmergencyCare1P07, Providence St. Joseph Health recommends a few changes to reduce burden or improve clarity. We agree with CMS that participants' access to emergency services is critical. That said, we suggest that the IA as currently written (34 questions) is overly complicated and strongly recommend it be simplified to reduce burden and confusion without compromising CMS' access to important information. Due to the complexity of this IA, we are offering general recommendations out of concern that by offering specific recommendations we will add to an already confusing set of questions. **Providence St. Joseph Health believes the focus should be on situations in which a participant/caregiver contacted the PO or a contracted provider regarding emergency services and emergency services were not utilized.** Finally, as it is currently structured, we believe that numerous columns, e.g., G, H, I, J, K, L, M, N, O, T, U, V, Z, AA, AB, would require in-depth medical record review to respond to the questions.

MedRecs1P22: the scope of this IA and the burden it would place on POs is extraordinary. This IA calls upon POs to undertake an exhaustive medical record review of all of its participants' entire medical records for a period of six-plus months. Depending on the size of the PO, a review for accuracy and/or completeness would involve reading hundreds of care plans, and thousands of assessments, progress notes, specialist notes, discharge summaries, lab reports, etc. Due to the comprehensiveness of participants' medical records, this is an overwhelming task. Based on our experience under the current audit protocol, we estimate such an undertaking would require more than 2,200 hours of clinical staff

time just to review the records in both our PACE organizations, in essence calling upon PO staff to look for items that do not appear in the record or may in some way be inaccurate.

This is a prime example of a situation in which a process developed to assess compliance for a MAO where the focus is on ensuring access does not work to assess compliance with provider-based requirements. Ideally, an alternative to an IA process will be developed**. If CMS chooses to maintain the proposed process for this IA, in addition to utilizing a sampling method or some process by which the number of impacted records is reduced very substantially, it is imperative that this IA be focused on a much more specific concern related to the issue identified by the auditors, e.g., missing lab reports.**

ProvisionofServices1P021P81andSrvcRestric1P90: the scope of these IAs are overwhelming in that they requires a comprehensive review of all documentation and/or evidence that relates to provision of services whether the issue is one of not providing necessary services or limiting the provision of necessary services. Undertaking such a review for hundreds and perhaps even thousands of participants would require an enormous amount of clinical staff time, diverting these resources from participant care. **Providence St. Joseph Health encourages CMS to develop an alternative to an IA process. If not, then we believe it is critical that CMS utilize a sampling method or some means by which the number of participants included in these IAs is reduced very substantially.**

Providence St. Joseph Health also asks that CMS raise the thresholds for requiring POs to undertake RCAs and IAs. It is our experience that in a large majority of instances in which auditors identify an issue of non-compliance, regardless of its severity, they are required to undertake RCAs and, in a very large percentage of these cases, IAs. Particularly with respect to the IAs, the thresholds that auditors appear to be using in 2019 to require IAs which involve multiple clinical staff and in some cases hundreds of hours of medical record review are too low.

We urge CMS to utilize a sampling methodology and allow for the PO to undertake an IA for a sample of records (e.g., SDRs, grievances, participants, etc.) depending on the issue. This is especially critical for those IAs involving exhaustive medical record review. If the results of the initial sample suggest a 100 percent review is needed, the remaining records can then be analyzed. Sampling is a well-recognized approach. The percentage of the population included in the IA should decline as the number of records increases, e.g., for an IA focused on participants enrolled during the audit review period, for a program of less than 50 participants, 25 percent of participants; for a program of between 51 and 100 participants, 20 percent of participants; for a program with more than 100 participants, 15 percent of participants. If the IA does not identify a systemic issue, the PO would not be required to extend the IA to additional subjects. If the IA suggests that non-compliance is widespread, a more comprehensive review could be included as part of the PO's correction action plan (CAP). **Providence St. Joseph Health believes this approach is particularly important for the IAs that require exhaustive medical record review** (e.g., CarePlanContent1P84, EmergencyCare1P07, MedRecs1P22, PracticeScope1P33, Grievances1P311P751P77, SDRIdentification1P76, MedErrors1P02, ProvisionofServices1P021P81, SrvcRestrict1P90, AlertIDT1P14, Appeals1P651P661P681P73).

LOPMR universe

Providence St. Joseph Health agrees with CMS's assessment that a six-month audit review period/universe data and documentation collection period (three months for On-Call universe) provides enough information for a thorough review of PO performance. However, the reduction in burden resulting from shortening universe data collection timeframes is overwhelmed by the increase in burden resulting from the substantial expansion of the List of Participant Medical Records (LOPMR) universe from 36 to 49 elements. Data for numerous of the proposed new fields cannot be easily accessed and would require PO staff to undertake manual reviews of participants' medical records for the audit review/data collection period. We are not aware of any examples in which this level of detailed information is requested on a per enrollee/beneficiary basis for MAOs, or Medicare or Medicaid provider types.

If implemented as proposed, completion of numerous elements of the LOPMR will require a detailed, manual review of the medical record. We estimate such a review would take our Washington PACE organization approximately 350 hours (30 minutes/participant) and Oregon PACE organization a staggering 750 hours. This is well in excess of the 80-hour estimate assigned to this portion of the audit. Due to the manual nature of the medical record review, the burden is much greater for larger POs like ours.

To reduce the burden associated with the LOPMR, we recommend CMS eliminate Specialist Ordered Medications, Delivery of Specialist Ordered Medications, Specialist Recommended Medications, Delivery of Specialist Recommended Medications (Columns X - AA) due to the excessive burden associated with completing these fields. CMS has included a new field for Specialist Consultations/Visits (Column N) which will allow auditors to select sample cases including one or more participants seen by a specialist(s) during the audit review period. **Furthermore, an increase in the number of targeted medical records from 10 to 15 will allow auditors to focus more attention on participants seen by specialists if they choose to do so.**

If it is necessary to increase the number of sample cases selected by auditors in order to address the areas of interest identified above, we believe it would be preferable to requiring POs to undertake a 100 percent manual medical record review to complete the LOPMR fields. CMS' assumption that these data are available electronically is mistaken. Rather than requiring POs to generate this information, we believe it is more appropriate for the auditors to address these issues in their review of sample cases.

Providence St. Joseph Health hopes that CMS will provide Excel templates for POs to use in submitting the data universes. Ideally, they will be available to POs by July 2019. If not by July, then no later than October, in order to provide POs a minimum three months to work with the new templates prior to audits beginning 2020 under the new protocol.

Finally, for POs that operate multiple centers, like our PACE organizations, if CMS is uncomfortable with limiting the lists to participants assigned to just one PACE center, then **Providence St. Joseph Health encourages the agency to provide the PO with a random sample of participants from two or more**

centers. The proportion of participants included in the sample should be lower for larger PACE organizations.

Multiple requests for duplicate information

Currently, grievances, appeals, and ED utilization are reported quarterly to CMS through HPMS and with the audit universes. This is redundant reporting and creates undue paperwork burden for the POs. **Providence St. Joseph Health strongly recommends that CMS eliminate this duplicate reporting requirement by removing grievances, appeals, and ED utilization from *either quarterly* HPMS quality reporting or from the 2020 Universes. At a minimum, we strongly recommend that CMS align all data reporting to be consistent between the Universes and HPMS.** One example of the misalignment of data reporting: in HPMS, the categories for "grievance source" are "participant, caregiver, family." On the 2018 universe, the choices are "participant, caregiver, other." In the 2020 guidance, the categories are reduced to "participant and caregiver" – further creating discrepancy between HPMS and the Universe as well as eliminating the ability to capture concerns reported by family members.

Overall cost to Providence St. Joseph Health PACE organizations

For Providence St. Joseph Health, we anticipate increase in burden in all areas due to additional categories on the universe and IA templates, as well as growth in our PO. As we stated earlier, as a large PO, the expectation of chart reviews would result in up to as much as 750 staff hours per IA. In the last audit, Providence ElderPlace Oregon had 8 IAs and Washington 11 IAs, which would result in up to **14,250 hours of staff time**. In order to meet this expectation, we would have to include IDT members, removing them from direct participant care. This could have a significant negative impact on our PACE members.

Overall, we estimate our hours on the following audit-related activities for each of our Oregon and Washington PACE organizations as follows:

Activity	OR Hours estimate for 2018	Hour estimate based on 2020 guide for OR	WA Estimates for 2018	Hour estimate based on 2020 guide for WA
Data Universe	330	350-370	140	180-200
Root Cause Analysis (related to audit findings)	162	216-232	136	204-221
Response to CMS' Draft Audit Report	1	No change	1	No change
Development and Submission of Corrective Action Plans	140	No change	80	No change

Thank you for the opportunity to provide information on this important proposed rule. We hope that you find our input informative. For more information, please contact Sarabeth Zemel, manager, federal regulatory affairs and engagement, at (425) 525-3228 or via email at Sarabeth.Zemel@providence.org.

Sincerely,

/s/	/s/
Ellen Garcia	Susan Tuller
Chief, PACE Oregon	Chief, PACE Washington
Providence ElderPlace	Providence ElderPlace