NATIONAL PACE ASSOCIATION
Support. Innovate. Lead.

May 21, 2019

Centers for Medicare & 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 (PACE) 2020 Audit Protocol

On behalf of the National PACE Association (NPA) and its 118 PACE organization members in 30 states, I am submitting comments on the Programs of All-Inclusive Care for the Elderly (PACE) 2020 Audit Protocol. In developing these comments, NPA has consulted with numerous of its PACE organization (PO) members and the audit and compliance subcommittee of NPA's Quality Committee. Our comment is based on a detailed review of the 2020 PACE audit protocol materials as well as POs' experience under the current (2017) version of the audit protocol which is the basis for the protocol the Centers for Medicare and Medicaid Services (CMS) is proposing for 2020.

We have taken great lengths to be as specific as possible in responding to CMS' request for feedback on burden estimates and in suggesting ways to reduce burden, and improve the quality, utility and clarity of information to be collected as part of POs' audits. Following general comments, we offer feedback and recommendations related to the specific information included in the supporting statement and associated materials for the proposed data collection.

General Comments

In 2017 CMS implemented a new audit protocol for PACE that, in broad terms, requires the following of POs being audited:

- Submission of detailed data universes and documentation prior to audit field work;
- Submission of documentation related to auditors' selection of sample cases for review during audit field work;
- Ongoing data submissions in response to auditors' requests during and following audit field work;
- Completion of Root Cause Analyses (RCA) and Impact Analyses (IA) in response to auditors' requests during and following audit field work;
- Review of draft audit report and submission of comments; and
- Submission and implementation of Corrective Action Plans (CAP), as needed.

The proposed PACE 2020 audit protocol retains these components with numerous changes to specific elements within them. We appreciate this opportunity to provide comments and recommendations on the audit process overall as well as its individual components and elements.

NPA and its members 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 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, grievances and appeals, when implemented in the context of PACE, they can lead to requirements to review 100% 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% 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 time period the PO is being audited. 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 POs can extract 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, they 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 IAs require exhaustive medical record reviews as we explain in greater detail below. Consequently, to our understanding, much more is required of POs than other provider types by their respective audits.

Of greatest concern to NPA are demands related to the 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. Such a review can only be performed manually by clinicians and

would consume hundreds of hours of their time. In developing our burden estimates for the 2020 PACE audit protocol, we have extrapolated from POs' experience with IAs under the current protocol under which we have seen a substantial increase in burden in 2019. We ask CMS to consider alternative ways, including use of a sampling methodology when IAs are determined absolutely necessary, to assess impact and thereby reduce the burden associated with the IA process, and offer both broad and specific recommendations for your consideration.

We also believe that the audit process as it relates to service delivery requests (SDRs) and grievances would be substantially more efficient and effective if CMS would proceed to provide further guidance on these elements to both POs and auditors. Since implementation of the audit protocol in 2017, CMS has indicated additional guidance related to SDRs and grievances would be forthcoming. In its absence, it is our belief that auditors are classifying communications between POs and participants and/or their representatives as SDRs or grievances in ways we do not believe are consistent with regulatory intent. More specifically, we believe SDRs should be distinguished from: 1) service related inquiries between participants/representatives and their health care providers regarding treatment options; and 2) participant/representative requests to modify existing items or services that do not change the amount or duration of the item/service such as requests to repair or replace existing items, requests to modify schedules for PACE center attendance or home care, etc. With respect to grievances, NPA has requested that POs be allowed some discretion in determining whether a participant's request or statement should be processed as a grievance, specifically in situations where a concern is addressed immediately to the participant's satisfaction, is not identified repeatedly, and does not negatively impact the participant's wellbeing. Even if not processed as grievances, PO still could utilize this information in their QAPI plans. We expect these clarifications would lead to a significant reduction in the number of RCAs and IAs for the SDAG audit element. We ask that CMS refer to NPA correspondence dated August 17, 2017 and October 10, 2018 for more detail. If necessary, we would be pleased to resend this information.

NPA Comments on CMS' Burden Estimates in Supporting Statement A

Based on input from PACE organizations that have undergone audits since 2017, NPA strongly believes that CMS' 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 medium size and larger POs. We appreciate CMS' recognition that its burden estimate for audits beginning in 2017 "did not appropriately account for the staff a PO may need to utilize during the course of the audit," leading to a 250% increase in the burden estimate from 240 to 600 hours in 2020. Despite this substantial increase, NPA feels 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.

In this section, consistent with the presentation of burden estimates in Supporting Statement A, we provide feedback on CMS' burden estimates for:

1) **Activities prior to the audit start** including preparation and submission of the six required data universes; completion and submission of PACE Supplemental Questions and Pre-Audit Issue Summary; and submission of the PO's Quality Assessment and Performance Improvement

(QAPI) plans, Participant Advisory Committee (PAC) minutes, and current organization chart. CMS estimates a total of 80 hours with no change from its estimate in 2017.

Data Universes: NPA agrees with CMS' 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. Further, we agree with CMS that a reduction in the universe data collection periods and the removal of the quality assessment universe will result in a burden reduction although it remains the case that POs must maintain data for the required six universes to ensure readiness at time of audit. 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.

More specifically, the inclusion of the following ten fields will increase enormously the time required to complete the LOPMR record layout for the reasons provided:

- *Specialist Ordered Medications, Delivery of Specialist Ordered Medications, Specialist Recommended Medications, Delivery of Specialist Recommended Medications (Columns X-AA) (new)*: Although POs are well aware of specialist ordered and recommended medications and whether they are delivered when following up on specialist consultations, at the time of a retrospective audit accessing this information would require an in-depth medical record review for those participants seen by specialists. After determining if a specialist recommended or ordered medications, a PO would have to review medical records or access its ordering system to determine if specialist ordered or recommended medications were delivered. While we understand CMS' interest in knowing whether prescriptions recommended by specialists are filled, requiring this detailed level of information in the LOPMR is not the only means of addressing this issue in the audit. Auditors can target participants for whom specialist consultations/visits took place during the audit review period to get at this issue via their review of sample cases. We note that there are situations in which a PACE primary care provider, based on his/her more intimate knowledge of the participant, may want to consult with the specialist prior to ordering the prescription and, after such consultation, it is determined that the prescription is not appropriate, e.g., concerns regarding interactions with other medications that the specialist may not have been aware of, existing prescriptions that the specialist may not have been aware of, etc.
- *Participant Pain (new) (Column AB)*: This question, "Did the participant report pain at any time during the data collection period?" is very broad and would require an in-depth review of all notes in the medical record—totaling in the hundreds and thousands for programs of significant size—to determine if any report of pain was made. We believe numerous other LOPMR data fields, including Pain Management (Column AC), the diagnosis fields, etc., will allow auditors to identify participants who may experience persistent pain.

- *Significant Weight Gain (new), Significant Weight Loss (revised) (Columns AN-AO)*: The current audit protocol requires POs to report on whether a participant "experienced significant unanticipated weight loss at any point during the audit period." In general, POs use guidelines consistent with the Minimum Data Set (MDS) definition of significant weight loss for nursing home residents, i.e., loss equal to or greater than 5% within a 30-day period or 10% within a 180-day period, to complete this field. The weight gain/weight loss fields in the proposed LOPMR call for POs to report weight gain/loss of 2 lbs. in 24 hours or 5 lbs. in 7 days. To provide this information, a detailed review of progress notes in the medical record would be required. Further, this metric implies an expectation that participants are weighed daily. We believe the MDS guidelines take into account normal fluctuations of weight and address concerns for nutritional and medical management.
- *Low Blood Glucose Level (new), High Blood Glucose Level (new), Oxygen Saturation Level (new) (Columns AP-AR)*: For many POs, access to this information is only available through a detailed review of the medical record, including service notes, progress notes, and lab reports.

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 for an average size PO of 300 participants will be 150 hours (30 minutes/participant), on its own well in excess of the 80-hour estimate assigned to this portion of the audit. Obviously, due to the manual nature of the medical record review, the burden is much greater for larger POs. On pp. 10-11 we offer recommendations for reducing the burden associated with the LOPMR.

PACE Supplemental Questions: We believe the increased burden related to the PACE Supplemental Questions is minimal. We offer recommendations to improve the clarity of the supplemental questions on pp. 8-9.

Pre-Audit Issue Summary: We agree there is no change in burden associated with the Pre-Audit Issue Summary.

Submission of PO's QAPI plans, PAC minutes, current organization chart: We do not believe there is a significant change in burden associated with the submission of these materials. We have a question related to the current organization chart on p. 17.

In sum, due to the substantial proposed changes to the LOPMR, we believe that 80 hours considerably underestimates the burden related to activities that occur prior to the audit start; and an estimate of 210 hours is much more realistic. We are hopeful that CMS will accept our recommendations for modifying the LOPMR to reduce burden substantially.

2) **Actual administration of the audit** for activities that take place during the audit fieldwork. CMS estimates a total of 160 hours up from 40 hours in 2017. If the changes in the proposed 2020 audit protocol were limited to increases in the number of sample cases for the SDAG and Clinical Appropriateness and Care Planning elements, reductions in requirements for sample case documentation for the Personnel element, and changes in how the auditors are

evaluating the Quality element, this would be a much more accurate estimate of the time required of staff to address auditors' needs, provide sample case documentation, assist auditors navigate participants' medical records, respond to on-site requests for documentation, participate in interviews regarding the PO's quality program and complete RCAs. However, we do not believe that the new requirement for the On-Site Observation Participant List is accounted for in the new estimate. We offer recommendations for reducing the burden associated with this document on pp. 11-12. If CMS accepts these recommendations, we agree with the 160 hours estimate. However, if CMS requires the list as proposed, significant PO staff time will be required to review participants' medical records to extract and report detailed information on medication administration, wound care and specialized diets for participants who receive these services; and the burden estimate should be increased from 160 to 200 hours.

3) **Review and response to documentation requests, impact analyses and draft audit report.** CMS estimates a total of 160 hours, up from 40 hours in 2017. While we appreciate CMS' recognition that the 2017 burden estimate was insufficient, we believe that CMS' burden estimate for 2020 continues to fall well short of accurately estimating the amount of time required of PO staff for this portion of the audit, in particular to respond to auditors' requests for IAs. Although the PRA crosswalk does not indicate any change in the burden associated with the IA component of the audit, 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 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' 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 larger POs which may be required to undertake 100% medical record reviews for 500 or more, or even 2,000 or more participants. Because of the detailed nature of the IAs, the information requested may only be accessible by having clinicians undertake an in-depth medical record review which can easily consume hundreds of hours per IA.

   Although we realize that IAs are collected as needed, POs audited in 2019 have reported having to complete nine, 11, 14, even 15 IAs with many requiring in-depth medical record review involving multiple clinical staff and in excess of 450, 600, 750 and, in one case 1,800-plus hours. Based on a limited review of the IA templates requested of several of NPA's PO members, the templates used in 2019 are more like those proposed for 2020 than those released as part of the PACE audit protocol in 2017, reinforcing concerns that the burden associated with the IAs as proposed for 2020 is much greater than it has been in the past. Due to the application of these IAs to provider aspects of the PACE program, the staff required to complete them are clinical staff whose primary responsibility is to provide care to PACE participants. 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. On pp. 13-16, we offer recommendations to address this issue.

At a minimum, NPA believe that the burden estimate for this component of the audit should be increased from 160 hours to 600 hours. We are hopeful that CMS will accept our recommendations to reduce this figure considerably.

4) **Submit and implement corrective action and audit close out activities**. CMS estimates a total of 200 hours. We concur with this estimate.

NPA's 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. Again, 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 larger POs.

NPA Comments on Necessity/Utility of Proposed Information Collection for CMS' Performance of Audit Responsibilities, and Recommendations to Reduce Burden and Enhance Quality, Utility and Clarity of Proposed Information Collection

In this section of our comment, we offer numerous recommendations on various aspects of the audit protocol that are intended to reduce the burden of the audit for both POs and auditors without sacrificing auditors' ability to identify significant lapses in compliance. In addition, we offer additional suggestions intended to improve the quality, utility and clarity of the proposed information collection. Please note that our recommendations are presented consistent with the order of the audit process and not necessarily in the order of their importance or significance.

1) **Disclosing Issues of Non-compliance Prior to Notification of Audit**:

Referring to CMS' request of POs to provide a list of all issues of non-compliance disclosed to CMS prior to the date of the audit engagement letter (p. 4 of the Audit Process and Data Request document), NPA believes that certain POs are at a disadvantage with respect to opportunities to disclose issues due to differences among account managers and/or regions with respect to program oversight and monitoring. For example, in one region, POs report requirements to provide detailed information to their account manager(s) on a monthly basis. This information includes sample cases for service delivery requests, grievances and personnel. Because issues discovered during routine CMS and State Administering Agency (SAA) monitoring are not considered self-disclosed, due to differences in practices among account managers and/or regions, advantages that may result from self-disclosures may not be afforded equally to all POs. For example, the potential for a condition to be categorized as a Corrective Action Required (CAR) rather than an Immediate Corrective Action Required (ICAR) may not be uniformly available to all POs, given variations in monitoring practices. Assuming that regional account managers have the discretion to differ in their approaches to PO oversight, NPA asks CMS to clarify that issues identified by a PO in preparation for a meeting with its account manager is eligible for self-disclosure and, subsequently, inclusion on

the Pre-Audit Issue Summary template if the PO contacts its account manager in advance of such meeting.

2) **Attachment II PACE Supplemental Questions**

The following recommendations related to several of the supplemental questions are offered with the objective of improving the efficiency of the audit and thereby reducing PO and auditor burden, or clarifying CMS' intent:

- *Question #4: Does your organization have the ability to provide remote access to medical records? If so, please provide instructions for CMS to be granted access.*

  In situations in which auditors access PACE participants' electronic medical records (EMRs), either remotely or onsite, we ask that a staff member of the PO who is experienced with the EMR system be present. In the case of remote access, the PO staff member should be available via teleconference and able to view the EMR along with the auditor. In this way, the staff member would be available to guide the auditor(s) to the elements of the EMR of interest to the auditor(s). By doing so, we hope to reduce substantially the number of documentation requests made of POs for which they must scan and upload documentation into HPMS.

  In addition, consistent with POs' obligations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), it is their responsibility to be able to report to participants when their records are accessed, if requested.

- *Question #6: Does your organization have any policies that place limits on the amount, duration, or frequency of the following items or services: a) Glasses/replacement glasses, b) Hearing aides/replacement hearing aides, c) Home care services (including services at night, on the weekends, or holidays)? d) Respite, e) Specialist consultations, f) Nursing facility services, g) Hospital or ER services, h) Dental services, i) DME, j) Personal alert systems, k) Medications. If you answer yes to any of the above items, please explain the policy or restriction. You may submit the policies directly into HPMS in lieu of an explanation (use the "Supplemental" file type to upload).*

  We request that CMS clarify that it is referring to fixed or predetermined limits and that it is not questioning the IDT's responsibility to develop care plans that are inclusive of/limited to services intended to address the needs of participants as assessed by the IDT in collaboration with the participant and/or his/her caregiver.

- *Question #9: Can participants obtain prescriptions written from any prescriber including specialists? If no, explain the process of reviewing the order and rewriting the prescription.*

  We assume that CMS is asking about prescription medications in this question. If this is not the case, please provide further clarification.

- *Question #16: Are there any participants who have opioid restrictions? If yes, please explain what the restrictions entail?*

  We request that this question be dropped from the list of supplemental questions because it is duplicative of information required of POs in the LOPMR, specifically Limitation on Opioid Usage (Column AE). Utilizing the information provided in the LOPMR, auditors have the ability to select sample cases involving participants for whom a limitation on opioid usage was imposed. Asking POs to provide participant-level explanations of any limitations on access to opioid medications in the context of Attachment II: PACE Supplemental Questions is burdensome and duplicative of the information available to auditors in the LOPMR.

3) PACE Record Layouts/Data Universes

Referring to pp. 18-35 of the proposed AttachmentIPACEAuditProcessDataRequest, Appendix A – Programs of All-Inclusive Care for the Elderly (PACE) Record Layouts, NPA offers the following recommendations to reduce burden or increase clarity of information required in the data universes:

- Table 1: Service Delivery Requests (SDR) Record Layout (pp. 18-20)
  - Please clarify how POs should complete the SDR record layout in situations in which a participant/designated representative withdraws a service delivery request or refuses an assessment, e.g., a designated representative requests hearing aids on behalf of a participant who does not want them, a family member requests respite and then changes vacation plans, or a participant chooses not to proceed with a service delivery request. These are not isolated situations. We recommend that the record layout include a field in which the PO can provide a reason for not completing the SDR process in situations such as these, e.g., SDR withdrawn, participant disenrolled, etc. This approach would incorporate real-world experience into the record layout and reduce auditors' requests for additional information and potentially IAs.
  - We recommend that Assessment(s) In-person (Column J) be reworded to take into account that multiple assessments may be required. As currently written, how would a PO complete this field if two assessments were required, both were completed and one was in-person?
  - Should Reason for Denial (Column L) allow for NA in situations when the request was approved? It is our understanding that fields in the record layouts should not be left blank.

- Table 2: Appeals Requests (AR) Record Layout (pp. 21-23)
  - Please provide clarification of how POs should complete the AR record layout in situations in which a participant/designated representative withdraws an appeal. This modification would incorporate real-world experience into the record layout and reduce auditors' requests for additional information and potentially IAs.

- Table 3: Grievance Requests (GR) Record Layout (p. 24)
  - Please provide clarification of how POs should complete the GR record layout in situations in which a participant/designated representative withdraws a grievance or does not want to be involved in the grievance process or notified of resolution. This modification would incorporate real-world experience into the record layout and reduce auditors' requests for additional information and potentially IAs.
  - The GR record layout requires specific information on grievances that also is requested from POs as part of PACE Quality Data. Comparing the GR record layout with instructions in the PACE Quality Monitoring & Reporting Guidance, much of the data required in the GR record layout is similar but not identical to the data POs are required to report quarterly via HPMS. For example, the HPMS grievance categories for source are: Caregiver, Family, Participant. The proposed GR record layout categories for "Person who submitted the Grievance" are: Participant, Caregiver. Grievance type for PACE Quality Data/HPMS is limited to 14 specific grievance types, in addition to "Other." The GR record layout does not include any predetermined categories for selection. Similar inconsistencies are noted for Appeals. The capture of the same data in slightly different ways yields no identifiable value to either quality or regulatory oversight but does add an additional burden to PO staff responsible for collecting and analyzing the data. We ask that CMS use HPMS language and terminology whenever possible in the GR and AR record layouts for consistency and clarity.

- Table 5: List of Participant Medical Records (LOPMR) Record Layout (pp. 27-34)
  - We recommend eliminating 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 as explained on p. 4. 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. 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.
  - We recommend eliminating Participant Pain (Column AB) as it is too broad and would require a medical record review as explained on p. 4. Numerous other fields in the record layout provide information auditors can use to identify participants who may have experienced pain during the audit review period and who can be chosen as sample cases, e.g., Number of Hospital Admissions/Observations (Column H), Number of Emergency Room Visits (Column J), Specialist Consultations/Visits (Column N), numerous diagnosis fields, Pain Management (Column AC), Opioid Utilization (Column AD), Number of Falls reported as a Level II event (Column AH), Pressure Ulcers (Column AK), etc.
  - We recommend retaining Significant Weight Loss from the 2017 LOPMR in place of CMS' proposed Significant Weight Loss (Column AN) and Significant Weight Gain (Column AO). As explained on p. 5, completing Columns AN and AO would require an

in-depth medical record review. CMS could define Significant Weight Loss in the 2017 LOPMR as loss equal to or greater than 5% within a 30-day period or 10% within a 180-day period and, if desired, could add a field for Significant Weight Gain defined as gain equal to or greater than 5% within a 30-day period or 10% within a 180-day period. Such fields would be consistent with definitions for significant weight loss/gain for nursing home residents as reported in MDS. The metrics proposed by CMS for 2020 imply that participants are weighed daily; further, they do not take into account differences in participants' baseline weights. If CMS is concerned about weight loss/gain among participants with specific diagnoses, e.g., CHF, they can be targeted for sample case review. We believe the MDS guidelines address concerns for nutritional and medical management.

- We recommend eliminating Low Blood Glucose Level (Column AP), High Blood Glucose Level (Column AQ) and Oxygen Saturation Level (Column AR) due to the burden of extracting this information from the medical record as explained on p. 5. Auditors may target participants for whom this is a concern in selecting sample cases. By increasing the number of medical records targeted for review from 10 to 15, auditors have greater opportunity to do so.
- Number of Falls reported as a Level II event (Column AH) should reference PACE Quality Data rather than Level II.

If it is necessary to increase the number of sample cases selected by auditors in order to address the areas of interest identified above, this would be preferable to requiring POs to undertake a 100% manual medical record review to complete the LOPMR fields. CMS' assumption that these data can be easily extracted 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.

Lastly, NPA is hopeful that CMS will be providing updated Excel templates for POs to use in submitting the data universes in 2020. Ideally, such templates would be available to POs by July 2019. If not by July then no later than October 2019 to provide POs a minimum of three months to work with the new templates prior to audits beginning 2020 under the new protocol.

4) Attachment IV: On-Site Observation Participant List

CMS indicates that its intent with the On-Site Observation Participant List is to "streamline the participant selection process and ensure current schedules and health conditions are considered." We acknowledge that completion of this list would streamline the process from the auditors' perspective, but the additional burden placed on the PO is considerable. The data request is excessive for the task of identifying participants for on-site observation. Based on our consultation with numerous POs, completion of this list would require the following:

a. Identifying participants who will either be attending a PACE center and/or receiving home care on each of five weekdays;
b. Identifying participants for whom medication administration, wound care and/or specialized diets are provided;

c. Merging the information generated in a. and b. to create a list of PACE center attendees and home care recipients who will receive either medication administration, wound care and/or specialized diets during the week of the auditors' on-site visit; and
d. Going through the list and manually entering the additional detail related to the specific types of medication administration, wound care and specialized diets the participants will receive based on a review of all the listed participants' medical records.

We assume it is CMS' expectation that electronic data capturing systems can easily be restructured to compile the list. This is not the case. While Steps a-c can be accomplished in a relatively reasonable amount of time, Step d would be extremely time consuming.

As an alternative to what CMS is proposing, we recommend that CMS focus on participants who attend one PACE center; if the PO operates multiple PACE centers, CMS would select the center. For each day of the week during which the on-site audit is taking place, the PO would provide a list of the participants assigned to the center who will be attending the center and/or receiving home care. The lists would include information on whether each participant receives medication administration and/or wound care and where. For participants attending the PACE center, the lists would indicate if they require a specialized diet. For participants receiving in-home care, the lists would indicate if the care is skilled care, unskilled care or chore services. The daily lists would not include detailed information on specific types of medication administration, wound care and specialized diet that CMS has incorporated into the proposed On-site Observation Participant List. Identification of participants' needs at this level would result from discussion between the auditors and PO staff. We believe this approach strikes a more appropriate balance between the needs of the auditors and demands placed on PO staff.

In situations where POs operate multiple centers, if CMS is uncomfortable with limiting the lists to participants assigned to just one PACE center, alternatively, CMS could provide the PO with a random sample of participants from two or more centers for whom it would provide the information described in the previous paragraph. The proportion of participants included in the sample should be lower for larger POs.

5) **Responding to Documentation Requests**

Referring to CMS' expectation (pp. 3-4 of Audit Process and Data Request document) that POs upload supporting documentation requested during the audit to the Health Plan Management System (HPMS) within timeframes specified by the CMS Audit Team, POs have repeatedly reported to NPA that:

- In situations when an Audit Team member asks PO staff to upload medical record documentation because he/she cannot locate it in the medical record, it would be much more efficient from the PO's perspective for the Audit Team member to ask PO staff to direct him/her to the appropriate place in the record. If the Audit Team member then wants a copy of this documentation, it could be uploaded to HPMS. We are hopeful that this would reduce considerably the burden POs are experiencing as a result of requests to upload documentation to HPMS.

- Multiple POs have reported to NPA that auditors have requested well in excess of 100 documents; in one instance, a PO was required to upload all of its participants' care plans for a six-month period which totaled well in excess of 300. Again, we are not aware of a provider-based audit in which this would be required and question whether comparable document requests are made of MAOs or PDPs considering the types of documentation they have available to them.
- Often PO staff is asked to upload the same documentation multiple times. Eliminating the need to upload the same documentation repeatedly would effectively reduce some of the burden POs are experiencing as a result of requests to upload documentation to HPMS.
- While problems with HPMS functionality have been reported in the past, POs report to NPA that it has improved considerably. We appreciate CMS' efforts in this regard.

6) Root Cause Analysis/Impact Analysis

With respect to the objectives of the Root Cause Analyses (RCAs) and Impact Analyses (IAs) in the audit protocol, we appreciate the CMS Audit Team's need to pursue additional information when possible conditions of non-compliance are identified. We are very concerned, however, about the enormous demands placed upon PO staff in responding to audit teams' requests for RCAs and IAs, in particular IAs requiring extensive involvement from multiple clinicians to undertake comprehensive medical record reviews in order to extract requested information. We are not aware of other provider types for which a comparable audit protocol is utilized and, for the provider aspects of the PACE model, feel an audit protocol developed for insurer-based plans is not a good fit. If fundamental modifications are not made to the protocol, at a minimum, it needs to be implemented differently in the context of a provider-based model.

Our concerns are even greater in light of POs' experience with the audit in 2019 (a number of POs report experiencing many more IAs than in their previous audits) and the enormous expansion in the number and scope of the IAs proposed for the 2020 protocol. As explained in detail on p. 6 in the context of our comments on the reasonableness of the burden estimates, the number and scope of IAs proposed for 2020 is much greater than the number approved as part of the 2017 protocol.

At a minimum, unless CMS provides instructions to the contrary, we believe that all 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, etc. to access the requested information which cannot be electronically extracted. For a PO of any size this requires many clinical staff to spend many hours combing through medical record documentation. Again, 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.

Referring to the burden estimates on pp. 6-7, POs have reported to NPA that they have had to complete multiple IAs, with the numbers of IAs increasing in 2019. POs have reported having to undertake IAs involving comprehensive medical record reviews for 100% of participants enrolled during the audit review period when non-compliance issues have been identified in a very small number of cases. We realize that IAs are required only when non-compliance has been identified; however, we are concerned that the thresholds for IAs are too low, i.e., that, in some cases, minor instances of non-compliance have led to IAs involving medical record reviews requiring hundreds of hours.

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. **NPA 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. In addition to these recommendations, we offer suggestions for specific modifications to the IA templates in Appendix I.**

- Consistent with comments on p. 3, we believe that auditors are over-interpreting regulatory requirements related to SDRs and grievances which then leads to excessive numbers of RCAs as well as IAs involving comprehensive medical record reviews that are not required to ensure participants' access to care. NPA requests that auditors exercise more discretion to limit the need for exhaustive IAs. For example, a PO reported that an auditor identified a situation in which a participant asked PO staff to repair a walker that had already been approved for the participant's use. Documentation existed that the repair was made timely, but the auditor felt the request should have been processed as an SDR requiring an assessment of the participant and the IDT's approval to proceed with the repair. We believe this is an inappropriate interpretation of the regulation at §460.104(d)(2) and, if it had not been resolved at the central office level, would have led to an IA. In another case, a participant remarked that he needed a shower; in another, that a participant wanted to go to the hospital. These requests were documented in the participants' medical records, and the auditor identified them as SDRs. In situations such as these when requests are made in the course of day to day interactions between PACE participants and staff and the care is provided, auditors should take into account the circumstances surrounding the request and exercise discretion in determining whether it was necessary to pursue the SDR process. Certainly, a request for hospitalization should be addressed immediately and not be processed as an SDR. Similarly, for grievances, in instances where auditors' findings are limited to simple concerns that are addressed in the moment, POs should not be required to undertake exhaustive medical record reviews to determine if complaints were accurately classified as grievances.

- We ask that CMS raise the thresholds for requiring POs to undertake RCAs and IAs. It is POs' 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.

When the number and seriousness of instances of non-compliance in a particular area are low, if an RCA suggests that the means by which the issue should be addressed are well understood, auditors should not proceed to request an IA, particularly when the IA requires substantial amounts of clinical staff time to complete. RCAs alone, together with dialogue between auditors and PO staff, can provide POs and their auditors considerable insight into the scope of the issue. We strongly recommend that auditors exercise more discretion and raise the threshold for requiring IAs. For example, the requirements of POs to maintain medical record documentation are extensive, requiring the medical record to include documentation of all services furnished across all settings, 24/7, 365 days a year. Thresholds for IAs related to medical record documentation should take into account the comprehensiveness of the requirement and the threshold for an IA should be adjusted accordingly so that minor omissions with no consequences for participant care do not lead to IAs consuming hundreds of hours of staff time. We do not believe that such discretion would jeopardize participant experiences or outcomes.

- In situations when a PO feels an IA is not warranted, the PO should have access to the PACE Audit Consistency Team (PACT) or the appropriate individual/staff in central office to express its concerns. The requirement of an IA, particularly when involving manual review of hundreds or even thousands of medical records warrants an opportunity for discussion and explanation that POs feel has not, up to this point, been available to them. We ask that the PACE Audit Process and Data Request document explain to POs how they can exercise such an opportunity.

- In situations in which auditors have concerns that the PO does not fully understand what needs to be done to address and/or remediate a non-compliance issue after completing an RCA and believe an IA is needed, CMS should utilize a sampling methodology and allow for the PO to undertake an IA for a sample, e.g., of 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% 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% of participants; for a program of between 51 and 100 participants, 20% of participants; for a program with more than 100 participants, 15% 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). 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.

7) **Informing PO of Results**

Referring to CMS' process for Informing PO of Results (pp. 4-5 of PACE Audit Process and Data Request document), while the audit process explicitly recognizes POs' ability to respond to conditions cited in the draft audit report, the process does not provide for opportunities for POs to communicate with the PACT regarding ICARs that are communicated by the Audit Team prior to issuance of the draft audit report. POs should have an opportunity to communicate directly with the PACT before ICARs are finalized if they believe the audit team may not have had the information necessary to fully represent the circumstances surrounding a non-compliance issue to the PACT.

8) Audit Survey

We appreciate the addition of the survey to the audit protocol which will provide the CMS an opportunity to gather information on an ongoing, systematic basis on POs' audit experience. In addition to the questions included in the proposed audit survey, we recommend the following:

- In the Pre-Audit Activities section, we ask CMS to include a question asking POs to provide an estimate of the time spent collecting and reviewing data to populate the record layouts/data universes and to identify challenges they encountered in doing so.
- In the Audit Activities section, in addition to asking if 10 business days was a reasonable timeframe for completing IAs, we ask CMS to include a question asking POs to provide an estimate of the total time spent responding to IAs and to identify the staff/disciplines involved in doing so.
- In the Audit Activities section, we request that CMS include an additional question regarding the reasonableness of timeframes for providing other documentation requested during and subsequent to audit field work.
- In the Audit Activities section, we request that CMS ask POs if the audit team utilized a document request log and if the log was accurately maintained for the entire length of the period that documentation requests were made of the PO.
- In the Audit Activities section, we request that CMS ask POs if they had an opportunity to respond to the audit team on conditions being cited and, if necessary, bring their concerns to the PACT. If so, what was the outcome of doing so?
- In the Post-Audit Activities section, we request that CMS ask POs if audit findings, i.e. ICARs, draft audit report, final audit report, were issued timely?
- In the Post-Audit Activities section, we request that CMS ask POs if they had an opportunity to respond to the issuance of an ICAR by discussing it with the PACT. If so, what was the outcome of doing so?
- In the Post-Audit Activities section, we request that CMS ask POs if they disputed any findings included in the draft report and, if so, what was the outcome of doing so, e.g., was a change made to the final audit score?

- In the General Audit Questions section, we ask CMS to expand Questions 3 and 4 to allow POs to provide CMS with specific information on how their audit experiences compared to those of other POs with which they shared information regardless of whether they were part of the same parent organization.

9) Additional Requests for Clarity

- Referring to p. 3 of Attachment1PACEAuditProcessDataRequest and subsequently in the document, we would like to confirm that the reference to "manual" is to the PACE manual. Please clarify.

- Referring to p. 4 of Attachment1PACEAuditProcessDataRequest, in Column AH of the LOPMR and possibly elsewhere in the audit materials, there are references to Level I and Level II data and events. References to Level I and Level II data should be replaced with "PACE Quality Data." This becomes increasingly important over time because new POs are not familiar with Level I and Level II terminology.

- Referring to p. 6 of Attachment1PACEAuditProcessDataRequest, what specifically is CMS requesting with respect to a "current organization chart including staff names and titles?" We assume this is a chart identifying leadership down to the department level and not a complete listing of all staff which is available in the List of Personnel (LOP) universe. Please confirm.

- Referring to p. 8 of Attachment1PACEAuditProcessDataRequest and CMS' instructions related to selecting samples, we seek CMS' confirmation that 1) regardless of whether the SDAG and Personnel elements are done onsite vs. via desk review, the PO will have 2 business days before the review of each element to provide required samples and 2) with respect to medical record samples which POs are required to provide one hour prior to the start of the review of the medical records, there are no expectations of the PO to make copies, print documents, etc. within that timeframe.

- Referring to p. 13 of Attachment1PACEAuditProcessDataRequest, CMS indicates that it will be reviewing, "Documentation that the PO provided Medicare and Medicaid benefits without any limitations or conditions related to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost-sharing." Our understanding of this is that CMS will be reviewing the record to ensure that the PO did not impose fixed or predetermined limitations or conditions related to amount, duration or scope of services, and that the PO did not charge any deductibles, copayments, coinsurance, or other cost-sharing. We request that CMS confirm that this is not intended to imply that the IDT does not have a critical role in assessing participant needs and developing care plans in collaboration with the participant and/or his/her caregiver that are inclusive of/limited to services intended to address these needs.

Thank you for your thoughtful consideration of NPA's comment. We are hopeful that our feedback will lead to CMS' reconsideration of numerous aspects of the proposed PACE 2020 Audit Protocol. If there is any need for additional information or dialogue, please reach out to me (shawnb@npaonline.org) or Chris van Reenen (chrisvr@npaonline.org), NPA's vice president of regulatory affairs. We would very much appreciate the opportunity for continued engagement with CMS staff on this important issue.

Sincerely,

Shawn M. Bloom
President and CEO

In addition to the general comments and recommendations offered on pp 13-16 to reduce the burden related to the IAs, the following are comments specific to individual IAs. For many of the IAs we identify the questions that would require in-depth medical record review and make recommendations for reducing burden. We want to emphasize that we are not offering the specific comments as substitutes for our general comments and recommendations. We are hopeful that CMS will consider and implement them together. Please note the column lettering relates to the IAs only and is exclusive of columns devoted to the RCA. To avoid confusion, column headers/titles are provided.

It is not clear to us if CMS intended for each field in the IA to be filled in. In some cases, instructions for using "NA" are provided; in others not. If CMS intends for POs to enter something for every column in a row, additional instructions for use of "NA" are needed for many of the IAs. Although we do not point this out for all proposed IAs, we have done so for Assessments1P491P501P82 as an example.

Assessments1P491P501P82

In-depth medical record review is required to respond to the following questions:

- Column P – Did any negative outcomes occur as a result of the failure to conduct in-person assessments in response to the change in participant status?
- Column AD – Did any negative outcomes occur as a result of the failure to conduct in-person annual or semi-annual assessments?
- Column AL – Did any negative outcomes occur as a result of the failure to conduct in-person initial assessments?
- Column AM – If yes, describe the negative outcomes.

Recommended changes to reduce burden or improve clarity:

- **Revise Column E – Date of Disenrollment**
  NA should be identified as an acceptable response in situations when the participant is still enrolled.
- **Drop Column I – Enter the IDT members who <u>completed</u> assessments.**
  Focus of this IA is to identify instances in which required IDT members were not involved in change of status assessment process. This information is provided in Column J. Eliminating Column I is an opportunity to reduce data entry.
- **Revise Column J – Enter the IDT members who did <u>not</u> complete assessments.**
  NA should be identified as an acceptable response in situations when all assessments were completed.
- **Revise Column N – Identify the assessments that were <u>not</u> completed in-person.**
  NA should be identified as an acceptable response in situations when all assessments were completed in-person.
- **Drop Column O – Were all required assessments completed in response to the change in status?**

This IA is specific to unscheduled assessments completed in response to change in status; Column O is duplicative of Column H – Is there documentation that assessments were completed by all required IDT members? Eliminating Column O is an opportunity to reduce data entry.

- **Drop Column V – List IDT members who <u>completed</u> assessments.**
  Focus of this IA is to identify instances in which required IDT members were not involved in annual/semiannual assessment process. This information is provided in Column W. Eliminating Column V is an opportunity to reduce data entry.
- **Revise Column W – List the IDT members who <u>DID NOT</u> complete assessments.**
  NA should be identified as an acceptable response in situations when all assessments were completed.
- **Revise Column Y – Identify the assessments that were not completed in-person.**
  NA should be identified as an acceptable response in situations when all assessments were completed in-person.
- **Drop Column AC – Where did the participant reside at the time of the assessments (e.g. home, SNF, ALF, hospital, etc.)?**
  While we understand that the auditors may be interested to know if missed assessments are correlated with place of residence, it is not necessary to request this information for all participants. This information likely would be revealed in the RCA or could be readily ascertained by a review of those participants for whom assessment were determined to be missing. Eliminating Column AC is an opportunity to reduce data entry.
- **Drop Column AF – List the IDT members that did complete assessments.**
  Focus of this IA is to identify instances in which required IDT members were not involved in initial assessment process. This information is provided in Column AG. Eliminating Column AF is an opportunity to reduce data entry.
- **Revise Column AG – List the IDT members who <u>DID NOT</u> complete assessments.**
  NA should be identified as an acceptable response in situations when all assessments were completed.
- **Revise Column AI – Identify any assessments not completed in-person.**
  NA should be identified as an acceptable response in situations when all assessments were completed in-person.

CarePlanContent1P84

In-depth medical record review is required to respond to the following questions:

- Column H – Based upon your PACE organization's care planning standards, were any problems, interventions, or measurable goals <u>missing</u> from the participant's care plan?
- Column I – Please enter the missing problems or interventions that <u>should have been</u> included in the participant's care plan. If multiple problems or interventions were missing, please enter each one on a new line.
- Column K – When should the problems/interventions/goals been included in the care plan?
- Column L – When were the interventions/problems/goals included in the care plan?

- Column M – if the participant experienced negative outcomes, did they occur, in some part, as a result of the failure to provide the service, item, or intervention included in the participant's care plan?
- Column N – If yes, describe the negative outcomes.

Recommended changes to reduce burden or improve clarity:

- **Drop Column F – How many times was the participant's care plan revised during the audit review period?**
  The focus of this IA is on the completeness of the most recent care plan revision. Eliminating Column F is an opportunity to reduce data entry without compromising the remainder of the IA.
- **Revise Column H – Based upon your PACE organization's care planning standards, were any problems, interventions, or measurable goals missing from the participant's care plan?**
  As written, this question would require PO clinical staff to undertake a painstakingly detailed review of each participant's medical record in an effort to second guess the IDT's development of participants' care plans. The scope of the IA should be more limited to address a more specific, objective concern with the PO's care planning process, e.g., are measurable goals missing from the care plan.
- **Revise Column I – Please enter the missing problems or interventions that should have been included in the participant's care plan. If multiple problems or interventions were missing, please enter each one on a new line.**
  Please refer to comments on Column H.
- **Revise Column K – When should the problems/interventions/goals been included in the care plan?**
  Please refer to comments on Column H.
- **Revise Column L – When were the interventions/problems/goals included in the care plan?**
  Please refer to comments on Column H.
- **Revise Column M – If the participant experienced negative outcomes, did they occur, in some part, as a result of the failure to provide the service, item, or intervention included in the participant's care plan? (Yes/No)**
  If left as written, this question should allow for NA as an acceptable response to account for situations in which the participant did not experience a negative outcome; alternatively, the question could be rewritten consistent with similar questions asked in Assessments1P491P501P82. Also, this IA is focused on situations in which problems/interventions/measurable goals are left out of the care plan. This question asks if negative outcomes result from the failure to provide a service, item, or intervention included in the participant's care plan. Please clarify.

CarePlanPartCGInvolvement1P20

In-depth medical record review is required to respond to the following questions:

- Column J – If the participant experienced negative outcomes, did they occur, in some part, as a result of the failure to develop and/or evaluate the care plan in collaboration with the participant or caregiver, or both?
- Column K – If yes, describe the negative outcomes.

Recommended changes to reduce burden:

- **Revise Column F – Date of Initial Development or re-evaluation of Care Plan**
  In the CarePlanContent1P84, the focus is on the most recent care plan revision. This approach could also be used for this IA as a way to reduce burden while still reviewing substantial numbers of care plans. If CMS agrees to this change, Column F would read "Date of the most recent care plan."
- **Drop Column H – Date of care plan development or review**
  Column H is duplicative of Column F.

CenterSrvs1P01

In-depth medical record review is required to respond to the following question:

- Column E – Did any participant attending a PACE Center that does not offer all of the required services experience any negative outcomes?
- Column F – If yes, describe the negative outcomes.

Recommended changes to improve clarity:

- **Revise Column E – Did any participant attending a PACE Center that does not offer all of the required services experience any negative outcomes?**
  Our assumption is that the PO is being asked about negative outcomes that are attributable to the absence of a required service at the Center. Please clarify.

EmergencyCare1P07

Recommended 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.

If the concern underlying this IA relates to instructions that a participant/caregiver may have received from the PO or one of its contracted providers related to accessing emergency services, this IA should be focused on situations in which a participant/caregiver contacted the PO or one of its contracted providers regarding emergency services, in particular those in which the participant did not subsequently access emergency care. We are unclear as to the purpose of

questions related to situations in which 1) the participant utilized emergency services without contacting the PO/contracted provider, or 2) the provider/caregiver contacted the PO/contracted provider and then utilized emergency services, other than to ensure that at no point was the participant or caregiver told that emergency services must be authorized or that steps, e.g., an assessment, must be taken prior to utilizing emergency services. Situations in which participants accessed emergency services without prior contact should not be included in this IA. 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. Further, we do not understand the need for review of emergency room records or the details related to payment for emergency services other than to ensure that the participant was not billed for emergency services as part of this IA. 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.

EmergencyCare1P79

In-depth medical record review is required to respond to the following question:

- Column I – Have any participants experienced negative outcomes that may have resulted from improperly equipped and/or maintained emergency supplies?
- Column J – If yes, describe the negative outcomes.

Recommended changes to reduce burden:

- **Drop Column H – How many participants could have been impacted as a result of improperly equipped and/or maintained emergency supplies?**
  Is CMS' expectation that all participants attending the PACE center could have been impacted by improperly equipped and/or maintained emergency supplies. What is the purpose of quantifying this? We believe the question in Column I, "Have any participants experienced negative outcomes that may have resulted from improperly equipped and/or maintained emergency supplies?", is more meaningful.

PACEIDT1P101P131P15

In-depth medical record review is required to respond to the following questions:

- Column M – If the participant experienced negative outcomes, did they occur, in some part, as a result of the failure to: Develop the initial comprehensive assessment (care plan) in a timely manner; Reevaluate the care plan on a semi-annual basis; or Ensure that all 11 members of the IDT were involved in the development of the initial comprehensive care plan or re-evaluation of the care plan?
- Column T – Were there any negative participant outcomes as a result of the missing IDT member(s)?
- Column U – If yes, describe the negative outcomes.

Recommended changes to reduce burden or improve clarity:

- **Revise Column H – If no, what disciplines were missing from the initial care plan development? List all that were missing.**

NA should be identified as an acceptable response if all required disciplines of the IDT were involved in the development of the initial comprehensive care plan OR the participant's initial enrollment occurred prior to the start of the audit period.

- **Column I – Date the semi-annual care plan revision <u>should</u> have been completed (during the audit review period).**
  We recommend rewording this question as follows: Was the most recent semi-annual care plan revised within 6 months of previous care plan? As in other IAs (CarePlanContent1P84), if more than one care plan revision occurred during the audit review period, we recommend that the IA focus on the most recent care plan revision. Answering a Yes/No question would be less burdensome than entering MM/DD/YYYY and provide assurance that the care plan was completed timely.
- **Column J – Date the semi-annual care plan evaluation was <u>actually</u> completed (during the audit review period).**
  As in other IAs (CarePlanContent1P84), if more than one care plan revision occurred during the audit review period, we recommend that the IA focus on the most recent care plan revision. This would reduce burden.
- **Column L – If no, what disciplines were missing from the semi-annual care plan development? List all that were missing.**
  NA should be identified as an acceptable response if all required disciplines of the IDT were involved in the development of the semi-annual care plan OR the participant should not have had a semi-annual care plan during the audit review period.
- **Column M – If the participant experienced negative outcomes, did they occur, in some part, as a result of the failure to develop the initial comprehensive assessment in a timely manner; reevaluate the care plan on a semi-annual basis; or ensure that all 11 members of the IDT were involved in the development of the initial comprehensive care plan or re-evaluation of the care plan?**
  The reference to "initial comprehensive assessment" should be replaced with "initial comprehensive care plan."

CDC1P25

In-depth medical record review is required to respond to the following question:

- Column L – Have any participants experienced negative outcomes that may have resulted from a failure to utilize CDC standard precautions?
- Column M – If yes, describe the negative outcomes and how many participants were affected.

Recommended changes to reduce burden:

- No specific comments.

MedRecs1P22

Recommended changes to reduce burden:
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. For an average size PO with approximately 300 participants, based on POs' experience under the current audit protocol, we estimate such an undertaking would require a minimum 300 hours of clinical staff time just to review the records, 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.

PracticeScope1P33

In-depth medical record review is required to respond to the following questions:
- Column L – Is there documentation that the staff member acted outside the scope of his or her authority to practice during the audit review period?
- Column N – Describe how the staff member acted outside the scope of his or her authority to practice?
- Column O – When did the staff member begin/start to act outside the scope of his or her authority to practice?
- Column P – When did the staff member stop acting outside the scope of his/her authority to practice?
- Column Q – Have any participants experienced negative outcomes that may have resulted of the staff member acting outside his or her authority to practice?
- Column R – If yes, describe the negative outcomes and how many participants were affected.

Recommended changes to reduce burden:
Requiring the PO to complete this IA for all staff, employed and contracted, who had direct participant contact in the PACE center or participant home during the audit review period is excessive. If the auditor identified a compliance issue with a particular staff person or type of staff position, at a minimum, the IA should be limited to that person/position.

Grievances1P311P751P77

In-depth medical record review is required to respond to the following questions:

- Column L – Did the participant experience any negative outcomes as a result of the failure to resolve all issues within a grievance?
- Column M – Did the participant, their family members, or representatives express a complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished during the audit review period?
- Column V – Were there any negative participant outcomes as a result of the failure to recognize complaints as grievances?
- Column Z – Were there any negative outcomes as a result of the participant not being informed of the grievance process?
- Column AB – If the participant experienced any negative outcomes, please describe the negative outcomes.

Recommended changes to reduce burden or improve clarity:

For the IA that is focused on "recognizing complaints as grievances," the requirement that POs review all participant medical records, on-call records, PAC minutes, etc. during the audit review period is burdensome. Again, this will involve review of a huge volume of materials, particularly with respect to participant medical records involving all assessments, progress notes, etc. Further, as discussed earlier, we are concerned that CMS has not responded to NPA's request for further clarification of grievances. In the event that a RCA is not sufficient, the sampling methodology that we recommend would limit the burden of the medical record review to something more manageable.

- **Column X – Is their (sic) documentation that the participant was informed of the grievance process, in writing, on an annual basis? (Yes/No) Enter NA if the participant was not disenrolled before the grievance process was reviewed or if the participant was newly enrolled.**

  Should the directions read: "Enter NA if the participant was disenrolled before the grievance process was reviewed or if the participant was newly enrolled."

Personnel

In-depth medical record review is required to respond to the following question:

- Column Y – Have any participants experienced negative outcomes as a result of non-compliance with personnel requirements?
- Column Z – If participants experienced negative outcomes, describe the negative outcomes and how many participants were affected.

Recommended changes to reduce burden:

We believe this IA could be organized more efficiently to prevent POs from having to enter unnecessary information. The Personnel Record Layout will be the basis for identifying the staff for which the IA applies. Our assumption is that NAs will be required for all columns that do not apply, e.g., if the IA is being requested for personnel competencies only, this approach would

eliminate the need for the PO to respond NA in all columns that do not relate to personnel competencies and would not require the PO to list personnel who were hired before the first day of the collection period and/or did not provide direct participant contact. We suggest it would be less cumbersome to separate this IA into separate IAs for each issue of non-compliance.

SDRIdentification1P76

In-depth medical record review is required to respond to the following questions:

- Column F – Did the participant or their representative request to initiate, eliminate or continue a particular item or service during the audit review period?
- If the PO responded "Yes" to Column F but did not process the request as an SDR, many of the following column would also require medical record review. If processed as an SDR, much of this information is available on the SDR record layout/data universe.
- Column Q – Were there any negative participant outcomes? We assume this would be related to non-compliance with identification or processing of SDR.
- Column R – If yes, describe the negative outcomes.

Recommended changes to reduce burden:

For this IA that is focused on identifying service delivery requests, the requirement that POs review all participant medical records, on-call records, PAC minutes, etc. during the audit review period is burdensome. Again, this will involve review of a huge volume of materials, particularly with respect to participant medical records involving all progress notes, etc. Further, as discussed earlier, we are concerned that CMS has not responded to NPA's request for further clarification of service delivery requests, so there are legitimate questions outstanding with respect to whether a request or inquiry qualifies as a service delivery request and requires the involvement of the full interdisciplinary team, e.g., requests to repair existing equipment or modify existing services in ways that do not change the amount, scope or duration of the service. While some auditors are requiring POs to pursue IAs in these instances, this seems to us an inappropriate interpretation of the regulation at 460.104(d)(2). Further, as written, many of the service delivery requests identified in Columns F (Did the participant or their representative request to initiate, eliminate or continue a particular item or service during the audit review period?) were included on the Service Delivery Requests Record Layout and the information required of POs in response to the IA is duplicative of information already provided, e.g., Description of the Request, Is there documentation that the request was processed as a service delivery request, Request Disposition, etc. At a minimum, we request that CMS limit the number of records subject to review by employing sampling methodology.

SDRExtensions1P58

In-depth medical record review is required to respond to the following question:

- Column P – Were there any negative participant outcomes?
- Column Q – If yes, describe the negative outcomes.

Recommended changes to reduce burden or improve clarity:

We believe this IA could be organized more efficiently to prevent POs from having to enter unnecessary information. The Service Delivery Requests Record Layout is the basis for identifying

service delivery requests for which an extension was taken, and the IA should be limited to service delivery requests for which the PO responded "Y" in Column M (Extension) of the SDR record layout/data universe. In this way the PO will not have to enter data for service delivery requests for which there was no extension.

- **Column M – Enter the date the service delivery request was approved or denied.**
  We recommend asking for the date the participant received oral or written notification; if both, the latter of the two dates; this is consistent with information requested in the SDR Record Layout.
- **Column P – Were there any negative participant outcomes?**
  The question should be more specific in terms of negative participant outcomes attributable to the SDR extension?

SDRs1P601P611P85

In-depth medical record review is required to respond to the following questions:

- Column L – Were there any negative participant outcomes as a result of the failure to provide oral and/or written notification including the specific reason for the denial in understandable language?
- Column Q – Were there any negative participant outcomes as a result of the failure to provide oral and/or written notification including appeal rights?
- Column Y – Were there any negative participant outcomes as the result of a failure to ensure that the service delivery request was reviewed by the complete IDT?
- Column Z – If yes, describe the negative outcomes.

Recommended changes to reduce burden:

- **Drop Column S – Which IDT members were involved in the review of the service delivery request?**
  Focus of this IA is to identify instances in which required IDT members were not involved in review of the service delivery request. This information is provided in Column T. Eliminating Column S is an opportunity to reduce data entry.

Effectuation1P021P111P30

In-depth medical record review is required to respond to the following questions:

- Column O – Did the participant experience any negative outcomes between the date the service was approved and the date that the service was provided?
- Column Y – If the participant requested to continue the service and the service was not continued, were there any negative participant outcomes?
- Column AJ – Did the participant experience any negative outcomes between the date the service was approved and the date that the service was provided?
- Column AK – If the participant experienced any negative outcomes, please describe the negative outcomes.
- Column AL – If the participant experienced negative outcomes, did they appear, in some part, as a result of the failure to provide the item or services?

Recommended changes to reduce burden or improve clarity:

- **Column H – Date the SDR was approved by the IDT**
  Is this necessary since the date oral/written notification is provided in Column I?
- **Column L – Was the service approved by the IDT?**
  Isn't this IA limited to approved SDRs? This question is duplicative.
- **Column AA – Was the service approved or denied by the third-party reviewer?**
  Should this be approved, denied or partially approved/denied?
- **Column AF – Was the final decision Approved, Denied, or Partially Approved/Denied?**
  If the participant did not pursue an additional appeal hearing through Medicare or Medicaid, is final decision same as decision of third-party reviewer in Column AA?
- **Column AH – If the service was approved or partially approved by either the third-party, Medicaid, or Medicare reviewer, enter the date that the service was provided or resumed. Enter NA if the service was denied by the third-party.**
  Should NA be expanded to include situations in which the service was denied by the third-party, Medicaid or Medicare reviewer?

HomeCare1P02

In-depth medical record review is required to respond to the following question:

- Column S – Were there any negative outcomes resulting from: a) A delay in the start of home care; b) Not providing home care; or c) A reduction in the number of hours of home care?
- Column T – If Yes, please describe the negative outcomes.

Recommended changes to improve clarity:

- **Column F – During the Audit Review Period a. Did the IDT recommend or approve home care; b. Did a physician or NP order home care; or c. Was home care included in the care plan.**
  Referring to "a. Did the IDT recommend or approve home care," we would appreciate clarification of the difference between "recommend" and "approve." If the IDT collectively recommends home care, home care would be approved. We suggest it would be clearer to refer to approval only, i.e., Did the IDT approve home care.
  Referring to "b. Did a physician or NP order home care," the decision to include home care in a participant's care plan is a collective IDT decision which may then lead to a physician order to effectuate. We suggest that b. should not be included as a distinct option for identifying whether or not home care should have been provided.
- **Column G – If the answer to Column F is Yes, please indicate whether the home care was: a. IDT recommended; b. Approved as part of a service delivery request; c. Approved as part of an appeal; d. Ordered by a physician or NP?**
  Consistent with comments on Column F, we suggest that a. be changed to a. IDT approved and that d. be eliminated.

ProvisionofServices1P021P81and SrvcRestric1P90

The scope of these IAs is overwhelming in that it 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. Ideally, an alternative to an IA process will be developed. If not, utilizing a sampling method or some means by which the number of participants included in these IAs is reduced very substantially is critical.

We also note that it is unclear to us why the options in Columns F and G of ProvisionofServices1P021P81 are not "Recommended by the IDT" without referencing an individual IDT member. The same is true in Columns F and H in SrvcRestric1P90. As written, the implication is that the IDT does not have an important role in considering information from individual IDT members and collectively developing a recommendation. This is a critical responsibility of the IDT.

AppealEx1P71

In-depth medical record review is required to respond to the following question:

- Column L – Were there any negative participant outcomes?
- Column M – If yes, describe the negative outcomes.

Recommended changes to improve clarity:

- **Column L – Were there any negative participant outcomes?**
  Please clarify that this question is focused on negative outcomes related to the extension of the expedited appeal.

AlertIDT1P14

The scope of this IA is overwhelming in that it requires a detailed review of all participant's medical record documentation and communications among IDT members, other providers and caregivers to determine if there were any instances in which a provider failed to communicate "pertinent information regarding the participant's medical, functional, or psychosocial condition to members of the IDT." Again, undertaking such a review for hundreds of participants would require an enormous amount of clinical staff time, diverting these resources from participant care. Ideally, an alternative to an IA process will be developed. If not, utilizing a sampling method or some means by which the number of participants included in this IAs is reduced very substantially is critical.

Appeals1P651P661P681P73

For the portion of IA focused on "categorizing appeals," is it CMS' expectation that the PO undertake an exhaustive medical record review for all participants during the audit review period? If so, this will involve review of a huge volume of materials inclusive of all assessments, progress notes, etc. In the event that a RCA is not sufficient, the sampling methodology that we recommend would limit the burden of the medical record review to something more manageable.

In addition, we note that the titles for each of the components of this IA are not descriptive of the entire scope of evaluation for non-compliance. More descriptive titles may avoid confusion.