Section in Current CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I PACE Audit Process and Data Request	2017	Removed specific year.	None.
Title Page		25 110 11	
Attachment I PACE Audit Process and Data Request Audit Purpose and General Guidelines Pre-Audit Identified Issues of Non-Compliance	Pre-Audit Identified Issues of Non-Compliance: POs will be asked to provide a list of all identified issues of non-compliance that occurred during the audit review period. This could include issues that were self-identified by the PO (that may or may not have been disclosed to CMS) or issues identified by CMS during the course of the audit review period. Please do not include all issues identified by your organization, just those that are relevant to the areas being audited. Also, please exclude Level I and Level II data that has already been reported to CMS. Within 5 business days after receipt of the engagement letter, POs must provide a description of each issue as well as the remediation status (what was corrected and when) using the Pre-Audit Issue Summary template (Attachment III). The PO's Account Manager	Modified the title and text to only include disclosed issues previously reported to CMS.	Pre-Audit Disclosed Issues of Non-Compliance: POs will be asked to provide a list of all disclosed issues of non-compliance that are relevant to the elements being audited and may be detected during the audit. A disclosed issue is one that has been reported to CMS prior to the receipt of the audit start notice (which is also known as the "engagement letter"). Issues identified by CMS or the SAA through on-going monitoring or other account management/oversight activities during the audit year are not considered disclosed. POs should exclude Level I and Level II data already reported to CMS. POs must provide a description of each disclosed issue as well as the status of correction and remediation using the Pre-Audit Issue Summary template (Attachment III). This template is due within 5
	will review the summary for accuracy and completeness. CMS will consider an issue corrected if the PO can demonstrate that correction or remediation was implemented prior to the engagement letter being sent. Issues that are reported as uncorrected may be cited as conditions in the CMS audit report. Issues reported as corrected after the date of the audit start notice will be treated as uncorrected issues. Issues that are reported as corrected prior to the audit review period will be assumed to be corrected. However, if the CMS discovers during the audit that the issue was not actually corrected, CMS may cite the applicable conditions in the audit report. For issues that are reported as corrected during the audit review period, CMS may validate correction during the audit. Auditors will validate correction if it can be accomplished simply (e.g., observing a wound dressing, pulling a medical record, etc.). When correction is validated the issue will be noted as an observation in the organization's audit report.		business days after the receipt of the audit start notice. The PO's Account Manager will review Attachment III to validate that "disclosed" issues were known to CMS prior to receipt of the audit start notice. When CMS determines that a disclosed issue was promptly identified, corrected (or is actively undergoing correction), and the risk to participants has been mitigated, CMS will not apply the ICAR condition classification to that condition.

Section in Current CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I PACE Audit Process and Data Request Audit Purpose and General Guidelines Impact Analysis (IA)	An impact analysis template must be submitted as requested by CMS for any issue discovered during the audit that has potential participant impact and may be cited as a condition of noncompliance. CMS may validate the accuracy of the IA submission(s).	Clarified language surrounding IA templates, including an extended timeframe for submitting IA templates (10 business days).	An impact analysis must be submitted as requested by CMS. The impact analysis must identify all participants subjected to or impacted by the issue of non-compliance. POs will have up to 10 business days to complete the requested impact analysis templates. CMS may validate the accuracy of the impact analysis submission(s). In the event an impact analysis cannot be produced, CMS will report that the scope of non-compliance could not be fully measured and impacted an unknown number of participants within the PO.
Attachment I PACE Audit Process and Data Request Audit Purpose and General Guidelines Calculation of Score	Observations will be recorded in the draft and final reports, but will not be scored and therefore will not be included in the program area and audit scores.	Deleted the term "program area" for clarity.	Observations will be recorded in the draft and final reports, but will not be scored and therefore will not be included in the audit scores.
Attachment I PACE Audit Process and Data Request Audit Purpose and General Guidelines Informing PO of Results	CMS will provide daily updates regarding conditions discovered that day (unless the case has been pended for further review).	Changed "the case" to "a sample" for clarity.	CMS will provide daily updates regarding conditions discovered that day (unless a sample has been pended for further review).
Attachment I PACE Audit Process and Data Request Universe Preparation & Submission Responding to Universe and Documentation Requests	The PO is expected to provide accurate and timely universe and documentation submissions within 30 calendar days of the engagement letter date. CMS may request a revised universe if data issues are identified. The resubmission request may occur before and/or after the entrance conference depending on when the issue is identified. POs will have a maximum of 3 attempts to provide complete and accurate universes, whether these attempts all occur prior to the entrance conference or they include submissions prior to and after the entrance conference. When multiple attempts are made, CMS will only use the last universe submitted. If the PO fails to provide accurate and timely universe submissions after three attempts, CMS will document this as an observation in the PO's program audit report.	Deleted text for clarity.	The PO is expected to provide accurate and timely universe and documentation submissions within 30 calendar days of the engagement letter date. CMS may request a revised universe if data issues are identified.

Section in Current CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I PACE Audit Process and Data Request Universe Preparation & Submission Pull Universes and Submit Documentation Documentation	 Completed PACE questionnaire (PACEQ) The PO's QAPI plan(s) that were in use during the audit review period PAC Minutes for the audit review period 	Replaced old name with updated/ corrected attachment name and spelled out acronyms.	Completed PACE Supplemental Questions (Attachment II) The PO's Quality Assessment and Performance Improvement (QAPI) plan(s) that were in use during the audit review period Participant Advisory Committee (PAC) Minutes for the audit review period
Attachment I PACE Audit Process and Data Request Universe Preparation & Submission Pull Universes and Submit Documentation Data Universes	For the quality assessment universe, the PO should identify each quality initiative that occurred and the corresponding data used in the quality initiative during the audit review period. Data could include examples such as hospitalizations, falls, grievances, appeals, medical records, audits, etc.	Included a definition of quality initiatives.	For the quality assessment universe, the PO should identify each quality initiative that occurred and the corresponding data used in the quality initiative during the audit review period. A quality initiative is a set of data used to measure and identify areas of good or problematic performance within a PACE organization. Data could include examples such as hospitalizations, falls, grievances, appeals, medical records, audits, etc.
Attachment I PACE Audit Process and Data Request Universe Preparation & Submission Pull Universes and Submit Documentation Data Universes	The universes should be 1) all inclusive, regardless of whether the request was determined to be approved, denied, or partially approved and 2) submitted in the appropriate record layout as described in Appendix A.	Replaced "partially approved" with "partially denied" for consistency.	The universes should be 1) all inclusive, regardless of whether the request was determined to be approved, denied, or partially denied and 2) submitted in the appropriate record layout as described in Appendix A.
Attachment I PACE Audit Process and Data Request Universe Preparation & Submission Submit Universes to CMS	No later than 72 hours following receipt of the request by the IDT. The PO may extend the decision up to 5 days when applicable.	Clarified language to better reflect the regulatory requirement.	No later than 72 hours following the date the request was received by the IDT. The PO may extend the decision up to 5 days when applicable.

Section in Current CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I PACE Audit Process and Data Request Universe Preparation & Submission Submit Universes to CMS	No later than 30 days from the date of receipt for standard appeals. No more than 72 hours from receipt for expedited appeals.	Clarified language by adding "of the appeal".	No later than 30 days from the date of receipt for standard appeals. No more than 72 hours from receipt of the appeal for expedited appeals.
Attachment I PACE Audit Process and Data Request Universe Preparation & Submission	None.	Added a fourth bullet called "selecting samples" to clarify CMS sampling process.	4. Selecting Samples: Auditors will review the universes collected from the PO and select samples in accordance with the instructions noted below. For each element, the selected samples will be given to the PO 1 business day before the review of that element begins.
Attachment I PACE Audit Process and Data Request Audit Elements Service Delivery Requests, Appeals and Grievances (SDAG) Select Sample Cases	In sampling, CMS will select 30 targeted cases that appear significant. CMS will attempt to ensure that the sample set is representative of various types of service requests, grievances and appeals. The sample set will be selected from the universe categories as follows:	Added clarification on how CMS will target samples.	In sampling, CMS will select 30 targeted cases that appear significant. CMS will attempt to ensure that the sample set is representative of various types of service requests, grievances and appeals. CMS will use the PAC Minutes, the On-Call Universe and the List of Participant Medical Records in order to target samples for review. The sample set will be selected from the universe categories as follows:
Attachment I PACE Audit Process and Data Request Audit Elements Service Delivery Requests, Appeals and Grievances (SDAG) Review Sample Case Documentation For Grievances	 Documentation showing resolution notification to the beneficiary and/or their representative. Copy of the written decision letter sent and documentation of date/time letter was mailed. If oral notification was given, copy of medical record notes and/or documentation of call including date/time stamp. 	Changed "beneficiary" to "participant". Changed "decision" to "resolution". Deleted "time stamp".	 Documentation showing resolution notification to the participant and/or their representative. Copy of the written resolution letter sent and documentation of date/time letter was mailed. If oral notification was given, copy of medical record notes and/or other documentation of call including the date.

Section in Current CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I PACE Audit Process and Data Request	3.1.4 Did the PO provide the participant with a reasonable opportunity to present evidence during their appeal?	Changed language to make it plural.	3.1.4 Did the PO provide the participants with a reasonable opportunity to present evidence during their appeals?
Audit Elements			
Service Delivery Requests, Appeals and Grievances (SDAG)			
Apply Compliance Standard			
Attachment I PACE Audit Process and Data Request Audit Elements	3.3.3 Did the PO process an appeal within 30 days, or, for expedited appeals, within 72 hours?	Clarified language to include "after the PO receives the appeal".	3.3.3 Did the PO process an appeal within 30 days, or, for expedited appeals, within 72 hours after the PO receives the appeal?
Service Delivery Requests, Appeals and Grievances (SDAG)			
Apply Compliance Standard			
Attachment I PACE Audit Process and Data Request Audit Elements	In sampling, CMS will select 10 targeted medical records that appear clinically significant. CMS will attempt to ensure that the sample set is representative of various types of service requests and care (e.g., hospitalizations, wound care, dialysis, social needs,	Added a sentence to clarify CMS sampling process.	In sampling, CMS will select 10 targeted medical records that appear clinically significant. CMS will attempt to ensure that the sample set is representative of various types of service requests and care (e.g., hospitalizations, wound care, dialysis, social needs, home bound,
Clinical Appropriateness & Care Planning	home bound, skilled nursing, etc.).		skilled nursing, etc.). CMS will also utilize the SDAG universes, the On-Call Universe, and the PAC minutes in order to appropriately target participants.
Select Sample Cases			

Section in Current CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I PACE Audit Process and Data Request Audit Elements Clinical Appropriateness & Care Planning Review Sample Case Documentation	Documentation that assessments were done in person when applicable	Removed "when applicable". Added a period at the end of the sentence.	Documentation that assessments were done in person.
Attachment I PACE Audit Process and Data Request Audit Elements Clinical Appropriateness & Care Planning Apply Compliance Standard	3.5 Did the PO develop and document an appropriate plan of care for the participants? 3.5.1 Did the PO promptly and appropriately develop a plan of care that meets the minimum requirements for each participant? 3.5.2 Did the PO appropriately evaluate and monitor the participants' plan of care? 3.5.3 Did the PO ensure that the appropriate IDT members were involved in creating the plan of care?	Changed "plan of care" to "care plan" for consistency.	3.5 Did the PO develop and document an appropriate care plan for the participants? 3.5.1 Did the PO promptly and appropriately develop a care plan that meets the minimum requirements for each participant? 3.5.2 Did the PO appropriately evaluate and monitor the participants' care plan? 3.5.3 Did the PO ensure that the appropriate IDT members were involved in creating the care plan?
Attachment I PACE Audit Process and Data Request Audit Elements Clinical Appropriateness & Care Planning Apply Compliance Standard	3.5.4 Was an explanation of care plan changes given to the participant, if appropriate? 3.5.5 Did the participant have a role in care plan decisions, if appropriate?	Removed "if appropriate" from the compliance standards.	3.5.4 Was an explanation of care plan changes given to the participant? 3.5.5 Did the participant have a role in care plan decisions?

Section in Current CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I PACE Audit	CMS will select a targeted sample of 10 personnel records. CMS	Added "volunteers" to be	CMS will select a targeted sample of 10 personnel records. CMS will
Process and Data Request	will attempt to ensure that the sample set is representative of various types of employees, including part-time, full-time,	consistent with universe description.	attempt to ensure that the sample set is representative of various types of employees, including part-time, full-time, contract,
Audit Elements	contract, etc.	description.	volunteers, etc.
Personnel Records			
Select Sample Cases			
Attachment I PACE Audit	3.5.1 Were competency evaluations done for individuals	Added a question mark at the	3.5.1 Were competency evaluations done for individuals performing
Process and Data Request	performing participant care	end of the sentence.	participant care?
Audit Elements			
Personnel Records			
Apply Compliance Standard			
Attachment I PACE Audit	CMS will observe 3 to 5 participants while onsite, one that	Modified language for clarity	CMS will observe 3 to 5 participants while onsite, including at least
Process and Data Request	receives care from home, and at least one that receives care at the center. CMS may observe more participants while onsite if an	and readability.	one who receives care from home and one who receives care at the center. CMS may observe more participants while onsite if an issue
Audit Elements	issue is noted that warrants additional review.		is noted that warrants additional review.
Onsite Review			
Select Participants for			
Observation			
Attachment I PACE Audit Process and Data Request	Review Sample Case Documentation: The PO should be able to provide the following access to CMS auditors:	Changed title to include "and Observations". Added	Review Sample Case Documentation and Observations: The PO should be able to provide the following access to CMS auditors:
1 Tocess and Data Request	A private area (can be the clinic) to view a	"willing" into first bullet.	A private area (can be the clinic) to view a willing
Audit Elements	participant receiving care,	Added a bullet for IDT	participant receiving care,
Onsite Review	A home visit of a willing participant, A distribution of the control of the	observations.	A home visit of a willing participant, A home visit of a willing participant, CNED if
Offsite Review	 A visit to an outside facility (such as a SNF), if applicable, 		A visit to an outside facility (such as a SNF), if applicable,
	 At least one transportation vehicle used to transport 		At least one transportation vehicle used to transport
	participants to and from the center,		participants to and from the center,
	Any emergency equipment the center has available.		 Any emergency equipment the center has available. An IDT meeting for CMS observation.

Section in Current CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I PACE Audit Process and Data Request Audit Elements Onsite Review Apply Compliance	3.1 Does the PO have a method of communicating between the van and the PACE organization?	Changed "organization" to "center" to align with regulation.	3.1 Does the PO have a method of communicating between the van and the PACE center?
Standard Attachment I PACE Audit Process and Data Request Audit Elements Onsite Review Apply Compliance Standard	3.3.1 Has the PACE organization appropriately established an interdisciplinary team at each PACE center?	Changed "PACE organization" to "PO" and "interdisciplinary team" to "IDT" for consistency.	3.3.1 Has the PO appropriately established an IDT at each PACE center?
Attachment I PACE Audit Process and Data Request Audit Elements Onsite Review Apply Compliance Standard	3.5 Does the PO follow appropriate infection control standards when providing care? 3.5.1 Did they wash/sanitize hands as appropriate? 3.5.2 Did they don and doff personal protective equipment as appropriate? 3.5.3 Did they follow aseptic technique, if applicable?	Changed "they" to "personnel" and removed compliance standard 3.5.3.	3.5 Does the PO follow appropriate infection control standards when providing care? 3.5.1 Did personnel wash/ sanitize hands as appropriate? 3.5.2 Did personnel don and doff personal protective equipment as appropriate?
Attachment I PACE Audit Process and Data Request Audit Elements Onsite Review Apply Compliance Standard	3.7.3 During an assessment or treatment, were any progress notes appropriately documented?	Removed "any" for clarity.	3.7.3 During an assessment or treatment, were progress notes appropriately documented?

Section in Current CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I PACE Audit Process and Data Request Audit Elements	3.8 Does the PO follow their dietary care plans by providing food in the form necessary for participant's needs?	Removed "their" for clarity.	3.8 Does the PO follow dietary care plans by providing food in the form necessary for participant's needs?
Onsite Review Apply Compliance Standard			
Attachment I PACE Audit Process and Data Request Audit Elements Onsite Review Onsite Review Results	If CMS auditors determine that requirements are not met while conducting the onsite review, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited.	Added the first sentence for consistency with other elements.	CMS will conduct onsite observations. If CMS auditors determine that requirements are not met while conducting the onsite review, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited.
Attachment I PACE Audit Process and Data Request Audit Elements Quality Assessment Select Sample Cases	CMS will select two tracers, using the quality assessment universe, appeals and grievances documentation, onsite interviews and discussions with the PO, a review of participant medical records, etc. to determine the effectiveness of the POs quality assessment and performance improvement (QAPI) program.	Changed "quality assessment universe" to "Quality Assessment Initiatives Records" universe for consistency.	CMS will select two tracers, using the Quality Assessment Initiatives Records universe, appeals and grievances documentation, onsite interviews and discussions with the PO, a review of participant medical records, etc. to determine the effectiveness of the POs quality assessment and performance improvement (QAPI) program.
Attachment I PACE Audit Process and Data Request Audit Elements Quality Assessment Sample Case Results	CMS will use the tracer to assess whether CMS requirements are met. If CMS requirements are not met, conditions (findings) are cited.	Changed "tracer" to "tracers" for consistency.	CMS will use the tracers to assess whether CMS requirements are met. If CMS requirements are not met, conditions (findings) are cited.

Section in Current CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I PACE Audit Process and Data Request Table 1 – Column ID F Column ID N Column ID O Column ID Q Column ID S Column ID U	Field Name: Time Service Delivery Request Received Field Name: Date of Decision Field Name: Time of Decision Field Name: Time of Oral Notification Field Name: Time of Written Notification Field Name: Quality Analysis	Deleted these columns from the record layout.	None.
Attachment I PACE Audit	Column ID L	Changed Column ID.	Column ID K
Process and Data Request	Field Name: Request Disposition	Changed field length from 10	Field Name: Request Disposition
	Field Length: 10	to 16. Changed field	Field Length: 16
Table 1 – Column ID L	Field Description: Provide the request disposition for the service delivery request. Valid fields include: Approved or Denied.	description to include "partially denied" as an option.	Field Description: Provide the request disposition for the service delivery request. Valid fields include: Approved, Denied or Partially Denied.
Attachment I PACE Audit	Field Name and Column ID:	Changed Column ID.	Field Name and Column ID:
Process and Data Request			
	Column ID G: Category of the Request		Column ID F: Category of the Request
Table 1 –	Column ID H: Description of the Request		Column ID G: Description of the Request
	Column ID I: Date(s) Assessment(s) Performed		Column ID H: Date(s) Assessment(s) Performed
Column ID	Column ID J: Discipline(s) Performing Assessment(s)		Column ID I: Discipline(s) Performing Assessment(s)
	Column ID K: Assessment(s) In Person		Column ID J: Assessment(s) In Person
	Column ID M: Extension		Column ID L: Extension
	Column ID P: Date of Oral Notification		Column ID M: Date of Oral Notification
	Column ID R: Date of Written Notification		Column ID N: Date of Written Notification
	Column ID T: Date service provided		Column ID O: Date service provided

Section in Current CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I PACE Audit Process and Data Request Table 2 – Introduction Text	Submit cases based on the date the PACE organization's decision was rendered or should have been rendered (the date the request was initiated may fall outside of the review period).	Changed "PACE organization's" to "PO's".	Submit cases based on the date the PO's decision was rendered or should have been rendered (the date the request was initiated may fall outside of the review period).
Attachment I PACE Audit Process and Data Request Table 2 – Column ID K Column ID M Column ID N	Field Name: Reviewer Field Name: Date of Decision Field Name: Time of Decision	Deleted these columns from the record layout.	None.
Attachment I PACE Audit Process and Data Request Table 2 – Column ID F	Field Length: 8 Field Description: Provide the time the appeal was received by the PO. Submit in HH:MM:SS format (e.g. 23:54:23). Enter NA for an appeal that was not expedited.	Changed field length to 5. Changed field description to no longer request seconds for time.	Field Length: 5 Field Description: Provide the time the appeal was received by the PO. Submit in HH:MM format (e.g. 23:54). Enter NA for an appeal that was not expedited.
Attachment I PACE Audit Process and Data Request Table 2 – Column ID J	Field Description: Provide a description of the issue and, for denials, an explanation of why the decision was denied.	Changed "the decision" to "the appeal".	Field Description: Provide a description of the issue and, for denials, an explanation of why the appeal was denied.
Attachment I PACE Audit Process and Data Request Table 2 – Column ID L	Column ID L Field Name: Request Disposition Field Length: 10 Field Description: Provide the request disposition for the appeal. Valid fields include: Approved or Denied.	Changed Column ID. Changed field length from 10 to 16. Changed field description to include "partially denied" as an option.	Column ID K Field Name: Request Disposition Field Length: 16 Field Description: Provide the request disposition for the appeal. Valid fields include: Approved, Denied or Partially Denied.

Section in Current CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I PACE Audit	Column ID P	Changed Column ID.	Column ID M
Process and Data Request	Field Name: Time of Oral Notification	Changed field length from 8	Field Name: Time of Oral Notification
1	Field Length: 8	to 5. Changed field	Field Length: 5
Table 2 – Column ID P	Field Description: Time the PO provided oral notification of the	description to no longer	Field Description: Time the PO provided oral notification of the
	decision to the participant or caregiver. Submit in HH:MM:SS	request seconds for time and	decision to the participant or caregiver. Submit in HH:MM format
	format (e.g. 23:59:59). Enter NA if no oral notification was	also added an option for NA if	(e.g. 23:59). Enter NA if no oral notification was provided or if the
	provided.	the request was not expedited.	request was not expedited.
Attachment I PACE Audit	Column ID R	Changed Column ID.	Column ID O
Process and Data Request	Field Name: Time of Written Notification	Changed field length from 8	Field Name: Time of Written Notification
	Field Length: 8	to 5. Changed field	Field Length: 5
Table 2 – Column ID R	Field Description: Time the PO provided written notification of	description to no longer	Field Description: Time the PO provided written notification of the
	the decision to the participant or caregiver. Submit in HH:MM:SS	request seconds for time and	decision to the participant or caregiver. Submit in HH:MM format
	format (e.g. 23:59:59). Enter NA if no oral notification was	also added an option for NA if	(e.g. 23:59). Enter NA if no written notification was provided or if
	provided.	the request was not expedited.	the request was not expedited.
Attachment I PACE Audit	Column ID T	Changed Column ID. Added	Column ID Q
Process and Data Request	Field Description: Yes (Y) / No (N) indicator on whether an	"particular" into the field	Field Description: Yes (Y) / No (N) indicator on whether an
T. I. 2 G. I. ID. T.	analysis of this appeal was included in your QAPI program?	description.	analysis of this particular appeal was included in your QAPI
Table 2 – Column ID T			program?
Attachment I PACE Audit	Field Name and Column ID:	Changed Column ID.	Field Name and Column ID:
Process and Data Request			
	Column ID O: Date of Oral Notification		Column ID L: Date of Oral Notification
Table 2 –	Column ID Q: Date of Written Notification		Column ID M: Date of Written Notification
	Column ID S: Date service provided		Column ID P: Date service provided
Column ID			
Attachment I PACE Audit	Field Description: Yes (Y) / No (N) indicator on whether an	Added "particular" into the	Field Description: Yes (Y) / No (N) indicator on whether an
Process and Data Request	analysis of this grievance was included in your QAPI program?	field description.	analysis of this particular grievance was included in your QAPI
Table 3 – Column ID L			program?

Section in Current CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I PACE Audit Process and Data Request Table 4 — Column ID J Column ID K Column ID L Column ID M	Field Name: Background Check Field Name: Excluded Provider List Field Name: Competency Evaluations Field Name: OSHA Training	Deleted these columns from the record layout.	None.
Attachment I PACE Audit Process and Data Request Table 4 – Column ID I	Field Length: 1 Field Description: Yes (Y) / No (N) indicator of whether the employee is licensed for their job with the PACE organization.	Changed field length to 2. Changed "PACE organization" to "PO" and changed field description to include an option for NA when the position does not require a license.	Field Length: 2 Field Description: Yes (Y) / No (N) indicator of whether the employee is licensed for their job with the PO. Enter NA if the employee's position for not require a license.
Attachment I PACE Audit Process and Data Request Table 5 – Introductory Text	Include all participants enrolled in the PACE organization at some point during the audit period.	Changed "PACE organization" to "PO" for consistency.	Include all participants enrolled in the PO at some point during the audit period.
Attachment I PACE Audit Process and Data Request Table 5 – Column ID H Column ID J Column ID Q Column ID U Column ID Z Column ID Z Column ID AP	Field Name: Most recent date of Hospitalization Field Name: Most recent date of Emergency Room Visit Field Name: Number of Falls Reported as a Level I Event Field Name: List of Infections Field Name: Ambulation Field Name: Quality Analysis	Deleted these columns from the record layout.	None.
Attachment I PACE Audit Process and Data Request Table 5 – Column ID K	Column ID K Field Description: Provide the number of skilled nursing facility/ nursing facility admissions that occurred during the audit review period.	Changed Column ID. Changed field description to include guidance on what sort of admissions should be included.	Column ID I Field Description: Provide the number of skilled nursing facility/ nursing facility admissions that occurred during the audit review period. This should include all SNF/NF admissions for any cause, including admission as a result of a request for services.

Current Section in CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I PACE Audit Process and Data Request Table 5 – Column ID O	Column ID O Field Length: 15 Field Description: Provide information on how often the participant currently attends the center. Enter both the number of days each week (e.g., 1, 3, 5) as well as whether attendance is full days or partial days (e.g., 3 Full, 2 Partial).	Changed Column ID. Changed field length to 1. Changed field description to only ask for the number of days a week the participant attends the center.	Column ID M Field Length: 1 Field Description: Provide information on how often the participant currently attends the center. Enter the number of days each week (e.g., 1, 3, 5).
Attachment I PACE Audit Process and Data Request Table 5 – Column ID R	Column ID R Field Description: Provide the number of falls a participant had during the audit review period that were reported as a level II event.	Changed Column ID. Changed field description to capitalize "level".	Column ID O Field Description: Provide the number of falls a participant had during the audit review period that were reported as a Level II event.
Attachment I PACE Audit Process and Data Request Table 5 – Column ID S	Column ID S Field Name: Currently recovering from a fall reported as either a Level I or Level II event Field Length: 3 Field Description: Yes (Y) / No (N) indicator on whether the participant is still recovering from a fall that was reported as either a Level I or Level II event?	Changed Column ID. Changed field name to delete reference to Level I. Changed field length to 2. Changed field description to delete reference to Level I and add an option for NA.	Column ID P Field Name: Currently recovering from a fall reported as a Level II event Field Length: 2 Field Description: Yes (Y) / No (N) indicator on whether the participant is still recovering from a fall that was reported as a Level II event? Enter NA if the participant did not have a fall reported as a Level II event.
Attachment I PACE Audit Process and Data Request Table 5 – Column ID T	Column ID T Field Description: Provide the number of infections the participant had during the audit review period. This includes all types of infections. Enter NA if the participant did not have an infection during the audit review period.	Changed Column ID. Changed field description to include guidance on how to identify infections.	Column ID Q Field Description: Provide the number of infections the participant had during the audit review period. This includes all types of infections as defined by your infection control plan. Enter NA if the participant did not have an infection during the audit review period.
Attachment I PACE Audit Process and Data Request Table 5 – Column ID V	Column ID V Field Name: Number of Pressure Ulcers Field Length: 3 Field Description: Provide the number of pressure ulcers that the participant had during the audit review period. Only include pressure ulcers that are staged II or above. Enter NA if the participant did not have any pressure ulcers during the audit review period.	Changed Column ID. Changed field name to delete reference to numbers. Changed field length to 1. Changed field description to request information in a yes/no format.	Column ID R Field Name: Pressure Ulcers Field Length: 1 Field Description: Yes (Y) / No (N) indicator on whether the participant has had one or more pressure ulcer(s) during the audit review period. Only include pressure ulcers that are staged II or above.

Current Section in CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I PACE Audit Process and Data Request	Column ID W Field Length: (none) Field Description: Yes (Y) / No (N) indicator on whether the	Changed Column ID. Added a field length of 1. Changed field description to clarify	Column ID S Field Length: 1 Field Description: Yes (Y) / No (N) indicator on whether the
Table 5 – Column ID W	participant is currently receiving treatment for a pressure ulcer?	treatment for pressure ulcers staged II or above.	participant is currently receiving treatment for a pressure ulcer staged II or above?
Attachment I PACE Audit Process and Data Request	Column ID AA Field Description: Yes (Y) / No (N) indicator on whether the	Changed Column ID. Changed field description to clarify that	Column ID V Field Description: Yes (Y) / No (N) indicator on whether the
Table 5 – Column ID AA	participant experienced significant weight loss at any time during the audit review period?	we are requesting on unanticipated weight loss.	participant experienced significant unanticipated weight loss at any time during the audit review period?
Attachment I PACE Audit Process and Data Request	Column ID AI Field Length: 500 Field Description: If the participant has received skilled	Changed Column ID. Changed field length to 1. Changed field description to ask for	Column ID AD Field Length: 1 Field Description: Yes (Y) / No (N) indicator on whether the
Table 5 – Column ID AI	therapy during the audit review period, please provide a brief description of that therapy (e.g., PT for leg, OT, etc.). Include all types of skilled therapy received. Enter NA if the participant did not receive skilled therapy during the audit review period.	information in a yes or no format.	participant has ever received skilled therapy during the audit review period. Include all types of skilled therapy received.
Attachment I PACE Audit	Column ID AL Field Descriptions Ves (V) / No (N) indicator on whether the	Changed Column ID. Changed	Column ID AG Field Descriptions Ves (V) / No (N) indicates on whether the
Process and Data Request	Field Description: Yes (Y) / No (N) indicator on whether the participant used oxygen during the audit review period?	field description to clarify what we consider oxygen use for	Field Description: Yes (Y) / No (N) indicator on whether the participant regularly used oxygen (as indicated by the care plan)
Table 5 – Column ID AL		purposes of audit.	during the audit review period (not as a result of an acute event)?
Attachment I PACE Audit	Column ID AN	Changed Column ID. Changed	Column ID AI
Process and Data Request	Field Description: Yes (Y) / No (N) indicator on whether the participant has impaired vision?	field description to clarify what we consider impaired vision for	Field Description: Yes (Y) / No (N) indicator on whether the participant has impaired vision (i.e, blind or vision is severely
Table 5 – Column ID AN	Landania arkania inchi	purposes of audit.	impaired without corrective lenses)?
Attachment I PACE Audit	Column ID AO	Changed Column ID. Changed	Column ID AJ
Process and Data Request	Field Description: Yes (Y) / No (N) indicator on whether the participant has impaired hearing?	field description to clarify what we consider impaired hearing	Field Description: Yes (Y) / No (N) indicator on whether the participant has impaired hearing (i.e., deaf or hearing is severely
Table 5 – Column ID AO		for purposes of audit.	impaired without an assistive hearing device)?

Current Section in CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I PACE Audit Process and Data Request	Field Name and Column ID:	Changed Column ID.	Field Name and Column ID:
Table 5 –	Column ID I: Number of Emergency Room Visits Column ID L: Currently in SNF/NF Column ID M: Received Home Care		Column ID H: Number of Emergency Room Visits Column ID J: Currently in SNF/NF Column ID K: Received Home Care
Column ID	Column ID N: Currently Receiving Home Care Column ID P: Transportation Services Provided Column ID X: Incontinent Column ID Y: Indwelling Catheter Column ID AB: Mechanically Altered Diet Column ID AC: Parenteral or Enteral Feeding Column ID AD: Dementia Column ID AE: Psychoactive Medications Column ID AF: Restraints Column ID AG: Assistance with Administering Medications Column ID AH: Pain Management Column ID AJ: Currently Receiving Skilled Therapy Column ID AK: Functional Decline Column ID AM: Dialysis		Column ID L: Currently Receiving Home Care Column ID N: Transportation Services Provided Column ID T: Incontinent Column ID U: Indwelling Catheter Column ID W: Mechanically Altered Diet Column ID X: Parenteral or Enteral Feeding Column ID Y: Dementia Column ID Z: Psychoactive Medications Column ID AA: Restraints Column ID AB: Assistance with Administering Medications Column ID AC: Pain Management Column ID AE: Currently Receiving Skilled Therapy Column ID AF: Functional Decline Column ID AH: Dialysis
Attachment I PACE Audit Process and Data Request Table 6 – Column ID H	Field Description: Provide the date the quality initiative was concluded. Submit in format CCYY/MM/DD (e.g. 2017/02/01).	Added an option for NA when the quality initiative is ongoing.	Field Description: Provide the date the quality initiative was concluded. Submit in format CCYY/MM/DD (e.g. 2017/02/01). Enter NA if the quality initiative has not concluded (it is ongoing).
Attachment I PACE Audit Process and Data Request Table 6 – Column ID K	Field Length: 1 Field Description: Yes (Y) / No (N) indicator on whether the PO implemented any corrective actions as a result of the quality initiative?	Changed field length to 2. Added an option for NA when no corrective action was necessary.	Field Length: 2 Field Description: Yes (Y) / No (N) indicator on whether the PO implemented any corrective actions as a result of the quality initiative? Enter NA if no corrective action was necessary.
Attachment I PACE Audit Process and Data Request Table 6 – Column ID L	Field Name: Date of Corrective Action Implementation Field Description: Provide the date the PO implemented corrective action as a result of the quality initiative. Submit in format CCYY/MM/DD (e.g., 2017/02/01).	Changed field name to clarify intention. Clarified field description for what we are requesting and added an option for NA.	Field Name: Start Date of Corrective Action Implementation Field Description: Provide the date the PO began implementing corrective action as a result of the quality initiative. Submit in format CCYY/MM/DD (e.g., 2017/02/01). Enter NA if no corrective action was necessary.

Original Language	Clarification or Change	Revised Language
 Include all after hour calls received by the PACE organization. 	Changed "PACE organization" to "PO" for consistency.	Include all after hour calls received by the PO.
None.	Created a new field for participant ID.	Column ID C Field Name: Participant ID Field Length: 25 Field Description: The identification number the PO uses to
Field Name: PO Follow-up Field Name: Date of PO Follow-up	Deleted these columns from the record layout.	identify the participant. None.
Column ID E Field Length: 8 Field Description: Provide the time the call was received. Submit in HH:MM:SS format (e.g. 23:54:23).	Changed Column ID. Changed field length to 5. Change field description to remove seconds from the time.	Column ID F Field Length: 5 Field Description: Provide the time the call was received. Submit in HH:MM format (e.g. 23:54).
Field Name and Column ID: Column ID C: Caller Information Column ID D: Date of Call Column ID F: Call Description/ Reason for Call Column ID G: Response to Call	Changed Column ID.	Field Name and Column ID: Column ID D: Caller Information Column ID E: Date of Call Column ID G: Call Description/ Reason for Call Column ID H: Response to Call
	Include all after hour calls received by the PACE organization. None. Field Name: PO Follow-up Field Name: Date of PO Follow-up Column ID E Field Length: 8 Field Description: Provide the time the call was received. Submit in HH:MM:SS format (e.g. 23:54:23). Field Name and Column ID: Column ID C: Caller Information Column ID D: Date of Call	Include all after hour calls received by the PACE organization to "PO" for consistency. Changed "PACE organization" to "PO" for consistency. Created a new field for participant ID. Column ID E

Current Section in CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachments II PACE Supplemental Questions	None.	Added a question regarding receipt of service delivery requests.	9. Please describe when your organization deems a service delivery request as received by the IDT. Please attach the portion of the policy or procedure that discusses receipt of a service delivery request.
Attachment I – PACE Audit Process and Data Request Appeal Impact Analysis Template Participant Impact Tab	None Did the PO notify the participant regarding the extension? Was the participant a Medicaid participant? Was the reviewer involved in the initial decision? Were there any negative outcomes caused by the failure to provide the service? Has the participant appealed again? (Medicare or Medicaid/SAA process)	Added a field and added instructions on populating yes or no in fields.	Was the Reviewer an Impartial Third Party that was Appropriately Credentialed? (Y/N) Did the PO notify the participant regarding the extension? (Y/N) Was the participant a Medicaid participant? (Y/N) Was the reviewer involved in the initial decision? (Y/N) Were there any negative outcomes caused by the failure to provide the service? (Y/N) Has the participant appealed again? (Medicare or Medicaid/SAA process) (Y/N)
Attachment I – PACE Audit Process and Data Request Personnel Impact Analysis Template Personnel Impact Tab	None	Added a new impact analysis template for personnel conditions.	Employee First Name Employee Last Name Job Title Job Description Date of Hire (MM/DD/YY) Date of Termination (MM/DD/YY) Type of Employment Direct Participant Contact (Y/N) License (Y/N) Was a background check performed on the employee prior to hire? Was the employee run through the OIG excluded provider list? (Y/N) Were competency evaluations conducted for the employee? (Y/N) Was OSHA training provided to the employee? (Y/N) For those staff that have direct participant contact, was the individual medically cleared for communicable diseases before engaging in direct participant contact? (Y/N)
Attachment I – PACE Audit Process and Data Request Clinical Appropriateness Impact Analysis Template_Assessments Participant Impact Tab	None None Dates the IDT members completed their initial assessments (Identify assessment date by discipline)(HH:MM:SS) Were any assessments not completed? Were assessments completed in person? Was there a change in the participant's status? Were any assessments not documented? Were there any negative participant outcomes?	Added two impact analysis fields and added clarification on how to populate fields with yes or no. Also corrected an error from entering time to entering dates.	If Hospitalized, Most recent date of hospitalization. (MM/DD/YY) If participant went to the emergency room, Most recent date of emergency room visit. (MM/DD/YY) Dates the IDT members completed their initial assessments (Identify assessment date by discipline)(MM/DD/YY) Were any assessments not completed? (Y/N) Were assessments completed in person? (Y/N) Was there a change in the participant's status? (Y/N) Were any assessments not documented? (Y/N) Were there any negative participant outcomes? (Y/N)

Current Section in CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I – PACE	None	Added two impact analysis	If Hospitalized, Most recent date of hospitalization.
Audit Process and Data		fields and added clarification	(MM/DD/YY)
Request	None	on how to populate fields with yes or no.	If participant went to the emergency room, Most recent date of emergency room visit. (MM/DD/YY)
Clinical Appropriateness	Did the plan of care require a revision?		Did the plan of care require a revision? (Y/N)
Impact Analysis	Was there a change in the participant's status?		Was there a change in the participant's status? (Y/N)
Template_Care Plan	Did the plan of care specify the care needed to meet the participant's medical, physical, emotional and social needs?		Did the plan of care specify the care needed to meet the participant's medical, physical, emotional and social needs?
Participant Impact Tab			(Y/N)
	Did the plan of care identify measurable outcomes to be achieved?		Did the plan of care identify measurable outcomes to be achieved? (Y/N)
	Were there any negative participant outcomes?		Were there any negative participant outcomes? (Y/N)
Attachment I – PACE Audit Process and Data	None.	Added two impact analysis fields and added clarification	If Hospitalized, Most recent date of hospitalization. (MM/DD/YY)
Request	None.	on how to populate fields with yes or no.	If participant went to the emergency room, Most recent date of emergency room visit. (MM/DD/YY)
Clinical Appropriateness Impact Analysis	Did the change require an assessment by one or more members of the IDT?		Did the change require an assessment by one or more members of the IDT? (Y/N)
Template IDT	Were the assessments documented in the medical record?		Were the assessments documented in the medical record? (Y/N)
Documentation	Were assessments completed in person?		Were assessments completed in person? (Y/N)
D (' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' '	Did the change require an update/ revision to the plan of care?		Did the change require an update/ revision to the plan of care?
Participant Impact Tab	Was the participant's plan of care updated/ revised?		(Y/N) Was the participant's plan of care updated/ revised? (Y/N)
	If the change in the participant's condition did not require an		If the change in the participant's condition did not require an
	assessment, was a progress note documented?		assessment, was a progress note documented? (Y/N)
	Were there any negative participant outcomes?		Were there any negative participant outcomes? (Y/N)
Attachment I – PACE	None.	Added two impact analysis	If Hospitalized, Most recent date of hospitalization.
Audit Process and Data		fields and added clarification	(MM/DD/YY)
Request	None.	on how to populate fields with yes or no.	If participant went to the emergency room, Most recent date of emergency room visit. (MM/DD/YY)
Clinical Appropriateness	Was the information lost, deleted, destroyed, etc.?		Was the information lost, deleted, destroyed, etc.? (Y/N)
Impact Analysis	Action taken by PO to recover loss, if any?		Action taken by PO to recover loss, if any? (Y/N)
Template_Med Rec Documentation	Were there any negative outcomes?		Were there any negative outcomes? (Y/N)
Participant Impact Tab			

Current Section in CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I – PACE Audit Process and Data Request Clinical Appropriateness Impact Analysis Template_Emergency Participant Impact Tab	None. None. Did the participant or caregiver contact the PO before seeking emergency care? Was emergency care provided? Was the participant held harmless for utilization of emergency care services? None. None.	Added four impact analysis fields and added clarification on how to populate fields with yes or no.	If Hospitalized, Most recent date of hospitalization. (MM/DD/YY) If participant went to the emergency room, Most recent date of emergency room visit. (MM/DD/YY) Did the participant or caregiver contact the PO before seeking emergency care? (Y/N) Was emergency care provided? (Y/N) Was the participant held harmless for utilization of emergency care services? (Y/N) Other data requested Other data requested
Attachment I – PACE Audit Process and Data Request Clinical Appropriateness Impact Analysis Template_Comp Care Participant Impact Tab	Was there a service delivery request by the participant/caregiver/participant representative? Were the assessments documented in the medical record? Was the service a Medicare covered service? Were there any negative participant outcomes?	Added clarification on how to populate fields with yes or no.	Was there a service delivery request by the participant/ caregiver/ participant representative? (Y/N) Were the assessments documented in the medical record? (Y/N) Was the service a Medicare covered service? (Y/N) Were there any negative participant outcomes? (Y/N)
Attachment I – PACE Audit Process and Data Request Clinical Appropriateness Impact Analysis Template_Infections Participant Impact Tab	Were any local, state, or federal agencies notified of the infection(s)? Were incidents of infection investigated? Were incidents of infection analyzed? Were any trends identified? Were there any negative outcomes?	Added clarification on how to populate fields with yes or no.	Were any local, state, or federal agencies notified of the infection(s)? (Y/N) Were incidents of infection investigated? (Y/N) Were incidents of infection analyzed? (Y/N) Were any trends identified? (Y/N) Were there any negative outcomes? (Y/N)

Current Section in CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I – PACE Audit Process and Data Request Clinical Appropriateness Impact Analysis Template_Providers Participant Impact Tab	Were there any negative outcomes?	Added clarification on how to populate a field with yes or no.	Were there any negative outcomes? (Y/N)
Attachment I – PACE Audit Process and Data Request Clinical Appropriateness Impact Analysis Template_Restraints Participant Impact Tab	Were assessments documented in the medical record? Were there any negative outcomes?	Added clarification on how to populate fields with yes or no.	Were assessments documented in the medical record? (Y/N) Were there any negative outcomes? (Y/N)
Attachment I – PACE Audit Process and Data Request Clinical Appropriateness Impact Analysis Template_Transportation Participant Impact Tab	Were assessments completed by members of the IDT? Were there any missed appointments, center attendance, etc? Were any vehicles available that were accessible to the participant? Were there any negative outcomes?	Added clarification on how to populate fields with yes or no.	Were assessments completed by members of the IDT? (Y/N) Were there any missed appointments, center attendance, etc? (Y/N) Were any vehicles available that were accessible to the participant? (Y/N) Were there any negative outcomes? (Y/N)
Attachment I – PACE Audit Process and Data Request Grievance Impact Analysis Template Participant Impact Tab	Were they ever resolved? For misclassified service requests, was the service request ever processed? Was the service request approved? Were there any negative outcomes? Did the PO fail to provide continued care during the grievance process?	Added clarification on how to populate fields with yes or no.	Were they ever resolved? (Y/N) For misclassified service requests, was the service request ever processed? (Y/N) Was the service request approved? (Y/N) Were there any negative outcomes? (Y/N) Did the PO fail to provide continued care during the grievance process? (Y/N)

Current Section in CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment I – PACE Audit Process and Data Request Service Delivery Impact Analysis Template Participant Impact Tab	Was appeal language included in the letter? Did the participant appeal? Was the approved service added to the care plan? Was emergency care provided?	Added clarification on how to populate fields with yes or no.	Was appeal language included in the letter? (Y/N) Did the participant appeal? (Y/N) Was the approved service added to the care plan? (Y/N) Was emergency care provided? (Y/N)
CMS-10630_Supporting Statement A Background	None.	Added a total number of POs.	There are currently 119 POs.
CMS-10630_Supporting Statement A Justification Improved Information Technology	Information collected from the POs for use in the audit is obtained electronically via Secure File Transfer Protocol (SFTP) or electronically through Health Plan Management System (HPMS). HPMS is a system that was developed and is maintained by CMS and that all POs have access too. This system is also secure, requiring users to request and gain access via CMS personnel and then must create and maintain a secure user id and password.	Deleted the reference to the "SFTP" as PACE audits will only use HPMS for file transfers in 2017.	Information collected from the POs for use in the audit is obtained electronically through Health Plan Management System (HPMS). HPMS is a system that was developed and is maintained by CMS and that all POs have access too. This system is also secure, requiring users to request and gain access via CMS personnel and then must create and maintain a secure user id and password.
CMS-10630_Supporting Statement A Justification Federal Register	The 2017 protocol, provided in this package will also be published a 60-day and subsequent 30-day Federal Register comment period. This package can be updated with specific dates when publication dates are known.	Deleted reference to 2017. Provided specific dates for previous 60 day comment period.	The audit protocol, provided in this package was published for a 60-day Federal Register comment period on August 5, 2016 and will be posted for a subsequent 30-day comment period. This package can be updated with specific dates when publication dates are known.
CMS-10630_Supporting Statement A Justification Burden Estimate Trial Year and Routine Audits	For each PACE organization we estimate an average of 100 hours for administrative and systemic work, 40 hours prior to the audit start to assemble and review the information for completeness, 40 hours for the actual administration of the audit, and 20 hours to review and respond to the draft audit report. We believe an additional 80 hours is spend on corrective action and audit close out activities. This is a total of approximately 180 hours for each PO. The average number of POs that will receive an audit annually is 72.	Adjusted the burden for POs based on comments received.	Additionally, for each PO that receives an audit in 2017, we estimate an average of 80 hours prior to the audit start to assemble and review the information for completeness, 40 hours for the actual administration of the audit, and 40 hours to review and respond to the draft audit report. We believe an additional 80 hours is spend on corrective action and audit close out activities. This is a total of approximately 240 hours for each PO. The average number of POs that will receive an audit annually is 72.

Current Section in CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
CMS-10630_Supporting Statement A Justification Burden Estimate One-Time Burden To Build Systems (New)	None.	Added a new section to include costs to POs for building a system for capturing, tracking and submitting data.	One-Time Burden to Build Systems We believe there will be a one-time burden of \$38,430 for each of the 119 POs to implement systems to capture, track and submit data as requested by CMS. This estimate includes building or creating systems to capture data in each of the seven requested universes. Specifically, we believe it will take 75 hours for a PO to build the service delivery requests universe, 40 hours to build the appeals universe, 75 hours for the grievance universe, 40 hours for the personnel universe, 100 hours for the quality assessment universe, 250 hours for the participant universe, and 50 hours for the on-call universe. This is a total of approximately 630 hours to build the universes included in the PACE protocol. With an estimated hourly wage of 61 dollars, times 630 hours per PO, this is a one-time estimate of \$38,430 per PO.
CMS-10630_Supporting Statement A Attachments All IA templates	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 3 to 5 days.	Changed response time to 10 days.	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
CMS-10630_Supporting Statement A Attachments Personnel Impact Analysis	None.	Created a personnel impact analysis and included it as an attachment.	Document Title: Personnel Impact Analysis Description: Personnel Impact Analysis Template Purpose: To assess impact on personnel Respondents: PACE organizations Reporting Frequency: We audit approximately 72 PACE organizations annually Time Per Response: Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
CMS-10630_Supporting Statement A Justification Burden Estimate Calculation of Total Audit Hours and Approximate Cost	Total audit hours (72 x 180) = 12,960 Average hourly wage = \$61 per hour Total Cost of Collection Effort = \$790,560	Adjusted total costs to account for increased audit hours.	Total audit hours (72 x 240) = 17,280 Average hourly wage = \$61 per hour Total Cost of Audit (17,280 x 61) = \$1,054,080 One-time Implementation Cost (119 x 38,430) = \$4,573,170 Total Cost of Collection Effort (Total Cost of Audit + One-Time Implementation Cost) = \$5,627,250

Current Section in CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
CMS-10630_Supporting Statement A Justification Burden Estimate Costs to Federal	For each audit we estimate an average of 200 hours for administrative and systemic work, 80 hours prior to the audit start to review the information for completeness and prepare for audit, 40 hours for the actual administration of the audit, and 80 hours to review audit documentation, discuss findings, and draft the report.	Removed part of the first sentence for clarity.	For each audit we estimate 80 hours prior to the audit start to review the information for completeness and prepare for audit, 40 hours for the actual administration of the audit, and 80 hours to review audit documentation, discuss findings, and draft the report.
Government CMS-10630_Supporting Statement A Justification Burden Estimate Costs to Federal Government Contractor Costs	None.	Added a new section to highlight contractor costs for the government, and added those costs into the total government costs.	Contractor Costs CMS has two audit support contractors that perform a variety of duties beyond just the performance of the audit. The duties performed related to this collection effort include performing team lead duties, acting as the documenter (i.e., documenting all audit findings) for each audit team, providing clinicians for portions of the audit, receiving, and analyzing and ensuring completeness of all audit data collected from POs. Based on invoices received by the government, each audit costs CMS approximately \$23,000 in contracted resources. Contractors assist with approximately 20 PACE audits each year. Consequently, the total cost to the government in contracted resources is as follows: \$23,000 per audit x 20 audits = \$460,000. Adding up the costs to the government of staff time, travel and contractor costs we can estimate total cost to the government as follows: Government Staff Cost \$1,679,212.80 Contractor Costs: \$460,000 Total Cost: \$2,139,212.80
Attachment III_Pre-Audit Issue Summary	How was the issue discovered (e.g. CMS discovered issue, self-identified, etc)?	Removed example.	How was the issue discovered?
Column D			

Current Section in CMS- 10630 (08/16)	Original Language	Clarification or Change	Revised Language
Attachment III_Pre-Audit Issue Summary Column G	Column G: Was the issue previously disclosed to CMS (e.g., Account Manager disclosure)? Y/N)	Removed column since we are only requesting disclosed issues.	None.
Attachment III_Pre-Audit Issue Summary Column I	Column I: To whom the issue was disclosed at CMS	Column shifted and clarified that we want the person in CMS that the issue was disclosed.	Column H: To whom the issue was disclosed at CMS (first and last name)