

**Responses to Comments Received
Federal Register Notice on (CMS-10630)
PACE Audit Protocol**

CMS received 4 public submissions, which included 10 distinct comments on the December 2, 2016 (CMS- 10630) The PACE Organization Monitoring and Audit Process proposed information collection. Comments are addressed below.

GENERAL COMMENTS

Comment 1: One commenter expressed concern that the proposed audit process presented an administrative burden to PACE Organizations (POs) and focuses on administrative requirements rather than the outcome of participant care. The commenter urged CMS to focus on the extent to which POs provide quality care to PACE participants through observation of participant care, quality measures and medical records review.

Response 1: We believe that this audit protocol significantly modified our previous audit structure to be more focused on outcomes and create less of an administrative burden. We have significantly reduced the administrative burden on POs by eliminating over 80 distinct policies and procedures that POs used to be required to produce. Instead, our audit is now focused on the participant experience within the PO and whether those participants are receiving the access to care required by federal regulations. We determined the best way to conduct these person centered audits would be to request real data on participants, in areas relating to access to services and care such as service requests, appeals and participant medical records. We then take that participant level data and examine whether the participant received medically necessary services and care. Additionally, our audit continues to place a heavy emphasis on both participant medical records and participant observations. We believe that by using real participant data and by conducting a review of medical records and observations we will be able to appropriately assess whether a PO is both meeting federal requirements, as well as providing appropriate, high quality care.

CMS Action 1: No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

Comment 2: One commenter stated that CMS' estimates for the preaudit phase significantly underestimate the PO's staff time to retrieve and prepare the detailed information that CMS is proposing. The commenter urged CMS to employ a sampling methodology that would enable CMS to note trends rather than request a full universe of data.

Response 2: While we appreciate this commenter's suggestion, we cannot only ask for data on a sample of participants and/or personnel. In order to do a comprehensive audit as required by regulation, we need all data requested. We will be targeting our samples in 2017, which means we need a full universe of information in order to appropriately select participants to review. Additionally, we will be running some tests at a universe level, such as the timeliness of service delivery requests, appeals and grievances. In order to appropriately run this test, we must have a full universe of all requests. We increased our burden following the 60 day comment period to account for the system changes that PACE organizations may need with an estimated one-time burden of \$38,430 for each of the 119 POs. We also increased the pre-audit burden estimates based on comments following the 60 day comment period.

CMS Action 2: No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

Comment 3: One commenter appreciated CMS extending the time POs have to complete the Impact Analysis (IA) templates from 3-5 days to 10 business days. That commenter, however, stated that 10 business days was still not enough time and urged CMS to consider giving POs 30 business days to submit IA templates.

Response 3: We significantly increased the time to populate and submit impact analysis based on comments received during the 60 day comment period. The time increased from a few days to 10 business days. We feel this is a reasonable amount of time to pull the data requested, while still allowing auditors to finalize and close audits within a reasonable period of time. We cannot increase the time allowed to submit IA templates without adversely affecting our ability to timely produce audit results and ensure corrective action is happening in an expeditious manner.

CMS Action 3: No change was made to the protocol in response to this comment. No change was made to the burden estimate as a result of this comment.

Comment 4: One commenter stated they were concerned that tracking and collecting data for the universe of approved service delivery requests was an administrative burden without benefit to the participant and believed that it may ultimately result in a delay in delivering approved services. That commenter strongly recommended that CMS remove the requirement to log approved service delivery requests.

Response 4: We disagree with this commenter. While we understand the importance of testing denied service requests, there is also a benefit to testing approved requests. First, regardless of whether the request is approved or denied, the PO must process that request within a specific timeframe, so those requests will also be run through the timeliness test. Second, once a request is approved, the PO should provide the service as expeditiously as the participant's health condition requires, and we may choose to review some samples to ensure services are being provided in a manner that meets that requirement.

CMS Action 4: No change was made to the protocol in response to this comment. No change was made to the burden estimate as a result of this comment.

Comment 5: One commenter requested that CMS provide samples at least five business days prior to the audit review starting, rather than the one business day currently allowed.

Response 5: We do not believe that POs need more than one business day to pull sample case files for audit. Several elements do not require files to be pulled, such as the onsite element, quality assessment, or clinical appropriateness and care planning. Only Service Delivery Requests, Appeals and Grievances (SDAG) and personnel require case files and the PO should have ample time to pull these files in a day. If the PO needs more time, a request can be made to the audit lead who can decide whether an exception should be granted on a case by case basis.

CMS Action 5: No change was made to the protocol in response to this comment. No change was made to the burden estimate as a result of this comment.

Comment 6: One commenter requested clarification regarding the quality assessment tracer methodology and what will be reviewed during the tracers.

Response 6: The quality assessment tracer will be a live walkthrough of the POs quality program with the PO's quality coordinator. Auditors will explain this process in more detail during the audit. POs will be given an appropriate amount of time to ask questions or provide any necessary information to auditors prior to conditions being cited.

CMS Action 6: No change was made to the protocol in response to this comment. No change was made to the burden estimate as a result of this comment.

Comment 7: One commenter requested clarification regarding populating the IA templates, specifically whether NA could be entered in a column, and whether the PO had to provide "seconds" when entering times.

Response 7: IA templates do not require specific formatting so POs can enter NA into a column if they do not have the information (or the column is not applicable). Additionally, POs do not have to enter "seconds" into the time field if they do not capture seconds when capturing time in their systems.

CMS Action 7: No change was made to the protocol in response to this comment. No change was made to the burden estimate as a result of this comment.

Comment 8: One commenter suggested that the implementation date for this audit protocol be January 1, 2018 given the complexity and scope of the audit requirements and changes to the audit process. This commenter stated a delay would allow POs to update and modify internal data collection systems and allocate staffing patterns appropriately to comply with the proposed audit requirements. This commenter also requested that, if a delay could not be granted, CMS would ensure that POs are not penalized if they are unable to submit a full universe of data in 2017.

Response 8: While we appreciate this commenter's suggestion, we feel that it is important to make improvements to the audit process immediately. Therefore we will continue implementing this new outcomes based auditing strategy for the audits conducted in calendar year 2017. In order to do this, we will need to collect the full universes of data from a PO. We believe that because much of the information we are requesting is already collected by the PO, POs will be able to populate the required universes within the allowed timeframe. However, we recognize that it may take some time to build systems and track this data, so CMS will be reasonable when accepting the data in the format requested.

CMS Action 8: No change was made to the protocol in response to this comment. No change was made to the burden estimate as a result of this comment.

Comment 9: One commenter stated that the grievance universe mirrored the grievance quality reporting collected through the Health Plan Management System (HPMS) and suggested that it was overly burdensome and duplicative to request the data twice.

Response 9: We agree with this commenter that we should avoid requesting duplicative information whenever possible. We also believe the information collected during audits is not duplicative of other collections. Information submitted quarterly or during Level I and Level II reporting is aggregate data. The information we are requesting on audit is participant specific.

This level of personal information is necessary for an audit to be conducted, while not necessarily needed for quarterly reporting or calls.

CMS Action 9: No change was made to the protocol in response to this comment. No change was made to the burden estimate as a result of this comment.

Comment 10: One commenter stated that the domain for Pressure Ulcer/Injury quality measurement for PACE initially included draft measures for PACE-Acquired Pressure Ulcer/Injury Prevalence and Pressure Ulcer/Injury Prevention. This commenter also said that following testing, the Falls, Falls with Injury and PACE-Acquired Pressure Ulcer Prevalence measures were submitted to the National Quality Forum for consideration of endorsement. Based on the results of validity and feasibility testing, the Pressure Ulcer/Injury Prevention measure was not included at this time.

Response 10: This comment appears to be related to quality measures which is outside the scope of this PRA package.

CMS Action 10: No change was made to the protocol in response to this comment. No change was made to the burden estimate as a result of this comment.