Current CMS-10630 (2020)	Summary of Changes in Proposed CMS-10630 (starting in 2023)	Type of Change	Explanation of Changes	Burden Impact
AttachmentIPACEAuditProtocol, Title Page: Programs of All-Inclusive Care for the Elderly (PACE) Audit Process and Data Request	• Retitled to "Programs of All-Inclusive Care for the Elderly (PACE) Audit Protocol"	Modify	Minor wording change for clarity	None
AttachmentIPACEAuditProtocol, Audit Purpose and General Guidelines	• Retitled this section to "Audit Purpose and Scope" • Updated terminology to reflect regulatory changes • Removed audit process instructions unrelated to the purpose and scope of the audit • Moved data collection periods by universe information to Appendix A	Modify	Technical changes, Changes due to regulatory updates (effective March 2021), Streamlined information	None
AttachmentIPACEAuditProtocol, Universe Preparation & Submission	• Retitled this section to "Initial Documentation and Data Submissions" • Removed audit process instructions unrelated to the collection of initial documentation and data submissions • Moved all instructions related to initial documentation and data submissions to this section • Added 3 new initial documentation requests	Modify	Technical changes, Changes due to regulatory updates (effective March 2021), Streamlined information, Changes for clarity based on audit experience	Moderate

Current CMS-10630 (2020)	Summary of Changes in Proposed CMS-10630 (starting in 2023)	Type of Change	Explanation of Changes	Burden Impact
AttachmentIPACEAuditProtocol, Audit Elements, Service Delivery Requests, Appeals, and Grievances (SDAG)	- Renamed this element to "Service Determination Requests, Appeals, and Grievances (SDAG)" - Removed audit process instructions unrelated to the collection of documentation and data for the Personnel element - Added new documentation requests and compliance standards - Modified current compliance standards - Added instructions on how to submit case files to CMS - Provided additional detail regarding CMS' approach to reviewing compliance standards	Modify	Technical changes, Changes due to regulatory updates (effective March 2021), Streamlined information, Clarified instructions, Changes for clarity based on audit experience	Moderate
AttachmentIPACEAuditProtocol, Audit Elements, Provision of Services	- Removed audit process instructions unrelated to the collection of documentation and data for the Personnel element - Added new documentation requests and compliance standards - Modified current compliance standards - Provided additional detail regarding CMS' approach to reviewing compliance standards	Modify	Technical changes, Changes due to regulatory updates (effective March 2021), Streamlined information, Clarified instructions, Changes for clarity based on audit experience	Moderate
AttachmentIPACEAuditProtocol, Audit Elements, Personnel Records	- Removed audit process instructions unrelated to the collection of documentation and data for the Personnel element - Made minor technical updates to compliance standards and compliance standard instructions - Provided additional detail regarding CMS' approach to reviewing compliance standards	Modify	Technical changes, Streamlined information, Clarified instructions	None

Current CMS-10630 (2020)	Summary of Changes in Proposed CMS-10630 (starting in 2023)	Type of Change	Explanation of Changes	Burden Impact
AttachmentIPACEAuditProtocol, Quality Assessment	• Renamed this element to "Compliance and Quality Improvement" • Removed audit process instructions unrelated to the collection of documentation and data for the Personnel element • Added new documentation requests and compliance standards related to compliance oversight • Provided additional detail regarding CMS' approach to reviewing compliance standards	Modify	Technical changes, Streamlined information, Clarified instructions, Changes for clarity based on audit experience	Moderate
CMS proposes a new AttachmentIPACEAuditProtocol section: "Analysis of Potential Non-Compliance" (No equivalent in the current protocol)	• Created a new section, "Analysis of Potential Non-Compliance", which streamlines instructions and further describes Root Cause Analysis, Impact Analysis, additional records review collection, and CMS' validation of the accuracy of documentation submitted by the PO during the audit	Modify	Clarified instructions	None
AttachmentIPACEAuditProtocol, Appendix A	• Consolidated universe related information to Appendix A	Modify	Technical changes, Clarified instructions	None
AttachmentIPACEAuditProtocol, Appendix A, Table 1: Service Determination Requests (SDR) Record Layout 16 columns in the Record Layout	• Added 10 new data fields • Removed 3 data fields • Modified current data fields	Modify	Technical changes, Changes due to regulatory updates (effective March 2021), Changes for clarity based on audit experience	Moderate
AttachmentIPACEAuditProtocol, Appendix A, Table 2: Appeal Requests (AR) Record Layout 15 columns in the Record Layout	• Added 3 new data fields • Modified current data fields	Modify	Technical changes, Changes due to regulatory updates (effective March 2021), Changes for clarity based on audit experience	Low

Current CMS-10630 (2020)	Summary of Changes in Proposed CMS-10630 (starting in 2023)	Type of Change	Explanation of Changes	Burden Impact
AttachmentIPACEAuditProtocol, Appendix A, Table 3: Grievance Requests (GR) Record Layout 9 columns in the Record Layout	• Revised name of the record layout to "Table 3: Grievance (GR) Record Layout" • Added 1 new data field • Modified current data fields	Modify	Technical changes, Changes due to regulatory updates (effective March 2021), Changes for clarity based on audit experience	Low
AttachmentIPACEAuditProtocol, Appendix A, Table 4: List of Personnel (LOP) Record Layout 11 columns in the Record Layout	• Added 3 new data fields • Removed 1 data field • Modified current data fields	Modify	Technical changes, Changes for clarity based on audit experience	Low
AttachmentIPACEAuditProtocol, Appendix A, Table 5: List of Participant Medical Records (LOPMR) Record Layout 40 columns in the Record Layout	• Added 12 new data fields • Removed 10 data fields • Modified current data fields	Modify	Technical changes, Changes due to regulatory updates (effective March 2021), Changes for clarity based on audit experience	Moderate
AttachmentIPACEAuditProtocol, Appendix A, Table 6: On-Call (OC) Record Layout 8 columns in the Record Layout	• Added 2 new data fields • Modified current data fields	Modify	Technical changes, Changes for clarity based on audit experience	Low
CMS proposes a new record layout in AttachmentIPACEAuditProtocol, Appendix A, Table 7: Contracted Entities and Providers (CEP) Record Layout. (No equivalent in the current protocol)	• New record layout added, AttachmentIPACEAuditProtocol, Appendix A, Table 7: Contracted Entities and Providers (CEP) Record Layout, which includes 7 data fields	New	Technical changes, Changes due to regulatory updates (effective March 2021), Changes for clarity based on audit experience	Moderate

Current CMS-10630 (2020)	Summary of Changes in Proposed CMS-10630 (starting in 2023)	Type of Change	Explanation of Changes	Burden Impact
AttachmentIIPACESupplementalQuestions	• Removed 2 questions • Modified questions to clarify the information requested • Made technical corrections to clarify questions and fix typographical errors	Modify	Typographical corrections, Technical changes, Changes due to regulatory updates (effective March 2021), Changes for clarity based on audit experience	Low
AttachmentIIIPreAuditIssueSummary	• Made minor technical changes	Modify	Technical changes, Clarified instructions	None
AttachmentIVObsPartList	• Renamed the document from "AttachmentIVOnsiteObsPartList" to "Attachment_IV_Obs_ParticipantList" • Made minor technical changes	Modify	Technical changes, Changes for clarity based on audit experience	None
AttachmentVAuditSurvey	• Removed 4 questions • Added 1 question • Modified 6 questions with minor technical changes	Modify	Technical Changes, Clarified instructions and questions, Changes for clarity based on audit experience	None
CMS proposes a new attachment: AttachmentVICorrectiveActionPlanProcess (No equivalent in the current protocol)	• This new attachment explains how a PACE organization must submit corrective action plans to CMS for any issue of non-compliance identified during a PACE audit • The attachment addresses corrective action plan requirements, implementation timeframes, Account Management technical assistance and documentation submission, and conditions of release from corrective action plan monitoring	New	New attachment clarifies an existing audit process	None

Current CMS-10630 (2020)	Summary of Changes in Proposed CMS-10630 (starting in 2023)	Type of Change	Explanation of Changes	Burden Impact
16 Impact Analyses templates	• 18 Impact Analysis templates	Add	Added three additional Impact Analysis templates: SpecialistRecommendations1P14, RequiredServices1P93, and CoordinationofCare1P95. Removed one IA from collection: AppealExt1P71.	Low
SDRs1P601P611P85 Impact Analysis • 22 columns on participant impact tab	SDRs1P601P611P85 Impact Analysis: • Added 5 columns to Participant Impact Tab • Modified 13 columns with minor wording changes • Updated instructions for completing participant impact tab	Modify	Modified and added columns to align with new regulatory provisions (effective March 2021).	Low
SDRIdentification1P76 Impact Analysis • 19 columns on participant impact tab	SDRIdentification1P76 Impact Analysis: • Added 2 columns to participant impact tab • Modified 14 columns on participant impact tab • Updated instructions for completing participant impact tab	Modify	Modified and added columns to align with new regulatory provisions (effective March 2021).	Low
MedErrors1P02 Impact Analysis • 20 columns on participant impact tab	MedErrors1P02 Impact Analysis: • Added 1 column to participant impact tab • Updated instructions for completing participant impact tab	Modify	Minor wording changes for clarity	Low
HomeCare1P02 Impact Analysis • 21 columns on participant impact tab	HomeCare1P02 Impact Analysis: • Added 1 column to participant impact tab • 5 columns removed • Modified 9 columns on participant impact tab • Updated instructions for completing participant impact tab	Modify	Minor wording changes for clarity	Low

Current CMS-10630 (2020)	Summary of Changes in Proposed CMS-10630 (starting in 2023)	Type of Change	Explanation of Changes	Burden Impact
AlertIDT1P14 Impact Analysis • 22 columns on participant impact tab	AlertIDT1P14 Impact Analysis: • Modified 15 columns on the participant impact tab • Removed 1 column on the participant impact tab • Added 1 column on the participant impact tab • Updated instructions tab	Modify	Wording changes for clarity and based on regulation changes (effective March 2021)	Low
Appeals1P651P661P681P73 Impact Analysis • 37 columns on the participant impact tab	Appeals1P651P661P681P73 Impact Analysis: • Updated instructions tab, including adding instructions for a new condition • Added 5 columns on the participant impact tab • Removed 2 columns on the participant impact tab • Modified 13 columns on the participant impact tab	Modify	Wording changes for clarity and based on regulation changes (effective March 2021)	Low
Assessments1P491P50 Impact Analysis • 30 columns on the participant impact tab	Assessments1P491P50 Impact Analysis: • Added 1 column on the participant impact tab • Modified 4 columns on the participant impact tab • Updated instructions tab	Modify	Wording changes for clarity	Low
Effectuation1P021P111P30 Impact Analysis • 34 columns on the participant impact tab	Effectuation1P021P111P30 Impact Analysis: • Added 2 columns on the participant impact tab • Removed 1 column on the participant impact tab • Modified 8 columns on the participant impact tab • Updated instructions tab	Modify	Minor wording changes for clarity	Low

Current CMS-10630 (2020)	Summary of Changes in Proposed CMS-10630 (starting in 2023)	Type of Change	Explanation of Changes	Burden Impact
EmergencyCare1P07 Impact Analysis: • 25 columns on the participant impact tab	EmergencyCare1P07 Impact Analysis: • Added 1 column to the participant impact tab • Modified 2 columns on the participant impact tab • Updated instructions tab	Modify	Minor wording changes for clarity	Low
Grievances1P311P751P77 Impact Analysis • 27 columns on the participant impact tab	Grievances1P311P751P77 Impact Analysis: • Added 1 column to the participant impact tab • Modified 3 columns on the participant impact tab • Updated instructions tab	Modify	Minor wording changes for clarity	Low
Personnel Impact Analysis • 25 columns on the participant impact tab	Personnel Impact Analysis: • Added 2 columns on the participant impact tab • Removed 1 column on the participant impact tab • Updated instructions tab	Modify	Minor wording changes for clarity	Low
ProvisionofServices1P02 Impact Analysis • 17 columns on the participant impact tab	ProvisionofServices1P02 Impact Analysis: • Added 1 column on the participant impact tab • Removed 2 columns on the participant impact tab • Modified 9 columns on the participant impact tab • Updated instructions tab	Modify	Minor wording changes for clarity	Low
Restraints1P09 Impact Analysis • 25 columns on the participant impact tab	Restraints1P09 Impact Analysis: • Added 3 columns on the participant impact tab • Removed 2 columns on the participant impact tab • Modified 6 columns on the participant impact tab • Updated instructions tab	Modify	Minor wording changes for clarity	Low

Current CMS-10630 (2020)	Summary of Changes in Proposed CMS-10630 (starting in 2023)	Type of Change	Explanation of Changes	Burden Impact
SrvcRestrict1P90 Impact Analysis • 19 columns on the participant impact tab	SrvcRestrict1P90 Impact Analysis: • Added 1 column on the participant impact tab • Deleted 1 column on the participant impact tab • Modified 5 columns on the participant impact tab • Updated instructions tab	Modify	Minor wording changes for clarity	Low
WoundCare1P02 Impact Analysis: • 23 columns on the participant impact tab	WoundCare1P02 Impact Analysis: • Added 1 column to the participant impact tab • Deleted 1 column on the participant impact tab • Modified 14 columns on the participant impact tab • Updated instructions tab	Modify	Minor wording changes for clarity	Low
RootCauseTemplate • 2 tabs (instructions and Root Cause)	RootCauseTemplate • Added 1 tab for detailed description of the individual non-compliance	Modify	Detailed non-compliance and the general request for a cause was combined on a single tab. This revision splits that information/request on to two tabs for clarity.	Low