

Current CMS-10630 (2023)	Summary of Changes in Proposed CMS-10630 (starting in 2026)	Type of Change	Explanation of Changes	Burden Impact
AttachmentIPACEAuditProtocol, Audit Purpose and Scope	<ul style="list-style-type: none"> Modified purpose and scope text 	Modify	Minor wording changes for clarity	None
AttachmentIPACEAuditProtocol, Initial Documentation and Data Submissions	<ul style="list-style-type: none"> Modified documentation for the compliance oversight program Removed Monitoring Reports 	Modify	Clarified instructions, Changes based on audit experience	High (reduction)
AttachmentIPACEAuditProtocol, Audit Elements, Service Determination Requests, Appeals, and Grievances (SDAG)	<ul style="list-style-type: none"> Added references to applicable universes in Appendix B and regulatory citations Modified instructions for submitting case files to CMS Modified current documentation requests and compliance standards Added new documentation requests and compliance standards Modified instructions for submitting responses to CMS 	Modify	Technical changes, Changes due to regulatory updates (effective June 2024), Clarified instructions	Low
AttachmentIPACEAuditProtocol, Audit Elements, Provision of Services	<ul style="list-style-type: none"> Added references to applicable universes in Appendix B and regulatory citations Modified instructions for observations and interviews Added new documentation requests and compliance standards Modified instructions for submitting responses to CMS Modified current compliance standards 	Modify	Technical changes, Changes due to regulatory updates (effective June 2024), Streamlined information, Clarified instructions	Low
AttachmentIPACEAuditProtocol, Audit Elements, Personnel Records	<ul style="list-style-type: none"> Added references to applicable universes in Appendix B and regulatory citations Added new documentation requests and compliance standards Modified instructions for submitting responses to CMS Modified current compliance standards 	Modify	Technical changes, Changes due to regulatory updates (effective June 2024), Clarified instructions	Low

Current CMS-10630 (2023)	Summary of Changes in Proposed CMS-10630 (starting in 2026)	Type of Change	Explanation of Changes	Burden Impact
AttachmentIPACEAuditProtocol, Compliance and Quality Improvement	<ul style="list-style-type: none"> Added references to universes in Appendix B and regulatory citations Added new documentation requests and compliance standards Modified instructions for submitting responses to CMS 	Modify	Technical changes, Clarified instructions, Changes for clarity based on audit experience	Low
AttachmentIPACEAuditProtocol, Analysis of Potential Non-Compliance	<ul style="list-style-type: none"> Added instructions for responding to requests for additional Information regarding potential issues non-compliance 	Modify	Clarified instructions	None
AttachmentIPACEAuditProtocol, Appendix A	<ul style="list-style-type: none"> Add instructions about data entry and formatting 	Modify	Clarified instructions	None
AttachmentIPACEAuditProtocol, Appendix A, Table 1: Service Determination Requests (SDR) Record Layout	<ul style="list-style-type: none"> Modified record layout instructions Modified current data fields 	Modify	Technical changes, Changes for clarity based on audit experience	None
AttachmentIPACEAuditProtocol, Appendix A, Table 2: Appeal Requests (AR) Record Layout	<ul style="list-style-type: none"> Modified record layout instructions Modified current data fields 	Modify	Technical changes, Changes for clarity based on audit experience	None
AttachmentIPACEAuditProtocol, Appendix A, Table 3: Grievance (GR) Record Layout 10 columns in the Record Layout	<ul style="list-style-type: none"> Modified record layout instructions Modified current data fields Removed 2 data fields Added 8 new data fields 	Modify	Technical changes, Changes due to regulatory updates (effective June 2024), Changes for clarity based on audit experience	Moderate
AttachmentIPACEAuditProtocol, Appendix A, Table 4: List of Personnel (LOP) Record Layout	<ul style="list-style-type: none"> Modified record layout instructions Modified current data fields 	Modify	Technical changes, Changes for clarity based on audit experience	None
AttachmentIPACEAuditProtocol, Appendix A, Table 5: List of Participant Medical Records (LOPMR) Record Layout 34 columns in the Record Layout	<ul style="list-style-type: none"> Modified current data fields Removed 4 data fields Added 3 new data fields 	Modify	Technical changes, Changes based on audit experience, Changes due to regulatory updates (effective June 2024)	Low
AttachmentIPACEAuditProtocol, Appendix A, Table 6: On-Call (OC) Record Layout	<ul style="list-style-type: none"> Modified current data fields 	Modify	Technical changes	None

Current CMS-10630 (2023)	Summary of Changes in Proposed CMS-10630 (starting in 2026)	Type of Change	Explanation of Changes	Burden Impact
AttachmentIPACEAuditProtocol, Appendix A, Table 7: Contracted Entities and Providers (CEP) Record Layout	<ul style="list-style-type: none"> Modified record layout instructions Modified current data fields 	Modify	Technical changes, Changes for clarity based on audit experience	None
AttachmentIIPACESupplementalQuestions (14 questions)	<ul style="list-style-type: none"> Modified questions to clarify the information requested Removed 1 question Added 4 questions 	Modify	Technical changes, Changes for based on audit experience	Low
AttachmentVCorrectiveActionPlanProcess	<ul style="list-style-type: none"> Modified instructions Removed implementation submissions 	Modify	Technical changes, Changes for clarity based on audit experience	Moderate (reduction)
CaseFileCoverSheet (No equivalent in the current protocol)	<ul style="list-style-type: none"> Added cover sheets for SDAG and Personnel case files to ensure all requested documentation is included. 	Add	New cover sheets provide checklist for submitting case file documentation	Low
RequestAdditionInformationTemplate (No equivalent in the current protocol)	<ul style="list-style-type: none"> Template explains how a PACE organization will submit information in response to requests for information related to potential issues of non-compliance identified during a PACE audit. 	Add	New template clarifies an existing audit process	None
RootCauseTemplate	RootCauseTemplate <ul style="list-style-type: none"> Added 1 column on the detailed sample information tab 	Modify	Allows for CMS assignment of an ID number for each issue of non-compliance identified during the audit.	None

Current CMS-10630 (2023)	Summary of Changes in Proposed CMS-10630 (starting in 2026)	Type of Change	Explanation of Changes	Burden Impact
18 Impact Analyses templates	<ul style="list-style-type: none"> 25 Impact Analysis templates 	Add	<p>Added seven additional Impact Analysis templates.</p> <p>Four added based on new regulatory provisions (effective June 2023 or 2024):</p> <p>ArrangingServices1P101, ParticipantRights1P1061P107, PlanofCare1P151P201P84, and RequiredSpecialistContracts1P100.</p> <p>Three separated out from existing templates for clarity based on audit experience:</p> <p>AppealRecognition1P65, Effectuation1P02, GrievanceRecognitionandNotification1P751P77</p>	Low
<p>AlertIDT1P14 Impact Analysis</p> <ul style="list-style-type: none"> 22 columns on participant impact tab 	<p>AlertIDT1P14 Impact Analysis:</p> <ul style="list-style-type: none"> Removed 1 column on the participant impact tab Modified 5 columns on the participant impact tab 	Modify	<p>Minor wording changes for clarity, Changes based on audit experience</p>	Low
<p>Appeals1P651P661P681P73 Impact Analysis</p> <ul style="list-style-type: none"> 42 columns on the participant impact tab 	<p>Appeals1P321P661P681P73 Impact Analysis:</p> <ul style="list-style-type: none"> Renamed impact analysis Updated instructions tab Added 2 columns on the participant impact tab Removed 10 columns on the participant impact tab Modified 13 columns on the participant impact tab 	Modify	<p>Minor wording changes for clarity, Changes based on audit experience</p>	Low

Current CMS-10630 (2023)	Summary of Changes in Proposed CMS-10630 (starting in 2026)	Type of Change	Explanation of Changes	Burden Impact
Assessments1P491P50 Impact Analysis <ul style="list-style-type: none"> 31 columns on the participant impact tab 	Assessments1P491P50 Impact Analysis: <ul style="list-style-type: none"> Added 3 column on the participant impact tab Removed 12 columns on the participant impact tab Modified 10 columns on the participant impact tab 	Modify	Minor wording changes for clarity, Changes based on audit experience, Changes to align with new regulatory provisions (effective June 2024)	Low
CoordinationofCare1P95 <ul style="list-style-type: none"> 25 columns on the participant impact tab 	CoordinationofCare1P95: <ul style="list-style-type: none"> Modified 3 columns on the participant impact tab 	Modify	Minor wording changes for clarity	None
Effectuation1P021P111P30 Impact Analysis <ul style="list-style-type: none"> 34 columns on the participant impact tab 	AppealsEffectuation1P111P30 Impact Analysis: <ul style="list-style-type: none"> Renamed impact analysis Updated instructions tab Added 2 columns on the participant impact tab Removed 15 columns on the participant impact tab Modified 8 columns on the participant impact tab 	Modify	Minor wording changes for clarity, Changes based on audit experience	Low
EmergencyCare1P07 Impact Analysis: <ul style="list-style-type: none"> 27 columns on the participant impact tab 	EmergencyCare1P07 Impact Analysis: <ul style="list-style-type: none"> Added 1 column to the participant impact tab Removed 2 columns on participant impact tab Modified 3 columns on the participant impact tab 	Modify	Minor wording changes for clarity	Low
Grievances1P311P751P77 Impact Analysis <ul style="list-style-type: none"> 29 columns on the participant impact tab 	Grievances Grievances1P311P1031P1041P105 Impact Analysis: <ul style="list-style-type: none"> Renamed impact analysis Updated instructions tab, including adding information for new conditions Added 20 columns to the participant impact tab Removed 14 columns on the participant impact tab Modified 3 columns on the participant impact tab 	Modify	Minor wording changes for clarity, Changes based on audit experience, Changes to align with new regulatory provisions (effective June 2024)	Low

Current CMS-10630 (2023)	Summary of Changes in Proposed CMS-10630 (starting in 2026)	Type of Change	Explanation of Changes	Burden Impact
HomeCare1P02 Impact Analysis <ul style="list-style-type: none"> 16 columns on participant impact tab 	HomeCare1P02 Impact Analysis: <ul style="list-style-type: none"> Added 1 column to participant impact tab Removed 3 columns on the participant impact tab Modified 5 columns on the participant impact tab 	Modify	Minor wording changes for clarity	Low
MedErrors1P02 Impact Analysis <ul style="list-style-type: none"> 22 columns on participant impact tab 	MedErrors1P02 Impact Analysis: <ul style="list-style-type: none"> Modified 4 columns on the participant impact tab 	Modify	Minor wording changes for clarity	Low
Personnel Impact Analysis <ul style="list-style-type: none"> 24 columns on the participant impact tab 	Personnel Impact Analysis: <ul style="list-style-type: none"> Updated instructions tab Added 9 columns on the participant impact tab Removed 4 columns on the participant impact tab Modified 10 columns on the participant impact tab 	Modify	Minor wording changes for clarity, Changes to align with new regulatory provisions (effective June 2024)	Low
ProvisionofServices1P02 Impact Analysis <ul style="list-style-type: none"> 19 columns on the participant impact tab 	ProvisionofServices1P02 Impact Analysis: <ul style="list-style-type: none"> Modified 10 columns on the participant impact tab 	Modify	Minor wording changes for clarity	Low
RequiredServices1P93 <ul style="list-style-type: none"> 29 columns on the participant impact tab 	RequiredServices1P931P100 <ul style="list-style-type: none"> Renamed impact analysis Updated instructions tab Added 1 column on the participant impact tab Removed 4 columns on the participant impact tab Modified 17 columns on the participant impact tab 	Modify	Minor wording changes for clarity, Changes based on audit experience	Low
Restraints1P09 Impact Analysis <ul style="list-style-type: none"> 26 columns on the participant impact tab 	Restraints1P09 Impact Analysis: <ul style="list-style-type: none"> Added 2 columns on the participant impact tab Removed 5 columns on the participant impact tab Modified 12 columns on the participant impact tab 	Modify	Minor wording changes for clarity, Changes based on audit experience	Low

Current CMS-10630 (2023)	Summary of Changes in Proposed CMS-10630 (starting in 2026)	Type of Change	Explanation of Changes	Burden Impact
SDRIdentification1P76 Impact Analysis <ul style="list-style-type: none"> 21 columns on participant impact tab 	SDRIdentification1P76 Impact Analysis: <ul style="list-style-type: none"> Modified 6 columns on participant impact tab 	Modify	Minor wording changes for clarity	Low
SDRs1P601P611P85 Impact Analysis <ul style="list-style-type: none"> 22 columns on participant impact tab 	SDRs1P041P601P611P85 Impact Analysis: <ul style="list-style-type: none"> Renamed impact analysis Updated instructions for completing participant impact tab Added 2 columns on the participant impact tab Removed 3 columns on the participant impact tab Modified 14 columns on the participant impact tab 	Modify	Minor wording changes for clarity, Changes based on audit experience	Low
SpecialistRecommendations1P94 <ul style="list-style-type: none"> 24 columns on participant impact tab 	RecommendedServices1P94 <ul style="list-style-type: none"> Renamed impact analysis Modified the instructions tab, including adding information for two new sections Added 19 columns on participant impact tab Removed 11 columns on participant impact tab Modified 6 columns on participant impact tab 	Modify	Minor wording changes for clarity, Changes to align with new regulatory provisions (effective June 2024)	Low
SrvcRestrict1P90 Impact Analysis <ul style="list-style-type: none"> 19 columns on the participant impact tab 	SrvcRestrict1P90 Impact Analysis: <ul style="list-style-type: none"> Updated instructions tab Added 7 columns on the participant impact tab Modified 4 columns on the participant impact tab 	Modify	Minor wording changes for clarity, Changes based on audit experience	Low
WoundCare1P02 Impact Analysis: <ul style="list-style-type: none"> 24 columns on the participant impact tab 	WoundCare1P02 Impact Analysis: <ul style="list-style-type: none"> Added 4 columns to the participant impact tab Removed 8 columns on the participant impact tab Modified 4 columns on the participant impact tab 	Modify	Minor wording changes for clarity, Changes based on audit experience	Low

Current CMS-10630 (2023)	Summary of Changes in Proposed CMS-10630 (starting in 2026)	Type of Change	Explanation of Changes	Burden Impact
CAPTemplate (No equivalent in the current protocol)	<ul style="list-style-type: none"> Template provides instructions for submitting corrective action plans for issues of non-compliance identified during a PACE audit. 	Add	New template clarifies an existing audit process	None