

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"> <li>Modified purpose and scope text</li> </ul>	Modify	Minor wording changes for clarity	None
AttachmentIPACEAuditProtocol, Initial Documentation and Data Submissions	<ul style="list-style-type: none"> <li>Modified documentation for the compliance oversight program</li> <li>Removed Monitoring Reports</li> </ul>	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"> <li>Added references to applicable universes in Appendix B and regulatory citations</li> <li>Modified instructions for submitting case files to CMS</li> <li>Modified current documentation requests and compliance standards</li> <li>Added new documentation requests and compliance standards</li> <li>Modified instructions for submitting responses to CMS</li> </ul>	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"> <li>Added references to applicable universes in Appendix B and regulatory citations</li> <li>Modified instructions for observations and interviews</li> <li>Added new documentation requests and compliance standards</li> <li>Modified instructions for submitting responses to CMS</li> <li>Modified current compliance standards</li> </ul>	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"> <li>Added references to applicable universes in Appendix B and regulatory citations</li> <li>Added new documentation requests and compliance standards</li> <li>Modified instructions for submitting responses to CMS</li> <li>Modified current compliance standards</li> </ul>	Modify	Technical changes, Changes due to regulatory updates (effective June 2024), Clarified instructions	Low

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AttachmentIPACEAuditProtocol, Compliance and Quality Improvement	<ul style="list-style-type: none"> <li>Added references to universes in Appendix B and regulatory citations</li> <li>Added new documentation requests and compliance standards</li> <li>Modified instructions for submitting responses to CMS</li> </ul>	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"> <li>Added instructions for responding to requests for additional Information regarding potential issues non-compliance</li> </ul>	Modify	Clarified instructions	None
AttachmentIPACEAuditProtocol, Appendix A	<ul style="list-style-type: none"> <li>Add instructions about data entry and formatting</li> </ul>	Modify	Clarified instructions	None
AttachmentIPACEAuditProtocol, Appendix A, Table 1: Service Determination Requests (SDR) Record Layout	<ul style="list-style-type: none"> <li>Modified record layout instructions</li> <li>Modified current data fields</li> </ul>	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"> <li>Modified record layout instructions</li> <li>Modified current data fields</li> </ul>	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"> <li>Modified record layout instructions</li> <li>Modified current data fields</li> <li>Removed 2 data fields</li> <li>Added 8 new data fields</li> </ul>	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"> <li>Modified record layout instructions</li> <li>Modified current data fields</li> </ul>	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"> <li>Modified current data fields</li> <li>Removed 4 data fields</li> <li>Added 3 new data fields</li> </ul>	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"> <li>Modified current data fields</li> </ul>	Modify	Technical changes	None

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AttachmentIPACEAuditProtocol, Appendix A, Table 7: Contracted Entities and Providers (CEP) Record Layout	<ul style="list-style-type: none"> <li>Modified record layout instructions</li> <li>Modified current data fields</li> </ul>	Modify	Technical changes, Changes for clarity based on audit experience	None
AttachmentIIPACESupplementalQuestions (14 questions)	<ul style="list-style-type: none"> <li>Modified questions to clarify the information requested</li> <li>Removed 1 question</li> <li>Added 4 questions</li> </ul>	Modify	Technical changes, Changes for based on audit experience	Low
AttachmentVCorrectiveActionPlanProcess	<ul style="list-style-type: none"> <li>Modified instructions</li> <li>Removed implementation submissions</li> </ul>	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"> <li>Added cover sheets for SDAG and Personnel case files to ensure all requested documentation is included.</li> </ul>	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"> <li>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.</li> </ul>	Add	New template clarifies an existing audit process	None
RootCauseTemplate	<p>RootCauseTemplate</p> <ul style="list-style-type: none"> <li>Added 1 column on the detailed sample information tab</li> </ul>	Modify	Allows for CMS assignment of an ID number for each issue of non-compliance identified during the audit.	None

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

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

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HomeCare1P02 Impact Analysis <ul style="list-style-type: none"> <li>16 columns on participant impact tab</li> </ul>	HomeCare1P02 Impact Analysis: <ul style="list-style-type: none"> <li>Added 1 column to participant impact tab</li> <li>Removed 3 columns on the participant impact tab</li> <li>Modified 5 columns on the participant impact tab</li> </ul>	Modify	Minor wording changes for clarity	Low
MedErrors1P02 Impact Analysis <ul style="list-style-type: none"> <li>22 columns on participant impact tab</li> </ul>	MedErrors1P02 Impact Analysis: <ul style="list-style-type: none"> <li>Modified 4 columns on the participant impact tab</li> </ul>	Modify	Minor wording changes for clarity	Low
Personnel Impact Analysis <ul style="list-style-type: none"> <li>24 columns on the participant impact tab</li> </ul>	Personnel Impact Analysis: <ul style="list-style-type: none"> <li>Updated instructions tab</li> <li>Added 9 columns on the participant impact tab</li> <li>Removed 4 columns on the participant impact tab</li> <li>Modified 10 columns on the participant impact tab</li> </ul>	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"> <li>19 columns on the participant impact tab</li> </ul>	ProvisionofServices1P02 Impact Analysis: <ul style="list-style-type: none"> <li>Modified 10 columns on the participant impact tab</li> </ul>	Modify	Minor wording changes for clarity	Low
RequiredServices1P93 <ul style="list-style-type: none"> <li>29 columns on the participant impact tab</li> </ul>	RequiredServices1P931P100 <ul style="list-style-type: none"> <li>Renamed impact analysis</li> <li>Updated instructions tab</li> <li>Added 1 column on the participant impact tab</li> <li>Removed 4 columns on the participant impact tab</li> <li>Modified 17 columns on the participant impact tab</li> </ul>	Modify	Minor wording changes for clarity, Changes based on audit experience	Low
Restraints1P09 Impact Analysis <ul style="list-style-type: none"> <li>26 columns on the participant impact tab</li> </ul>	Restraints1P09 Impact Analysis: <ul style="list-style-type: none"> <li>Added 2 columns on the participant impact tab</li> <li>Removed 5 columns on the participant impact tab</li> <li>Modified 12 columns on the participant impact tab</li> </ul>	Modify	Minor wording changes for clarity, Changes based on audit experience	Low

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SDRIdentification1P76 Impact Analysis <ul style="list-style-type: none"> <li>21 columns on participant impact tab</li> </ul>	SDRIdentification1P76 Impact Analysis: <ul style="list-style-type: none"> <li>Modified 6 columns on participant impact tab</li> </ul>	Modify	Minor wording changes for clarity	Low
SDRs1P601P611P85 Impact Analysis <ul style="list-style-type: none"> <li>22 columns on participant impact tab</li> </ul>	SDRs1P041P601P611P85 Impact Analysis: <ul style="list-style-type: none"> <li>Renamed impact analysis</li> <li>Updated instructions for completing participant impact tab</li> <li>Added 2 columns on the participant impact tab</li> <li>Removed 3 columns on the participant impact tab</li> <li>Modified 14 columns on the participant impact tab</li> </ul>	Modify	Minor wording changes for clarity, Changes based on audit experience	Low
SpecialistRecommendations1P94 <ul style="list-style-type: none"> <li>24 columns on participant impact tab</li> </ul>	RecommendedServices1P94 <ul style="list-style-type: none"> <li>Renamed impact analysis</li> <li>Modified the instructions tab, including adding information for two new sections</li> <li>Added 19 columns on participant impact tab</li> <li>Removed 11 columns on participant impact tab</li> <li>Modified 6 columns on participant impact tab</li> </ul>	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"> <li>19 columns on the participant impact tab</li> </ul>	SrvcRestrict1P90 Impact Analysis: <ul style="list-style-type: none"> <li>Updated instructions tab</li> <li>Added 7 columns on the participant impact tab</li> <li>Modified 4 columns on the participant impact tab</li> </ul>	Modify	Minor wording changes for clarity, Changes based on audit experience	Low
WoundCare1P02 Impact Analysis: <ul style="list-style-type: none"> <li>24 columns on the participant impact tab</li> </ul>	WoundCare1P02 Impact Analysis: <ul style="list-style-type: none"> <li>Added 4 columns to the participant impact tab</li> <li>Removed 8 columns on the participant impact tab</li> <li>Modified 4 columns on the participant impact tab</li> </ul>	Modify	Minor wording changes for clarity, Changes based on audit experience	Low

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CAPTemplate (No equivalent in the current protocol)	<ul style="list-style-type: none"><li>• Template provides instructions for submitting corrective action plans for issues of non-compliance identified during a PACE audit.</li></ul>	Add	New template clarifies an existing audit process	None