

| Proposed CMS-10913 (Prior to 60-Day Comment Period) Document | Summary of Changes in Proposed CMS-10913 (Following 60-Day Comment Period) | Type of Change | Explanation of Changes | Burden Impact |
|---|---|-----------------------|---|----------------------|
| All documents | Replaced “Sponsoring organization” with Medicare Advantage organization (MAO) throughout all documents. | Modified | Minor wording change to align with regulation | None |
| Medicare PartC_UM_AnnualDataSubmission | Retitled the document from “Medicare Part C Utilization Management (UM) Annual Data Request” to “Medicare Part C Utilization Management (UM) Annual Data Submission” to be consistent with titling throughout the document. | Modified | Minor word change | None |
| Medicare PartC_UM_AnnualDataSubmission | Starting on page 2, replaced the document header title words “Utilization Management Data Request” with “Annual Data Submission”. | Modified | Minor wording change to align the document title and header | None |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Universe Submission Subsection: Removed the .txt file format as an allowable file format for the universe submission. | Modified | Modified allowable universe file format to ensure proper formatting of data | None |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Universe Submission Subsection: Replaced the words “record layout” with “field” to clarify that universe “data must be limited to the request specified in each field.” | Modified | Clarified instruction | None |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Universe Submission Subsection: | Modified | Modified the document to clarify CMS may | Low (increase) |

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| | Added additional guidance explaining that the CMS may validate universe submissions if errors are noted. | | validate universe submissions | |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Utilization Management Annual Submission (UMAS) Record Layout Subsection, Instructions: Clarified that the universe should include internal coverage in use during the applicable calendar year. | Modified | Clarified the applicable timeframe | None |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Utilization Management Annual Submission (UMAS) Record Layout Subsection, Instructions: Defined service using the definition in 42 C.F.R. 400.202 and clarified that the term “service” includes services, items, and Part B drugs for the purposes of the record layout. | Modified | Clarified the definition of “service” | None |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Utilization Management Annual Submission (UMAS) Record Layout Subsection, Instructions: Clarified that, for the purposes of the UMAS universe, “service” does not include step therapy for Part B drugs. | Modified | Clarified what constitutes internal coverage criteria | None |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Utilization Management Annual Submission (UMAS) Record Layout Subsection, Instructions: | Modified | Clarified how to enter internal coverage criteria applicable in | None |

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| | Clarified instructions for entering criteria when there are different versions of criteria used in different service areas. | | different service areas | |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Utilization Management Annual Submission (UMAS) Record Layout Subsection, Instructions: Clarified instructions for entering information in comma-separated lists. | Modified | Clarified data entry instructions | None |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Utilization Management Annual Submission (UMAS) Record Layout Subsection, Instructions: Added a reference to the Utilization Management Annual Submission (UMAS) Record Layout with Examples document. | Modified | Modified instructions to mention the Utilization Management Annual Submission (UMAS) Record Layout with Examples document | None |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Utilization Management Annual Submission (UMAS) Record Layout Subsection, (Original) Column A: Moved the original column A to column B, modified the name of the column, and modified the instructions. We believe making the criteria the primary category | Modified | Modified the name, the instructions, and moved the column from A to B | Low (reduction) |

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| | (rather than service) will reduce burden for MAOs by more clearly identifying which information must be reported. | | | |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Utilization Management Annual Submission (UMAS) Record Layout Subsection, (Original) Column C: Removed the original column C. | Remove | Removed CPT and HCPCS codes from the information collection to reduce burden | High (reduction) |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Utilization Management Annual Submission (UMAS) Record Layout Subsection, (Original) Column D: Re-lettered the original column D to column C due to the removal of the original column C. Clarified instructions. | Modified | Modified column lettering and revised instructions for clarity | None |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Utilization Management Annual Submission (UMAS) Record Layout Subsection, (Original) Column E: Re-lettered the original column E to column D due to the removal of the original column C. The column name was revised, and the instructions were modified. | Modified | Modified column lettering, column name and instructions | None |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Utilization Management Annual Submission (UMAS) Record Layout Subsection, (Original) Column F: | Modified | Modified column lettering and revised | None |

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| | Re-lettered the original column F to column E due to the removal of the original column C. Instructions were clarified. | | instructions for clarity | |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Utilization Management Annual Submission (UMAS) Record Layout Subsection, (Original) Column G: Re-lettered the original column G to column F due to the removal of the original column C. Instructions were clarified. | Modified | Modified column lettering and revised instructions for clarity | None |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Utilization Management Annual Submission (UMAS) Record Layout Subsection, (Original) Column H: Re-lettered the original column H to column G due to the removal of the original column C. The name of the column and the instructions were modified. | Modified | Modified column lettering, column name and instructions | None |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Utilization Management Annual Submission (UMAS) Record Layout Subsection, (Original) Column I: Re-lettered the original column I to column H due to the removal of the original column C. Instructions were clarified. | Modified | Modified column lettering and revised instructions for clarity | None |
| Medicare PartC_UM_AnnualDataSubmission | Annual Data Submission Section, Utilization Management Annual Submission (UMAS) | Modified | Modified column lettering and | None |

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| | Record Layout Subsection, (Original) Column J: Re-lettered the original column J to column I due to the removal of the original column C. Instructions were clarified. | | revised instructions for clarity | |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | Purpose: Clarified instructions to ensure MAOs were aware of compliance standards and requirements that would be applicable to the data collection. | Modified | Modified instructions to identify requirements that will apply, including when new issues arise. | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | General: Clarified the meaning of “service” to include services, items, and Part B drugs. | Modified | Clarified the meaning of the term service | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | Compliance Standards Section, 1.1: Clarified that auditors would select up to 20 services for review from the Utilization Management Criteria (UMC) Record Layout. | Modified | Clarified how auditors would select services | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | Compliance Standards Section, 1.5: Removed the compliance standard. | Modified | Modified the compliance standards to remove the original standard 1.5. | High (reduction) |

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| Medicare PartC_UM_AuditProtocolDataRequest.pdf | Compliance Standards Section, 1.7: Removed the compliance standard. | Modified | Modified the compliance standards to remove the original standard 1.7. | High (reduction) |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | Compliance Standards Section, 1.6 and 1.8 through 1.10: Renumbered the original compliance standards 1.6 and 1.8 through 1.10 to 1.5 through 1.8 to account for the removal of the original compliance standards 1.5 and 1.7. | Modified | Technical change | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | Compliance Standards Section: Revised standards to make minor, non-substantive wording changes. | Modified | Minor wording changes | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Audit Engagement and Universe Submission Phase Subsection: Added additional guidance explaining that the CMS List of Targeted Services will be provided with the audit engagement letter. | Modified | Modified the document to clarify when the CMS List of Targeted Services will be provided | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Audit Engagement and Universe Submission Phase Subsection: Added the due date for the Supplemental Questions document into the audit protocol | Modified | Modified the document to clarify when the Supplemental | None |

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| | to ensure consistency and transparency. The due date was previously only included in the Supplemental Questions document. | | Questions document is due | |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Universe Submission Subsection: Removed the .txt file format as an allowable file format for the universe submission. | Modified | Modified allowable universe file format to ensure proper formatting of data | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Universe Submission Subsection: Added additional instructions to clarify that MAOs do not need to submit additional information at the time of universe submission. Also added reference to an optional excel template that MAOs may use which includes examples of how to populate instructions. | Modified | Clarified that additional documentation does not have to be submitted with the universe | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Instructions: Clarified that information submitted should be based on the status of the service at the time of universe submission. | Modified | Clarified the timeframe associated with the requested information | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column A: | Modified | Minor wording changes | None |

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| | Renamed the column and made minor wording changes to consistently use 'service' rather than 'service or item.' | | | |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column B: Removed the original column B. | Remove | Removed CPT and HCPCS codes from the information collection to reduce burden | High (reduction) |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column C: Re-lettered the original column C to column B due to the removal of column B. Modified the instructions for clarity. | Modified | Modified the column letter and clarified instructions | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column D: Re-lettered the original column D to column C due to the removal of column B. Modified the information collected from 'Locality' to 'MAC Jurisdiction' to reduce burden. | Modified | Modified the column letter and the information collected | Low (reduction) |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column E: Re-lettered the original column E to column D due to the removal of column B. Modified the instructions for clarity. | Modified | Modified the column letter and clarified instructions | None |

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| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column F: Removed the original column F. | Remove | Removed applicable Medicare regulations to reduce burden for MAOs | Low (reduction) |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column G: Removed the original column G. | Remove | Removed national coverage determinations to reduce burden for MAOs | Low (reduction) |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column H: Removed the original column H. | Remove | Removed local coverage determinations to reduce burden for MAOs | Low (reduction) |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column I: Re-lettered the original column I to column E due to the removal of columns B and F-H. Modified the instructions for clarity. | Modified | Modified the column letter and clarified instructions | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column J: Re-lettered the original column J to column F due to the removal of columns | Modified | Modified the column letter and clarified instructions | None |

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| | B and F-H. Modified the instructions for clarity. | | | |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column K: Re-lettered the original column K to column G due to the removal of columns B and F-H. Renamed the column and modified the instructions for clarity. | Modified | Modified the column letter, column name, and clarified instructions | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column L: Re-lettered the original column L to column H due to the removal of columns B and F-H. Renamed the column and modified the instructions for clarity. | Modified | Modified the column letter, column name, and clarified instructions | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column M: Re-lettered the original column M to column I due to the removal of columns B and F-H. Modified the instructions for clarity. | Modified | Modified the column letter and clarified instructions | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column N: Re-lettered the original column N to column J due to the removal of columns B and F-H. Renamed the column and modified the instructions for clarity. | Modified | Modified the column letter, column name, and clarified instructions | None |

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| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column O: Re-lettered the original column O to column K due to the removal of columns B and F-H. Modified the instructions for clarity. | Modified | Modified the column letter and clarified instructions | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column P: Removed the original column P. | Remove | Removed UM committee approval to reduce burden for MAOs | Low (reduction) |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column Q: Removed the original column Q. | Remove | Removed publicly accessible to reduce burden for MAOs | Low (reduction) |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Utilization Management Criteria (UMC) Record Layout, Column R: Re-lettered the original column R to column L due to the removal of columns B, F-H, and P-Q. Renamed the column and modified the instructions for clarity. | Modified | Modified the column letter, column name, and clarified instructions | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Supporting Documentation Submissions: Renamed the section and clarified that CMS will select a subset of 20 services from the UMC universe to review. | Modified | Modified the subsection name and clarified the instructions | None |

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| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Supporting Documentation Submissions: Created new sub-sections to clarify process and due dates: including a section for Initial Submissions, a section for CMS review and Data Validation, and a section for "Evidentiary Source Submission" | Modified | Created new sub-sections to clarify audit fieldwork process | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Supporting Documentation Submissions: Under the new Initial Submissions, we broke out documentation types by the services that have internal coverage criteria and the services that do not. | Modified | Clarified documentation due initially to CMS | Low (reduction) |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Supporting Documentation Submissions: Modified the instructions to clarify that the Analysis of Internal Coverage Criteria document must be completed for all documents that contain internal coverage criteria. Additionally, clarified that Um committee notes, and the individual internal coverage criteria policies must be submitted in the initial submission | Modified | Clarified the types of documents that must be included in the initial submission | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Supporting Documentation Submissions: Clarified what documentation must be submitted for all services (regardless of | Modified | Modified instructions to better outline expectations | Low (increase) |

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| | whether they have internal coverage criteria) including any operational tools, guidelines, or other methods of disseminating and applying criteria. Additionally, clarified instructions related to the identification of denial letters for the validation review. | | related to documentation submissions during fieldwork | |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Supporting Documentation Submissions: Moved information from the data validation section into the documentation submission section under a new subsection titled CMS Review and Data Validation. | Modified | Adjusted placement of data validation information to better align with audit process | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Supporting Documentation Submissions: Added information into the CMS review and Data Validation section to clarify how CMS will identify and review denial letters and/or validate the submitted internal coverage criteria | Modified | Clarified how information would be gathered and assessed during validation | Low (increase) |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Supporting Documentation Submissions: Created a new subsection titled “Evidentiary Sources Submission” to create new guidance on a second submission of data in response to burden concerns. This section will allow CMS to narrow our | Modified | Reduced burden by creating a secondary submission of information on a smaller subset of data | High (decrease) |

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| | secondary request for information to avoid over burdening the organization. | | | |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Supporting Documentation Submissions: Created a new timeframe for evidentiary sources to be submitted to CMS of 10 business days. | Modified | Reduced burden by creating a secondary submission of information on a smaller subset of data | High (decrease) |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Supporting Documentation Submissions: Made minor edits to improve the clarity of the instructions. | Modified | Minor wording changes | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Data Validation Subsection: Removed data validation section and merged information into the documentation submission under audit fieldwork. | Modified | Removed section and shifted information into a different section to clarify audit process | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Impact Analysis Submissions Subsection: Modified the instructions to allow for IA extensions on a case-by-case basis. | Modified | Modified the instructions to allow for extensions | Low (reduction) |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, UM Internal Criteria Impact Analysis (UMIC-IA) Record Layout Subsection: | Modified | Clarified instructions | None |

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| | We revised the UM Internal Criteria Impact Analysis (UMIC-IA) instructions to specify that CMS will furnish MAOs with the UMIC-IA in Microsoft Excel (.xlsx) format and with columns A-C populated by CMS. UMIC-IA will no longer be accepted as a .txt file. | | | |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, UM Internal Criteria Impact Analysis (UMIC-IA) Record Layout Subsection: We clarified that MAOs must complete columns D-P. | Modified | Clarified instructions | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, UM Internal Criteria Impact Analysis (UMIC-IA) Record Layout Subsection: We added instructions stating that we would limit the IA timeframe based on the service. | Modified | Clarified instructions | High (decrease) |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, UM Internal Criteria Impact Analysis (UMIC-IA) Record Layout Subsection: We added instructions stating that the IA should only include Level 1 reconsiderations. | Modified | Clarified instructions | Medium (decrease) |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, UM Internal Criteria Impact Analysis (UMIC-IA) Record Layout Subsection, Column A: | Modified | Minor wording changes | None |

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| | Renamed the column and made minor wording changes to consistently use 'service' rather than 'service or item.' Made minor revision to clarify that CMS will enter the information in this column. | | | |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, UM Internal Criteria Impact Analysis (UMIC-IA) Record Layout Subsection, Column B: Made minor revision to clarify that CMS will enter the information in this column. | Modified | Minor wording changes | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, UM Internal Criteria Impact Analysis (UMIC-IA) Record Layout Subsection, (New) Column C: We added a new column C to account for a decreased timeframe for collecting IA data. | Modified | Modified the IA to limit the data collection timeframe in order to reduce burden | High (reduction) |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, UM Internal Criteria Impact Analysis (UMIC-IA) Record Layout Subsection, (Original) Columns C-F: Original columns C-F were re-lettered due to the addition of new column C. The columns were also renamed, and minor wording changes were made to consistently use 'service' rather than 'service or item.' | Modified | Minor wording changes | None |

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| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, UM Internal Criteria Impact Analysis (UMIC-IA) Record Layout Subsection, (Original) Columns G-I: Original columns G-I were re-lettered due to the addition of new column C and minor wording changes were made to consistently use 'service' rather than 'service or item.' | Modified | Minor wording changes | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, UM Internal Criteria Impact Analysis (UMIC-IA) Record Layout Subsection, (Original) Columns J-L: Original columns J-L were re-lettered due to the addition of new column C. The columns were also renamed, and minor wording changes were made to consistently use 'service' rather than 'service or item.' | Modified | Minor wording changes | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, UM Internal Criteria Impact Analysis (UMIC-IA) Record Layout Subsection, (Original) Columns M-O: Original columns M-O were re-lettered due to the addition of new column C. | Modified | Minor wording changes | None |
| Medicare PartC_UM_AuditProtocolDataRequest.pdf | UM Audit Data Request Section, Verification of Information Collected: Created a new section at the end of the audit protocol to reiterate that CMS will | Modified | Added a section to reiterate intention to validate | None |

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| | validate information submitted and may require resubmissions when there are concerns about the accuracy of the information. | | submitted information | |
| Standardized Formatting of Internal Criteria (now titled Analysis of Internal Coverage Criteria) | Retitled the “Standardized Formatting of Internal Criteria “ document to “Analysis of Internal Coverage Criteria“. | Modified | Minor wording change | None |
| Standardized Formatting of Internal Criteria (now titled Analysis of Internal Coverage Criteria) | Converted the document from Word to Excel | File type change | Modified format for ease of readability and data entry | None |
| Standardized Formatting of Internal Criteria (now titled Analysis of Internal Coverage Criteria) | Services Selected by CMS tab: A ‘Services Selected by CMS’ tab was added to the Excel version of the document. This will be completed by CMS and is a reference for MAOs. | Modified | Modified the document to add reference material that will be completed by CMS | None |
| Standardized Formatting of Internal Criteria (now titled Analysis of Internal Coverage Criteria) | Standardized Formatting Tab, General Instructions: This section was added to the document to clarify how MAOs should complete the document. | Modified | Clarified instructions | None |
| Standardized Formatting of Internal Criteria (now titled Analysis of Internal Coverage Criteria) | Standardized Formatting Tab, Part 1: Five rows (Coverage Criteria Unique Weblink, Coverage Criteria applicable to Medicare Members, Applicable Medicare Rules, Medicare Coverage Included or | Remove | Modified the table in Part 1 to remove rows and decrease data entry | High (reduction) |

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| | Excluded, and Explicit Flexibility for Additional Coverage) were removed in order to decrease burden by eliminating duplicative data entry. | | | |
| Standardized Formatting of Internal Criteria (now titled Analysis of Internal Coverage Criteria) | Standardized Formatting Tab, Part 1: The names and instructions for two rows/data points (Organization Name and Applicable Service Area) were modified. | Modified | Modified the table in Part 1 to revise row names and clarify the types of data needed | None |
| Standardized Formatting of Internal Criteria (now titled Analysis of Internal Coverage Criteria) | Standardized Formatting Tab, Part 1: Added additional instructions to clarify how the document should be completed by MAOs. | Modified | Modified instructions to provide additional clarity | None |
| Standardized Formatting of Internal Criteria (now titled Analysis of Internal Coverage Criteria) | Standardized Formatting Tab, Part 2, Columns A-B: Added additional instructions to clarify the information needed and decrease burden when completing the document. | Modified | Modified rows A-B to provide additional clarity | None |
| Standardized Formatting of Internal Criteria (now titled Analysis of Internal Coverage Criteria) | Standardized Formatting Tab, Part 2, Column C: The information from the original column C was shifted to column D. CMS requested additional information in column C that is necessary to evaluate regulatory compliance. The additional information | Modified | Modified row C to collect additional information needed to assess compliance | Low (increase) |

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| | requested only requires MAOs to enter “A,” “B,” or “C.” | | | |
| Standardized Formatting of Internal Criteria (now titled Analysis of Internal Coverage Criteria) | <p>Internal Coverage Criteria tab, Part 2, Column D: The information from the original column C was shifted to column D and additional instructions were provided to increase clarity.</p> <p>The information originally requested in column D (Citation associated with Medicare language) was moved to column E.</p> | Modified | Modified the table to shift the original column C to column D, the original column D to column E, and add additional instructions for clarity. | None |
| Standardized Formatting of Internal Criteria (now titled Analysis of Internal Coverage Criteria) | <p>Internal Coverage Criteria tab, Part 2, Column E: The information from the original column D was shifted to column E and additional instructions were provided to increase clarity.</p> <p>The information originally requested in column E (Provide a statement as to how this specific clinical criteria provides clinical benefits that are highly likely to outweigh any clinical harms) was removed to decrease burden for MAOs.</p> | Modified | Modified the table to shift the original column D to column E and remove the information originally collected in column E to reduce burden. | High (reduction) (Related to the removal of the information originally requested in column E.) |

| Proposed CMS-10913 (Prior to 60-Day Comment Period) Document | Summary of Changes in Proposed CMS-10913 (Following 60-Day Comment Period) | Type of Change | Explanation of Changes | Burden Impact |
|--|--|-----------------------|--|----------------------|
| Standardized Formatting of Internal Criteria (now titled Analysis of Internal Coverage Criteria) | Internal Coverage Criteria tab, Part 2, Column F: This column was added to reduce MAO burden when completing column G. This column will be completed by CMS. | Modified | Modified the table to add column F in order to reduce the burden associated with column G. | High (reduction) |
| Standardized Formatting of Internal Criteria (now titled Analysis of Internal Coverage Criteria) | Internal Coverage Criteria tab, Part 2, Column G: This column was added to incorporate the information originally requested in Part 3 into Part 2. The instructions were also modified to provide additional clarity. | Modified | Modified the table to incorporate the information originally requested in Part 3. | None |
| Standardized Formatting of Internal Criteria (now titled Analysis of Internal Coverage Criteria) | Internal Coverage Criteria tab, Part 3: Part 3 was removed, and the requested information was moved to Part 2, column G. | Modified | Remove Part 3 of the document and incorporated the requested information in the table in Part 2. | None |
| Standardized Formatting of Internal Criteria (now titled Analysis of Internal Coverage Criteria) | Internal Coverage Criteria tab, Part 4: Part 4 was removed in order to decrease MAO burden. | Modified | Removed Part 4 | Low (reduction) |
| Instructions on Entering and Submitting Criteria (now merged) | Removed instructions from a standalone document and added them into the | Modified | Merged instructions into the document | None |

| Proposed CMS-10913 (Prior to 60-Day Comment Period) Document | Summary of Changes in Proposed CMS-10913 (Following 60-Day Comment Period) | Type of Change | Explanation of Changes | Burden Impact |
|---|--|-----------------------|--|----------------------|
| into Analysis of Internal Coverage Criteria) | Analysis of Internal Coverage Criteria in the first tab. | | they relate to for ease of MAO | |
| Instructions on Entering and Submitting Criteria (now merged into Analysis of Internal Coverage Criteria) | General Header: This section was added to provide additional instructions for completing the Analysis of Internal Coverage Criteria document. | Modified | Clarified instructions | None |
| Instructions on Entering and Submitting Criteria (now merged into Analysis of Internal Coverage Criteria) | Services Selected by CMS Tab Header: This section was added to clarify the purpose of the 'Service Selected' tab in the Analysis of Internal Coverage Criteria document. | Modified | Clarified instructions | None |
| Instructions on Entering and Submitting Criteria (now merged into Analysis of Internal Coverage Criteria) | Internal Coverage Criteria tab, Part 1 Sub-header: Instructions for the rows retained in Part 1 of the Analysis of Internal Coverage Criteria document were modified to provide additional clarity. | Modified | Modified instructions for additional clarity | None |
| Instructions on Entering and Submitting Criteria (now merged into Analysis of Internal Coverage Criteria) | Internal Coverage Criteria tab, Part 1 Sub-header: Instructions for the rows removed from Part 1 of the Analysis of Internal Coverage Criteria document were removed. | Modified | Removed instructions for rows removed from the Analysis of Internal Coverage Criteria document | None |

| Proposed CMS-10913 (Prior to 60-Day Comment Period) Document | Summary of Changes in Proposed CMS-10913 (Following 60-Day Comment Period) | Type of Change | Explanation of Changes | Burden Impact |
|---|--|-----------------------|---|----------------------|
| Instructions on Entering and Submitting Criteria (now merged into Analysis of Internal Coverage Criteria) | Internal Coverage Criteria tab, Part 2 Sub-header: Instructions pertaining to the columns in Part 2 of the Analysis of Internal Coverage Criteria document were modified to provide additional clarity (for columns that were retained in Part 2) or added (for newly added columns in Part 2). | Modified | Modified instructions for additional clarity and added instructions as needed | None |
| Instructions on Entering and Submitting Criteria (now merged into Analysis of Internal Coverage Criteria) | Internal Coverage Criteria tab, Part 3 Sub-header: Instructions were removed because Part 3 of the Analysis of Internal Coverage Criteria document was incorporated into Part 2. | Modified | Removed instructions that were incorporated into Part 2 | None |
| Instructions on Entering and Submitting Criteria (now merged into Analysis of Internal Coverage Criteria) | Internal Coverage Criteria tab, Part 4 Sub-header: Instructions were removed because Part 4 of the Analysis of Internal Coverage Criteria document was removed. | Modified | Removed instructions for Part 4 of the Analysis of Internal Coverage Criteria document since Part 4 was removed | None |
| CMS List of Targeted Services | Modified the CMS List of Targeted Services' Instructions to include the 42 C.F.R. 400.202 definition of "services" and to provide examples of types of services included per the cited definition. | Modified | Clarified definition of "services" and provided examples of applicable "services" | None |

| Proposed CMS-10913 (Prior to 60-Day Comment Period) Document | Summary of Changes in Proposed CMS-10913 (Following 60-Day Comment Period) | Type of Change | Explanation of Changes | Burden Impact |
|---|--|-----------------------|---|----------------------|
| CMS List of Targeted Services | Modified the CMS List of Targeted Services' Instructions to clarify that the list could include Part B drugs. | Modified | Clarified instructions | None |
| CMS List of Targeted Services | Modified the CMS List of Targeted Services' Instructions to clarify that the list may contain up to 50 unique services, items, or Part B drugs to be consistent with the Audit Field Work Phase process described in the UM Audit Protocol Data Request. | Modified | Clarified instructions | None |
| CMS List of Targeted Services | Modified the CMS List of Targeted Services' Instructions to clarify that MAOs do not need to submit copies of internal criteria or other information for the services on the CMS List of Targeted Services, only the requested universe of information in the Part C UM Audit Protocol and Data Request. | Modified | Clarified instructions | Moderate (reduction) |
| CMS List of Targeted Services | Modified the CMS List of Targeted Services' Instructions to clarify that MAOs can expect to receive the CMS List of Targeted Services with the CMS audit engagement letter, instead of on a calendar year basis. | Modified | Clarified Instructions | None |
| CMS List of Targeted Services | Modified the Targeted Services Table column header "Brief Description of Service" to include "(if applicable)". | Modified | Clarified instructions | None |
| CMS List of Targeted Services | Modified the Targeted Services Table format to include 50 rows, which is consistent with the CMS List of Targeted | Modified | Modified the table formatting for consistency | None |

| Proposed CMS-10913 (Prior to 60-Day Comment Period) Document | Summary of Changes in Proposed CMS-10913 (Following 60-Day Comment Period) | Type of Change | Explanation of Changes | Burden Impact |
|---|--|-----------------------|-------------------------------|----------------------|
| | Services instructions that allow up to 50 unique services, items, or Part B drugs on the list. | | | |
| UMSupplementalQuestions | Modified the file name to display “UMSupplementalQuestions” when opened to ensure consistency between the document title and file name. | Modified | Minor wording change | None |
| UMSupplementalQuestions | Modified the Instructions tab to provide a data collection period example using the year 2026 instead of 2025 to align with CMS’ proposed implementation timeframe. | Modified | Minor wording change | None |
| UMSupplementalQuestions | On the UM Supplemental Questions tab, for the section of questions titled “Questions on Public Accessibility of Criteria”, we replaced the term “Accessibility” with “Availability”. | Modified | Minor wording change | None |
| UMSupplementalQuestions | On the UM Supplemental Questions tab, replaced the term “beneficiaries” with “members, non-members” in questions 2, 3, and 4. | Modified | Minor wording change | None |
| UMSupplementalQuestions | On the UM Supplemental Questions tab, modified question 8 to reference “Part B drugs” in addition to “items and services”. | Modified | Clarified instructions | None |
| UMSupplementalQuestions | On the UM Supplemental Questions tab, modified question 2 to remove duplicate terminology. | Modified | Minor wording change | None |

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|--|--|----------------|---|---------------|
| NA | Created a reference document that provides example data to guide the submission of the UM Annual Data Submission Utilization Management Annual Submission (UMAS) Record Layout. New document is titled "Utilization Management Annual Submission (UMAS) Record Layout with Examples" | New | Created an excel template that directly aligns with data requests to clarify data submissions by providing examples to MAOs | None |
| NA | Created a reference document that provides example data to guide the submission of the UM Audit Protocol Data Request Utilization Management Criteria (UMC) Record Layout. New document is titled "Utilization Management Criteria (UMC) Record Layout with Examples" | New | Created an excel template that directly aligns with data requests to clarify data submissions by providing examples to MAOs | None |
| NA | Created a template for the Root Cause Analysis that is discussed in the UM Audit Protocol and Data Request. This template was inadvertently left out of the original package, however, it was discussed in the protocol and accounted for in the burden estimates. | New | Created a template for the Root Cause Analysis | None |