

**Centers for Medicare and Medicaid Services Response to Public Comments Received for CMS-10913; OMB 0938-1488**

The Centers for Medicare and Medicaid Services (CMS) received 15 public submissions from Medicare Advantage (MA) organizations (MAOs), healthcare providers, professional organizations, and individuals during the 30-day comment period on the proposed CMS-10913 issued December 23, 2024. This is the reconciliation of the comments. CMS combined the public submissions into comment summaries based on topics and provided responses in the document below. Comments are categorized first by those that are general in nature, then by those specific to the collection instruments, and finally, by those that pertain to burden.

**General Comments**

Comment: A couple of commenters expressed concerns that some of the data CMS proposed to collect in this PRA package may already be available through existing sources, such as annual Part C data submissions, publicly accessible information on MAOs' websites, and through the data required by the Interoperability and Prior Authorization final rule (89 FR 8758). These commenters also expressed concerns with the proposal for a separate audit process for Internal Coverage Criteria (ICC) in this PRA package and recommended combining that audit process with the current Part C and Part D program audit process to alleviate burden on MAOs. Another commenter stated they had insufficient time to review the PRA documents following the modifications made after the 60-day comment period and requested that CMS release another PRA notice to allow plans sufficient time to analyze the changes and provide meaningful feedback.

Response: CMS thanks commenters for their feedback. Although CMS finds that the data needed for oversight is not systematically accessible through the sources suggested by commenters, it remains committed to regularly evaluating the value of all available data and determining whether it provides relevant and necessary information to fulfill the agency's duties. Likewise, if data becomes available and/or readily accessible through other means, CMS will take that into account when revising future iterations of this PRA package.

In alignment with that principle, CMS has taken steps to streamline this PRA package and realize process efficiencies. First, CMS is limiting the scope of the annual data collection to only ICC that are used for Part C services that require prior authorization, and CMS removed fields from the annual data collection that would require manual review to provide the requested data as discussed in more detail below. Second, CMS will not be finalizing the audit protocol portion of this PRA package (Medicare PartC\_UM\_AuditProtocolDataRequest.docx) or the related data collection tools (CMS List of Targeted Services.docx, Medicare Part C UM Root Cause Analysis.xlsx, UMSupplementalQuestions.xlsx, Analysis of Internal Coverage Criteria.xlsx and Utilization Management Criteria (UMC) Record Layout with Examples.xlsx). Instead, CMS will consider commenters' suggestions to incorporate portions of the proposed ICC review into the current program audit protocols (CMS-10717) to streamline the review of MAOs' adoption and application of coverage criteria.

CMS acknowledges the commenters' feedback regarding additional time to review the PRA materials and appreciates that organizations will require time to develop strategies for annual data reporting. Therefore, CMS agrees to provide technical assistance and extend deadlines as needed to facilitate smooth data submissions.

Comment: While a commenter appreciated CMS's efforts to provide more examples on the types of services it intends to collect through this PRA package, the commenter stated the definition remains overly broad and does not provide MAOs with adequate clarity to assess existing documentation and adjust internal processes to meet the audit request. Another commenter requested that CMS determine which services have fully established CMS criteria rather than leaving that up to the MAOs.

Response: CMS appreciates the opportunity to provide further clarification. In the 30-day PRA protocol, CMS included the definition of services in 42 C.F.R. § 400.202, which defines services as, "medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital, CAH, or SNF facilities." In this revised PRA package, CMS continues to define services consistent with the definition in 42 C.F.R. § 400.202; however, CMS will only be focusing on services that require PA. Additionally, CMS would like to clarify that, for the purposes of this data collection, Part B drugs are considered services when they have ICC and are also subject to PA for the calendar year. ICC for Part B drugs does not include step therapy policies applicable to Part B drugs. CMS also confirms that organizations are not required to submit supplemental benefit policies in response to this data collection, criteria related to Medicaid only services, or criteria related to non-Medicare covered services. MAOs are already required to track the services where prior authorization is required, and therefore the applicable services for this collection should be readily available. MAOs will be asked to submit high-level identifying information related to any ICC used for making prior authorization decisions for those services.

Comment: A couple of commenters requested CMS delay the annual data collection in this PRA package, with a commenter specifically requesting a delay to 2027 and another asking for sufficient lead time with no specific date. CMS also received a few comments requesting a later implementation date to allow more time to update systems and reduce the need for a manual review to provide the requested data. Another commenter requested CMS to confirm whether UM audits will be conducted in 2025.

Response: Because CMS has significantly reduced the scope and number of data fields required for the annual collection, and eliminated the proposed audit protocol from this PRA package, CMS believes it is not necessary to extend the timeframe for implementation to 2027. However, CMS agrees to extend deadlines as needed to facilitate smooth data submissions. Finally, CMS is not conducting any UM audits in 2025.

Comment: Multiple commenters were opposed to CMS publicly posting MAOs' responses to the annual data collection in a central repository. One commenter misunderstood CMS's suggestion to mean the MAOs would have to post the collection data to their own websites. Another

commenter stated that because MAOs are continuously revising ICC as new evidence becomes available, the annual data collections would be out-of-date as soon as CMS published them.

Response: CMS thanks commenters for their feedback. CMS had solicited comment on whether CMS should maintain a public repository of the annual collection data on its website; however, based on feedback received, CMS has decided not to pursue this effort at this time.

Comment: A commenter recommended that CMS require MAOs to include the name of the person performing the UM review in any denial letter as the commenter expressed concern that the MAO UM reviewers should have expertise in whatever condition they review.

Response: CMS appreciates the commenter's concerns; however, this request is outside the scope of this data collection.

### **Annual Data Collection**

#### **Medicare Part C Utilization Management Annual Data Submission**

Comment: A couple of commenters expressed concern about the January 31<sup>st</sup> due date for the proposed annual data submission and noted that January is generally a busy time of year when other Part C and Part D reporting is due. These commenters requested a due date after the proposed January 31<sup>st</sup> deadline. One of these commenters also indicated they would need to review the previous year's data to determine the ICC that should be reported to CMS.

Response: CMS agrees with commenters and has adjusted the due date of the annual data collection to February 28<sup>th</sup> of each year. For 2026, CMS will also consider and approve individual requests to extend this timeframe as needed to ensure organizations have sufficient time to prepare and submit the data. CMS would also like to reiterate that this collection does not collect the ICC that was used for services in the prior year, and therefore, organizations do not need to spend time reviewing previously made decisions. Instead, this is a collection of the ICC that an MAO determines will be applicable to the Medicare Part C services that are subject to prior authorization in the **current** calendar year. Since the UM committee must review and approve criteria before it is implemented, CMS expects this information to be largely collected prior to the start of the year in which the criteria would be used.

Comment: CMS received a comment on the Utilization Management Annual Data Submission universe template. The commenter requested CMS add "Field Type" and "Field Length" into the record layouts

Response: CMS appreciates the suggestion but is not inclined to add "Field Type" and "Field Length" at this time. The "Description" column identifies the type and format of the information that must be entered therefore a "Field Type" column is not necessary. The identification of specific field lengths in the record layout is also not necessary; CMS has assured that the field lengths in the Health Plans Management System (HPMS) will accommodate plan user entered data.

Comment: CMS received a few comments requesting clarification of the information being collected in the annual data submission. A commenter requested CMS clarify whether Column C

(Date of Most Recent Approval) is the date the vendor's UM committee approves the criteria or the date the MAO's UM committee approves the first-tier, downstream, and related entity's (FDR) criteria. Another commenter indicated that this data field would not be automatically populated and would require a manual review of each policy. Another commenter asked CMS to clarify if Column D (Medicare Administrative Contractor (MAC) Jurisdictions) only pertains to local MACs since beneficiaries may seek services outside of their local MAC jurisdiction. Finally, a commenter requested clarification on whether the annual data collection should be submitted at the parent organization level or contract level.

Response: In response to comments received, CMS is removing Column C (Date of Most Recent Approval). For the field MAC jurisdictions, CMS is interested in any MAC jurisdiction where the specific ICC policy or document may be used as a normal course of business. The annual data collection should be submitted at the parent organization level and organizations will identify the applicable contracts associated with each ICC policy. If a parent organization uses the same ICC across all contracts, a single submission would be sufficient.

Comment: CMS received a comment recommending that Column G (FDR) be modified to allow organizations the option to indicate that a criterion applies to either "all FDRs" or "all FDRs excluding" to save time in populating the data.

Response: CMS thanks the commenter for their feedback. The instructions for Column G were modified to allow organizations to enter one of three options. If all entities (the organization and all FDRs) use the specific ICC policy or document in question, the organization may enter, "ALL." If some but not all entities utilize the specific ICC policy or document in question, the organization may report the information by entering all applicable entities or by entering, "All excluding" and all applicable entities that do not use this specific ICC policy or document, whichever is easiest for the organization reporting the data.

Comment: CMS received a comment regarding Column H (Organization or Vendor) and Column I (Website Link) and stated the data collected in these columns are not typically found in UM systems. The commenter further stated that populating this information would create burden on organizations.

Response: CMS thanks the commenters for their feedback. CMS has removed Column I (Website Link) in the Utilization Management Annual Submission (UMAS) Record Layout. However, CMS has maintained column H (Organization or Vendor) because this information provides valuable insight into organizations' UM practices. CMS does not anticipate collection of this field would present a challenge to organizations because the vendor or organization that created the ICC policy is easily identifiable.

Comment: A commenter requested that CMS modify the example document to reflect the same date format in Column C as the audit protocol.

Response: CMS thanks the commenters for their feedback. CMS has removed Column C (Date of Most Recent Approval) from the UMAS Record Layout. CMS has also updated the example template to reflect the additional changes made to this collection.

## **Audit Protocol**

### **CMS List of Targeted Services**

Comment: CMS received a comment requesting confirmation that the services selected for an audit will come from the List of Targeted Services, which CMS will populate based on the Annual Data Collection submission. CMS also received a comment requesting that CMS populate the field “Brief Description of Service” in the CMS List of Targeted Services at a higher level, similar to how CMS requires MAOs to populate universes for other audit activities such as the ODAG tables found in the Part C and Part D program audit protocols.

Response: CMS thanks commenters for their feedback. However, because CMS is only moving forward with the Annual Data Collection in this PRA package, it will not be updating or using the CMS List of Targeted Services for this collection.

### **Medicare Part C Utilization Management (UM) Audit Protocol and Data Request**

Comment: CMS received several comments on the Medicare Part C Utilization Management (UM) Audit Protocol and Data Request, many seeking clarification and offering recommendations to reduce burden. Commenters asked for clearer guidance on what is meant by “minimum information necessary” in the denials report and whether MAOs may use information from the organization determination, appeals and grievances (ODAG) universe collected during the CMS Part C program audits to populate it. Several commenters also requested clarification on the audit process and timelines, including whether CMS would select a different service if a sampled service lacks denial letters and whether ICC under review would apply to the 2024 plan year.

Other suggestions focused on improving data validation and reporting. Commenters recommended using procedure codes instead of service names, standardizing the impact analysis (IA) review timeframes, combining the denials report with the IA request, and extending submission deadlines for both the IA and universe data. Some also suggested modifying sample sizes—one recommending a cap of no more than 20 targeted services—to make reporting more manageable.

CMS also received comments on Universe Table 1, with requests to clarify definitions like “service area” for MAOs operating in multiple jurisdictions and questions about how to populate data when coverage criteria differ by dosage or strength, particularly for Part B drugs. Several commenters noted that they do not currently collect all requested data in their UM systems and expressed concerns about the reporting burden. Finally, one commenter recommended CMS consider pilot audits limiting the number of targeted services and participating MAOs to better study how plans develop and use ICC.

Response: CMS thanks commenters for their feedback. However, because CMS is only moving forward with the Annual Data Collection in this PRA package, it will not be updating or using the Medicare Part C UM Audit Protocol and Data Request for this collection.

### **Analysis of Internal Coverage Criteria**

Comment: CMS received several comments on the Analysis of Internal Coverage Criteria submission, primarily seeking clarification and reduced burden. Commenters requested clearer guidance on the scope of the analysis, how to populate spreadsheet columns, and whether responses should be assessed per criterion, noting that they did not believe that a one-to-one comparison with Medicare criteria may always be feasible. Some asked CMS to confirm whether all internal criteria, such as FDR, Medicare, Milliman Care Guidelines, and MAO policies, must be included and how to handle off-label use of medications.

Several commenters suggested modifications to simplify reporting. These included allowing MAOs to submit policy links instead of full language, consolidating the analysis with other data collection requests, or enabling CMS to obtain certain information directly from MAO websites. One commenter also recommended CMS request the validation denials report during targeted service selection to further reduce burden.

Response: CMS thanks commenters for providing feedback. However, because CMS is only moving forward with the Annual Data Collection in this PRA package, it will not be updating or using the Analysis of Internal Coverage Criteria spreadsheet.

### **Utilization Management Supplemental Questions**

Comment: CMS received a few comments on the UM Supplemental Questions. One commenter asked for clarification on question 4, noting they do not track which services have ICC and do not believe this tracking is required. Another commenter requested CMS clarify whether “redetermination” in question 8 should instead reference “reconsideration.” Finally, a commenter suggested narrowing the scope of question 8 to include only FDRs for the selected services.

Response: CMS thanks commenters for providing feedback. However, because CMS is only moving forward with the Annual Data Collection in this PRA package, it will not be updating or using the Utilization Management Supplemental Questions.

### **Burden**

Comment: CMS received several comments concerning the burden the proposed data collection would have on MAOs. A few commenters stated that CMS underestimates the hours and resource commitment required to provide the requested information. One of these commenters further discussed how providing the data requested in the proposed PRA package would require manual research and data collection.

Response: CMS has carefully considered commenters’ recommendations and has removed the audit protocol and all corresponding audit tools from the proposed data collection. CMS is only requiring the Annual Data Collection in this PRA package and has modified the collection tool (based on comments) to significantly reduce burden whenever possible. The most significant changes include limiting the scope of the Annual Data Collection to only those services which require prior authorization, which excludes collecting and reporting ICC used in concurrent reviews, retrospective reviews, and payment decisions; and removing the fields that might require a manual data entry. These changes will significantly reduce the associated burden of this PRA package, and CMS revised the burden estimates to reflect those reductions.