Supporting Statement – Part B
Medicare Part C RADV Audit Documentation Submission Requirements
(CMS-10980; 0938-NEW)

Introduction

Section 1853(a)(1)(C) of the Social Security Act requires that CMS risk-adjust payments made to MA organizations. Risk adjustment strengthens the MA program by ensuring that accurate payments are made to MA organizations based on the health status and demographic characteristics of their enrolled beneficiaries, and that MA organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees who are expected to incur lower health care costs, and more for less healthy enrollees who are expected to incur higher health care costs). Making accurate payments to MA organizations also ensures we are safeguarding federal taxpayer dollars.

The diagnosis data that MA organizations submit to CMS do not undergo a validation review by CMS before being relied on by CMS to calculate each enrollee's risk score and make payments. CMS conducts post-payment risk adjustment data validation (RADV) audits of MA organization-submitted diagnosis data from a selection of MA organization contracts for specific payment years to ensure that the diagnoses they submitted are supported by enrollees' medical records. CMS requires MA organizations to submit a sample of medical records to CMS for validation of risk adjustment data pursuant to 42 C.F.R. § 422.310(e).

1. Respondent Universe and Sampling

CMS announced an aggressive strategy to enhance and accelerate MA audits in May 2025. This strategy included increasing the number of eligible MA contracts selected for audits. CMS identified enrollees that it believes are at most risk for being associated with payment error in MA and focused audits on these enrollees. However, some contracts that did not have enrollees that met the top 25 percent threshold were subject to random selection for audits. CMS estimates it will include approximately 492 contracts for payment years 2022 and 2023 RADV audits and approximately 590 MA contracts in payment year 2025 and later payment years using this methodology.

CMS publishes audit methods and instructions describing the statistical sampling and extrapolation methods that it intends to use for each MA contract-specific RADV audit. Each MA contract-specific RADV audit includes:

1 Planning: CMS defines a sample unit, sampling frame, and sample selection method.
2 Initiation: CMS sends an Audit Notice, provides audit methods and instructions, and makes an enrollee data list (EDL) available for download in the RADV secure system, the Centralized Data Abstraction Tool (CDAT).
3 Medical Record (MR) Submission: The MA organization submits MRs to CMS during a MR submission window for enrollees selected in the audit sample.
4 Analysis and Issuance of an Audit Report Package: CMS analyzes the output from MR reviews, calculates payment errors, and issues an Audit Report Package to the MA organization.

This section describes an example of a sampling frame, sample unit definition, sample design, and sample selection method that may be used for a RADV audit. A sampling frame of enrollees could include, for example, enrollees who:

1. Were continuously enrolled in an audited MA contract from January of the data collection year (DCY) through January of the specific payment year (PY);
2. Were enrolled in Medicare Part B coverage for 12 months during DCY;
3. Had at least one risk adjustment diagnosis in the International Classification of Diseases, Clinical Codes with a date of service that led to at least one HCC assignment for the specific PY;
4. Were not in an End Stage Renal Disease status from January of the DCY through January of the specific PY;
5. Were not in a hospice status from January of the DCY through January of the specific PY;
6. Were not part of an Office of Inspector General (OIG) audit or other pertinent settlements that included data from January of the DCY through January of the specific PY;
7. Were not enrolled in a Chronic Condition Special Needs Plan (C-SNP), an Institutional Special Needs Plan (I-SNP) or a Fully Integrated Dual Eligible Special Needs Plan (FIDE-SNP) from January of the DCY through January of specific PY; and
8. Were ranked by CMS's analysis as being in the top quartile of the specific PY RADV-eligible enrollees predicted to have the greatest reduction in their risk score as a result of a RADV audit across all RADV-eligible MA contracts.

The sample unit is an MA contract enrollee that meets the sampling frame criteria.

2. Data Collection Procedures

a. Statistical Methodology and Sample Selection

CMS selected a statistically valid random sample of enrollees from the sampling frame by:

1. Establishing a seed number using a random number generator,
2. Sorting enrollees (i.e., sample units) included in the sampling frame by CMS' unique identifier for each enrollee, and
3. Using a statistical software tool to select a simple random sample (without replacement) to randomly select 35, 50, 100, or 200 enrollees.

b. Estimation Procedures

Not applicable to contract-specific RADV audits.

c. Degree of Accuracy Needed for Purpose Described in the Justification

Each audited MA organization must submit at least one valid MR and MR coversheet to CMS to support each audited hierarchical condition code (CMS-HCC) included in the EDL.

d. Unusual Problems Requiring Specialized Sampling Procedures

There are no unusual problems requiring specialized sampling procedures for contract-specific RADV audits.

e. Any Use of Periodic data Collection Cycles to Reduce Burden

There is no use of periodic (less frequent than annual) data collection cycles for contract-specific RADV audits.

3. Maximizing Response Rates/Non-response and Issues of Accuracy, Reliability, and Validity

Pursuant to 42 C.F.R 422.310(e)[1], CMS conducts RADV audits requiring MA organizations to submit a sample of medical records to CMS for validation of risk adjustment data. CMS maintains a dedicated webpage[2], which provides resources for audited MA organizations to review during contract-specific RADV audits. Included in the resources are FAQs, audit schedule, general guidance documents, and for each payment year there is a MA RADV Audit Methods and Instructions document and a list of audited contracts. Additionally, there a two CMS email support resources. The points of contact associated with an audited MA contract may request technical support regarding use of the CDAT system by sending an email to the CDAT Technical Support Email Box at RADVCONTechsupport@radvcdat.com. Individuals with general questions about CMS' MA contract-specific RADV audits may send an email to radv@cms.hhs.gov.

An audited MA organization must submit at least one valid medical record and medical record coversheet to CMS to support each audited HCC During RADV audits CMS provides feedback about each submitted medical record file and coversheet throughout the medical record intake process. An MA organization's point of contract may access an Intake Feedback Report (IFR) within CDAT. The IFR provides the status of intake processing for each medical record submitted during the medical record submission window. Once intake processing is complete for a given medical record, the IFR is updated to indicate if the medical record passed all intake validity checks. If it did not, then the IFR will list the reason(s) why it did not pass. Instructions for how to access the IFR are included in the CDAT User Guide in the Plan Library within CDAT. The IFR will be available to the MA organization's points of contact throughout the audit lifecycle.

4. Past and Ongoing Tests of Procedures, Trainings, and Quality Improvement Activities; Collaborator and Contractor Participation

CMS and the RADV contractor work together on an ongoing basis to ensure the CDAT system functions correctly and that MA organizations can submit data during RADV audits.

Before each RADV audit cycle, CMS and the contractor test CDAT functionality — including medical record intake, data storage and reporting — to confirm the system performs as intended. Any defects, system unavailability, or access issues identified during testing or during live use are logged, triaged, and resolved by the contractor, with fixes verified before being deployed to the production environment that MA organizations use.

CMS and the contractor hold weekly meetings, supplemented by additional meetings as needed, to:

- Review open issues or defects affecting the CDAT system's performance or availability
- Discuss system maintenance updates and upcoming enhancements
- Evaluate feedback from MA organizations and RADV contractors on usability or data submission challenges
- Identify process improvements based on lessons learned from completed audit cycles
- Determine when updates to the CDAT User Guide are needed to reflect system changes or clarify instructions

[1] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-G/section-422.310
[2] https://www.cms.gov/data-research/monitoring-programs/medicare-risk-adjustment-data-validation-program

The contractor maintains and updates the CDAT User Guide, which walks MA organizations through using the system correctly to respond to RADV audit requests. The contractor also maintains a CDAT helpdesk that provides direct support to users, including but not limited to: troubleshooting and resolving CDAT unavailability, resolving user access issues and answering questions about system functionality during active audits

By combining regular system testing, structured CMS–contractor collaboration, documentation updates, and dedicated user support, this process helps ensure MA organizations have the tools, guidance, and assistance needed to respond accurately and timely to RADV audits.

5. Names and telephone numbers of individuals consulted on statistical aspects of the survey and implementation design and names of agency units, contractor(s), grantee(s), or other persons(s) who collect and/or analyze the information for the agency.

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