Supporting Statement – Part A
Medicare Part C RADV Audit Documentation Submission Requirements
(CMS-10980 – OMB Control Number: 0938-NEW)

A. Background

Section 1853(a)(1)(C) of the Social Security Act requires that CMS risk-adjust payments made to MA organizations. Risk adjustment strengthens the Medicare Advantage (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 does 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, contract-specific risk adjustment data validation (RADV) audits of MA organization-submitted diagnosis data from a selection of MA organizations for specific payment years to ensure that the diagnoses they submitted are supported by their enrollees' medical records. For RADV audits, MA organizations are required to submit a sample of medical records to CMS for validation of risk adjustment data pursuant to 42 C.F.R. § 422.310(e).

In the event MA organizations experience extraordinary circumstances beyond their control that may make it difficult to meet medical record submission or other audit requirements they may request a hardship exception. MA organizations requesting hardship exceptions are required to submit supporting documentation that clearly demonstrates an extraordinary circumstance(s) exists and includes all relevant details required for CMS to comprehensively assess the incident or issue. Supporting documentation includes, but is not limited to, any communications associated with the incident and all available evidence substantiating that the incident occurred.

Collection of information to conduct contract-specific RADV audits was previously included in CMS-10191, which expired on June 30, 2023. CMS-10191 has since been replaced by a more streamlined collection of information under CMS-10717.

CMS-10717 is specific to CMS's compliance audits designed to ensure MA organizations comply with all Medicare Parts C and D program requirements. This is accomplished by conducting audits that focus on high-risk areas with the greatest potential for beneficiary harm, thereby strengthening CMS's oversight and accountability framework for MA organizations. Therefore, CMS is proposing a new collection that includes RADV audits, as CMS has determined that the collection of information pursuant to contract-specific RADV audits should be included in its own dedicated PRA package.

This Paperwork Reduction Act (PRA) package informs the public of the information collected in

connection with and to comply with contract-specific RADV audits requirements. Specifically, the collection covers information necessary to:

- Designate a Lead Point of Contact (POC) to access CMS's RADV secure system, called the Centralized Data Abstraction Tool (CDAT);
- Submit a medical record coversheet and medical records in response to audit requirements; and
- Request a hardship exception, where applicable.

Upon conclusion of RADV audits, MA organizations are afforded an opportunity to appeal their audit findings pursuant to 42 C.F.R. § 422.311(c). Information collected by CMS from MA organizations in connection with RADV appeals is exempt from PRA, as such the data collection is a result from an administrative action.

B. Justification

1 . Need and Legal Basis

Section 1853(a)(1)(C) of the Social Security Act requires that CMS risk-adjust payments made to MA organizations. CMS conducts RADV audits pursuant to 42 C.F.R. § 422.310(e), which requires MA organizations to submit a sample of medical records to CMS for validation of risk adjustment data. The data collected during a RADV audit allow CMS to determine diagnoses submitted by MA organizations to CMS are supported by their enrollees' medical records.

2. Information Users

The information gathered during a contract-specific RADV audit is used by CMS to validate risk adjustment data submitted by MA organizations, calculate payment errors, and recover improper payments. CMS reviews documentation submitted by MA organizations for hardship exception requests to determine if MA organizations demonstrated they have experienced an extraordinary circumstance preventing them from complying with audit requirements.

3. Use of Information Technology

Information collected from MA organizations for use in a contract-specific RADV audit is obtained electronically via CMS's designated secure electronic portal, the Centralized Data Abstraction Tool (CDAT), This system is secure, requiring users to request and gain access by submitting points of contact information and then must create and maintain a secure user id and password.

MA organizations submit medical records, medical record coversheets, and hardship exception requests in CDAT.

Except for the Lead POC form completed by MA organizations to access CMS's secure CDAT system, this collection is currently available for completion electronically. No part of the

collection requires a signature from the respondents.

4. Duplication of Efforts

This information collection does not duplicate any other effort, and the information cannot be obtained from any other source.

5. Small Businesses

There are various types of Medicare health and drug plans, including MA organizations, demonstrations, section 1876 cost plans, Part D prescription drug plans (PDPs), and PACE organizations. There are a variety of ways to assess whether MA organizations meet the $41.5 million threshold for small businesses. The assessment can be done by examining net worth, net income, cash flow from operations, and/or projected claims as indicated in their bids. Using projected monetary requirements and projected enrollment for 2018 from submitted bids, 32 percent of the MA organizations fell below the $41.5 million threshold for small businesses. Additionally, an analysis of 2016 data shows that 32 percent of all MA organizations fall below the minimum threshold for small businesses.

While some of the entities affected by this collection of information are not-for-profit organizations and small businesses, the impact is not significant. No changes are made to long-standing audit documentation standards as a result of this rule; therefore, there is no significant impact to small entities (or any entities). MA organizations provide medical record documentation to CMS as a normal business practice pursuant to RADV audits.

6. Less Frequent Collection

Section 1853(a)(1)(C) of the Social Security Act requires CMS to risk adjust payments made to MA organizations. Making accurate payments to MA organizations ensures CMS is safeguarding federal taxpayer dollars. Contract-specific RADV audits are CMS's main corrective action to identify overpayments made to MA organizations when there is a lack of documentation in medical records to support the diagnoses reported by MA organizations for risk adjusted payments.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;

- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day notice published in the Federal Register on November 19, 2026 (91 FR 74680).

No outside consultation was sought.

9. Payments/Gifts to Respondents

No payments or gifts are provided to respondents in connection with this information collection. MA organizations are required to submit a sample of medical records to CMS for validation of risk adjustment data.

10. Confidentiality

CMS will adhere to all statutes, regulations, and agency policies regarding confidentiality. While MA organizations are required to provide CMS access to records, data and other enrollee information, CMS will ensure that the collected information and any sensitive or personal information will be transferred and/or stored through CDAT.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates (Hours & Wages)

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2025 National Occupational Employment and Wage Estimates for all salary estimates (https://data.bls.gov/oes/#/area/0000000/2025). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage. We selected the following personnel for our burden estimate based on our previous experiences conducting similar Part C program audits.

National Occupational Mean Hourly Wage and Adjusted Hourly Wage

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr.)	Fringe Benefit ($/hr.)	Adjusted Hourly Wage ($/hr.)
Medical and Health Services Managers	11-9111	67.77	67.77	135.54
Legal Support Workers, All Other	23-2099	43.10	43.10	86.20
Medical Records Specialists	29-2072	27.30	27.30	54.60
Medical Secretaries and Administrative Assistants	43-6013	22.5	22.50	45.00

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

The following table shows the burden (hours) and total cost by occupation, and total cost for an average audited contract. The average hourly wage for the RADV audit information collection is $52.05, which is derived by dividing Total Cost ($37,946.48) by the Burden (729).

National Occupational Mean Hourly Wage and Adjusted Hourly Wage

Occupation	**Adj Hourly Wage**	**Burden (Hours)**	**Total Cost**
Medical and Health Service Managers	$135.54	21.4	$2,900.56
Legal Support Workers, All Other	$86.20	21.4	$1,844.68
Medical Records Specialists	$54.60	241.9	$13,207.74
Medical Secretaries and Administrative Assistants	$45.00	444.3	$19,993.50
Total		**729**	**$37,946.48**

The table shows the burden (hours) and total cost by occupation, and total cost for an average audited contract. The average hourly wage for the Hardship Exception information collection is $59.55, which is derived by dividing Total Cost ($595.47) by the Burden (10).

National Occupational Mean Hourly Wage and Adjusted Hourly Wage

Occupation	Adj Hourly Wage	Burden (Hours)	Total Cost
Medical and Health Service Managers	$135.54	0.5	$67.77
Legal Support Workers, All Other	$86.20	1.5	$129.30
Medical Records Specialists	$54.60	4	$218.40
Medical Secretaries and Administrative Assistants	$45.00	4	$180.00
Total		**10**	**$595.47**

Burden Summary

Based on our audit strategy, contract-specific audits are conducted for each payment year. For each MA organization, we estimate an average of 729 hours for administrative and systemic work to assemble the requested information, review the information for completeness, and submit the information to CMS.

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 errors 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.

Based on prior contract-specific RADV audits approximately 50 percent of MA organizations' contracts submit hardship exception requests. On average, it takes an MA organization 10 hours to review requirements, complete, and submit a hardship exception request with all required supporting documentation. Information collected by MA organizations during an audit will also be used to compile the information as part of a hardship exception request, reducing duplicative effort.

MA organizations that want to submit hardship exception requests must submit required information and upload relevant supporting documents in the RADV secure system, the Centralized Data Abstraction Tool (CDAT). Each hardship exception request must include hardship justification and supporting documentation. Additionally, MA organizations must designate the type of hardship exception request they are submitting: contract, enrollee, or HCC.

Burden Hour and Cost Totals

Information Collection	Respondents	Responses (per Respondent)	Total Responses	Burden per	Total Annual	Labor Cost of	Total Cost

				Response (hours)	Burden (hours)	Reporting ($/hr)	
RADV audits	590	336	198,240	729	430,110	$52.05	$22,388,421
Hardship exception request	295	1	295	10	2,950	$59.55	$175,664
TOTAL			**198,535**		**433,060**		**$22,564,085**

13. Capital Costs

There is no capital cost associated with this collection

14. Cost to Federal Government

The costs to the federal government include staff time to participate in the audit, and money used to fund audit support contracts that are used as staff extenders during audit.

15. Changes to Burden

This is a new information collection.

16. Publication/Tabulation Dates

A list of audited contracts and audits results may be compiled and published by payment year and CMS may aggregate results. The information regarding contract-specific RADV audits is available on the CMS website at: https://www.cms.gov/data-research/monitoring-programs/medicare-advantage-risk-adjustment-data-validation-radv-program/radv-documents-data.

17. Expiration Date

CMS would like an exemption from displaying the expiration date as these forms are used on a continuing basis. To include an expiration date would result in having to discard a potentially large number of forms

18. Certification Statement

There are no exceptions.