Supporting Statement Part A
Medicare Part C and Part D Program Audit Protocols
(CMS-10717; OMB 0938-1395)

Background

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR Parts 422 and 423, Medicare Part D plan sponsors and Medicare Advantage organizations (herein after referred to as *Sponsoring organizations*) are required to comply with all Medicare Parts C and D program requirements. The Centers for Medicare and Medicaid's (CMS) annual audit plan ensures that CMS evaluates Sponsoring organizations' compliance with these requirements by conducting program audits that are designed to evaluate high-risk areas that have the greatest potential for beneficiary harm. As such, CMS has developed the following audit protocols[1] for use by Sponsoring organizations to prepare for their audit:

- Parts C and D Compliance Program Effectiveness (CPE) [2]
- Part D Formulary and Benefit Administration (FA)
- Part D Coverage Determinations, Appeals, and Grievances (CDAG)
- Part C Organization Determinations, Appeals, and Grievances (ODAG) [3]
- Special Needs Plans Care Coordination (SNPCC)

Each year, CMS conducts program audits of a subset of Sponsoring organizations at the parent organization (as defined in 42 CFR 422.2 and 423.4) level. These audits collect limited data sets from each Sponsoring organization specific to the program areas that are within scope of CMS's review. For example, if a Sponsoring organization does not offer a special needs plan, or an accrediting organization has deemed a special needs plan compliant with CMS regulations and standards, CMS would not apply the SNPCC protocol. Likewise, CMS would not apply the ODAG audit protocol to an organization that offers only a standalone prescription drug plan since that organization does not offer the MA benefit. In addition, CMS may conduct limited scope audits wherein all program area protocols may not be applied.

As part of a robust program audit process, CMS also requires Sponsoring organizations with identified deficiencies to undergo validation activities to demonstrate correction. In the past, those validation activities were conducted through a validation audit that leveraged the same audit protocols and updated data collections, but limited testing to the program areas and elements where deficiencies were found. Starting in 2027, validation activities

[1] Once approved by OMB, the Part C and Part D Program Audit protocols will be posted to CMS's website at: https://www.cms.gov/medicare/compliance-and-audits/part-c-and-part-d-compliance-and-audits/programaudits.
[2] Please note the CPE protocol will no longer be used to review its own program area. Instead, it's been revised to complement the other program area protocols to support a more complete review process.
[3] The ODAG protocol also evaluates the integrated organization determinations, appeals, and grievances of Sponsoring organizations offering an applicable integrated SNP plan with exclusively aligned enrollment as

defined at 42 CFR § 422.561.

may be conducted through either an audit or through other activities including a more streamlined documentation and data review.

CMS is requesting a "Revision" type of OMB approval due to several modifications. Please refer to section 15 and the Crosswalk of Changes for a complete summary of updates made to this collection request. In addition to general comments from the public, CMS is soliciting input on the following:

Justification

1. Need and Legal Basis

CMS is responsible for overseeing the Medicare Advantage (MA) and Part D programs to ensure that beneficiaries receive appropriate and timely benefits, services, and drugs. Under Sections 1857(d) and 1860D-12 of the Social Security Act, and related regulations at 42 CFR §§ 422.503, 422.504, 422.516, 423.504, and 423.505, CMS has the authority to inspect, evaluate, and monitor the benefits provided by Sponsoring organizations.
To carry out this oversight, Sponsoring organizations must provide CMS with access to relevant records, documentation, and systems. They are also required to report information on service utilization and other data as requested by CMS to confirm ongoing compliance with program requirements. CMS uses the data collected by way of these audit protocols to thoroughly assess whether Sponsoring organizations are meeting specific federal requirements, including:

- Compliance Program Effectiveness—42 CFR, §§ 422.503 and 423.504
- Part D Formulary and Benefit Administration—42 CFR, Part 423, Subpart C
- Part D Coverage Determinations, Appeals, and Grievances—42 CFR, Part 423, Subpart M
- Part C Organization Determinations, Appeals, and Grievances—42 CFR, Part 422, Subparts C and M
- Special Needs Plans Care Coordination —42 CFR §§§ 422.4(a)(iv), 422.101(f), and 422.152(g)

2. Information Users

The information gathered during this program audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM) to assess Sponsoring organizations' compliance with Medicare program requirements. MOEG reviews submitted data and selected samples from that data to ensure appropriate enrollee access to benefits, services and drugs. Specifically, CMS reviews data to ensure Part D organizations are administering their formulary and transition benefit in accordance with their CMS-approved formulary; CMS reviews coverage requests and appeals to ensure regulatory requirements are followed when enrollees request services; and, if the audited MA organization offers a SNP, MOEG's review evaluates whether the SNP is coordinating care in accordance with CMS

requirements.

If outliers or other data anomalies are detected, MOEG requires audited organizations to provide impact analyses to better understand and report the scope of the noncompliance. These Sponsoring organizations then receive their audit results, are required to implement corrective actions, and to demonstrate correction of all conditions cited in the final audit report by undergoing validation activities. If the validation effort demonstrates substantial correction of the conditions, MOEG will communicate its decision to close the audit in a letter to the Sponsoring organization. Any new or isolated issues of noncompliance that remain will be referred to the CMS Account Manager for follow-up. CMS Account Managers will work in collaboration with MOEG and other divisions within CMS for resolution.

3. Use of Information Technology

Sponsoring organizations can produce approximately 65 percent of requested information from their internal systems. CMS obtains another 30 percent via its internal systems. The remaining 5 percent of data is manually entered by audited Sponsoring organizations in response to questionnaires or other audit requests.

Information collected from the Sponsoring organizations for use in the audit is obtained electronically via the Health Plan Management System (HPMS), a system that was developed and is maintained by CMS and to which all Sponsoring organizations have access. This system is secure: users must first request access through CMS personnel. Once approved, users are required to create and maintain a secure user ID and password.

An overwhelming majority of CMS program audits are conducted remotely using either secure webinar technology or desk review following collection of data from the Sponsoring organization. This approach saves CMS and audited Sponsoring organizations time, money, and other resources needed to complete the audit.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source. CMS will begin collecting Part C initial determination and appeal data from MA organizations as a part of the OMB approved “Service Level Data Collection for Initial Determinations and Appeals” collection (CMS-10905). Once the service level data collection is fully implemented, CMS will suspend collection of some data in the ODAG protocol to ensure there is no duplication of information. CMS has noted the universes of data that will not be collected once the service level data is made available for use. CMS will continue to collect audit universes that are not duplicative of the service level data collection to ensure appropriate oversight activities can be conducted.

5. Small Businesses

This collection will have a minimal impact on small businesses since applicants must possess an insurance license and be able to accept substantial financial risk. Generally, state statutory licensure requirements effectively preclude small businesses from being

licensed to bear risk needed to serve Medicare beneficiaries.

6. Less Frequent Collection

42 CFR Part 423 Subpart K and 422 Subpart K stipulate that CMS is responsible for oversight of Sponsoring organizations' compliance with CMS requirements. CMS generally aims to audit coverage for at least 95 percent of MA and Part D covered enrollees by conducting program audits at the parent organization level. Organizations with the largest number of enrollees are typically prioritized for earlier audits, while those with fewer enrollees or no prior audit history are usually scheduled later. The number of audits CMS conducts each year varies based on available resources, typically ranging from 13 to 40. Audit frequency for a given organization may be influenced by factors such as identified compliance issues, referrals, significant growth in enrollment, or the elapsed time since its last audit. Less frequent data collection from Sponsoring organizations would significantly hinder CMS's ability to conduct timely and accurate oversight of Medicare Parts C and D, potentially increasing risks to Medicare beneficiaries.

7. Special Circumstances

CMS requires Medicare Advantage and Part D organizations to maintain records for 10 years. Upon receiving a program audit Engagement Letter, Sponsoring organizations must submit pre-audit materials to CMS within 15 business days. During and after audit fieldwork, Sponsoring organizations must respond to CMS requests for root cause analyses within two business days and impact analyses within ten business days. While these submissions are required in fewer than 30 days of receipt of the individual notices, these timeframes are essential for completing audits efficiently. In certain cases, CMS may request clarification or validation of submitted data within 30 days or initiate limited scope audits that require faster responses to data requests.

Otherwise, 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 secret, 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

The 60-day Federal Register notice published in the Federal Register (90 FR 59834) December 22, 2025.

CMS received 35 public submissions, which included 315 comments. We combined the unique comments into comment summaries and provided responses in an attached document. Revisions made during this period can be reviewed within section 15 and the attached Crosswalk.

Following the response to comments, the audit protocols and tools CMS published a subsequent 30-day Federal Register (91 FR 41039) comment period July 7, 2026. This data collection has been updated with specific dates regarding the publication dates.

9. Payments/Gifts to Respondents

There are no payments or gifts to respondents associated with this information collection request. MA and Part D organizations are required to comply with CMS oversight (produce records for examination, etc.) and CMS could terminate a contract for failure to comply.

10. Confidentiality

CMS will adhere to all statutes, regulations, and agency policies regarding confidentiality. While Sponsoring organizations are required to provide CMS access to records, data and other beneficiary information, CMS will ensure that the collected information and any sensitive or personal information will be transferred and/or stored through the Health Plan Management System (HPMS) which is a secure site.

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) Wage Estimates

Wage Estimates

To estimate wages for program audits under this revised package, CMS used data from the U.S. Bureau of Labor Statistics (May 2025).[4] Based on past audit experience, CMS selected relevant occupational roles and calculated the average hourly wage, added fringe benefits (calculated at 100 percent of salary),[5] and presented the adjusted hourly wage in the following table.

National Occupational Mean Hourly Wage and Adjusted Hourly Wage

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr.)	Fringe Benefit ($/hr.)	Adjusted Hourly Wage ($/hr.)
General and Operations Managers (Program Director)	11-1021	$64.87	$64.87	**$129.74**
Compliance Officer	13-1041	$42.50	$42.50	**$85**
Management Analysts	13-1111	$54.71	$54.71	**$109.42**
Business Operations Specialists (Quality Assurance Specialist)	13-1199	$45.18	$45.18	**$90.36**
Computers and Information Systems Manager	11-3021	$92.39	$92.39	**$184.78**
Secretaries and Administrative Assistants	43-6014	$23.73	$23.73	**$47.46**
Claims Adjuster, Examiner, Analyst	13-1031	$38.69	$38.69	**$77.38**
Project Management Specialist	13-1082	$53.24	$53.24	**$106.48**

Based on the table above, CMS rounded the adjusted hourly wage to the nearest dollar and multiplied it by the estimated number of individuals needed for each role. Then, CMS added up the total costs for all roles and divided that amount by the total number of individuals to get an **average hourly rate of $103** ($3,311/32 positions).

[4] See the *National* table for Cross-industry, Private, Federal, State, and Local Government under *Occupational Employment and Wage Statistics* for all salary estimates (https://data.bls.gov/oes/#/industry/000000)

[5] To estimate labor costs, CMS applied a 100 percent adjustment to the mean hourly wage rate for each occupational title to account for fringe benefits and overhead. While this method is approximate—due to variability in employer costs and estimation practices—it is a practical and commonly accepted approach for calculating burden.

Occupation Title	Adjusted Hourly Wage	Quantity	Total
Program Directors	$130	4	**$520**
Compliance Officer	$85	1	**$85**
Management Analysts	$109	5	**$545**
Project Management Specialist	$106	1	**$106**
Quality Assurance Specialists	$90	6	**$540**
Computer & Information Systems Managers	$185	5	**$925**
Administrative Assistants	$47	6	**$282**
Claims Analysts	$77	4	**$308**
TOTAL		**32**	**$3,311**

Burden Estimates

Program Audit Activities and Estimated Burden

Program audits are typically scheduled between February and October based on CMS's annual audit plan. CMS may incorporate extra audits, or tailor audit activities, if referrals are received or if CMS needs to quickly review specific program areas due to new oremerging issues. CMS anticipates the burden associated with program audits will be reduced once CMS is able to use the data collected in the "Service Level Data for Initial Determinations and Appeals" (CMS-10905). Therefore, CMS prepared a *per Organization* burden estimate for the first year of this package, and a separate burden estimate for the two subsequent years.

Program Audit Activities Burden Estimate in Hours

	Year 1 Hours	Year 1 Minutes	Years 2 and 3 Hours	Years 2 and 3 Minutes
Pre-fieldwork administrative and systems work	175	0	100	0
Review information for completeness	20	0	20	0
Submit information to CMS	0	30	0	30
Audit fieldwork	125	0	125	0
Respond to documentation requests (including	40	0	60	0

analyses)				
Review and respond to draft audit report	10	0	10	0
Complete optional post-audit survey	0	10		10
TOTAL	**370**	**40**	**315**	**40**
ROUNDED TOTAL	**371**		**316**	

CMS estimates the annual number of parent organizations that will undergo a program audit to be **30**.

Validation Activities and Estimated Burden

Each Sponsoring organization selected for a program audit will also be responsible for activities related to validation and audit close-out. CMS has refined its validation procedures to further reduce the associated burden. Moving forward, CMS will implement **one of three validation methods**, each accompanied by a corresponding burden estimate. A comprehensive explanation of these updates is provided in *Section* of this supporting statement.

Validation through non-audit activity:

CMS estimates **10 hours of effort for validation activities conducted outside formal audits.** These include webinars and desk reviews to confirm corrective actions. For the **17 Sponsoring organizations** CMS estimates will be validated through this approach, the total burden is **381 hours** in the first year and **326 hours** in years 2 and 3:

	Year 1 Hours	**Years 2 and 3 Hours**
Audit	371	316
Validation	10	10
TOTAL	**381**	**326**

Validation through an Independent Audit:

Sponsoring organizations may be required to hire an independent auditor to conduct validation activities in accordance with 42 CFR § 422.503 (d)(2)(iv) and § 423.504 (d)(2)(iv). CMS estimates **3 Sponsoring**

organizations will incur an additional **165 hours** for independent validation audit activities, allocated as follows:

Validation Activity	Hours
Populate validation work plan	25
Respond to CMS Input	8
Assemble and data	35
Quality check data	10
Participate in validation audit	50
Respond to requests for supporting documentation	10
Review validation report	25
Submit validation report to CMS	2
TOTAL	**165**

Total burden hours for Sponsoring organizations required to hire an independent validation auditor are as follows:

	Year 1 Hours	Years 2 and 3 Hours
Audit	371	316
Validation	165	165
TOTAL	**536**	**481**

In addition to burden hours, Sponsoring organizations required to hire an independent auditing firm will incur the auditing firm's fee. While those costs will vary, CMS estimates the average cost is **$200,000**.

Validation through a CMS-led Audit:

CMS estimates **10 Sponsoring organizations** will undergo a CMS-led validation audit. While these organizations will not incur the expense of hiring an independent auditing firm, they will incur an additional **100 hours** of burden to assemble, review and submit data to CMS; participate in the validation audit; and, respond to CMS's requests for additional information. Total burden hours for Sponsoring organizations required to undergo a CMS led validation audit are as follows:

	Year 1 Hours	Years 2 and 3 Hours

Audit	371	316
Validation	100	100
TOTAL	**471**	**416**

Summarized Burden Estimate for Sponsoring organizations

Information Collection Activity	**Average # of Respondents**	**Burden per Response (hours)**	**Year 1 Total Annual Burden (hours)**	**Labor Cost ($/Hour)**	**Total Cost**	**Burden per Response (hours)**	**Years 2 and 3 Total Annual Burden (hours)**	**Labor Cost ($/Hour)**	**Total Cost**
Program Audit, non-validation audit	17	381	6,477	$103	$667,131	326	5,542	$103	$570,826
Program Audit, Independent validation audit [6]	3	536	1,608	$103	$165,624	481	1,443	$103	$147,186
Program Audit, CMS-led validation audit	10	471	4,710	$103	$485,130	416	4,160	$103	$424,320
TOTAL					**$1,317,885**				**$1,136,790**

[6] These totals do not account for the cost of hiring an independent auditing firm. CMS previously estimated each organization required to hire an independent auditing firm will incur an additional $200,000 cost.

13. Capital Costs

There is no capital cost associated with this collection.

14. Cost to Federal Government

The federal government's expenses include staff time for participating in audits, travel costs, and oversight and funding of two audit support contracts. These contracts not only extend staff during audits but also handle various other audit and enforcement tasks unrelated to this collection effort.

CMS Staff Time

CMS staff are assigned to program audits in one of three roles:

- Team leads implement the protocol of an assigned program area (e.g., CDAG, ODAG, FA, etc.) to evaluate Sponsoring organizations' compliance with applicable regulatory and contract requirements. They are assisted by team members who document all audit findings in internal audit work papers.

- Auditors-in-charge are the point person for the whole audit and oversee application of all program area protocols. Additionally, they are responsible for leading the review of Sponsoring organizations' compliance program discussions. They document their own findings, and review and approve all team findings and internal work papers.

- Audit Liaisons oversee the entire audit team to ensure timely progression of the audit and provide support to the audit team when needed. Audit Liaisons are the primary point-of-contact for the auditor-in-charge throughout the audit process, and are responsible for the accuracy for audit deliverables. Audit Liaison may also travel to the Sponsoring organization's location when necessary.

CMS estimates **10 staff** will conduct approximately **10 program audits** annually. On average, each CMS staff member spends **200 hours per audit**, totaling **20,000 hours per year**. Most CMS auditing staff are GS-12s or GS-13s, with varying step level and locality adjustments. For estimation purposes, CMS used the salary for a GS-13, step 5, approximately **$66/hour**.[7] CMS anticipates CMS will staff approximately 10 program audits per year.

Estimated cost to the federal government for CMS staff time:
- 10 staff × 200 hours/audit × 10 audits = **20,000 hours**
- 20,000 hours × $66/hour = **$1,320,000**

[7] *2026 Salary Table (general schedule) (see https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2026/general-schedule/) GS 13 step 5 plus locality adjustment for Washington-Baltimore-Arlington, DC-MD-VA-WV-PA.*

Implementation of the CDAG and ODAG program area protocols require the assistance of a Medical Director (either CMS-staffed or contracted) to complete the review of a Sponsoring organization's *Processing of Coverage Requests*. The average number of hours a medical director spends on an audit is **8 hours per each of these 2 program areas**. CMS uses **1 medical director per audit** and is again estimating participation in **10 audits**. The average hourly rate for a CMS Medical Director is **$91.00/hour**.

Estimated cost to the federal government for CMS Medical Director time:

- 1 Medical Director × 8 hours/program area x 2 program areas/audit × 10 audits = **160 hours**
- 160 hours × $91/hour = **$14,560**

Estimated cost to the federal government for combined CMS staff time is $1,334,560 (=$1,320,000 + $14,560).

Travel Costs

CMS has reduced travel-related expenses for this data collection by using webinar technology. If an on-site audit of a Sponsoring organization becomes necessary, the estimated travel cost to the federal government is approximately **$10,000**.

Contractor Costs

As previously mentioned, CMS has two audit support contractors that perform duties related to this collection effort including: staffing Auditor-in-Charge and Team Lead roles; documenting all audit findings; providing a Medical Director when the CMS Medical Director is not available; receiving, analyzing, and ensuring completeness of all audit data; generating the draft and final audit reports; and conducting some of the subsequent validation activities. Based on invoices received, audits associated with this data collection costs CMS approximately **$327,710 per audit**. CMS anticipates the contractor staffing approximately **20 program audits per year**. Consequently, the total cost to the federal government for contractor costs associated with this data collection is **$6,554,200** (or $327,710 per audit x 20 audits).

Adding up the total costs to the federal government for CMS staff time, travel and contractor costs, CMS estimates total cost of this data collection package is **$7,898,760**:

CMS Staff Time	$1,334,560
Travel	$10,000
Contractor	$6,554,200
TOTAL	**$7,898,760**

15. Changes to Burden

Summary of program audit burden changes:

	Previous Burden Hours	Previous Burden Minutes	New: Year 1 Hours	New: Year 1 Minutes	New: Years 2 and 3 Hours	New: Years 2 and 3 Minutes
Pre-fieldwork administrative and systems work	200	0	175	0	100	0
Review information for completeness	60	0	20	0	20	0
Submit information to CMS	0	30	0	30	0	30
Audit fieldwork	160	0	125	0	125	0
Respond to documentation requests (including analyses)	40	0	40	0	60	0
Review and respond to draft audit report	40	0	10	0	10	0
Complete optional post-audit survey	0	10	0	10		10
TOTAL	**500**	**40**	**370**	**40**	**315**	**40**

Summary of validation activity burden changes:

CMS reduced the hours necessary to conduct validation activities from 200 hours for all organizations to 165 hours, 100 hours, and 10 hours as noted in Section 12.

Explanation of changes:

CMS reduced the hours for the *pre-fieldwork portion* of the audit in our initial proposed package from 200 hours to 150 for the first year, and 100 for the subsequent years; and the hours to review completeness of the information from 60 to 20 hours. In response to 60 day comments, we increased the Year 1 pre-fieldwork burden from 150 to 175 to account for the new inclusion language in ODAG. Our estimates were revised due to the following changes, both originally proposed and in response to 60 day comments:

- Modifying CMS's approach to assessing a Sponsoring organization's compliance program effectiveness, including removal of tracer samples; which reduces the volume of data collected pre-fieldwork and time spent during fieldwork.
- Reducing the volume of data collected pre-fieldwork by removing collection of 4 universes including:

Protocol/ Program Area	Table Number (in previous collection)	Table Name

FA	Table #3	Prescription Drug Event (PDE)
CDAG	Table #7	Comprehensive Addiction and Recovery Act At-Risk Determination
ODAG	Table #4	Part C Effectuations of Overturned Decision by the IRE, ALJ, or MAC
ODAG	Table #6	Dual Special Needs Plan Applicable Integrated Plan Reductions, Suspensions and Terminations

- Refraining from significantly modifying most of the ODAG universes to limit the number of changes Sponsoring organizations must make to their systems or approach to collecting Part C data; this assumes Sponsoring organizations are rather sophisticated and should not be overly burdened by the relatively minor changes to the data fields.
- Reducing the hours Sponsoring organizations allocate to reviewing the information that is pulled and submitted pre-fieldwork (from 60 hours to 20 hours), because of the changes described above and the increased sophistication of systems now in use by Sponsoring organizations.
- Proposed procedures in the ODAG protocol to utilize the "Service Level Initial Determinations and Appeals" data collection in lieu of data collected in the ODAG universes which allows for significant burden reduction in pre-fieldwork for years 2 and 3; and therefore CMS estimated a burden reduction from 175 hours to 100.

CMS modified the hours a Sponsoring organization would participate in audit fieldwork from 160 to 125 based on the following changes:

- Spreading the review of the FA, CDAG, ODAG, and SNPCC (*if applicable*) program areas over the course of two weeks by eliminating the CPE tracer reviews which allows for Sponsoring organizations to better allocate staffing.
- Conducting some, or portions of, program audits via desk review; this saves time for Sponsoring organization staff since CMS will review information prior to engaging them with questions, and limits questions to cases with unresolved concerns, thereby reducing the duration of time some Sponsoring organizations will spend with CMS during fieldwork.

CMS modified post-fieldwork hours from 40 hours for responding to documentation requests to 60 hours in years 2 and 3, and reducing the time Sponsoring organizations spend on the draft audit report from 40 hours to 10 hours.

- Modified the hours for audit documentation submission from 40 to 60 to account for potential mitigating information needed for Sponsoring organizations when utilizing the service level data instead of the ODAG universes.
- Reducing the time Sponsoring organization allocates to reviewing the draft audit report because the CMS audit process is focused on transparency throughout fieldwork and Sponsoring organizations should not need to spend a lot of time understanding the draft report once it is issued.

CMS modified the hours needed to undergo validation of audit conditions based on the following changes:

- Introducing three different validation approaches that no longer require all conditions

to be subject to the same level of testing prior to closing an audit.

- Including a validation audit workplan template and a validation audit report template to enhance transparency around the information CMS needs to consider closing a program audit which should reduce the time Sponsoring organizations spend on preparing materials to submit to CMS.

In order to keep up with the growth of the Medicare Advantage program in recent years, CMS increased the number of audits from 25 to **30 per year**. Burden estimates were also updated to reflect the most current published data for all labor rates.

Accounting for all of these changes, CMS calculated a weighted average that reduces the hourly burden estimate from **701 hours** for all activities associated with this data collection request to **390 hours**.

Information Collection Activity	**Average # of Respondents**	**Year 1 Burden per Response (hours)**	**Year 1 Total Burden (hours)**	**Year 2 Burden per Response (hours)**	**Year 2 Total Burden (hours)**	**Year 3 Burden per Response (hours)**	**Year 3 Total Burden (hours)**
Program Audit, non-validation audit	17	381	6,477	326	5,542	326	5,542
Program Audit, Independent validation audit	3	536	1,608	481	1,443	481	1,443
Program Audit, CMS-led validation audit	10	471	4,710	416	4,160	416	4,160
Subtotal			***12,795***		***11,145***		***11,145***
GRAND TOTAL FOR 3 YEARS							**35,085**

Estimated hours associated with this data collection request:

- **30 audits per year** x 3 years = **90 audits** over 3 years
- **35,085 hours** over 3 years ÷ **90 audits** = **390 hours per audit** *(rounded up to the nearest whole number)*

In addition to the changes noted above, CMS also removed the burden associated with the Part C Timeliness Monitoring Project. The timeliness monitoring project was included as part of this protocol package, but CMS no longer collects industry wide data or conducts this monitoring effort, so all associated burden has been removed from this supporting statement.

The attached Crosswalk of Changes further details the data collection changes for which CMS anticipates burden changes.

16. Publication/Tabulation Dates

The information collected during audits may be compiled from all audits in a given year and CMS may include aggregate level results in an annual audit report.

17. Expiration Date

The expiration date will be displayed on all of the documents associated with this information, including the following documents:

- CPE Protocol
- FA Protocol
- CDAG Protocol
- ODAG Protocol
- SNPCC Protocol
- Pre-audit Issue Summary Template
- CPE Questionnaire
- CPE Power Point Presentation (optional)
- FA Questionnaire
- SNPCC Questionnaire
- CDAG PCR Impact*
- CDAG CR Impact*
- SNPCC Impact*
- SNPCC HRA TMA*
- ODAG PCR Impact*
- ODAG CR Impact*
- ODAG Timeliness MT*
- FA Enrollee Impact*
- Root Cause Analysis Template*
- Independent Validation AWP
- Attendance Log Template
- Program Audit CMS RAI
- Independent Validation ART

* These documents are only collected as needed during a program audit when noncompliance is identified.

Certification Statement
There are no exceptions.