Supporting Statement Part A
Medicare Parts C and D Program Audit Protocols and Data Requests
(CMS-10191, OMB 0938-1000)

Note: *This information collection request was originally approved by OMB in 2016 under the title, "Medicare Parts C and D Program Audit Protocols and Data Requests, CMS-10191, OMB 09381000"and is scheduled to expire on April 30, 2020. CMS proposed to extend the current instruments for one year (with minor updates) in a 60-day notice that was published in the Federal Register on August 16, 2019. These minor updates included the addition of Part D Formulary and Benefit Administration (FA) and Special Needs Plan Model of Care (SNP-MOC) questionnaires, the removal of Coverage Determinations, Appeals, and Grievances (CDAG) and Organization Determinations, Appeals, and Grievances (ODAG) questionnaires and removal of the requirement to collect Part C and Part D Call Logs from the respective data requests. We also eliminated data fields within our Compliance Program Effectiveness (CPE) data request record layouts, and removed audit elements from the FA and SNP-MOC protocols that are no longer evaluated as part of the program audit process. A subsequent 30-day notice was published in the Federal Register on December 27, 2019 addressing public comments that were received in response to the August 16, 2019 notice. If approved by OMB, this iteration that addresses public comment received in response to the December 27, 2019 notice would extend the expiration date through April 30, 2021. The OMB control number and the CMS ID number are unchanged. Additional changes are discussed below under section 15.*

In addition, on December 6, 2019, we published a new collection request as a 60-day notice under OMB control number 10938-NEW (CMS-10717) that reflects the recent regulatory changes and strikes a better balance between simplifying the data collection tools, minimizing the number of system changes, and providing sufficient time to implement needed system changes. In the coming days, we plan to publish the subsequent 30-day notice addressing public comments that were received in response to the December 6, 2019 notice. If approved by OMB, the new collection request would be implemented for use beginning in audit year 2021. That collection request is available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.

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 are required to comply with all Medicare Parts C and D program requirements. CMS' annual audit plan ensures that we evaluate sponsoring organizations' compliance with these requirements. CMS program audits focus on high-risk areas that have the greatest potential for beneficiary harm. As such, CMS has developed several audit protocols that are included within the program area data request documents and that are posted to the CMS website each year for use by sponsoring organizations to prepare for their audit. As part of a robust audit process, CMS also requires sponsoring organizations who have been audited and found to have

deficiencies to undergo a validation audit to ensure correction. The validation audit utilizes the same audit protocols, but only tests the elements where deficiencies were found, as opposed to readministering the entire audit.

CMS uses the following 5 protocols to audit sponsoring organization performance: FA; CDAG; ODAG; SNP-MOC (only administered on organizations who operate SNPs); and, CPE. The data collected is detailed in each of these protocols and the exact fields are located in the record layouts, at the end of each protocol. In addition, this collection request includes a pre-audit issue summary, three CPE questionnaires, one CPE organizational structure presentation template, one FA impact analysis template, two CDAG impact analysis templates, four OAG impact analysis templates, three SNP-MOC impact analysis templates, and a SNP-MOC questionnaire.

A. Justification

1. Need and Legal Basis

Section 1857(d) of the Social Security Act (Act), added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implementing regulations at 42 CFR 422.503 and 422.504state that CMS must oversee a Medicare Advantage (MA) organization's continued compliance with the requirements for a MA organization.

Section 1860D-12 of the Act, added by MMA and implementing regulations at 42 CFR 423.504 and 423.505 state that CMS must oversee a Part D plan sponsor's continued compliance with the requirements for a Part D plan sponsor.
The data collected with the audit protocols included in this package allow CMS to conduct a comprehensive review of MA and Part D organizations' compliance within specific program areas. CMS uses the data collected with these tools to test an organization's compliance with federal requirements. More specifically:

Part D Formulary and Benefit Administration (FA)—42 CFR, Part 423, Subpart C
Part C Organization Determinations, Appeals, and Grievances (ODAG) —42 CFR, Part 422, Subpart M
Part D Coverage Determinations, Appeals, and Grievances (CDAG)—42 CFR, Part 423, Subpart M
Compliance Program Effectiveness (CPE)—42 CFR, §§422.503 and 423.504
Special Needs Plan Model of Care (SNP MOC)—42 CFR §§ 422.4(a)(iv), 422.101(f), and 422.152(g)

2. Information Users

The information gathered during this audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM) and CMS Regional Offices to assess sponsoring organizations' compliance with Medicare program requirements. Specifically, as part of its FA review, MOEG reviews samples of rejected claims to

ensure that the point-of-sale rejections are appropriate; its purpose is to ensure Part D organizations are administering their formulary and transition benefit in accordance with their CMS-approved formulary and the overriding regulations. MOEG's ODAG and CDAG reviews focus on the timeliness of coverage decisions and grievances related to requests for services and drugs. ODAG and CDAG universes are collected and reviewed at the universe level to ensure organizations are meeting the notification and effectuation timeframe requirements outlined in regulation, and samples are reviewed to ensure proper procedures are followed in processing these requests, such as providing appeal rights for denied requests, ensuring the appropriate level of review when initial requests are denied for lack of medical necessity, etc. As part of its CPE review, MOEG uses audit universes and information collected via questionnaires to assess the extent to which Part C and Part D organizations have adopted and implemented an effective compliance program, inclusive of measures that prevent, detect, and correct non-compliance with CMS' program requirements. And finally, if the audited MA organization offers a SNP, MOEG's review evaluates a sample of SNP enrollees to ensure the SNP is coordinating care, administering health risk assessments, updating individual care plans, and assigning interdisciplinary care teams in accordance with the CMS-approved model of care.

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 MA and Part D 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 a validation audit. If the validation audit demonstrates substantial correction of the conditions, MOEG will communicate its decision to close the audit in a letter to the MA and Part D organization. Any new or isolated issues of non-compliance that remain will be referred to the CMS Account Manager for follow-up. Regional Offices will work in collaboration with MOEG and other divisions within CMS for resolution.

3. Use of Information Technology

Sponsoring organizations are able to produce approximately 65 percent of requested information from their internal systems. CMS is able to obtain the remaining 30 percent via our internal systems. The remaining 5 percent of data is manually entered by the sponsoring organization 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 also secure, requiring users to request and gain access via CMS personnel and then must create and maintain a secure user id and password.

Most of our audit is conducted remotely, utilizing secure webinar technology. This has saved 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.

5. Small Businesses

This collection does not impose a significant impact on small businesses and other entities.

6. Less Frequent Collection

42 CFR part 423 subpart K and 422 subpart K stipulate that CMS must oversee a sponsoring organization's continued compliance with CMS requirements. In general, CMS attempts to audit coverage for at least 95 percent of MA and Part D covered enrollees by conducting program audits at the parent organization level within a given audit cycle. Each audit cycle averages 4 years in duration, and organizations with the most MA and Part D enrollees tend to be audited at the beginning of each audit cycle. Organizations with less MA and Part D enrollees, or organizations that have never been subject to a program audit, tend to be scheduled in the latter half of the cycle. Given the variance in total enrollment, the number of audits conducted each year can range from 13 to 40 audits, and the frequency with which an audit occurs can also be influenced by the identification of compliance issues, referral for program audit, a spike in the size of an organization, and the amount of time since the last audit. In addition, CMS conducts annual timeliness monitoring of Part C organization determinations and appeals, and Part D coverage determinations and appeals. Less frequent collection of the data from sponsoring organizations would severely limit CMS' ability to perform accurate and timely oversight, monitoring, and compliance and auditing activities around the Parts C and D Medicare benefits and could result in an increased potential for harm to Medicare beneficiaries.

7. Special Circumstances

42 CFR 422.504(d) and 423.505(d) stipulates records are to be maintained for 10 years. CMS could potentially require clarification around or validation of submitted data and, therefore need to contact Medicare Part D plan sponsors and Medicare Advantage organizations within 30 days of data submission. Ad hoc audits initiated in response to an audit referral could also require immediate action giving a sponsoring organization less than 30 days to respond to universe requests. However, in general, and as outlined in the five program area data requests, within 15 business days of receipt of the program audit Engagement Letter, each of the pre-audit collection instruments (i.e., all except the program area data request templates) must be populated and submitted to CMS. Sponsoring organizations are also required to provide responses 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 necessary to complete the entire program audit process timely. 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

Federal Register

The 60-day notice published in the Federal Register on August 16, 2019 (84 FR 41991). CMS received 35 public submissions, which included 250 comments. We then combined the 250 comments into 109 unique comments and provided responses in the comment and response summary that is included in this collection request. We adopted many of the commenters' suggestions and believe that those corresponding edits simplify and clarify the collection instruments. First, we simplified and provided greater clarity in the 5 protocols by removing columns within the universes that were no longer needed (e.g., to better align with regulatory changes) or to promote consistency across the program-area instructions. For example, within the CDAG, ODAG and SNP-MOC protocols, we renamed the Cardholder ID as Enrollee ID and defined it as the Medicare Beneficiary Identifier (MBI). We also updated the dates of examples provided in each of the 5 protocols to provide more meaningful guidance. We also removed several CDAG and ODAG universes entirely, renumbered the remaining CDAG universes and removed duplicative or unnecessary SNP-MOC compliance standards. Finally, we added a SNP-MOC questionnaire to this collection request.

The 30-day notice published in the Federal Register on December 27, 2019 (84 FR 71428). CMS received 24 public submissions, which included 155 comments. We then combined the 155 comments into 74 unique comments and provided responses in the comment and response summary that is included in this collection request. The majority of comments centered around the following categories: clarifying the universe timeframes, clarification in populating the program area universes, retaining or removing data points and input or questions regarding collection request CMS-10717. The comments on CMS-10717 were beyond the scope of this request and therefore, not addressed. Responses to the remaining comments are included in the comment response summary that is part of this collection request. In summary, minimal edits were made to the collection instruments in response to public comment.

First, we inserted clarification into CDAG Tables 6 and 8 to address at-risk redeterminations and safety edit exceptions. Second, for ODAG Table 4, within Column O, we clarified that NA could apply for reconsideration requests; for ODAG Table 7, within Column K, we clarified that NA could apply for denied or untimely cases and ODAG Tables 1 through 10, we updated the instructions to clarify clarified that in the event ICD-10 codes are unavailable, organizations should provide a description of the diagnosis, or provide the 11-digit NDC for drugs. Finally, we removed questions 3, 7, 9, 10, 11 and 14 from the SNP MOC Questionnaire and clarified language in question # 12.

Please refer to the Crosswalk of Changes for a complete summary of updates made to this collection request since the December 27, 2019 publication.

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 during audit to provide CMS access to records, data and other beneficiary information, CMS will ensure that the information is maintained and used in a confidential format. 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)

No changes were made to the hours and wages burden estimates since the December 27, 2019 collection request.

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). 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 program audits in Part C and Part D and public comment from the 2016 collection request.

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	59.56	59.56	119.12
Compliance Officer	13-1041	34.86	34.86	69.72
Management Analysts	13-1111	45.38	45.38	90.76
Business Operations Specialists (Quality Assurance Specialist)	13-1199	37.00	37.00	74.00
Computers and Information Systems Manager	11-3021	73.49	73.49	146.98
Administrative Assistants	43-6014	18.28	18.28	36.56
Lead Claims Analyst	13-1031	32.47	32.47	64.94

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.

Wage Estimates for Routine Audits

Based on the table above, we then added the estimated hourly rate (rounded to the nearest whole dollar) for each position and divided by the total number of positions to get the average hourly rate.

2 Program Directors	$119/hr x 2	$238
1 Compliance Officer	$70/hr x 1	$70
6 Management Analysts	$91/hr x 6	$546
6 Quality Assurance Specialists	$74/hr x 6	$444
5 Computer & Information Systems Managers	$147/hr x 5	$735
6 Administrative Assistants	$37/hr x 6	$222
4 Claims Analysts	$65/hr x 4	$260
Total		$2,515

Taking the average of the above rates, we estimate an average hourly rate of **$84/hr** ($2,515/30 positions).

Wage Estimates for Industry-Wide Monitoring

We also created a burden estimate for the industry- wide monitoring effort using the same table above.

2 Computer & Information Systems Managers	$147/hr x 2	$294
2 Administrative Assistants	$37/hr x 2	$74
2 Claims Analysts	$65/hr x 2	$130
Total		$498

Taking the average of the above rates, we estimate an average hourly rate of **$83/hr** ($498/6 positions.

Burden Estimates

No changes were made to the burden estimates for routine audits or the industry-wide timeliness monitoring project since the December 27, 2019 collection request.

Routine Audits

Based on our audit strategy, routine audits are defined as the audits scheduled throughout the year. For each sponsoring organization, we estimate an average of 200 hours for administrative and systemic work to assemble the requested information, 60 hours to review the information for completeness, 30 minutes to submit the information to CMS, 160 hours for the actual administration of the audit, 40 hours to respond to audit documentation requests, 40 hours to review and respond to the draft audit report and 10 minutes to complete the optional post-audit survey. The total burden equals 500 hours and 40 minutes, rounded up to 501 hours. The number of parent organizations that will undergo routine audits in audit year 2020 is estimated at 25.

Each organization selected for a routine audit will also incur validation and close out activity burden. We estimate an additional 200 hours for these activities, regardless of whether the sponsoring organization is required to hire and independent auditing firm (in accordance with 42 CFR 422.503 (d)(2)(B)(iv) and 423.504 (d)(2)(B)(iv)) or rely on CMS to conduct the validation audit. Based on CMS experience between 2016 and 2018 (i.e., since the effective date of requiring sponsoring organizations to hire independent auditing firms)), we estimate that 93 percent of sponsoring organizations were required to hire an independent auditing firm. However, we have decreased that estimate to 82 percent in this package based on changes that were made to the threshold that is used in determining whether an organization must hire independent auditing firm. Initially, a sponsoring organization with more than five conditions of any kind in its final audit report was required to hire an independent auditor. Starting in 2019, a sponsoring organization with more than five *non-CPE* conditions identified in its final audit report must hire an independent auditing firm. As a result of

this change, we estimate that the number of sponsoring organizations that would be required to hire an independent auditing firm would decrease by approximately 11 percent: we estimate that annually, 21 of the 25 sponsoring organizations (82 percent of audited organizations) will be required to hire independent auditing firms.

For each sponsoring organization that will be required to hire an independent auditing firm, we estimate an average of 55 hours to populate the validation work plan, 8 hours to respond to CMS input, 35 hours for administrative and systemic work in assembling/reviewing the required information, 10 hours reviewing the information for completeness, 50 hours participating in the independent audit, 10 hours responding/requesting validation audit documentation, 30 hours to drafting/reviewing the validation audit report and 2 hours to submit the information to CMS. In addition to burden hours, sponsoring organizations that will be required to hire an independent auditing firm will incur the auditing firm's fee. While those costs will vary, we estimate the average cost is $150,000.

For each sponsoring organization that will be required to undergo a CMS-led validation audit, we estimate an average of 200 hours in assembling, reviewing and submitting data to CMS, participating in the audit with CMS, and responding to CMS' requests for additional information. Sponsoring organizations that undergo a CMS-led validation audit do not incur the independent auditing firm expense.

Combining the routine and validation audit burden, we estimate a total of approximately **701 hours** for each sponsoring organization. We have included this cost in the total audit estimate.

Yearly Industry-Wide Timeliness Monitoring Project

We estimate a total of 182 sponsoring organizations will be subject to data collections for the industry-wide timeliness monitoring effort[1]. For the industry-wide timeliness monitoring effort, For each sponsoring organization we estimate an average of 80 hours for administrative and systemic work to assemble the requested information, 24 hours to review the information for completeness, 30 minutes to submit the information to CMS, and 16 hours to conduct validation webinars to ensure accurate information. This is a total of approximately **120.5 hours** for each sponsoring organization.

1 This monitoring effort will be performed on each of the 201 sponsoring organizations in 2020. However, we have adjusted the total from 201 to 182 to more accurately reflect the burden of the monitoring experience. Specifically, sponsoring organizations that underwent a program audit in 2019 are exempt from submitting new data for the timeliness monitoring in 2020 unless they were unable to produce all of the data as required during their program audit. As a result, the monitoring effort only requires, on average, a response from 182 sponsoring organizations each year (201 total sponsoring organizations minus an estimated 19 organizations that underwent a program audit in the prior year and successfully submitted all applicable universes).

Burden Summary

Information Collection	Respondents	Responses (per Respondent)	Total Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)
Routine Audits	25	1	25	701	17,525	$84.00	$1,472,100 *
Information Collection	**Respondents**	**Responses (per Respondent)**	**Total Responses**	**Burden per Response (hours)**	**Total Annual Burden (hours)**	**Labor Cost of Reporting ($/hr)**	**Total Cost ($)**
Yearly Timeliness Monitoring	182	1	182	120.5	21,931	$83.00	$1,820,273
Total	207	1 - 2	207**	varies	39,456	Varies	3,292,373*

*This total does not account for costs of hiring an independent auditing firm.
**The total accounts for 1 -2 annual responses per respondent.

Total Costs ($)

Routine Audits	1,472,100
Independent Auditing (21 x 150,000)	3,150,000
Monitoring	1,820,273
Total Cost	6,442,373

Attachments (Timeliness Monitoring)

Document Title	Description	Purpose	Respondents	Reporting Frequency	Time Per Response
Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request *(AttachmentIIICDAGAuditProcessDataReques.pdf)*	CDAG audit process and data request	To evaluate Coverage Determinations, Appeals and Grievances for MA and Part D Sponsors	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually. Additionally we will monitor timeliness on all sponsors annually.	These collection tools are administered simultaneously and responses for all areas does not exceed 8 weeks

Document Title	Description	Purpose	Respondents	Reporting Frequency	Time Per Response
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request *(AttachmentIVODAGAuditProcessDataRequest.pdf)*	ODAG audit process and data request	To evaluate Organization Determinations, Appeals and Grievances for MA and Part D Sponsors	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually. Additionally we will monitor timeliness on all sponsors annually.	These collection tools are administered simultaneously and responses for all areas does not exceed 8 weeks

Attachments (Routine Audits)

Document Title	Description	Purpose	Respondents	Reporting Frequency	Time Per Response
Part C and D Compliance Program Effectiveness (CPE) Program Area Audit Process and Data Request *(AttachmentICPEAuditProcessDataRequest.pdf)*	Compliance Program Effectiveness audit process and data request	To evaluate Compliance Program Effectiveness for MA and Part D Sponsors	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	These collection tools are administered simultaneously and responses for all areas does not exceed 8 weeks
ttachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness (CPE) Compliance Officer Questionnaire (CO-Q) *(AttachmentIBCPECompliance OfficerQuestionnaireCOQ.pdf)*	Compliance Program Effectiveness Compliance Officer Questionnaire	Evaluate Compliance Program Effectiveness for MA and Part D Sponsors	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	These collection tools are administered simultaneously and responses for all areas does not exceed 8 weeks
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness (CPE) Audit Organizational Structure and Governance PPT Template *(AttachmentICCPEOrganizationalStructureGovernancePPTTemplate.pdf)*	Compliance Program Organizational Structure and Governance Template	Evaluate Compliance Program Effectiveness for MA and Part D Sponsors	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	These collection tools are administered simultaneously and responses for all areas does not exceed 8 weeks

Document Title	Description	Purpose	Respondents	Reporting Frequency	Time Per Response
Attachment I-C Medicare Advantage and Prescription Drug Compliance Program Effectiveness (CPE) Sponsor's Accountability for Oversight of First-Tier, Downstream and Related Entities Questionnaire (FDR-Q) (*AttachmentIDCPEFDROversightQuestionnaireFDRQ.pdf*)	Compliance Program Effectiveness Oversight of FDR's Questionnaire	Evaluate Compliance Program Effectiveness for MA and Part D Sponsors	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	These collection tools are administered simultaneously and responses for all areas does not exceed 8 weeks
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness (CPE) SIU/FWA Prevention and Detection Questionnaire (FWA-Q) (*AttachmentIECPESIUFWAQuestionnaireFWAQ.pdf)*	Compliance Program Effectiveness SIU/FWA Questionnaire	Evaluate Compliance Program Effectiveness for MA and Part D Sponsors	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	These collection tools are administered simultaneously and responses for all areas does not exceed 8 weeks
Part D Formulary and Benefit Administration (FA) Program Area Audit Process and Data Request *(AttachmentIIFAAuditProcessDataRequest.pdf)*	Formulary audit process and data request	To evaluate Formulary Administration Benefit Administration for MA and Part D Sponsors	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	These collection tools are administered simultaneously and responses for all areas does not exceed 8 weeks
Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request *(AttachmentIIICDAGAuditProcessDataRequest.p df)*	CDAG audit process and data request	To evaluate Coverage Determinations , Appeals and Grievances for MA and Part D Sponsors	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually. Additionally we will monitor timeliness on all sponsors annually	These collection tools are administered simultaneously and responses for all areas does not exceed 8 weeks

Document Title	Description	Purpose	Respondents	Reporting Frequency	Time Per Response
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request *(AttachmentIVODAGAuditProcessDataRequest.pdf)*	ODAG audit process and data request	To evaluate Organization Determinations, Appeals and Grievances for MA and Part D Sponsors	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually. Additionally we will monitor timeliness on all sponsors annually	These collection tools are administered simultaneously and responses for all areas does not exceed 8 weeks
Special Needs Plan Model of Care (SNP MOC) Program Area Audit Process and Data Request *(AttachmentVSNPMOCAuditProcessDataRequest.pdf)*	SNP MOC audit process and data request	Evaluate Special Needs Plan Model of Cares for MA and Part D Sponsors	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	These collection tools are administered simultaneously and responses for all areas does not exceed 8 weeks
CDAG CDM IA (pdf) *(CDAGCDMImpact.pdf)*	CDAG CDM Impact Analysis	To assess beneficiary impact	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact, but should not exceed 10 business days.
CDAG GRV IA (pdf) *(CDAGGRVImpact.pdf)*	Impact Analysis	To assess beneficiary impact	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact, but should not exceed 10 business days.
FA IA (pdf) *(FAImpactAnalysis.pdf)*	Impact Analysis	To assess beneficiary impact	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact, but should not exceed 10 business days.

Document Title	Description	Purpose	Respondents	Reporting Frequency	Time Per Response
ODAG CDM IA (pdf) *(ODAGCDMImpact.pdf)*	Impact Analysis	To assess beneficiary impact	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact, but should not exceed 10 business days.
ODAG DIS Impact *(ODAGDISImpact.pdf)*	Impact Analysis	To assess beneficiary impact	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact, but should not exceed 10 business days.
ODAG GRV IA (pdf) *(ODAGGRVImpact.pdf)*	Impact Analysis	To assess beneficiary impact	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact, but should not exceed 10 business days.
ODAG PYMT IA (pdf) (ODAGPYMTImpact.pdf)	Impact Analysis	To assess beneficiary impact	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact, but should not exceed 10 business days.
SNP MOC IA (pdf) *(SNPMOCImpact.pdf)*	Impact Analysis	To assess beneficiary impact	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact, but should not exceed 10 business days.

Document Title	Description	Purpose	Respondents	Reporting Frequency	Time Per Response
SNP MOC ICP ICT IA (pdf) *(SNPMOCICPICTImpact.pdf)*	Impact Analysis	To assess beneficiary impact	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact, but should not exceed 10 business days.
SNP MOC Training IA (pdf) *(SNPMOCTrainingImpact.pdf)*	Impact Analysis	To assess beneficiary impact	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact, but should not exceed 10 business days.
Pre-Audit Issue Summary *(PreAuditIssueSummary. pdf)*	Summary of any pre-audit issues	To evaluate MA and Part D Sponsors	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	No more than 1 week
SNP-MOC Questionnaire	SNP-MOC Questionnaire	Evaluate SNPMOC care coordination.	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	These collection tools are administered simultaneously and responses for all areas does not exceed 8 weeks

13. Capital Costs

There is no capital cost associated with this collection.

14. Cost to Federal Government

No changes were made to the cost to the federal government since the December 27, 2019 collection request.
The costs to the federal government include staff time to participate in the audit, travel expenses and money used to fund two audit support contracts that are used as staff extenders during audits, but that also perform a host of other audit and enforcement activities outside of activities related to this collection effort.

Staff Time

CMS staff serve as either team leads (TLs) or team members, or auditors-in-charge (AICs). Team leads run their portion of the audit (e.g., CDAG, ODAG, FA, etc.) by administering the protocol and evaluating that portion of the sponsoring organization's operation. They are assisted by team members who document all audit findings in the internal audit work papers.
The AIC oversees the entire audit and is the sponsoring organization's primary point of contact throughout the audit process. The AIC issues the audit start notice, hosts the entrance, status and exit conference calls and travels onsite to accompany the CPE team (the only portion of the audit that is conducted face-to-face). The AIC is also responsible for the final review and issuance of the draft and final audit report.

The average annual number of CMS staff conducting program audits is 137. The average number of hours that each CMS staff member spends on an audit is 170. Most CMS auditing staff are GS-12s or GS-13s, with varying step level and locality adjustments. The median total base salary plus locality adjustment for a CMS staff member is roughly $51.00/hr ($105,109 annually). (Refer to the 2019 Salary Table for the average GS-12 and GS-13, step 5-6 salary plus locality adjustment at: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salarytables/pdf/2019/DCB.pdf).

Costs to the government for CMS staff time is as follows:

137 CMS staff x 170 hours/audit = 23,290 hours
23,290 hours x $51/hour = **$1,187,790**

For two protocols, CDAG and ODAG, CMS is assisted by either a CMS Medical Director or a contracted medical director during the Clinical Decision Making portion of the audit, this portion of the audit generally lasts one to two days. The average number of hours a medical director spends on an audit is 8 hours. There are 2 medical directors per audit, meaning a total of 90 medical directors. Due to limited resources, only 10 of the 90 slots are staffed by a CMS Medical Director, the remaining 80 come from contracted resources and will be included in the section discussing the budget to fund these contracts. The average hourly rate for a CMS Medical Director is $76.80/hr.

Costs to the government for the medical director's time is as follows:

10 Medical Directors x 8 hours per audit = 80 hours
80 hours x $76.80/hr = **$6,144**

Total costs to the government for staff time:

CMS staff cost =	$1,187,790
MD cost =	6,144
Total cost =	**$1,193,934**

Travel Costs

The total costs of travel for audits has been greatly reduced due to CMS' use of webinar technology. Only the CPE audit team and AIC travel during the second week of the audit to the sponsoring organization's location. The total travel costs to the federal government are **$84,000**.

Contractor Costs

As previously mentioned, CMS has two audit support contractors that perform a variety of duties beyond just the performance of the audit. The duties performed related to this collection effort include performing AIC duties, performing TL duties, acting as the documenter (i.e., documenting all audit findings) for each audit team, providing the medical director for the CDAG and ODAG portions of the audit, receiving, analyzing and ensuring completeness of all audit data collected from sponsoring organizations and draft and final audit report generation and any subsequent validation activities. Based on invoices received by the government. Each audit costs CMS approximately $218,000 in contracted resources. Consequently, the total cost to the government in contracted resources is as follows:

$218,000 per audit x 25 audits = **$5,450,000**

For the timeliness monitoring project, the duties from the contractor include receiving, analyzing and ensuring the completeness of all of the data collected from 182 sponsoring organizations annually. Additionally, contractors will run validation webinars with the sponsoring organizations to ensure that the data in each universe contain accurate information. Finally, the contractor will conduct timeliness tests on the universes and report out on the results. We estimate that the cost to the contractors will be **$910,000** for this monitoring effort per year.

Therefore we estimate the total contractor costs of this package to be:

$5,450,000 + $910,000 = **$6,360,000**

Adding up the costs to the government of staff time, travel and contractor costs we can estimate total Cost to the government as follows:

Staff Cost:	$1,193,934
Travel Cost:	84,000
Contractor Costs:	6,360,000
Total Cost:	**$7,637,934**

15. Changes to Burden

As indicated in Section 8 above, we made minimal changes to the CDAG Data Request, ODAG Data Request and SNP MOC Questionnaire. These changes resulted in no change to burden, as the updates either: clarified data points already collected within this package; aligned the format of these data points with formats already familiar to stakeholders per other CMS reporting requirements; or, aligned data points with updated regulations finalized as a result of comment and rulemaking. In addition, the removal of the CDAG and ODAG questionnaires from this data collection were replaced by questionnaires within the FA and SNP MOC data requests, and CMS still is able to complete the same level of sample case review with the removal of CDAG and ODAG universes, as well as the removal of questions that were deleted from the newly added SNP MOC questionnaire.

As summarized in the 60-day collection request, we estimate the total hourly burden for routine program audits **at 701 hours** to reflect the entirety of the audit process. The total number of **routine program audits** is estimated at 25 and the corresponding **total burden is 17,525 hours.**

The total hourly burden for the industry wide timeliness monitoring project remains at 120.5 hours per respondent. As described above, the number of respondents for this timeliness monitoring project is 182 sponsoring organizations per year (201 total sponsoring organizations minus an estimated 19 organizations that underwent a program audit in the prior year and successfully submitted all applicable universes). **Consequently, the total burden for the industry wide monitoring effort is 21,931 hours.**

16. Publication/Tabulation Dates

The information collected during audits will be compiled and CMS may detail the information at an aggregate level in an annual audit report.

17. Expiration Date

The expiration date will be displayed on the following twenty-one documents:

- Attachment_I_CPE_AuditProcess_DataRequest;
- Attachment_I-A_CPE_Compliance _Officer_Questionnaire_CO-Q;
- Attachment_I-B_CPE_Organizational_Structure_Governance _PPT_ Template;
- Attachment_I-C_CPE_FDR_Oversight_Questionnaire_FDR-Q;
- Attachment_I-D_CPE_SIU_FWA_Questionnaire_FWA-Q;
- Attachment_II_FA_AuditProcess_DataRequest;
- Attachment_III_CDAG_AuditProcess_DataRequest;
- Attachment_IV_ODAG_AuditProcess_DataRequest;
- Attachment_V_SNP-MOC_AuditProcess_DataRequest;
- Pre-AuditIssueSummary;

- FA_ImpactAnalysis;
- CDAG_CDM_Impact;
- CDAG_GRV_Impact;
- ODAG_CDM_Impact;
- ODAG_DIS_Impact;
- ODAG_GRV_Impact;
- ODAG_PMNT_Impact;
- SNP-MOC_HRA_ICP_ICT_Impact;
- SNP-MOC_Impact;
- SNP-MOC_Training_Impact; and
- SNP-MOC Questionnaire

18. Certification Statement

There are no exceptions.

B. Collections of Information Employing Statistical Methods

No statistical methods are applied to any of the audit information.