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 is currently approved by OMB under the title, "Medicare Parts C and D Universal Audit Guide." This iteration revises the title as set out above. The OMB control number and the CMS ID number are unchanged. Additional changes are discussed below under section 15.

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. In 2010, the explosive growth of these sponsoring organizations forced CMS to develop an audit strategy to ensure we continue to obtain meaningful audit results. As a result, CMS' audit strategy reflected a move to a more targeted, data-driven and risk-based audit approach. We focused on high-risk areas that have the greatest potential for beneficiary harm.

To maximize resources, CMS will focus on assisting the industry to improve their operations to ensure beneficiaries receive access to care. One way to accomplish this is CMS will develop an annual audit strategy which describes how sponsors will be selected for audit and the areas that will be audited. CMS has developed several audit protocols and these are posted to the CMS website each year for use by sponsors to prepare for their audit. Currently CMS utilizes the following 6 protocols to audit sponsor performance: Formulary Administration (FA), Coverage Determinations, Appeals & Grievances (CDAG), Organization Determination, Appeals and Grievances (ODAG), Special Needs Model of Care (SNPMOC) (only administered on organizations who operate SNPs), Compliance Program Effectiveness (CPE), and Medication Therapy Management (MTM). 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. Any proposed changes to this package will be resubmitted for approval through the appropriate Paperwork Reduction Act process. In addition, questionnaires are distributed as part of our CDAG, ODAG and CPE audits. These questionnaires are also included in this package. Additionally, CMS will continue to pilot the Provider Network Accuracy (PNA) validation in 2017 as described in the HPMS memo released on March 16, 2016 (CY 2016 Pilot Audit Protocol Release and Updates: Medication Therapy Management (MTM) and Provider Network Accuracy (PNA)). This memo can be found in the *Downloads* section on the following webpage: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html.

As a reminder, there is no protocol for the PNA pilot, as we are simply validating that previously identified errors in a sponsor's online provider directory have been corrected. Additionally, PACE organizations have been removed from this collection request and have been submitted under a different PRA package, which is OMB Control number 0938-1327, as the collection

instruments and burden estimates for this collection and a PACE audit differ greatly.

As part of a robust audit process, CMS also requires sponsors 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 re-administering the entire audit. Finally, to assist in improving the audit process, CMS sends sponsors a link to a voluntary survey at the end of each audit to complete in order to obtain the sponsors' feedback.

We have changed the number of respondents for one portion of our audits. In previous years, if during the course of the ODAG or CDAG portion of the audit, it was determined that not all cases were processed in accordance with CMS requirements, namely forwarding certain cases to an independent review entity, CMS lowered the Star Rating for the relevant appeals measures to one star. For instance, in 2015, the majority of audited contracts had Star ratings reduced because it was determined not all cases were properly sent to the IRE. This was done because the data that was used to inform those appeal Star ratings was data reported by the IRE to CMS. If the audit uncovered that not all cases were properly sent to the IRE, then the data could no longer be considered complete for purposes of Star ratings. Sponsors raised concerns with this practice, claiming it unduly harmed sponsors selected for audit in a given year, since CMS only collected this data from the sponsors selected for audit. Based on these concerns, the high rate of contracts not properly processing cases according to CMS requirements, and wanting the best data for the Star Ratings, CMS will expand the number of sponsors who will be required to submit universes annually for their coverage/organization determinations and appeals to all MA and Part D sponsors. The universes will be submitted in the same format as required for audits under the Part D CDAG protocol and the Part C ODAG protocol. The universes will then be analyzed for timeliness on an annual basis, as was done previously during the audit. This will allow a more comprehensive review of the accuracy of Part C and D appeals data to calculate Star Ratings. Additionally, since sponsors continue to have deficiencies in these two program areas (i.e., CDAG and ODAG) the collection of this data will support increased oversight of sponsors. The burden estimate now reflects the expanded number of respondents who will be submitting this audit data each year.

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 422.502(d) states 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 423.503(d) states 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:

Formulary and Benefits Administration—42 CFR, Part 423, Subpart C
Part C Organization Determination, Appeals and Grievances—42 CFR, Part 422, Subpart M
Part D Coverage Determinations, Appeals and Grievances—42 CFR, Part 423, Subpart M
Compliance Program Effectiveness—42 CFR, §§422.503 and 423.504
Special Needs Plan Model of Care—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 sponsors' compliance with Medicare program requirements. If outliers or other data anomalies are detected, Regional Offices will work in collaboration with (MOEG) and other divisions within CMS for follow-up and resolution. Additionally, MA and Part D organizations will receive the audit results and will be required to implement corrective action to correct any identified deficiencies.

3. Use of Information Technology

Sponsoring organizations are able to produce approximately 60% of requested information from their internal systems. CMS is able to obtain the remaining 30% via our internal systems. The remaining 10% of data is manually entered by the sponsoring organization in response to questionnaires or other audit requests.

Information collected from the sponsors for use in the audit is obtained electronically via Secure File Transfer Protocol (SFTP), with a few exceptions. Correspondence such as the audit start notice, draft and final audit reports and certain attestations provided by sponsors are all transmitted through the Health Plan Management System (HPMS). A system that was developed and is maintained by CMS and that all sponsors have access too. 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 sponsors 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 J of the final rule stipulate CMS must oversee a sponsoring organization's continued compliance with CMS requirements. In general, CMS attempts to audit sponsors once every 5 years. However, the frequency with which an audit occurs for a sponsor can be based on a variety of factors, including the identification of compliance issues, the size of the organization and amount of time since last audit. Based on industry feedback, CMS conducts annual timeliness monitoring of Part C organization determinations and appeals, and Part D coverage determinations and appeals. Additionally, CMS conducts comprehensive program audits on an as-needed basis based on a variety of factors including an internal risk assessment and referrals. Less frequent collection of the data from sponsoring organizations would severely limit CMS' ability to perform accurate and timely oversight, monitoring, compliance and auditing activities around the Part 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 submitted data, and therefore CMS may need to contact Medicare Part D plan sponsors and Medicare Advantage organizations within 30 days of data submission.

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/Outside Consultation

Federal Register

The 60-day notice published in the Federal Register on June 13, 2016 (81 FR 38187). Comments were received and our response to those comments has been added to this PRA package.

The 30-day notice published in the Federal Register on November 4, 2016 (81 FR 76946). Comments were received and our response to those comments has been added to this PRA package.

Subsequent to the publication of the 60-day notice, and as indicated above in the Background section, CMS expanded its collection of CDAG and ODAG data to all MA and Part D sponsors, called the timeliness monitoring project (TMP) in this information collection request. The monitoring effort will expand testing of timeliness of all Part C organization determinations, Part D coverage determinations and Part C and D appeals for each of the 201 sponsoring organizations in the MA and Part D programs to better evaluate sponsors' performance in the respective appeals Star Rating measures and increase monitoring and oversight of sponsor performance overall in these two program areas given sponsors continue to struggle with compliance in these program areas.

Outside Consultation

During the development of each protocol, we pilot them for a period of at least one year and then hold industry listening sessions, to get input and feedback on the protocols, including recommendations for improvement from sponsors who were subject to an audit, specifically of the piloted audit area. We also receive year round feedback from sponsors and outside entities on our protocols at conferences and through our public facing mailbox. We post the protocols on our website and in the HPMS system, so sponsors can access them year round.

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 MA and Part D sponsors 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)

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2015 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. Additionally, we took feedback from the 60 day comment period and adjusted both the personnel involved in audit, as well the hours they were involved.

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	57.44	57.44	114.88
Compliance Officer	13-1041	33.26	33.26	66.52
Management Analysts	13-1111	44.12	44.12	88.24
Business Operations Specialists (Quality Assurance Specialist)	13-1199	35.33	35.33	70.66
Computers and Information Systems Manager	11-3021	67.79	67.79	135.58
Administrative Assistants	43-6014	16.92	16.92	33.84
Lead Claims Analyst	13-1031	30.91	30.91	61.82

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	$115/hr x 2	$230
1 Compliance Officer	$67/hr x 1	$67
6 Management Analysts	$88/hr x 6	$528
6 Quality Assurance Specialists	$71/hr x 6	$426
5 Computer & Information Systems Managers	$136/hr x 5	$680
6 Administrative Assistants	$34/hr x 6	$204
4 Claims Analysts	$62/hr x 4	$248
Total		$2,383

Taking the average of the above rates, we estimate an average hourly rate of **$81.00/hr** ($2,430/30 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	$136/hr x 2	$272
2 Administrative Assistants	$34/hr x 2	$68
2 Claims Analysts	$62/hr x 2	$124
Total		$464

Taking the average of the above rates, we estimate an average hourly rate of **$77.33/hr** ($464/6 positions.

Burden Estimates

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 post audit survey. We believe an additional 200 hours is spend on validation and audit close out activities. This is a total of approximately **740 hours** for each sponsoring organization. Based on previous years' experiences, the average number of parent organizations that will receive a routine audit annually is 40. Organizations are picked for audit based on an internal risk assessment which allows CMS to select sponsors most at risk for non-compliance. However, while this estimate accounts for sponsor time spent before, during and after the audit, for many sponsors there is an additional cost of hiring an Independent Auditing Firm for validation. We are estimating that 65% of sponsors (26 sponsors) will need to hire an Independent Auditing Firm, and while costs for that will vary, we estimate the average cost is $250,000. We will add this cost to the total audit estimate.

Yearly Industry-Wide Timeliness Monitoring Project

For the industry- wide 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. This monitoring effort will be done on each of the 201 sponsoring organizations each year.

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	40	1	40	740	29,600	81.00	2,397,600*
Yearly Timeliness Monitoring	201	1	201	120.5	24,220.5	77.33	1,872,971
Total	201	1 - 2	241**	varies	53,821	Varies	4,270,571*

*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	2,397,600
Independent Auditing (26 x 250,000)	6,500,000
Monitoring	1,872,971
Total Cost	10,770,571

Attachments (Timeliness Monitoring)

Document Title	Description	Purpose	Respondents	Reporting Frequency	Time Per Response
Part D Coverage Determinations, Appeals and Grievances (CDAG)	CDAG audit process and data request	To evaluate Coverage Determinations, Appeals	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan	These collection tools are administered simultaneously and

Program Area Audit Process and Data Request *(Attachment_III_CDAG_AuditProcess__DataRequest.pdf)*		and Grievances for MA and Part D Sponsors		Sponsors annually. Additionally we will monitor timeliness on all sponsors annually.	responses for all areas does not exceed 8 weeks
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request *(Attachment_IV_ODAG_AuditProcess_DataRequest.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 *(Attachment_I_CPE_AuditProcess_DataRequest.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
Attachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness Self-Assessment Questionnaire *(Attachment_I_A_CPE_Self-Assessment_Questionnaire_SA-Q.pdf)*	Compliance Program Self-Assessment Questionnaire	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
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness (CPE) Compliance Officer Questionnaire (CO-Q) *(Attachment_I_B_CPE_Compliance_Officer_*	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

Document Title	Description	Purpose	Respondents	Reporting Frequency	Time Per Response
Questionnaire_CO-Q.pdf)					
Attachment I-C Medicare Advantage and Prescription Drug Compliance Program Effectiveness (CPE) Audit Organizational Structure and Governance PPT Template *(Attachment_I_C_CPE_Organizational_Structure_Governance_PPT_Template.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
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness (CPE) Sponsor's Accountability for Oversight of First-Tier, Downstream and Related Entities Questionnaire (FDR-Q) (*Attachment_I_D_CPE_FDR_Oversight_Questionnaire_FDR-Q.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-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness (CPE) SIU/FWA Prevention and Detection Questionnaire (FWA-Q) (*Attachment_I_E_CPE_SIU_FWA_Questionnaire_FWA-Q.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 *(Attachment_II_FA_AuditProcess_DataReques.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	CDAG audit process and data request	To evaluate Coverage Determinati	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and	These collection tools are administered

Document Title	Description	Purpose	Respondents	Reporting Frequency	Time Per Response
Grievances (CDAG) Program Area Audit Process and Data Request *(Attachment_III_CDAG_AuditProcess__DataRequest.pdf)*		ons, Appeals and Grievances for MA and Part D Sponsors		Part D Plan Sponsors annually. Additionally we will monitor timeliness on all sponsors annually.	simultaneously and responses for all areas does not exceed 8 weeks

Document Title	Description	Purpose	Respondents	Reporting Frequency	Time Per Response
CDAG Supplemental Questions *(Attachment_III_A_CDAG_SupplementalQuestions.pdf)*	Coverage Determinations, Appeals and Grievances supplemental questions	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	These collection tools are administered simultaneously and responses for all areas does not exceed 8 weeks
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request *(Attachment_IV_ODAG_AuditProcess_DataRequest.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
ODAG Supplemental Questions *(Attachment_IV_A_ODAG_SupplementalQuestionnaire.pdf)*	Organization Determinations, Appeals and Grievances supplemental questions	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	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 *(Attachment_V_SNP-MOC_AuditProcess_DataRequest.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
Part D Medication Therapy Management (MTM) Program Area PILOT Audit Process and Data Request *(Attachment_VI_MTM_AuditProcess_DataRequest.pdf)*	MTM Program Area Audit Process and Data Request	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	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
CDAG CDM IA (pdf) *(CDAG_CDM_Impact.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) *(CDAG_GRV_Impact.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) *(FA_ImpactAnalysis_.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 CDM IA (pdf) *(ODAG_CDM_Impact.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 *(ODAG_DIS_Impact.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 GRV IA (pdf) *(ODAG_GRV_Impact.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) *(SNP-MOC_Impact.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 ICP ICT IA (pdf) *(SNP-MOC_ICP_ICT_Impact.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.
MTM Impact Analysis (*MTM_ImpactAnalysis.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 *(Pre-AuditIssueSummary.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
Audit Survey	Post audit survey	Allows MA and Part d sponsors to provide anonymous feedback on CMS' performance and quality of our audit	MA and Part D Plan Sponsors	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually	Ten minutes.

		tools, audit process and preparedness .			

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, 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, enforcement and data analytic activities outside of activities related to this collection effort.

*Staff Time**

CMS staff fill two primary roles while on audit, some serve as a team lead (TL)—of which there is one assigned to each program area being audited (e.g., CDAG, FA, ODAG, etc.) and the auditor-in-charge (AIC).

Team leads run their portion of the audit by administering the protocol and evaluating that portion of the sponsor's operation. They are assisted by a documenter—who documents all audit findings in our internal audit work papers. For two protocols administered, CDAG and ODAG we are 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 day.

The AIC oversees the entire audit and is the sponsor's primary point of contact throughout the audit process. They issue the audit start notice, schedule all calls and webinars for the various audit teams and travel onsite for the second week of the audit 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 number of hours that a team lead spends on an audit is 140 hours. There are 6 team leads per audit (PNA is done off cycle and is fully conducted by contractors, so costs will be included there). Therefore, six team leads per audit multiplied by 40 audits is 240 team leads. Approximately 10 percent of team leads are staffed by contracted resources (240-24 = 216 TLs). The average salary of a team lead is roughly $42.34/hr (90,000 annually). Most team leads are GS-12s or GS-13s, but their step level within those grade levels and locality pay adjustments, depending on their duty station, can vary greatly, making an exact salary estimate very difficult to determine.

**2016 Salary Table (general schedule) (see https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/GS.pdf) average GS-12 and -13 and grade 10, step 10.*

Costs to the government for team leads' time is as follows:

216 TLs x 140 hours/audit = 30,240 hours
30,240 hours x $42.34/hr = $1,280,361.60 (rounded up to **$1,280,362**)

The average number of hours that an AIC spends on an audit is 200 hours. There is one AIC per audit and 40 audits, so there is roughly 40 AICs. Approximately 10 percent of AICs are staffed by contracted resources (40 – 4 = 36 AICs). The average salary of an AIC is roughly $42.34/hr (90,000 annually). Most AICs are GS-12s or GS-13s, but their step level within those grade levels and locality pay adjustments, depending on their duty station, can vary greatly, making an exact salary estimate very difficult to determine.

Costs to the government for the AICs time is as follows:

36 AICs x 200 hours/audit = 7,200 hours
7,200 hours x $42.34/hr = **$304,848**

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 80 medical directors. Due to limited resources, only 10 of the 80 slots are staffed by a CMS Medical Director, the remaining 70 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:

TL cost =	$1,280,362
AIC cost =	$304,848
MD cost =	$6,144
Total cost =	**$1,591,354**

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 sponsor's location. The total travel costs to the federal government are **$132,000**.

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 sponsors and draft and final audit report generation and any subsequent validation activities. Based on invoices received by the government. Each audit costs CMS approximately $180,000 in contracted resources.

Consequently, the total cost to the government in contracted resources is as follows:

$180,000 per audit x 40 audits = **$7,200,000**

For the timeliness monitoring project, the duties from the contractor include receiving, analyzing and ensuring the completeness of all of the data collected from each of the 201 sponsors. Additionally, contractors will run validation webinars with the sponsors 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 **1.7 million dollars** for this monitoring effort per year.

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

$7,200,000 + $1,700,000 = **$8,900,000**

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:	$1,591,354
Travel Cost:	$132,000
Contractor Costs:	$8,900,000
Total Cost:	**$10,623,354**

15. Changes to Burden

Based on industry feedback during the 60 day comment period, we adjusted the total hourly burden for routine audits from **121 hours to 740 hours** to more accurately reflect the entirety of the audit process. Additionally, ad hoc audits have been removed from the burden estimate because ad hoc audits have not exceeded 3 per year in the last 5 years and routine audits have not exceeded 30 in the last 3 years. Therefore, we believe the

total number of **40 routine audits** more accurately reflects the burden associated with this collection. **Consequently, the total burden has been adjusted from 23,595 hours to 29,600 hours.**

Additionally, PACE organizations have been removed from this collection request. The burden for PACE audits is now detailed in a different PRA package, and the OMB control number for the new package is 0938-1327. In reviewing the last CMS 10191, it listed the burden as 35 PACE audits per year and estimated the costs to be the same as an MA or Part D audit, which is not accurate. Consequently, this package is now reduced to 40 audits per year, down from 75 audits per year in the last submission. However, the hours and costs have been increased in response to industry feedback, so even though 35 PACE audits have been removed, the overall burden has increased since the last package. We believe this increase is a more accurate reflection of the time and effort MA and Part D sponsors spend during the course of an audit.

Additionally, we increased the number of respondents who will submit coverage determinations, organization determinations and appeals universes, as we will be conducting industry-wide monitoring of timeliness to be used for Star Rating purposes. We adjusted the total hourly burden for the industry wide timeliness monitoring project to 120.5 hours per respondent. The number of respondents for this timeliness monitoring project is 201. Consequently, the total burden for the industry wide monitoring effort is 24,220.5 hours.

We have also prepared a detailed crosswalk of all the changes to the burden, as well as crosswalks detailing all changes to documents from the 60-day to the 30-day comment period. Please see the crosswalks for changes.

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. Additionally, if CMS takes a compliance action based off of an audit, that compliance action will be released to the public (i.e., a Civil Money Penalty or Sanction).

17. Expiration Date

The expiration date will be displayed on the following documents: Part C and D Compliance Program Effectiveness (CPE) Program Area Audit Process and Data Request; Part D Formulary and Benefit Administration (FA) Program Area Audit Process and Data Request; Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request; Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request; Special Needs Plan Model of Care (SNP MOC) Program Area Audit Process and Data Request; and the Part D Medication

Therapy Management (MTM) Program Area PILOT Audit Process and Data Request.

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.