2019 Part C and Part D Program Audit and Enforcement Report

Medicare Parts C and D Oversight and Enforcement Group
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EXECUTIVE SUMMARY
The Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Centers for Medicare & Medicaid Services (CMS) is responsible for conducting program audits of Medicare Advantage (MA) and Prescription Drug Plan (PDP) organizations. Regular and consistent auditing of these organizations (referred to as sponsors or sponsoring organizations) provides measurable benefits by:

- Ensuring enrollees have adequate access to health care services and medications,
- Verifying sponsors’ adherence to selected aspects of their contracts with CMS,
- Providing a forum to share audit results and trends, and
- Soliciting feedback from the sponsor community and external stakeholders on potential audit improvements.

The Program Audit and Enforcement Report emphasizes pertinent analyses and information sponsors and other stakeholders can adopt to continue improving performance within their respective organizations. We update the report each year to include data from the most recently completed year of audits and provide information about the initiatives undertaken by CMS to advance the transparency, accuracy, and reliability of the entire audit cycle. This report includes results from the program audits conducted in 2019.

Highlights

- **Audit Landscape**

  The sponsors audited by CMS in 2019, which was the first year of the third audit cycle, cover approximately 71% of beneficiaries enrolled in the MA and PDP programs.

- **Audit Innovations and Process Improvements**

  CMS continually seeks to improve audits by soliciting sponsor feedback on our audit protocols and processes. Gathering feedback from sponsors and external stakeholders is key to improving program audit documentation, processes, and procedures and allows for better education and support. The feedback we received in response to the 2018 program audits led to CMS making a number of enhancements in 2019, including:

  - Suspending the Website audit element review from the Formulary and Benefit Administration protocol, as well as the Enrollment Verification audit element review from the Special Needs Plans Model of Care (SNP-MOC) protocol.
  - Suspending collection of Part C and Part D Call Logs universes and assessing an organization’s oversight of its call routing process during the Compliance Program Effectiveness (CPE) review.
  - Suspending the collection of several questionnaires at the time of the engagement letter so that we only collect that information when sponsors are required to produce root cause and impact analyses to qualify/quantify CMS-identified non-compliance.
  - Clarifying that the collection of specific data points within several CPE record layouts is optional as they were no longer necessary for sample selection.
Combining our Program Process Overview Document with our Program Audit Validation and Close Out guidance into a single 2019 Program Audit Process Overview document on our program audit website to streamline information for sponsoring organizations.

Updating the threshold for requiring sponsoring organizations to hire an independent auditor in accordance with the Calendar Year 2019 Final Call Letter.

In the 2018 Program Audit and Enforcement Report, we solicited public comments about the types of analyses stakeholders would like to see included in the report. A few commenters requested analyses related to audit trends over several years and more granular audit results by the enrollment size of the sponsors audited, which we have included in this report (see Figure 6 and Table 1, respectively). In addition, a number of commenters requested that we include information on the common conditions cited during program audits, with some also requesting additional information on common causes of non-compliance. At this time, we are continuing to explore how best to analyze and present this information in a manner that is useful for sponsors, but does not provide a misleading representation of sponsors’ overall performance or that widespread or significant issues exist in the program when they do not. The goal of any future changes to how we report common conditions would be to improve how we characterize the underlying processes that resulted in non-compliance so that the information provides readers the appropriate context to better understand any identified non-compliance.

➢ Audit Results

The data analyses resulting from the 2019 program audits show the following:

- Changes in overall audit scores from 2018 to 2019:
  - The average overall audit score decreased from 1.03 in 2018 to 0.77 in 2019.

- Changes in audit scores by program area from 2018 to 2019:
  - The average program area scores decreased from 2018 to 2019 in several program areas: CPE, Part D Coverage Determinations, Appeals and Grievances, (CDAG), Part C Organization Determinations, Appeals and Grievances (ODAG), Medicare-Medicaid Plan Service Authorization Requests, Appeals and Grievances (MMP-SARAG), and Medicare-Medicaid Plan Care Coordination and Quality Improvement Program Effectiveness (MMP-CCQIPE).
  - The largest point decrease from 2018 to 2019 was in MMP-SARAG where scores decreased from 2.87 to 1.21 across the two years.
  - The largest percentage decrease from 2018 to 2019 was in CPE, where scores decreased by approximately 78% (from 0.60 to 0.13) across the two years.

➢ Audit Enforcement Actions

- CMS imposed eight CMPs totaling $1,605,722 and two intermediate sanctions against sponsors for non-compliance identified in 2019.
• There were about the same number of CMPs imposed for 2019 program audits compared to 2018 (i.e., 5 in 2019 vs. 6 in 2018).
INTRODUCTION
The Medicare Advantage (Part C) and Prescription Drug (Part D) programs administered by CMS provide health and prescription drug benefits to eligible individuals 65 years old and older, and eligible individuals with disabilities. CMS contracts with private companies, known as sponsors, to administer these benefits. Some of these sponsors may partner with CMS and the state(s) to integrate primary, acute, and behavioral health care, and long-term services and support for Medicare-Medicaid enrollees through the Medicare-Medicaid Financial Alignment Initiative.

MOEG, which is in the Center for Medicare (CM), conducts program audits to evaluate sponsors’ delivery of health care services and medications to Medicare beneficiaries enrolled in the Part C and Part D programs. When program audits identify systemic non-compliance, sponsors are required to undergo validation audits to ensure correction of cited deficiencies. In addition to conducting program audits, MOEG develops, maintains, and oversees the requirement for each sponsor to implement an effective compliance program, which includes ensuring compliance with key fraud, waste, and abuse program initiatives. CMS’ enforcement authorities allow MOEG to impose CMPs, intermediate sanctions (suspension of payment, enrollment, and/or marketing activities), and for-cause contract terminations.

This report summarizes MOEG’s audit-related activities, including the scope of audits for the 2019 audit year. It also discusses the current audit landscape, audit process improvements, results of data analyses from the 2019 audits, and a summary of enforcement activities.

In the report, there are text boxes entitled “Sponsor Tips.” A sponsor should consider the information in the boxes when determining how to improve its internal compliance and audit activities.
AUDIT SCOPE

In order to conduct a comprehensive audit of a sponsor’s operation and to maximize Agency resources, CMS conducts program audits at the parent organization level. The 2019 program audits evaluated sponsor compliance in the following program areas:

- Compliance Program Effectiveness (CPE)
- Part D Formulary and Benefit Administration (FA)
- Part D Coverage Determinations, Appeals, and Grievances (CDAG)
- Part C Organization Determinations, Appeals, and Grievances (ODAG)
- Special Needs Plans Model of Care (SNP-MOC)
- Medicare-Medicaid Plan (MMP) Service Authorization Requests, Appeals and Grievances (MMP-SARAG)
- Medicare-Medicaid Plan (MMP) Care Coordination and Quality Improvement Program Effectiveness (MMP-CCQIPE)

CMS audited each sponsor in all program areas applicable to its operation. For example, if a sponsor did not operate a SNP plan, then we did not conduct a SNP-MOC audit. Likewise, we would not audit a standalone PDP using the ODAG protocol since it does not offer the MA benefit.
CURRENT PROGRAM AUDIT LANDSCAPE

The figures below show the progress of program audits on Parts C and D by enrollment and percentage of sponsors audited. These figures are based on enrollment and parent organization data as of January 2020 and include coordinated care plans (CCPs), private fee-for-service (PFFS) plans, demonstrations, and standalone prescription drug plans (PDPs). Organizations offering 1876 contracts are also included, provided that the organizations do not operate only 1876 contracts. Figures 1 and 2 represent only those organizations (and associated enrollments) that still operate Medicare contracts in 2020.

Figure 1*

*These enrollment data are summed by parent organization at the contract level. All contracts active in 2020 that are associated with sponsors that were audited in 2019 are reflected in this chart.
Due to the enrollment size of the sponsors we audited in 2019, we were able to audit sponsors representing just over 71% of Parts C and D enrollment in 12 audits (Figure 2). Note that we actually conducted 13 separate audits but are only reporting on 12 audits in Figure 2 because one of the sponsors audited in 2019 was acquired by another sponsor audited in 2019.

**Figure 2**

![Sponsors Covered by 2019 Audits](image)

Figure 3 shows the percentage of Medicare beneficiaries in each state that were covered by the program audits we conducted in 2019. The largest percentage of beneficiaries covered in any one state was Texas with approximately 70% (note that these enrollment data are at the plan level, whereas all other figures reporting on enrollment in this document are at the contract level). Figure 4 depicts the percentage of plans in each state that were included in the 2019 program audits. The largest percentage of plans audited in any of these states was in Oklahoma, where approximately 59% of plans were audited.
Figure 3

Percentage of Enrollees in Each State Included in 2019 Program Audits
Figure 4

Percentage of Plans in Each State Included in 2019 Program Audits

The map shows the percentage of plans included in 2019 program audits across the United States. States are color-coded according to the percentage of plans included in audits:

- Dark blue: 45.9% - 52.2%
- Light blue: 52.3% - 53.9%
- Light orange: 54.0% - 55.7%
- Dark red: 55.8% - 56.7%
AUDIT LIFECYCLE
The lifecycle of an audit begins the day a sponsor receives an engagement letter and concludes with the sponsor’s receipt of an audit closeout letter. In total, there are four distinct phases of the program audit process: audit engagement and universe submission, audit fieldwork, audit reporting, and audit validation and close out. Note, however, that in rare instances not all phases are completed in their entirety. For example, if an organization decides to terminate its contract the year following the audit, CMS may choose not to conduct validation activities to ensure correction of any deficiencies discovered during the audit.

Figure 5 on the following page describes important milestones in each phase of an audit.
### Figure 5

#### Phase I: Audit Engagement and Universe Submission

- **Engagement Letter** – CMS notification to sponsoring organization of audit selection, identification of audit scope and logistics, and instructions for audit submissions
- **Universe Submission** – Sponsoring organization submission of requested universes and supplemental documentation to CMS
- **Universe Integrity Testing** – CMS integrity testing of sponsoring organization's universe submissions
- **Audit Sample Selection** – CMS selection of sample cases to be tested during field work

#### Phase II: Audit Fieldwork

- **Entrance Conference** – Discussion of CMS audit objectives and expectations, sponsoring organization voluntary presentation on organization
- **Webinar Reviews** – CMS testing of sample cases and review of supporting documentation live in sponsoring organization systems via webinar
- **Onsite Audit of Compliance Program Effectiveness** – Sponsoring organization presentation of compliance program tracer reviews and submission of supporting documentation (screenshots, root cause analyses, impact analyses, etc.), CMS documentation analysis
- **Preliminary Draft Audit Report Issuance** – CMS issuance of a preliminary draft report to sponsoring organization identifying the preliminary conditions and observations noted during the audit
- **Exit Conference** – CMS review and discussion of preliminary draft audit report with sponsoring organization

#### Phase III: Audit Reporting

- **Condition Classification and Audit Scoring** – CMS classification of non-compliance and calculation of sponsoring organization’s audit score
- **Notification of Immediate Corrective Action Required (ICAR) conditions** – CMS notification to sponsoring organization of any conditions requiring prompt corrective action before issuance of the final report, sponsoring organization ICAR Corrective Action Plan (CAP) submission within three business days
- **Draft Audit Report Issuance** – CMS issuance of draft audit report, inclusive of condition classification and audit score, to sponsoring organization approximately 60 calendar days after exit conference
- **Draft Audit Report Response** – Sponsoring organization submission of comments to draft audit report within 10 business days of draft audit report receipt
- **Final Audit Report Issuance** – CMS issuance of final audit report with CMS responses to sponsoring organization's comments and updated audit score (if applicable) approximately 10 business days after receipt of sponsoring organization's comments to draft audit report

#### Phase IV: Audit Validation and Close Out

- **Non-ICAR CAP Submission** – Sponsoring organization's submission of non-ICAR CAPs within 30 calendar days of final audit report issuance
- **CAP Review and Acceptance** – CMS performance of CAP reasonableness review and notification to sponsoring organization of acceptance or need for revision
- **Validation Audit** – Sponsoring organization demonstration of correction of audit conditions cited in the final audit report via validation audit within 180 calendar days of CAP acceptance
- **Audit Close Out** – CMS evaluation of the validation audit report to determine whether conditions have been substantially corrected and notification of next steps or audit closure
AUDIT RESULTS AND TRENDING
The audit score for each sponsor is based on the number and severity of non-compliant conditions detected during the audit. In this scoring system, a lower score represents better performance on the audit. Because the calculated audit score uses the number of non-compliant conditions discovered, the maximum audit score is unlimited. In addition, we weight conditions to ensure that those conditions that have a greater impact on beneficiary access to care have a greater impact on the overall score. The audit score assigns zero points to observations, one point to each corrective action required (CAR), one point to each invalid data submission (IDS), and two points to each immediate corrective action required (ICAR). We then divide the sum of these points by the number of audit elements tested. The formula for calculating the audit score is:

\[
\text{Audit score} = \frac{(# \text{ CARs} + # \text{ IDSs}) + (# \text{ of ICARs} \times 2)}{\# \text{ of audited elements}}
\]

We calculate a score for each audited program area and an overall audit score. The score quantifies a sponsor’s performance and allows comparisons across sponsors. The figures on the following pages compare scores across years and display overall and program-area specific audit scores for sponsors audited in 2019.

As noted in the executive summary, in 2019 we solicited public comments about the types of analyses stakeholders would like us to include in the report. While we have always included charts reflecting year-to-year audit results, our experience has shown that these comparisons are less meaningful than comparing results in a given year, and readers sometimes misinterpret the data and mistakenly conclude that widespread or significant issues exist in the program when they do not. Thus, we caution against reading too much into the data contained in the report without having a full understanding of the audit program, including how improvements made to audit processes each year affect audit scores irrespective of actual audit performance.

Comparison of Year-to-Year Audit Results
Figure 6 depicts the average audit score in each program area audited from 2017 through 2019. From 2017 through 2019, scores have generally trended downward in every program area except in FA and in SNP-MOC. In FA, while performance has remained consistently strong, there has been no particular trend over this time period, though the average scores from 2017 through 2019 are all lower than in 2015 and 2016, where the average FA scores were 1.61 and 0.91 respectively. Therefore, over a longer time period there has been a generally positive trend in FA. In SNP-MOC scores have increased. One possible explanation for the increase in SNP-

SPONSOR TIP: Is your organization undergoing a program audit? Do you think you will undergo an audit in the near future? The audit protocols are valuable resources for audit preparation and detail the process for audits. Sponsors are encouraged to perform mock audits, including generating universes. Mock audits will not only help you prepare for an actual CMS audit, but may help you improve your operations by identifying areas that are problematic or otherwise non-compliant with CMS regulations.
MOC scores is that we stopped auditing for the enrollment verification element, which was typically an element where there was relatively little non-compliance.

Regarding the 2018 results vs. 2019 results, audit scores in CPE, CDAG, ODAG, MMP-SARAG and MMP-CCQIPE decreased in 2019. MMP-SARAG and MMP-CCQIPE results are listed in this chart for the first time because these two program areas became fully operational in 2018. The 2019 audit year provided a second year of audit results, enabling us to show a comparison.

The program area where average scores improved by the largest percentage from 2018 to 2019 was CPE, where the average score decreased from 0.60 to 0.13, a decrease of approximately 78%. MMP-SARAG saw the largest average absolute point improvement from 2018 to 2019; average MMP-SARAG scores decreased from 2.87 to 1.21, a 1.66-point decrease (an improvement of approximately 58%).

Table 1 shows 2017 through 2019 audit results broken down by both program area and the enrollment size of the sponsors we audited. The three enrollment bands used in the table correspond to those used to determine how many months of data we need to collect for certain audited program areas, such as CDAG and ODAG. Small sponsors are organizations with total enrollments of below 50,000; medium sponsors are organizations with total enrollments of between 50,000 and 250,000; and large sponsors are organizations with total enrollments of over 250,000.

Sponsors’ performance has continued to improve. The average number of conditions cited per audit in 2012 was 38 and decreased to an average of approximately 11 per audit in 2019. This improvement is significant because over time we have expanded the number of condition types, as well as the number of program areas we audit. We believe our audits have played an important role in improving performance over the years.

SPONSOR TIP: If you use delegated entities to perform any of the functions currently included in a program audit, ensure you are able to collect and consolidate the relevant universe data accurately. When performing internal audits, sponsors should practice the submission of the universe data from delegated entities and ensure its accuracy to prepare for a future audit and to ensure compliance with CMS requirements. It is important that both your organization and any delegated entities are prepared for all aspects of a CMS audit.
Figure 6*

*Audit scores are analyzed at the sponsor (parent organization) level. The average audit score is an unweighted score across all audited sponsors within each group. A lower audit score represents better audit performance. Note that the MMP-SARAG and MMP-CCQIPE program area pilots ended in 2017, meaning that no scores for these program areas appeared in final audit reports before 2018. Consequently, there are no MMP-SARAG or MMP-CCQIPE results to report for 2017.
Table 1

<table>
<thead>
<tr>
<th>Program Area</th>
<th>2017 Average Audit Scores by Enrollment Band</th>
<th>2018 Average Audit Scores by Enrollment Band</th>
<th>2019 Average Audit Scores by Enrollment Band</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;50K</td>
<td>Between 50K and 250K</td>
<td>&gt;250K</td>
</tr>
<tr>
<td>Overall</td>
<td>1.25</td>
<td>0.96</td>
<td>0.86</td>
</tr>
<tr>
<td>CPE</td>
<td>0.87</td>
<td>0.29</td>
<td>0.17</td>
</tr>
<tr>
<td>FA</td>
<td>0.78</td>
<td>1.05</td>
<td>0.59</td>
</tr>
<tr>
<td>CDAG</td>
<td>1.02</td>
<td>1.29</td>
<td>1.42</td>
</tr>
<tr>
<td>ODAG</td>
<td>2.17</td>
<td>1.18</td>
<td>1.50</td>
</tr>
<tr>
<td>SNP-MOC</td>
<td>1.24</td>
<td>0.50</td>
<td>0.44</td>
</tr>
<tr>
<td>MMP-SARAG</td>
<td>N/A*</td>
<td>N/A*</td>
<td>N/A*</td>
</tr>
<tr>
<td>MMP-CCQIPE</td>
<td>N/A*</td>
<td>N/A*</td>
<td>N/A*</td>
</tr>
</tbody>
</table>

*Audits in MMP-SARAG and MMP-CCQIPE were pilots in 2017. Consequently, there are no audit results to report for 2017.

**No audit was conducted for a sponsor in this particular enrollment band.
**Program Audit Scores**

Figures 7-14 array the overall and individual program area audit scores. The audit scores are displayed from best (lowest) to worst (highest) score moving from left to right across the graph. The line in each graph represents the average audit score across all audited sponsors.

The program areas with the least number of conditions continue to be CPE, FA, and CDAG. In addition, at least half of the audits we conducted in 2019 resulted in no conditions of non-compliance for CPE and FA. We conducted 13 audits in CPE in 2019, 12 audits in both FA and CDAG, 10 audits in ODAG, and 8 audits in SNP-MOC, MMP-SARAG, and MMP-CCQIPE. For CPE, 10 of 13 audits (77%) were without findings. For six of the 12 FA audits (50%), no conditions were cited. We attribute the strong performance in CPE to the fact that we have been auditing this program area since 2010, there have been few regulatory changes that relate to CPE, and sponsors have dedicated significant resources to establishing compliance programs that meet CMS’ requirements. We believe the FA results are largely attributable to the Pharmacy Benefit Managers (PBMs) ability to quickly correct identified issues for all of the sponsors with which they contract. See Table 2 for a more complete overview of these results.
Figure 7*

*A lower audit score represents better audit performance. The average audit score is an unweighted score across all sponsors audited in 2019.
Figure 8*

* A lower audit score represents better audit performance. The average audit score is an unweighted score across all sponsors audited for the CPE program area in 2019.
*Figure 9*

*A lower audit score represents better audit performance. The average audit score is an unweighted score across all sponsors audited for the FA program area in 2019.*
Figure 10*

*A lower audit score represents better audit performance. The average audit score is an unweighted score across all sponsors audited for the CDAG program area in 2019.*
Figure 11*

*A lower audit score represents better audit performance. The average audit score is an unweighted score across all sponsors audited for the ODAG program area in 2019.
Figure 12*

*A lower audit score represents better audit performance. The average audit score is an unweighted score across all sponsors audited for the SNP-MOC program area in 2019.
Figure 13*

*A lower audit score represents better audit performance. The average audit score is an unweighted score across all sponsors audited for the MMP-SARAG program area in 2019.

Figure 14*

*A lower audit score represents better audit performance. The average audit score is an unweighted score across all sponsors audited for the MMP-CCQIPE program area in 2019.
<table>
<thead>
<tr>
<th></th>
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<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>1</td>
<td>2.56%</td>
<td>1</td>
<td>2.56%</td>
<td>1</td>
<td>7.69%</td>
</tr>
<tr>
<td>CPE</td>
<td>12</td>
<td>30.77%</td>
<td>8</td>
<td>20.51%</td>
<td>10</td>
<td>76.92%</td>
</tr>
<tr>
<td>FA</td>
<td>3</td>
<td>7.69%</td>
<td>17</td>
<td>43.59%</td>
<td>6</td>
<td>50.00%</td>
</tr>
<tr>
<td>CDAG</td>
<td>8</td>
<td>20.51%</td>
<td>7</td>
<td>17.95%</td>
<td>5</td>
<td>41.67%</td>
</tr>
<tr>
<td>ODAG</td>
<td>0</td>
<td>0.00%</td>
<td>1</td>
<td>2.94%</td>
<td>1</td>
<td>10.00%</td>
</tr>
<tr>
<td>SNP-MOC</td>
<td>5</td>
<td>35.71%</td>
<td>4</td>
<td>20.00%</td>
<td>2</td>
<td>25.00%</td>
</tr>
<tr>
<td>MMP-SARAG</td>
<td>N/A</td>
<td>N/A</td>
<td>0</td>
<td>0.00%</td>
<td>1</td>
<td>12.50%</td>
</tr>
<tr>
<td>MMP-CCQIPE</td>
<td>N/A</td>
<td>N/A</td>
<td>1</td>
<td>20.00%</td>
<td>1</td>
<td>12.50%</td>
</tr>
</tbody>
</table>
**FA and CDAG Scores by Number of Formularies**

Figures 15 and 16 display the average 2019 FA and CDAG scores across audited sponsors broken into two groups: those that operate one formulary, which comprised a small minority of sponsors we audited in 2019, and those that operate more than one formulary. In the latter group, the number of formularies used ranged from 2 to 21. In both FA and CDAG, sponsors with only one formulary performed better on audit in 2019 than sponsors that operated more than one formulary. The difference in performance between the two groups of sponsors was larger in FA.

**Figure 15**

*Audit scores are analyzed at the sponsor (parent organization) level. The average audit score is an unweighted score across all audited sponsors within each group. A lower audit score represents better audit performance.*
* Audit scores are analyzed at the sponsor (parent organization) level. The average audit score is an unweighted score across all audited sponsors within each group. A lower audit score represents better audit performance.
Number of Conditions and ICARs by Program Area
Figure 17 displays the average number of conditions and ICARs cited in the FA, CDAG, ODAG, and MMP-SARAG program areas for 2019. In total, 4 ICARs were cited in FA, 7 ICARs were cited in CDAG, 4 ICARs were cited in ODAG, and 6 ICARs were cited in MMP-SARAG. The largest number of ICARs cited to an individual sponsor in 2019 was 4, and the lowest number was 0.

**Figure 17**

![Average Number of Conditions and ICARs per 2019 Audit](image)
ENFORCEMENT ACTIONS
In 2019, CMS imposed various enforcement actions resulting from violations discovered during audits and other monitoring efforts conducted by CMS. This section of the report details the number and types of enforcement actions imposed, the basis for those actions, and provides additional information about the sponsors that were sanctioned and/or received a CMP, as well as the amounts of the CMPs issued. The first part of this section focuses on the enforcement actions imposed based on all referrals received in calendar year 2019 and early 2020 due to non-compliance detected in 2019. These referrals encompass actions for violations from 2019 program audits, as well as violations discovered through other audits or monitoring efforts. The second part of this section focuses more specifically on data from enforcement actions imposed for 2019 program audit violations.

General Enforcement Background
CMS has the authority to impose CMPs, intermediate sanctions, and for-cause terminations against MA plans, PDPs, Programs of All-Inclusive Care for the Elderly (PACE) Organizations, and Cost Plans. MOEG is the group responsible for imposing these types of enforcement actions when a sponsor is substantially non-compliant with CMS’ program requirements, such as the Medicare Parts C and D and PACE program requirements. Sponsors may appeal all enforcement actions either to the Departmental Appeals Board (for CMPs) or to a CMS hearing officer (for intermediate sanctions and terminations).

Prior to issuing an enforcement action, MOEG obtains clearance from the Office of General Counsel within the Department of Health and Human Services. In addition, for any CMPs, MOEG obtains clearance from the Office of Inspector General and the Department of Justice. All enforcement actions are posted on the Part C and Part D Compliance and Audits website.1 All information contained in referrals that involve suspected fraud, waste, and abuse are referred to the Center for Program Integrity for investigation.

2019 Process Improvements
On June 21, 2019, CMS released and implemented a revised Civil Money Penalty Methodology Calculation after considering public comments. In the revised Methodology, CMS increased standard and aggravating penalty amounts and provided a plan for increasing penalty amounts no more than every three years. CMS is proposing to codify in regulation the methodology for increasing civil money penalties.2

MOEG also continues its efforts to engage with sponsors throughout the evaluation process to ensure enforcement actions use data that accurately reflect the impact of violations on beneficiaries. For example, CMS recognizes the complexity involved in completing an impact analysis and developing methodologies for pulling the data. This year, MOEG increased its outreach with sponsors to discuss and validate sponsor-submitted impact analyses in order to

2. See Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (85 FR 9002).
provide those organizations with additional opportunities to review the accuracy of their submissions and explain the data in further detail.

In addition, MOEG continues to implement and refine process improvements from 2018, such as:

- Affected sponsors received timely notice when being referred for a potential enforcement action, and the referral notices contained more information about the specific conditions or violations that are under review;
- Sponsors were given timely notice when CMS decided not to take an enforcement action against them;
- Sponsors subject to a CMP received a detailed, written explanation of the calculation of their penalty;
- MOEG improved efforts to obtain additional and/or mitigating data from sponsors during the analysis phase and clarified findings when necessary;
- MOEG strongly encouraged sponsors to fully evaluate discovered non-compliance and provide any additional information during the audit phase; and
- MOEG considers sponsors’ comments to the draft audit reports when evaluating referrals.

**ENFORCEMENT ACTIONS IMPOSED BASED ON 2019 REFERRALS**

This section provides information on enforcement actions taken in calendar year 2019 and early 2020 due to non-compliance detected by CMS in 2019. For this time period, CMS issued 8 CMPs and 2 intermediate sanctions against sponsors and imposed 1 for-cause termination.

Referrals were based on non-compliance detected through routine audits, ad hoc audits, routine monitoring and surveillance activities, and the identification of significant instances of non-compliance both self-reported and discovered by CMS. In 2019, there were 53 referrals; approximately 37% were due to non-compliance detected through PACE audits and 20% were referred based on Medicare Parts C and D program audit results. The other bases for enforcement action referrals in 2019 included:

- Medicare Parts C and D Program Validation Audit results (13%)
- One-Third Financial Audit results (13%)
- Failure to send accurate and/or timely Annual Notice of Change/Evidence of Coverage (ANOC/EOC) (6%)
- Failure to maintain an adequate Medical Loss Ratio (MLR) for four consecutive years, as determined by reviews of self-reported MLR data (4%)
- Failure to process enrollment applications and mail required plan materials timely (4%)
- Failure to maintain fiscal soundness (2%)
- Inappropriate marketing practices (2%)

Table 3 shows the referral details and displays the number of enforcement actions by referral type.
Table 3

<table>
<thead>
<tr>
<th>Referral Type</th>
<th># of Referrals</th>
<th># of Referral Closeouts</th>
<th># of Referrals Under Review</th>
<th># of Enforcement Actions Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Programs of All-Inclusive Care for the Elderly</td>
<td>20</td>
<td>18</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Medicare Parts C and D Program Audits</td>
<td>11</td>
<td>5</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Medicare Parts C and D Program Validation Audits</td>
<td>8</td>
<td>3</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>One-Third Financial Audits</td>
<td>7</td>
<td>2</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Annual Notice of Change/Evidence of Coverage</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Medical Loss Ratio</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Enrollment</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Financial Solvency</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Marketing</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

CIVIL MONEY PENALTIES (CMPs)

CMPs imposed for non-compliance detected in 2019 totaled $1,605,722, with an average of $200,715 per CMP. The highest CMP imposed was $381,272 and the lowest CMP imposed was $41,552. The following table shows the sponsors that received a CMP based on 2019 referrals:

Table 4

<table>
<thead>
<tr>
<th>Date of Imposition</th>
<th>Organization Name</th>
<th>Basis for Referral</th>
<th>CMP Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/05/2019</td>
<td>WellCare Health Plans, Inc.</td>
<td>Enrollment</td>
<td>$373,800</td>
</tr>
<tr>
<td>12/04/2019</td>
<td>Solis Health Plans, Inc.</td>
<td>Marketing Violations</td>
<td>$41,552</td>
</tr>
<tr>
<td>02/28/2020</td>
<td>Health Care Service Corp.</td>
<td>2018 &amp; 2019 Program Audit</td>
<td>$381,272</td>
</tr>
<tr>
<td>02/28/2020</td>
<td>Tufts Health Plan, Inc.</td>
<td>2019 Program Audit</td>
<td>$28,302</td>
</tr>
<tr>
<td>02/28/2020</td>
<td>Humana Inc.</td>
<td>2019 Program Audit</td>
<td>$257,262</td>
</tr>
<tr>
<td>02/28/2020</td>
<td>Triple-S Management Corp.</td>
<td>2019 Program Audit</td>
<td>$329,872</td>
</tr>
<tr>
<td>02/28/2020</td>
<td>WellCare Health Plans, Inc.</td>
<td>2019 Program Audit</td>
<td>$45,156</td>
</tr>
<tr>
<td>02/28/2020</td>
<td>California Physicians' Service</td>
<td>2019 Program Audit</td>
<td>$148,506</td>
</tr>
</tbody>
</table>

The average CMP amount, broken down by enrollment size of the parent organization’s audited contracts, is as follows:3

- For one organization with < 1,000 enrollees, the CMP was $41,552.
- For three organizations with 1,000 – 200,000 enrollees, the average CMP was $168,893.

3 Organizations that received more than one CMP could be included in an enrollment band more than once.
For one organization with 200,000 – 3,000,000 enrollees, the CMP was $381,272.
For three organizations with 3,000,000 or more enrollees, the average CMP was $225,406.

The amount of the CMP does not automatically reflect the overall performance of a sponsor. As discussed below, the majority of CMPs depend on the number of enrollees impacted by certain violations. Consequently, the CMP amount may be higher for sponsors with larger enrollment or when a violation affected a high number of enrollees.

The type of contract(s) involved, as well as the nature and scope of the violation(s), determined the total CMP a sponsor received. A standard CMP amount applies for each deficiency cited in a CMP notice, based on either a per-enrollee or a per-determination basis. A sponsor’s CMP is increased if aggravating factors apply to certain deficiencies:

- **Aggravating Factors:** The standard penalty for a deficiency for a contract may increase if the violation involved the following:
  - Drugs that are used to treat acute conditions that require immediate treatment,
  - Enrollees were not provided access to their inappropriately denied medical services or medications,
  - Expedited cases,
  - Financial impact over $100,
  - Annual Notice of Change (ANOC) documents: ANOC/errata documents were not mailed by Dec. 31, and/or
  - A history of prior offense.

Consistent with our approach in 2018, CMS considered other available evidence indicating that harm to enrollees was minimized when determining whether to move forward with a CMP for a particular violation or remove beneficiaries from the CMP calculation. For example, if beneficiaries received the drug on the same day (after an initial rejection at the point of sale), those beneficiaries may have been excluded from the total CMP calculation. In addition, the CMP methodology established limits to ensure that penalty amounts do not exceed certain thresholds based on enrollment size.

There were 8 CMPs imposed for 13 specific violations:
- 12 on a per-enrollee basis resulting in $1,435,602 (89% of the total CMP amount).
- 1 on a per-determination basis resulting in $170,120 (11% of the total CMP amount).

For CMPs taken as a result of 2019 audits, Figure 18 and Figure 19 show the total number of violations and dollar amount of violations by calculation type.

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4 These numbers include CMPs from program audit, enrollment, and marketing failures that adversely affected an enrollee or had the substantial likelihood of adversely affecting an enrollee.
INTERMEDIATE SANCTIONS

Intermediate sanctions can either suspend a sponsor’s ability to market to and enroll new Parts C or D beneficiaries or to receive payment for new enrollees. For PACE Organizations, CMS’ sanction authority includes either suspending their ability to enroll eligible PACE participants or payment for new enrollees. In 2019, there were two intermediate sanctions imposed. These actions were imposed because of non-compliance with CMS’ MLR requirements and 2019 PACE audit deficiencies.

Intermediate sanctions remain in place until the deficiencies which formed the basis of the sanction are corrected and are not likely to recur. There was one sponsor that remained under a sanction for the duration of 2019 (initial imposition was in 2018). This sponsor requested to mutually terminate its MA-PDP contract number and cease all operations by February 29, 2020.

Table 5 lists the sponsors and PACE organizations that were under intermediate sanction during 2019.
Table 5

<table>
<thead>
<tr>
<th>Date of Imposition</th>
<th>Organization Name</th>
<th>Basis for Referral</th>
<th>Type of Intermediate Sanction</th>
<th>Date of Intermediate Sanction Release</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/11/2019</td>
<td>Care Improvement Plus South Central Insurance Company</td>
<td>Medical Loss Ratio</td>
<td>Enrollment Suspension</td>
<td>1/1/2021</td>
</tr>
<tr>
<td>08/22/2019</td>
<td>Senior LIFE York, Inc.</td>
<td>2019 PACE Audit</td>
<td>Enrollment Suspension</td>
<td>TBD</td>
</tr>
</tbody>
</table>

TERMINATIONS
CMS may at any time terminate a contract with a sponsor. On June 30, 2019, CMS terminated its contract with Constellation Health LLC (Constellation). This action was imposed because Constellation substantially failed to carry out its contracts and experienced financial difficulties so severe that its ability to make necessary health services available was impaired to the point of posing an imminent and serious risk to the health of its enrollees.

ENFORCEMENT ACTIONS RELATED TO 2019 PROGRAM AUDITS
This section provides additional details regarding enforcement actions imposed as a result of 2019 program audits and offers a comparison of those data to enforcement actions taken based on 2018 program audits. For full details of enforcement actions taken related to 2018 program audits, please see the 2018 Part C and Part D Program Audit and Enforcement Report.

Of the 13 organizations audited during 2019, 6 (46%) received an enforcement action. Figure 20 compares the cumulative CMP amounts and types of enforcement actions imposed on sponsors for 2018 and 2019 program audits.

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5 Health Care Service Corporation’s 2018 and 2019 program audit results were evaluated together; however, CMS only imposed a CMP on their 2018 program audit results because the 2019 results were not significant enough to warrant a CMP. For the purposes of this report, however, we have included HCSC’s CMP results in the 2019 data because the action was imposed in 2019 and was evaluated with all other 2019 program audits.

Although there were about the same number of CMPs imposed for 2019 program audits compared to 2018 (i.e., 5 in 2019 vs. 6 in 2018), the CMP amounts for 2019 program audits were substantially higher. This is because CMS audited larger organizations in 2019, which resulted in more impacted enrollees and higher calculated penalties.\(^7\)

Figures 21 and 22 compare the number of FA, CDAG, ODAG, and MMP-SARAG conditions included in the CMP violations for 2018 and 2019 program audits. There were no FA conditions included in 2018 program audit CMPs.

\(^7\) The average enrollment size of sponsors receiving a CMP in 2019 was 2,221,072 compared to 14,376 in 2018.
For 2019 program audits, 1 CMP violation was imposed on a per-determination basis (total CMP amount of $170,120) and 10 CMP violations were imposed on a per-enrollee basis (total CMP amount of $1,020,250).

Figure 23 shows the average number of CMP violations by program area for 2018 and 2019 program audits. The number of CDAG violations decreased and the number of ODAG/MMP-SARAG violations increased between program audit years 2018 and 2019.
PROGRAM AUDIT INTERMEDIATE SANCTIONS
Sanctions are imposed to protect current and future beneficiaries when CMS determines a sponsor has substantially failed to carry out the terms of its contract with CMS. Immediate intermediate sanctions are imposed when CMS determines a sponsor’s action or inaction either poses or potentially poses a serious threat to an enrollee’s health and safety, such as denying or delaying access to medications or services. There were no intermediate sanctions imposed for 2019 program audit referrals.

2020 AUDIT PROCESS IMPROVEMENTS
The goal in 2020 is to streamline the audit data collection and submission process to the greatest extent possible. In support of that goal, CMS finalized PRA Collection Request 10191, OMB 0938-1000 for use in audit year 2020. That collection request can be found at: https://www.cms.gov/files/zip/2020-medicare-parts-c-and-d-program-audit-protocols.zip.

In addition, to improve user experience in submitting data via HPMS, CMS increased the HPMS file size limitations for:

- Universe files from 1 GB in 2019 to 2 GB in 2020 and
- All other files from 20 MB in 2019 to 50 MB in 2020.

CONCLUSION
We continue to strive for increased transparency in relation to audit materials, performance, findings, and enforcement actions. The focus on program audits (and the resulting consequences of possible enforcement actions) continues to drive improvements in the industry. The audits help increase sponsors’ compliance with core program functions in the MA and Part D programs. We hope sponsors will use the information in this report to inform their internal auditing, monitoring, and compliance activities. We encourage feedback and look forward to continued collaboration with sponsors in developing new approaches to improve compliance.