



2018 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) provides measurable benefits by:

- Ensuring enrollees have adequate access to health care services and medications;
- Verifying sponsors' adherence to selected aspects of their contract 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 2018. We are also soliciting your input on the overall value of the report and the data in it (see the "Request for Comment" section below).

Highlights

➤ **Audit Landscape**

The sponsors audited by CMS in 2018, which was the fourth year of the current audit cycle, cover approximately 2% of beneficiaries enrolled in the MA and PDP programs. This brings the total percentage of beneficiaries covered during the current audit cycle to 95%. Due to the relatively small enrollment size of sponsors audited in 2018, a small percentage of beneficiaries were covered during the audits.

➤ **Audit Innovations and Process Improvements**

CMS continually seeks to improve audits by soliciting sponsor feedback on our audit protocols and processes. The feedback led to CMS making the following enhancements in 2018:

- Updated or suspended pilot protocols based on lessons learned in previous audit years;
- Expanded technological capabilities and reduced scope of data collection to streamline universe submissions;
- Extended the fieldwork phase of the audit from two weeks to three weeks to provide sponsors with additional time to respond to audit requests and prepare for the onsite Compliance Program Effectiveness (CPE) audit; and
- Improved the program audit validation and close-out process in response to feedback obtained at a July 18, 2017 listening session.

➤ **Audit Results and Analyses**

The data analyses resulting from the 2018 program audits show the following:

- Changes in overall audit scores from 2017 to 2018:
 - The average overall audit score decreased from 1.10 in 2017 to 1.03 in 2018, despite many sponsors not having had the benefit of a previous CMS audit.
- Changes in audit scores by program area from 2017 to 2018:
 - The average program area scores decreased from 2017 to 2018 in two of the five program areas: Part D Formulary and Benefit Administration (FA) and Part C Organization Determinations, Appeals and Grievances (ODAG).
 - Average FA scores continued to show significant improvement with a reduction of 62% in 2018.

➤ **Audit Enforcement Actions**

- CMS imposed 10 CMPs totaling \$396,736 and three intermediate sanctions against sponsors for non-compliance identified in 2018.
- There were significantly fewer CMPs imposed for 2018 program audits compared to 2017 (i.e., 5 in 2018 vs. 18 in 2017).

Request for Comment

The fundamental goal of CMS' program audits is to ensure enrollees have adequate access to health care services and medications. The program audits achieve that goal by helping sponsors improve their overall performance. As part of our commitment to industry-wide improvement, we continue to refine and improve our audit processes and audit tools, and recognize the value of collaborating with sponsors and external stakeholders in that process. To that end, we are seeking comment on the value of the information provided in this report. More specifically, we would like to understand if any of the information is not useful or if there are other types of analyses or information that CMS should include in future reports.

CMS has identified over time analyses included in the reports that were not specific enough to help sponsors proactively identify issues and implement meaningful improvements in advance of an audit, and/or could lead someone to conclude that widespread issues exist when they do not. We removed some of those analyses from the 2018 report. For example, we removed the common conditions section from the report because the information in it was so broad that it was not actionable and the findings could easily be misinterpreted.

We are interested in whether there are other analyses that CMS could remove from or include in the report in order to help sponsors improve their oversight efforts. Please submit your comments to our Parts C and D audit mailbox: part_C_part_D_audit@cms.hhs.gov (include "Comments on the Part C and Part D Program Audit and Enforcement Report" in the subject line). We will accept comments sent to this email address for a period of 60 days following the publication date of this report.

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 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 and the audit selection process, for the 2018 audit year. It also discusses the current audit landscape, audit process improvements, results of data analyses from the 2018 audits, and a summary of enforcement activities.

In several areas of the report, there are text boxes entitled "Sponsor Tips." A sponsor should consider the information in the boxes when determining how to improve its compliance and audit activities.

AUDIT SCOPE AND SPONSOR SELECTION

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 2018 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 applied, since it does not offer the MA benefit.

Sponsor selection for audit relies on a number of sources, including a yearly risk assessment. The risk assessment is data-driven and uses various data related to the Medicare Parts C and D programs, as well as other operational information (e.g., large enrollment growth in a short period of time) to identify the level of risk of each sponsor.

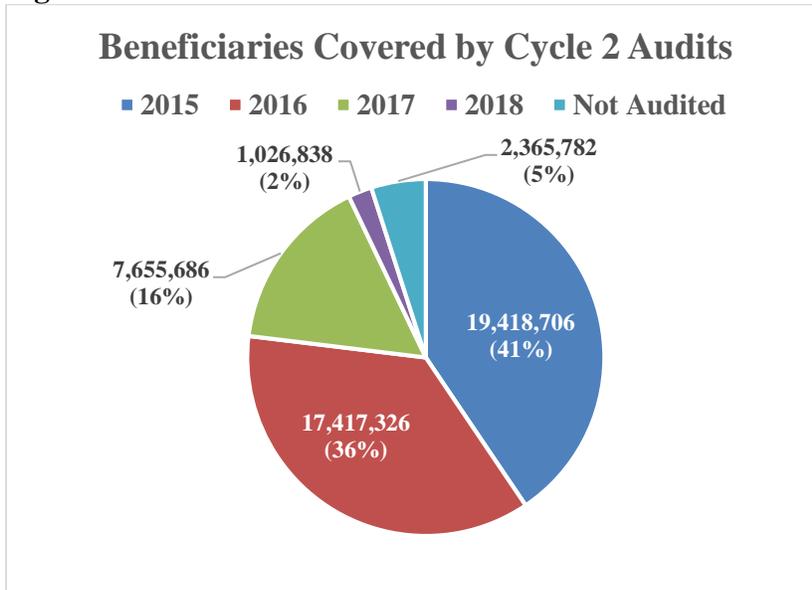
Other factors in the selection process include audit referrals (from Regional Offices and/or Central Office) and whether a given sponsor underwent a program audit in the current audit cycle. Consequently, some of the sponsors selected for audit in a given year may not always be the highest-risk, as calculated by the risk assessment.

In 2018, approximately two thirds of the sponsors we audited had an enrollment size of 15,000 or smaller. This represents a larger proportion of sponsors with a smaller enrollment size than we typically audit in a given year. The rationale for auditing a large percentage of relatively small sponsors is two-fold. First, 2018 was the final year of the second audit cycle, and CMS audited most of the large- and medium-size sponsors earlier in the cycle. CMS could therefore audit more organizations with lower enrollment than in previous years. Second, the 2018 audits focused on sponsors we had never audited before, and those sponsors tended to be smaller than the sponsors we typically audit.

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 2019 and include all coordinated care plans (CCPs), private fee-for-service (PFFS) plans, 1876 cost plans, standalone PDPs, and employer group waiver plans (800 series). However, Figures 1 and 2 represent only those organizations (and associated enrollments) that still operate Medicare contracts.

Figure 1*



* These enrollment data are summed by parent organization at the contract level. All contracts active in 2019 that are associated with sponsors that were audited in 2018 are reflected in this chart.

As noted earlier, the majority of sponsors audited in 2018 had low enrollment, and consequently these audits accounted for only 2% (i.e., roughly 1.03 million beneficiaries) of the total MA, other Medicare managed care health plan, and PDP enrollment (Figure 1). Overall, approximately 95% of all Part C and Part D enrollees were covered by sponsors audited during our second audit cycle.

From 2015 to 2018, CMS audited 56% of the sponsors that currently have active Medicare contracts (Figure 2). However, the total number of sponsors audited during the second cycle is under-represented due to acquisitions over time by other organizations or sponsors no longer participating in the Medicare Parts C and D programs. For instance, while Figure 2 shows 14 sponsors audited in 2015, we actually audited 22 distinct sponsors that year.

Figure 2

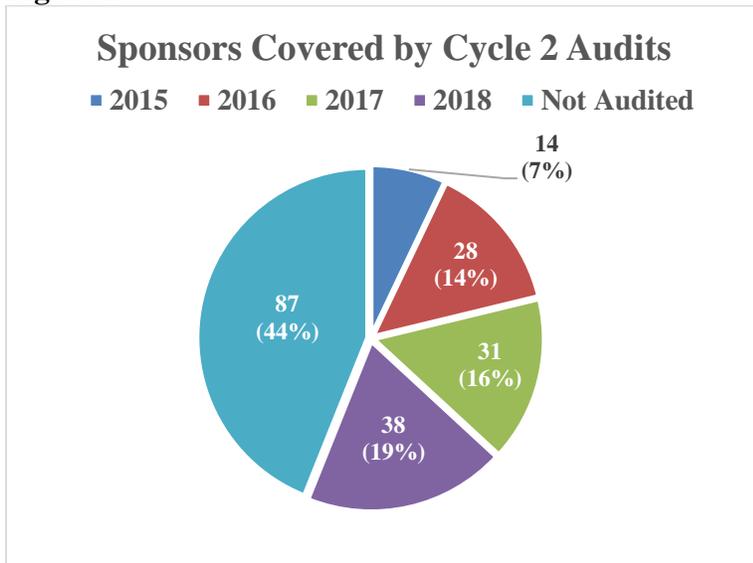


Figure 3 on the following page shows the percentage of Medicare beneficiaries in each state that were covered by the program audits conducted in 2018. The largest percentage of enrollees audited in any one state or territory was approximately 13% (note that these enrollment data are at the plan level, whereas all other figures reporting on enrollment in this document are at the contract level). By comparison, in the 2017 report the largest percentage of enrollees audited in any one state was approximately 33%. Figure 4 depicts the percentage of plans in each state included in 2018 program audits.

Figure 3

Percentage of Medicare Enrollees in Each State Included in 2018 Program Audits

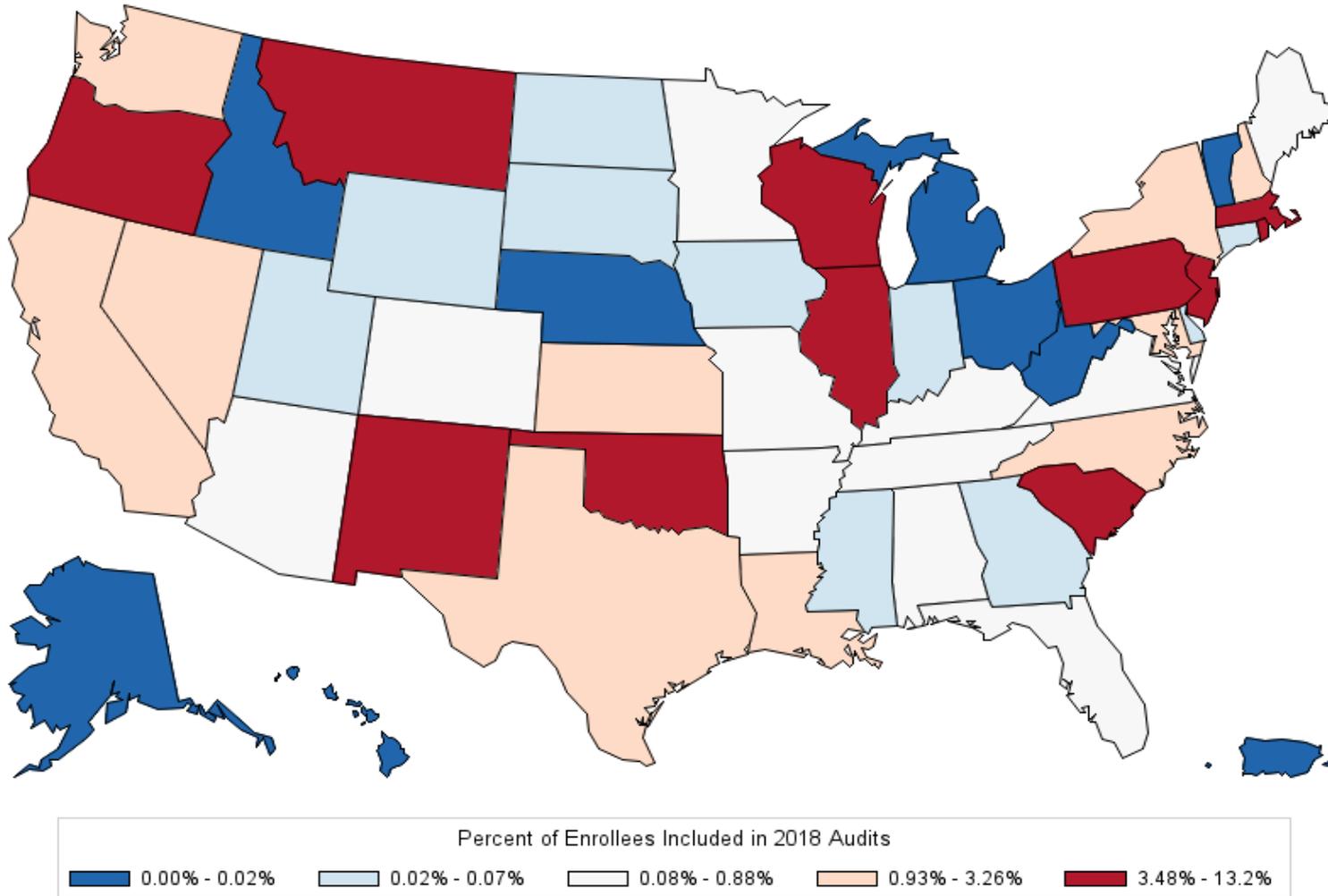
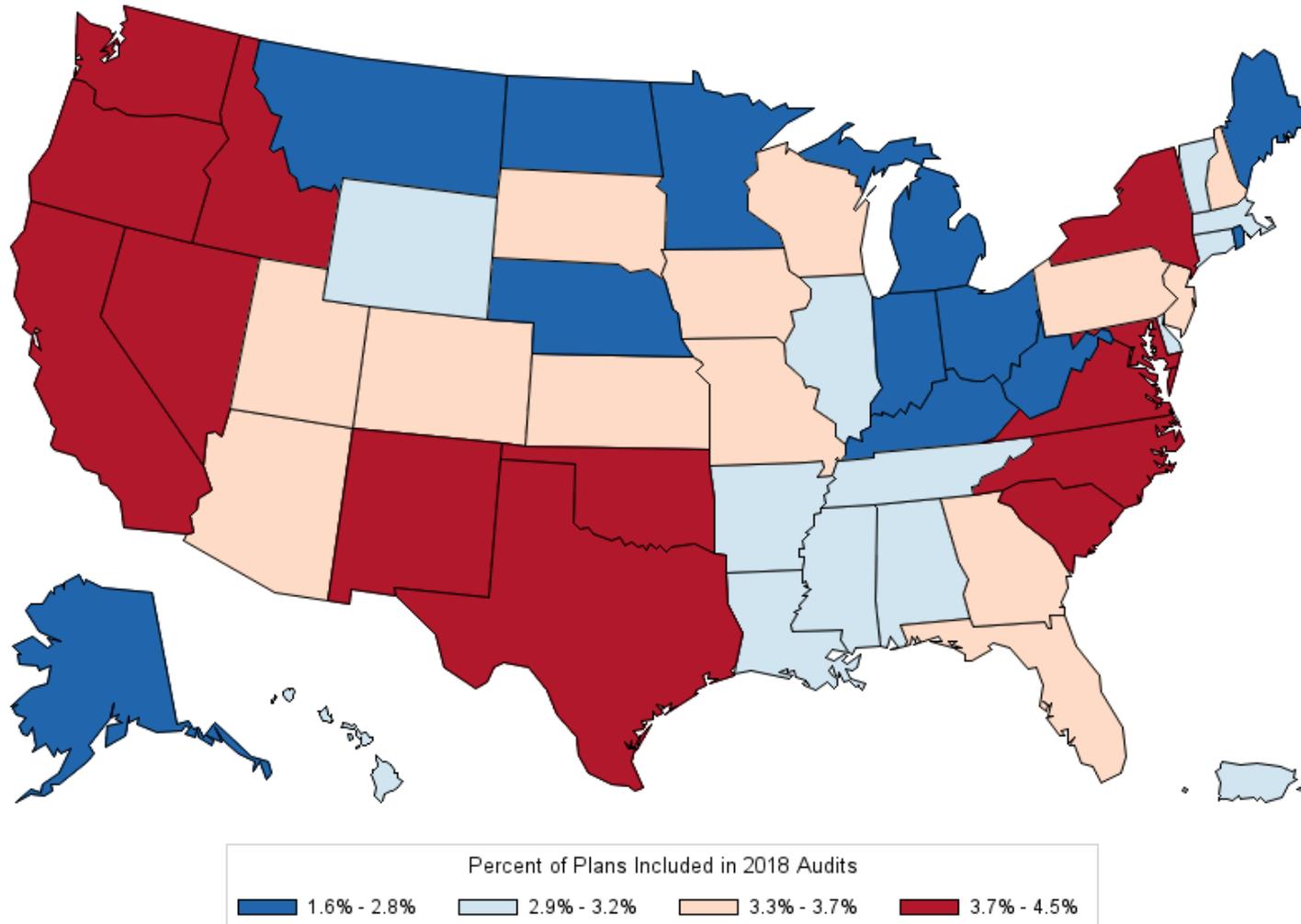


Figure 4

Percentage of Medicare Plans in Each State Included in 2018 Program Audits



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. The average amount of time to complete various post-audit fieldwork activities is shown below in Table 1.

Table 1

| Audit Phase | 2016 | 2017 | 2018 | 2016 to 2018 Change |
|---|------|-------|--------|---------------------|
| Average Time between Exit Conference and ICAR Email (in days) | 27 | 31 | 23 | -4 |
| Average Time between Exit Conference and Draft Audit Report (in days) | 101 | 62 | 58 | -43 |
| Average Time between Exit Conference and Final Audit Report (in days) | 129 | 88 | 80 | -49 |
| Average Time between Final Audit Report and Audit Closeout (in days) | 278* | 304** | TBD*** | TBD |

*Based on 36 of the 37 program audits conducted in 2016 as of 08/20/2019

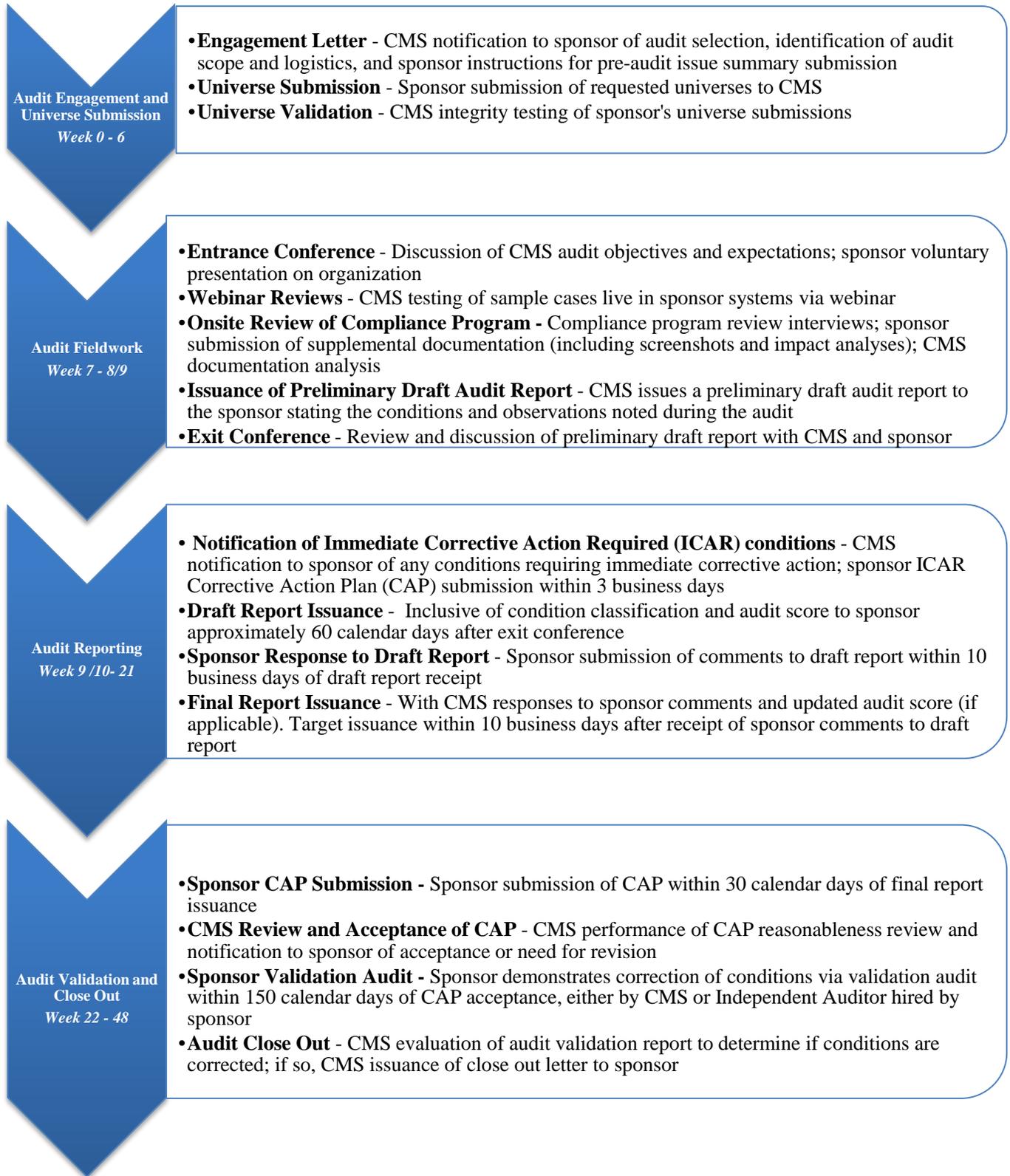
** Based on 36 of the 38 audit validations conducted based on 2017 audits, as of 08/20/2019

*** Only 15 of the 39 audits we conducted in 2018 have been closed out as of 08/20/2019

As shown in Table 1 above, the average amount of time that elapsed between the exit conference and the ICAR email, as well as between the exit conference and the issuance of the draft and final audit reports decreased between 2016 and 2018. We are not reporting on the average amount of time that has elapsed between the final report and audit closeout for 2018 because, as of mid-August 2019, only 15 2018 audits had been closed out. We attribute the aforementioned decreases to a number of factors. They include improved internal documentation, which has provided greater clarity to auditors, more specific and stronger training of auditors, which has improved their knowledge and contributed to increased consistency in applying auditing principles, and greater transparency regarding our audit protocols and guidance documents, which has resulted in organizations knowing better what to expect during an audit.

Figure 5 on the following page provides an overview of each stage of the 2018 audit process and the estimated timeframe for the completion of each stage.

Figure 5



2018 AUDIT INNOVATIONS AND PROCESS IMPROVEMENTS

Gathering feedback from sponsors and external stakeholders is key to improving program audit documentation, processes, and procedures and allows for better education and support. Recent feedback resulted in the following improvements:

- Expanded technological capability, which allowed for the submission of all audit-related documentation to the Health Plan Management System (HPMS) and eliminated the need to submit universes via an external Secure File Transfer Protocol.
- Fully operationalized the two MMP-specific protocols and expanded our audit plan to account for organizations that offer only MMP-type contracts.
- Reduced the scope of Part C and Part D Call Log universes collected for program audits.
- Suspended the Medication Therapy Management (MTM) pilot protocol.
- Extended audit fieldwork from two to three weeks to provide sponsors with additional time to respond to audit requests and prepare for the onsite CPE audit.
- Published a blank audit submission checklist on the program audit website for sponsors to use when conducting their own mock audits.
- Published information related to the validation audit and program audit closeout processes on our program audit website.
- Increased the amount of time sponsoring organizations had to complete a validation audit from 150 to 180 days.

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.

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:

Audit score = $((\# \text{ CARs} + \# \text{ IDS}) + (\# \text{ of ICARs} \times 2)) / \# \text{ of audited elements}$

Calculations produce an overall audit score, as well as a score for each program area. As previously mentioned, not all sponsors audited in 2018 had every program area audited. The score quantifies a sponsor's performance and allows comparisons across sponsors. The figures on the following pages compare scores between 2017 and 2018 and display overall and program-area specific audit scores for sponsors audited in 2018.

Comparison of 2017 and 2018 Audit Results

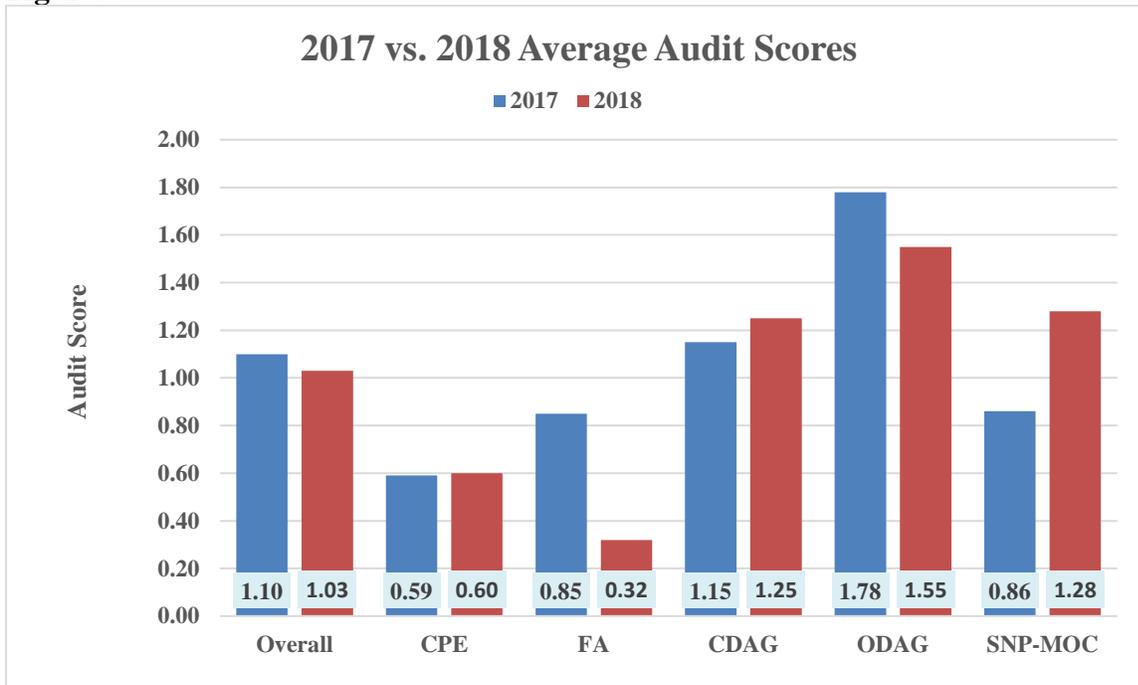
Figure 6 depicts the average audit score in each program area audited in 2017 compared to 2018 scores. The overall scores in 2018 are better than in 2017, as are the scores in FA and ODAG. CPE scores stayed consistent across the two years. The two MMP program areas are not shown in this chart as those program areas were pilots in 2017 and the scores did not appear in final audit reports. We anticipate including the MMP results in future iterations of this chart.

The program area with the largest average score improvement from 2017 to 2018 was FA, where the average score improved by more than 60% (i.e., from 0.85 in 2017 to 0.32 in 2018). We believe the improvement in FA scores may be attributable to the relatively small number of Pharmacy Benefit Managers (PBMs) and the fact that once an issue is discovered and remediated, PBMs typically correct the issue for all of the sponsors with which they contract.

Over the course of almost two audit cycles, sponsors' performance continues to improve. The average number of conditions cited per audit in 2012 was 38 and was down to an average of approximately 13 per audit in 2018, even though since 2015 we increased the number of condition types we can assign to non-compliance discovered during audits. 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 their 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*

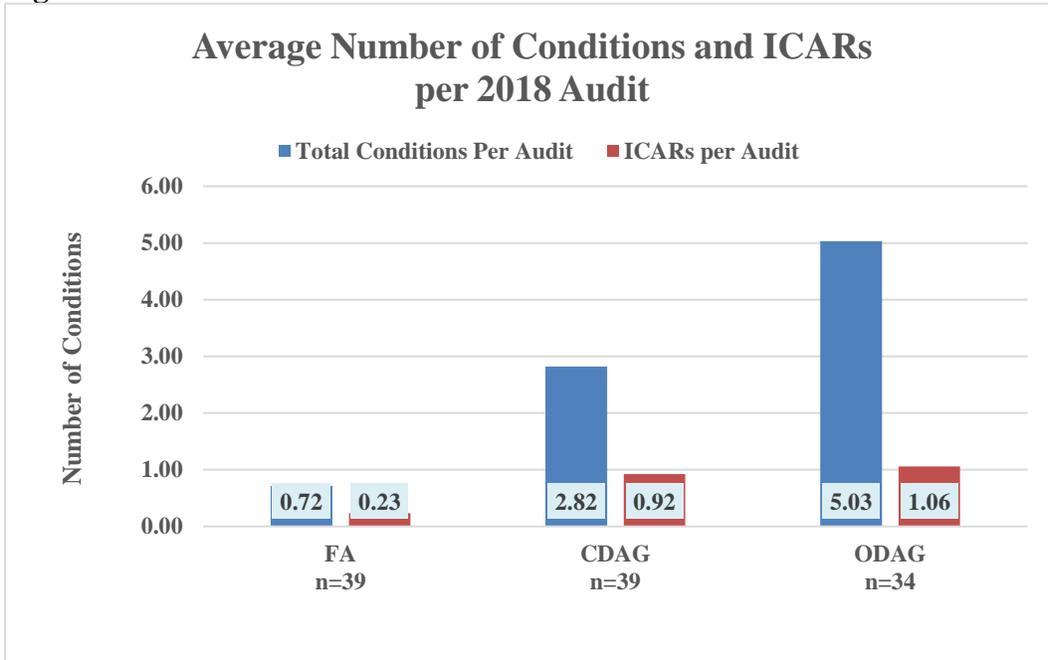


* Audit scores are analyzed at the sponsor (parent organization) level. The average audit score is an unweighted score across all audited sponsors within each group. A lower audit score represents better audit performance. MMP audit results are excluded from this chart as the MMP audits were pilots in 2017 and no scores were included in final audit reports.

Number of Conditions and ICARs by Program Area

Figure 7 displays the average number of conditions and ICARs cited in the FA, CDAG, and ODAG program areas for 2018. These were the only program areas with ICARs in both 2017 and 2018. In total, nine ICARs were cited in FA, 36 ICARs were cited in CDAG, and 36 ICARs were cited in ODAG. The number of ICARs cited during audits we conducted in 2018 ranged from zero to seven. While the range of ICARs cited across audits was unchanged in 2018, the total number of ICARs cited across the different program areas fell markedly in 2018, due to FA where the number of ICARs decreased from 28 in 2017 to 9 in 2018. In 2017, 375 total conditions were cited in FA, CDAG and ODAG. In 2018, this number decreased to 309 total conditions. In 2017, a total of 93 ICARs were cited for FA, CDAG and ODAG. In 2018, the total for these program areas decreased to 81.

Figure 7



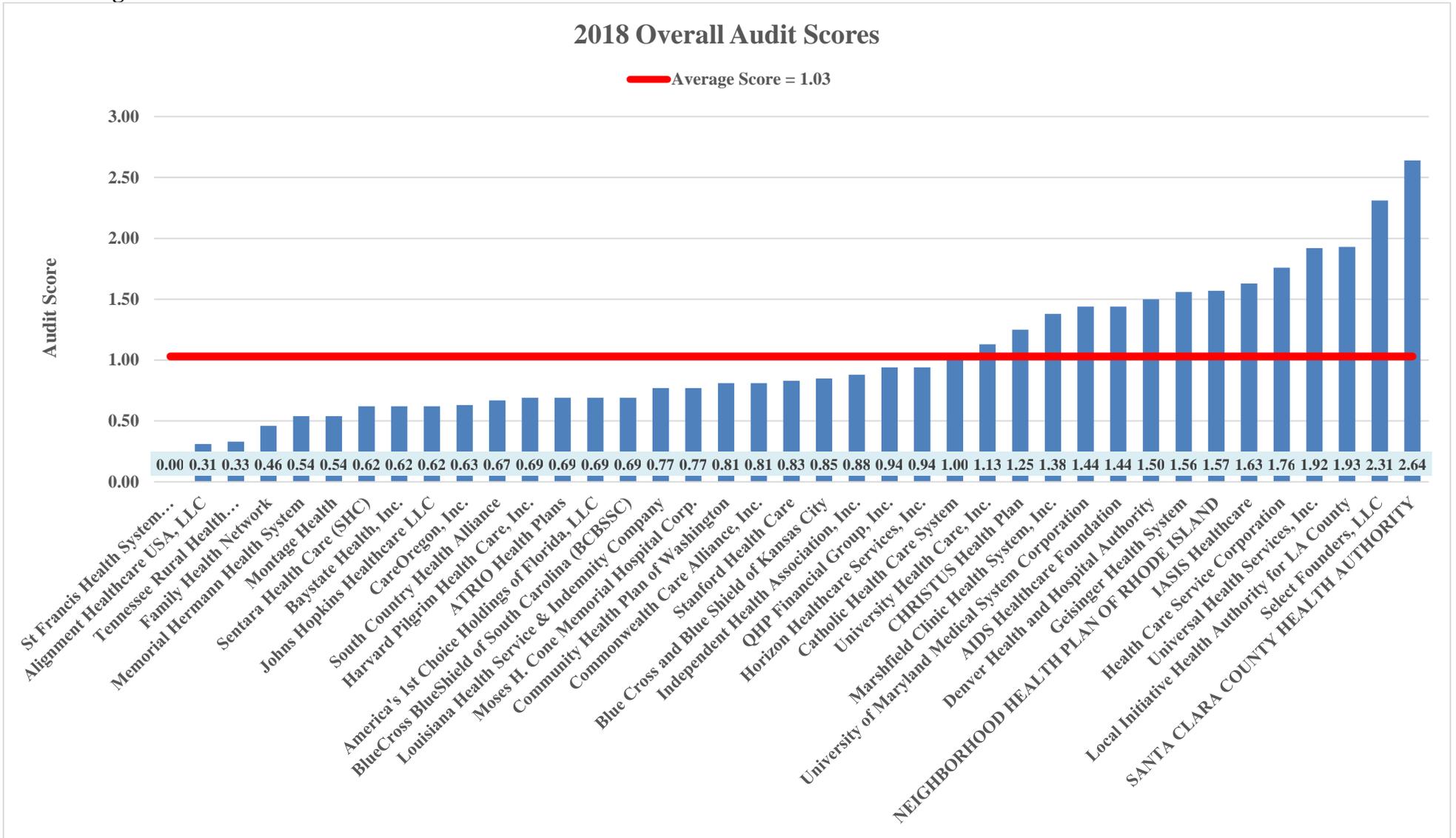
Program Audit Scores

Figures 8-15 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 red line in each graph represents the average audit score across all audited sponsors.

Figure 8*

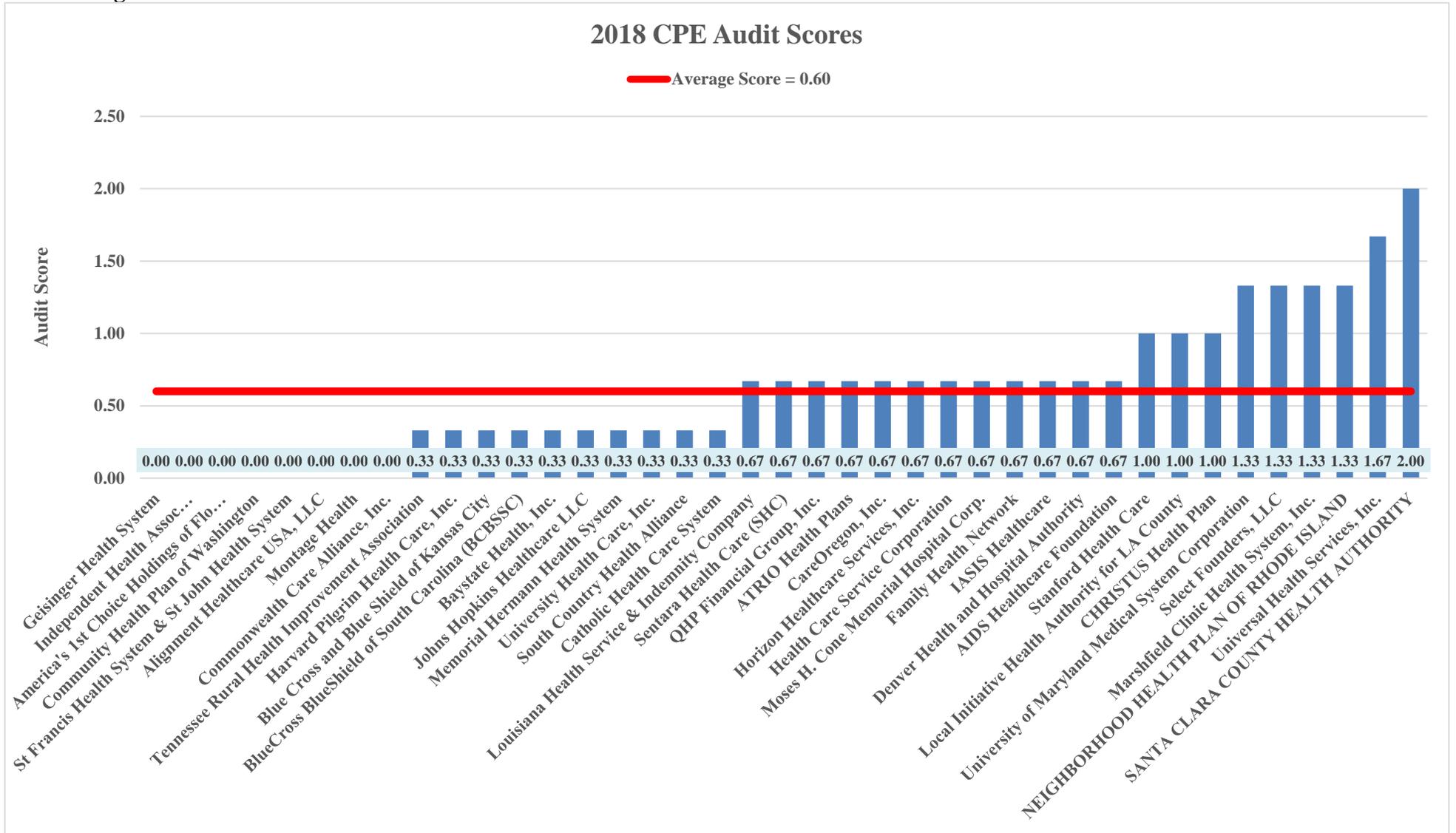
2018 Overall Audit Scores

Average Score = 1.03



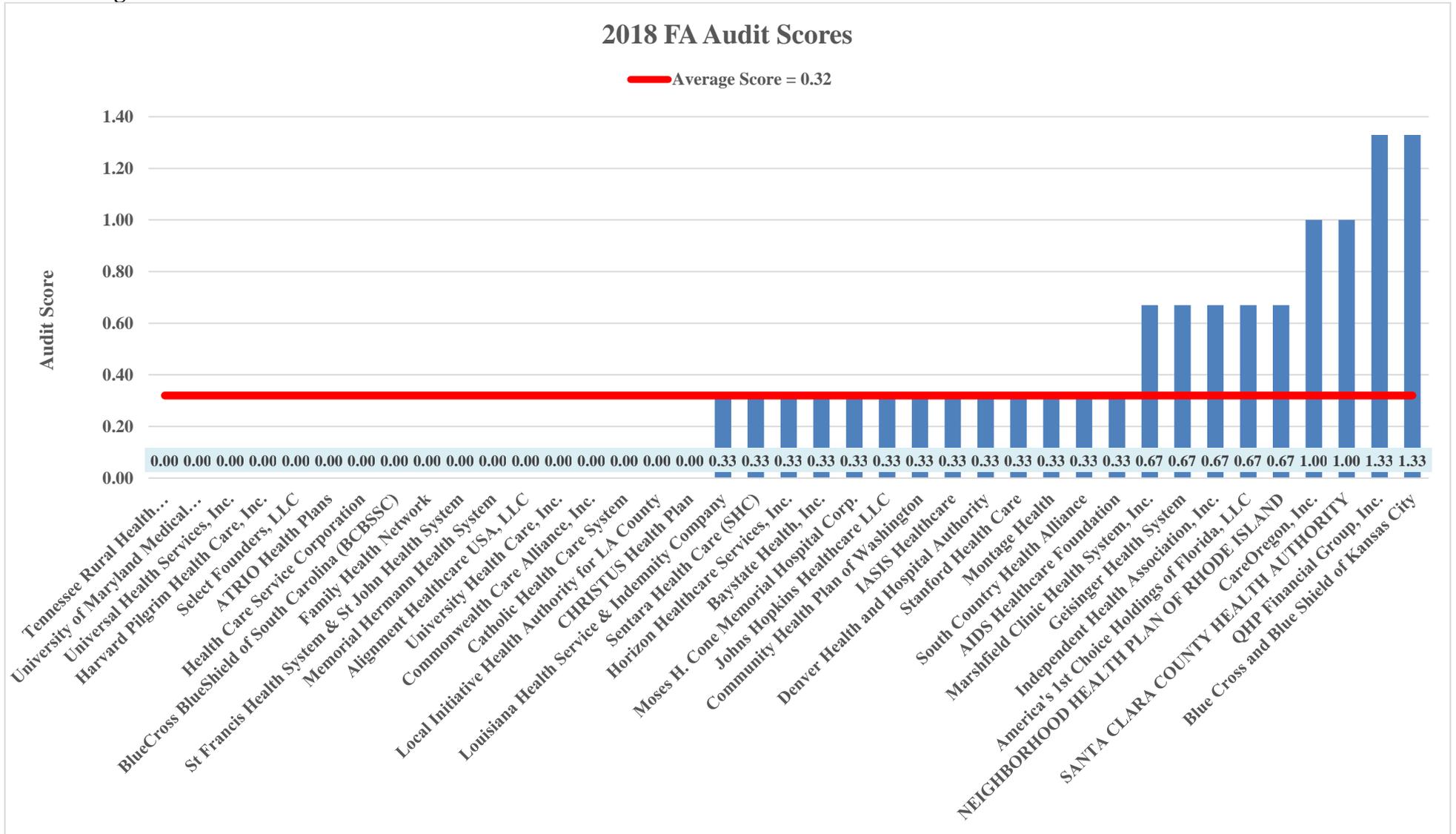
*A lower audit score represents better audit performance. The average audit score is an unweighted score across all sponsors audited in 2018.

Figure 9*



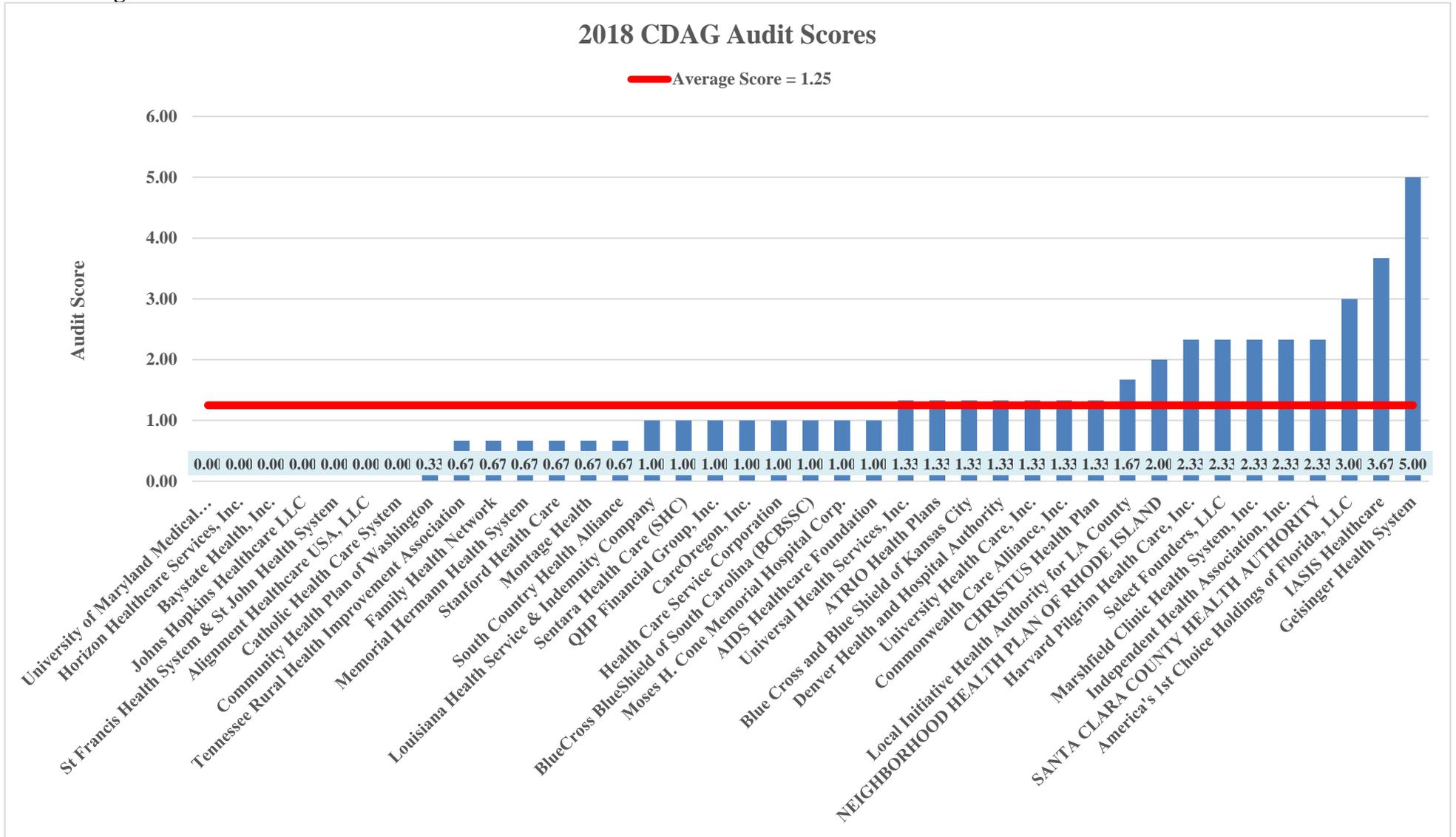
*A lower audit score represents better audit performance. The average audit score is an unweighted score across all sponsors audited for the CPE program area in 2018.

Figure 10*



*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 2018.

Figure 11*

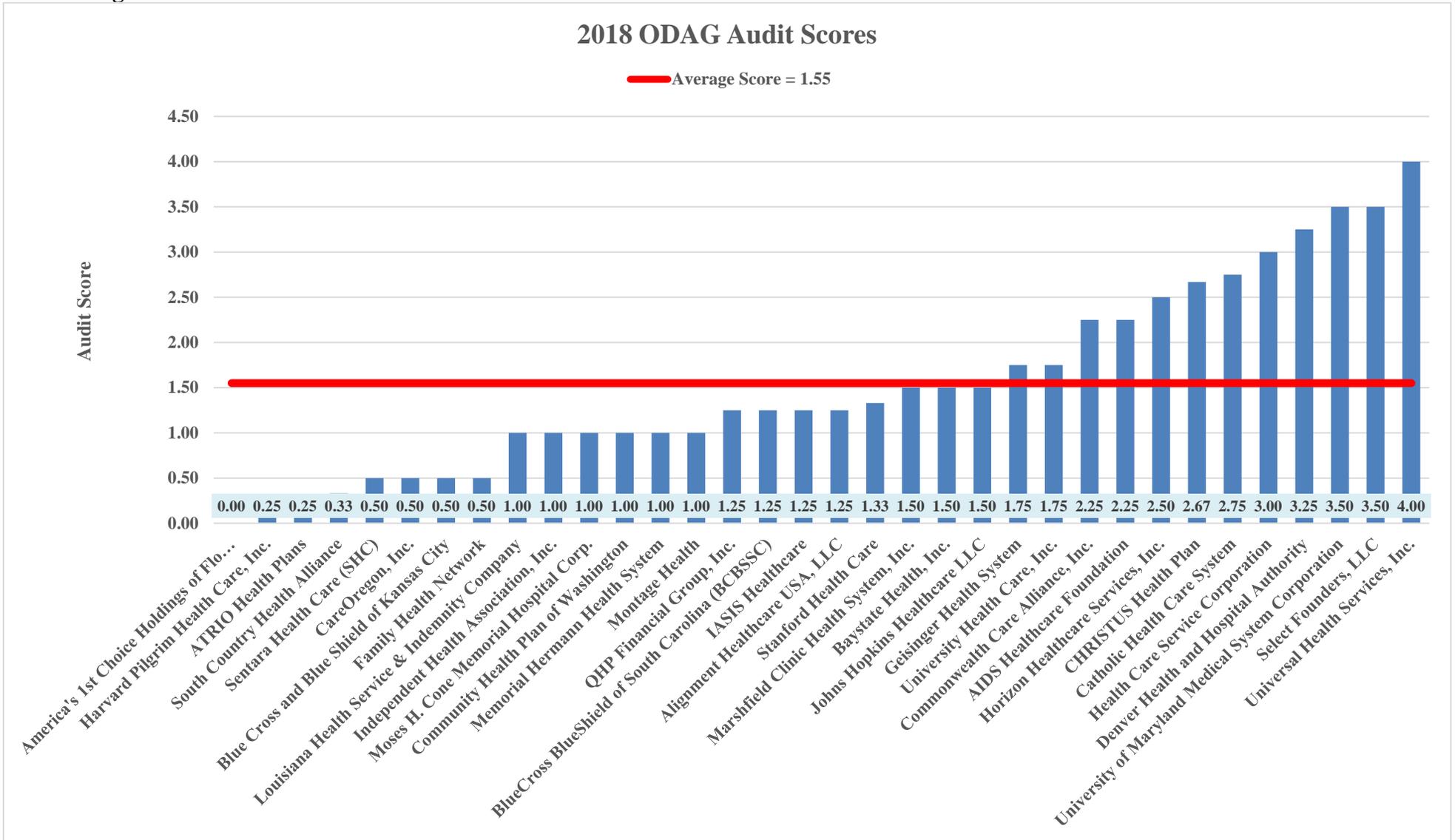


*A lower audit score represents better audit performance. The average audit score is an unweighted score across all sponsors audited for the CDAG program area in 2018.

Figure 12*

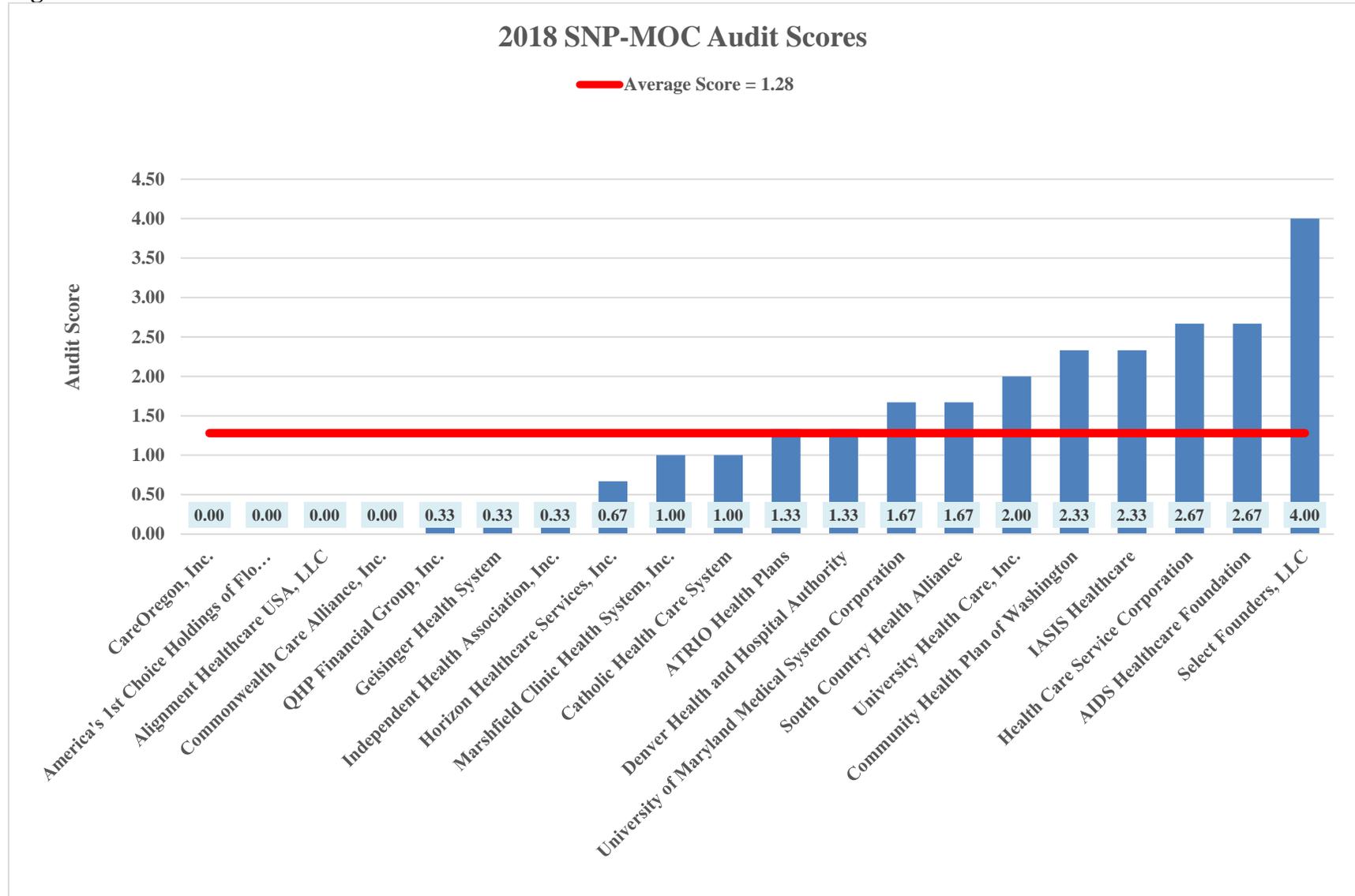
2018 ODAG Audit Scores

Average Score = 1.55



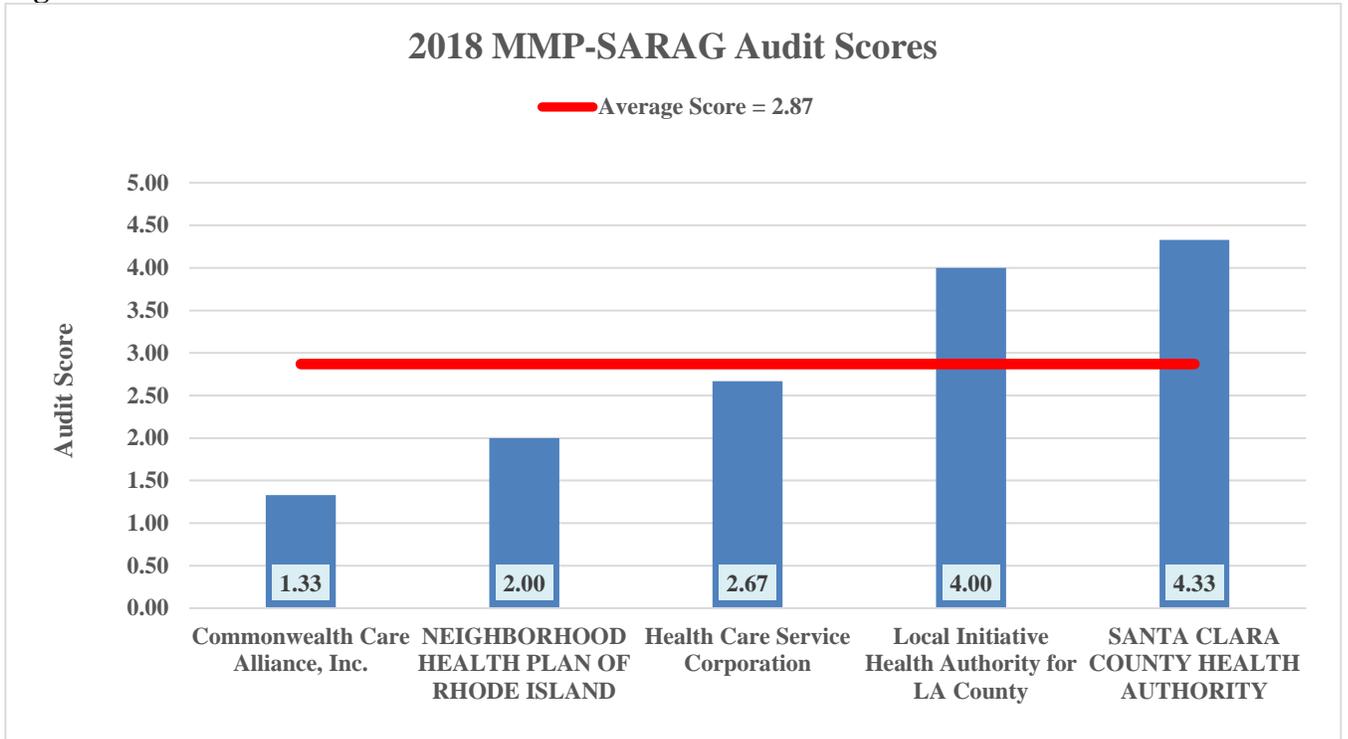
*A lower audit score represents better audit performance. The average audit score is an unweighted score across all sponsors audited for the ODAG program area in 2018.

Figure 13*



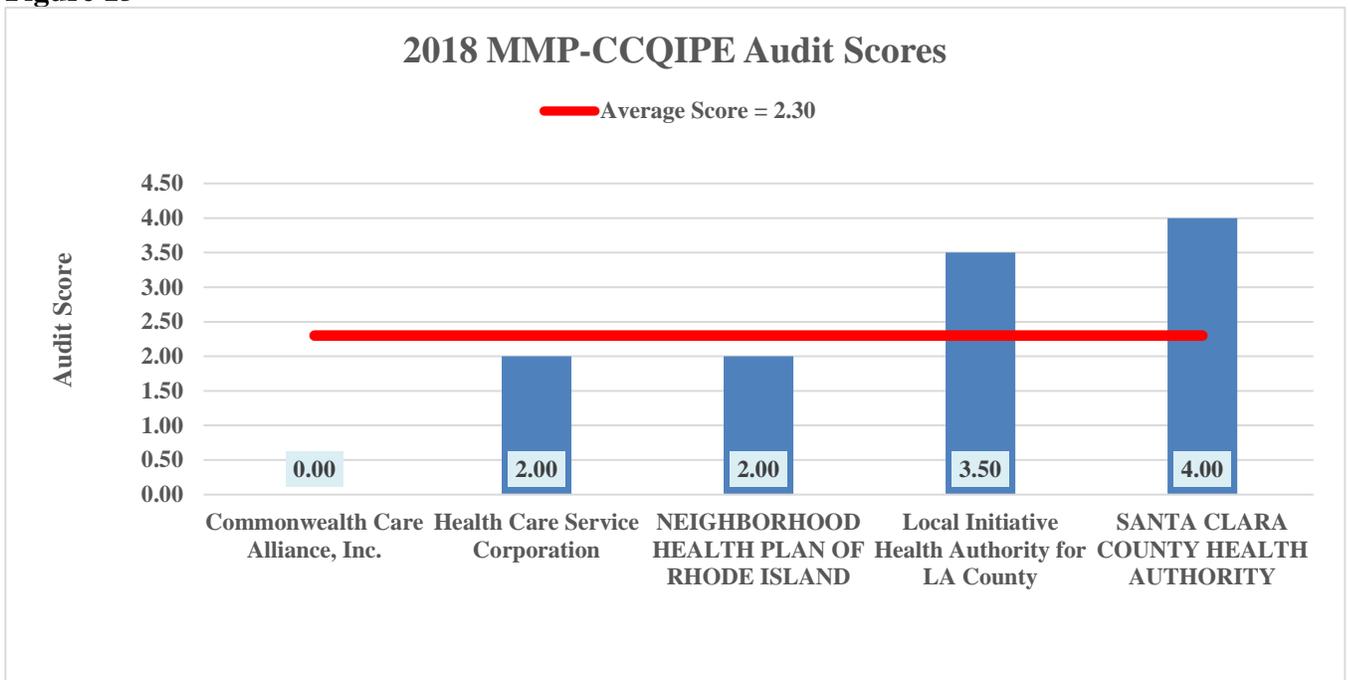
*A lower audit score represents better audit performance. The average audit score is an unweighted score across all sponsors audited for the SNP-MOC program area in 2018.

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-SARAG program area in 2018.

Figure 15*

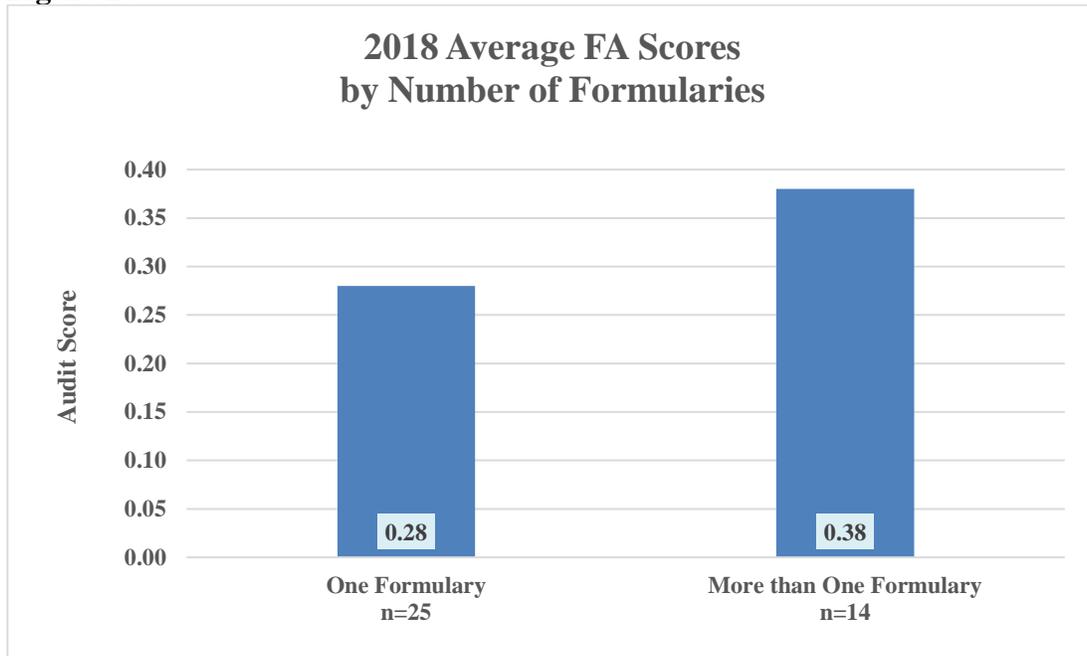


* A lower audit score represents better audit performance. The average audit score is an unweighted score across all sponsors audited for the MMP-CCQIPE program area in 2018.

FA and CDAG Scores by Number of Formularies

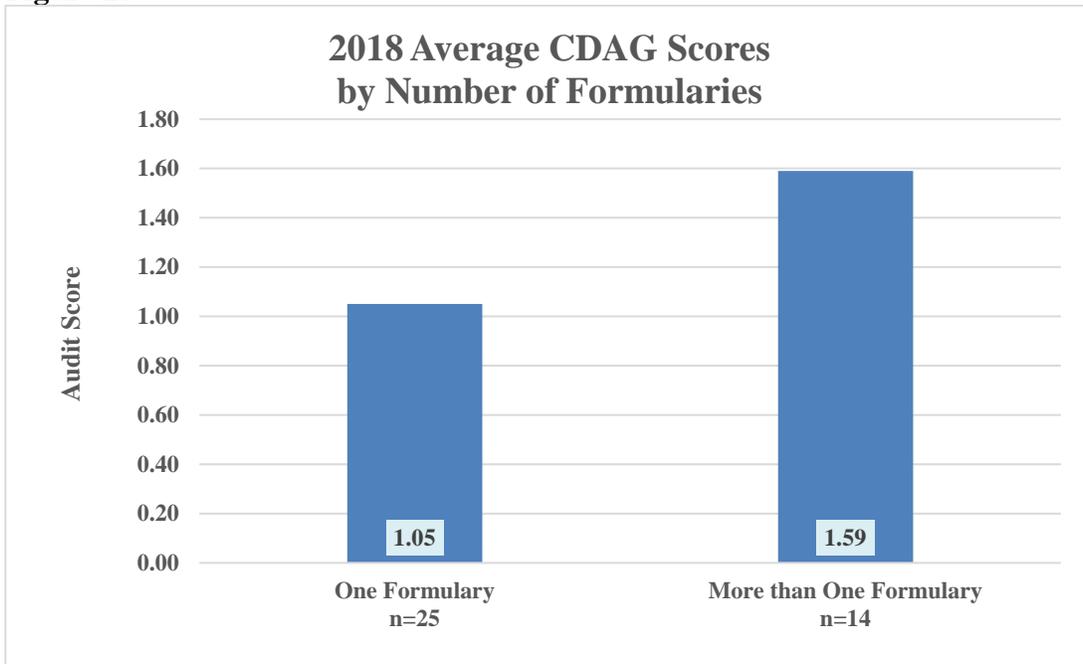
The figures below display the average 2018 FA and CDAG scores across audited sponsors broken into two groups: those that operate one formulary, which comprised the majority of organizations, and those that operate more than one formulary. In the latter group, the number of formularies used ranged from two to seven. In both FA and CDAG, sponsors with only one formulary fared better on audit in 2018 than sponsors that operated more than one formulary. The difference in performance between the two groups of sponsors was significantly larger in CDAG; however, the average scores across all 2018 audits were low, especially in FA. In the 2017 audits, sponsors with more than one formulary also fared worse on average in CDAG, and sponsors with more than one formulary actually fared better in FA.

Figure 16*



* 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.

Figure 17*



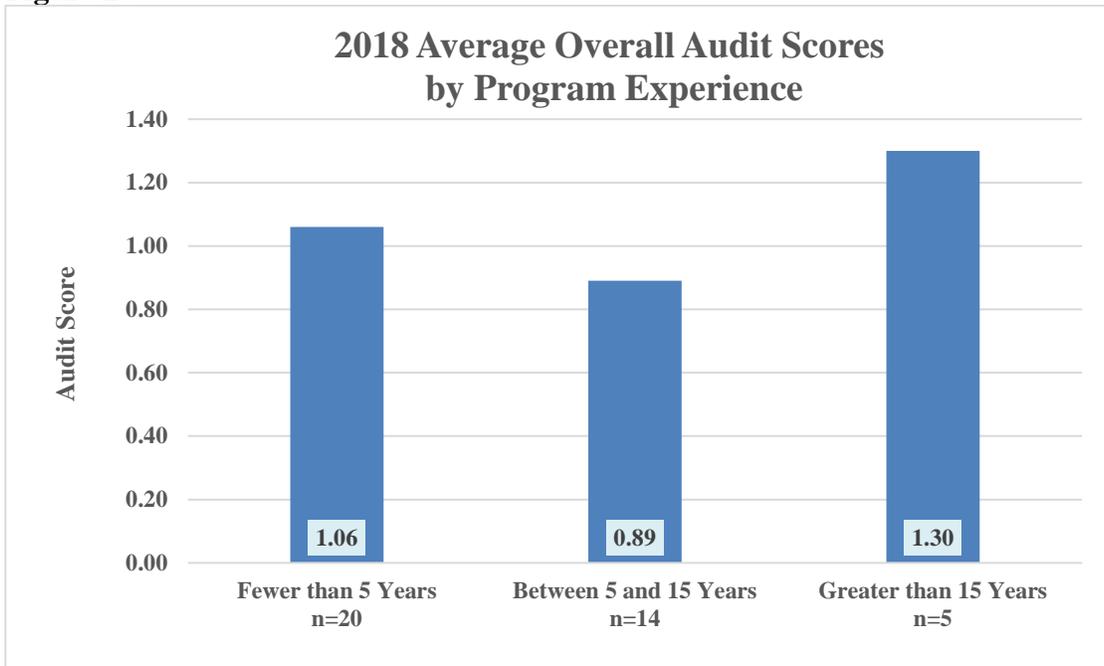
* Audit scores are analyzed at the sponsor (parent organization) level. The average audit score is an unweighted score across all audited sponsors within each group. A lower audit score represents better audit performance.

Overall Audit Scores by Program Experience

Figure 18 breaks the 2018 average overall audit scores into three categories, depending on how long a sponsor has had an active Medicare contract. A sponsor’s earliest effective contract date was used to determine the length of program experience. For example, if a sponsor has one contract dating back to 2008 and five contracts dating back to 2017, they were included in the “Between 5 and 15 Years” category below. The average scores across all groups were low and comparable to previous years, despite many of the sponsors audited in 2018 having fewer years of experience and not having a past program audit.

The sponsors operating Medicare contracts for between 5 and 15 years were, on average, the lowest of the three groups. Sponsors operating Medicare contracts in excess of 15 years had, on average, the highest audit scores for the first time since we began doing this analysis in the 2015 report. However, with respect to the audits we conducted in 2018, it is worth noting that there were a relatively small number of organizations in this category, therefore causing outlier scores to have a larger impact on the average score for the category.

Figure 18*

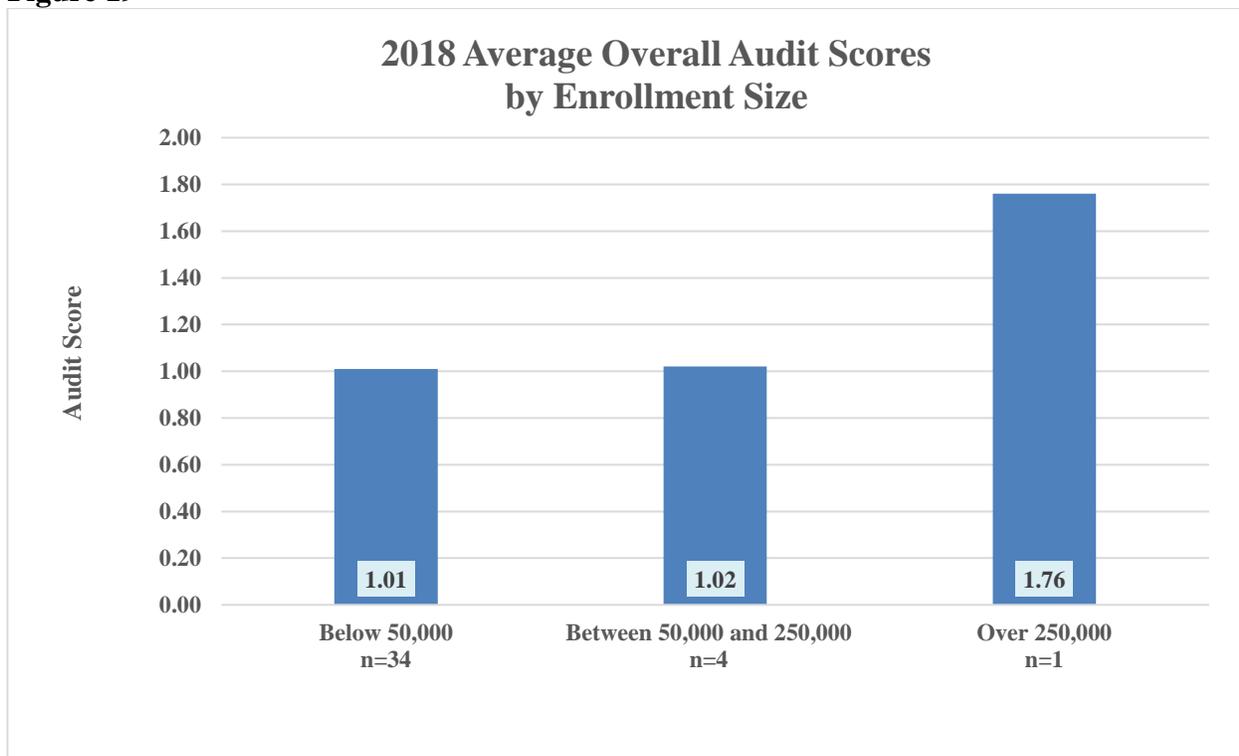


* Audit scores are analyzed at the sponsor (parent organization) level. The length of time a sponsor has offered Medicare contracts is based on the contract a sponsor has with the earliest effective date. The average audit score is an unweighted score across all audited sponsors within each group. A lower audit score represents better audit performance.

Overall Audit Scores by Enrollment Size

Figure 19 displays 2018 average overall audit scores by the size of enrollment for a given sponsor. In 2018, the majority of audited sponsors were categorized as having low enrollment as compared to last year where roughly half of the sponsors we audited were in the medium and large groups. This is attributed in part to the selection of more sponsors in 2018 that had never previously been audited and typically have lower enrollment and fewer years of experience in Medicare. Small- and medium-size sponsors had approximately equal audit scores on average in 2018. The sponsors in the small-size group fared on average better on audit in 2018 than 2017 (i.e., the average score for this group improved from 1.25 to 1.01). There was only one sponsor audited in 2018 that had an enrollment in excess of 250,000, and that sponsor fared worse than the average score of the small and medium groups. In the 2017 audits, the group of small-size sponsors had, on average, the highest audit scores, and the large-size group had, on average, the lowest audit scores.

Figure 19*



* 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.

ENFORCEMENT ACTIONS

In 2018, 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 Civil Money Penalty (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 2018 and early 2019 due to non-compliance detected in 2018. These referrals encompass actions for violations from 2018 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 2018 program audit violations.

General Enforcement Background

CMS has the authority to impose CMPs, intermediate sanctions, and for-cause terminations against MA plans, PDPs, PACE Organizations, and Cost Plans. MOEG is the group responsible for imposing these types of enforcement actions when a sponsor is substantially noncompliant with CMS' program requirements, such as the Medicare Parts C and D or 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, 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.

Process Improvements

During 2018, we continued to calculate CMPs consistent with the methodology published on December 15, 2016.² On March 15, 2019, CMS released a number of proposed revisions to the CMP methodology for comment, which included a proposed new approach for calculating increases to the standard CMP amounts. CMS finalized the updated methodology on June 21, 2019. MOEG also implemented other enhancements to increase transparency in the enforcement referral evaluation process:

- Affected sponsors received more 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 more timely notice when CMS decided not to take an enforcement action against them; and
- Sponsors subject to a CMP received a more detailed written explanation of the calculation of their penalty.

¹ <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDEnforcementActions-.html>

² The CMP Methodology is on our enforcement action website in the above footnote.

MOEG also continued its efforts to engage with sponsors throughout the evaluation process to ensure enforcement actions used data that accurately reflected the impact of violations on beneficiaries. To that end, MOEG:

- Increased its efforts to obtain additional and/or mitigating data from sponsors from the analysis phase and verify findings when necessary;
- Strongly encouraged sponsors to fully evaluate discovered non-compliance and provide any additional information during the audit phase; and
- Took sponsors' comments to the draft audit reports into consideration when evaluating referrals.

ENFORCEMENT ACTIONS IMPOSED BASED ON 2018 REFERRALS

This section provides information on enforcement actions taken in calendar year 2018 and early 2019 due to non-compliance detected by CMS in 2018. CMS issued 10 CMPs and 3 intermediate sanctions against sponsors because of non-compliance identified in 2018, but did not issue any for-cause terminations.

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 2018, there were 84 referrals; approximately 43% were due to non-compliance detected through the Medicare Parts C and D program audits. In addition, there was a noticeable increase in referrals from audits of the Program of All-Inclusive Care for the Elderly (PACE) organizations (21% of the referrals were due to non-compliance detected through PACE audits). This is due to the enhanced PACE audit protocols that were recently implemented which focus more on non-compliance directly related to participant care outcomes and experiences. The other bases for enforcement action referrals in 2018 included:

- Non-compliance found during One-Third Financial Audits (18%);
- Medicare Parts C and D program Validation Audits (7%);
- Failure to send accurate and/or timely Annual Notice of Change/Evidence of Coverage (ANOC/EOC) found during routine monitoring activities (5%);
- Failure to make timely decisions related to Part D coverage determinations, appeals, and grievances identified through routine monitoring activities with the Independent Review Entity (2%);
- Inappropriately capturing and tracking maximum out-of-pocket (MOOP) costs (1%);
- Failure to provide CMS with evidence of a valid license to accept enrollments (1%); and
- Failure to maintain an adequate Medical Loss Ratio (MLR) for four consecutive years, as determined by reviews of self-reported MLR data (1%).

Table 2 shows the referral details, and displays the number of enforcement actions by referral type.

Table 2

| Referral Type | # of Referrals | # of Referral Closeouts | # of Referrals Under Review | # of Enforcement Actions Taken |
|--|----------------|-------------------------|-----------------------------|--------------------------------|
| Medicare Parts C & D Program Audits | 36 | 29 | 1 | 6 |
| Program of All-Inclusive Care for the Elderly | 18 | 14 | 0 | 4 |
| One-Third Financial Audits | 15 | 14 | 0 | 1 |
| Medicare Parts C & D Program Validation Audits | 6 | 6 | 0 | 0 |
| Annual Notice of Change/Evidence of Coverage | 4 | 4 | 0 | 0 |
| Part D Untimely Decisions | 2 | 2 | 0 | 0 |
| Maximum Out-of-Pocket Limit | 1 | 1 | 0 | 0 |
| State Licensure | 1 | 0 | 0 | 1 |
| Medical Loss Ratio | 1 | 0 | 0 | 1 |

CIVIL MONEY PENALTIES (CMPs)

CMPs imposed for non-compliance detected in 2018 totaled \$396,736, with an average of \$39,674 per CMP. The highest CMP imposed was \$49,600 and the lowest CMP imposed was \$29,800. The following table shows the sponsors that received a CMP based on 2018 referrals:

Table 3

| Date of Imposition | Organization Name | Basis for Referral | CMP Amount |
|--------------------|--|---------------------------|------------|
| 01/08/2019 | CenterLight TeamCare | 2018 PACE Audit | \$38,159 |
| 02/27/2019 | Commonwealth Care Alliance, Inc. | 2018 Program Audit | \$42,900 |
| 02/27/2019 | Neighborhood Health Plan of Rhode Island | 2018 Program Audit | \$29,800 |
| 02/27/2019 | Local Initiative Health Authority of LA County | 2018 Program Audit | \$43,600 |
| 02/27/2019 | Santa Clara County Health Authority | 2018 Program Audit | \$39,000 |
| 02/27/2019 | Arkansas Superior Select, Inc. | 2018 Program Audit | \$49,600 |
| 03/06/2019 | Senior LIFE Lehigh Valley, Inc. | Participant Care Concerns | \$38,159 |
| 03/12/2019 | Agewell New York, LLC | 2016 Financial Audit | \$39,200 |
| 04/29/2019 | Community PACE at Home, Inc. | 2018 PACE Audit | \$38,159 |
| 04/29/2019 | Franciscan ACO, Inc. | 2018 PACE Audit | \$38,159 |

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

³ Organizations that received more than one CMP could be included in an enrollment band more than once.

- For organizations with < 1,000 enrollees, the average CMP was \$38,159
- For organizations with 1,000 – 5,000 enrollees, the average CMP was \$42,320
- For organizations with 10,000 – 20,000 enrollees, the average CMP was \$37,467
- For one organization with 20,000 or more enrollees, the CMP was \$42,900

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;
 - Expedited cases;
 - Financial impact over \$100;
 - A prevalence of failed audit samples;
 - A Top-5 common condition; and/or
 - A history of prior offense.

Consistent with our approach in 2017, 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 10 CMPs imposed for 15 specific violations:⁴

- 11 on a per-enrollee basis resulting in \$244,100 (62% of the total CMP amount).
- 4 on a per-determination basis resulting in \$152,636 (38% of the total CMP amount).

For CMPs taken as a result of 2018 audits, Figure 20 and Figure 21 show the total number of violations and dollar amount of violations by calculation type.

Figure 20

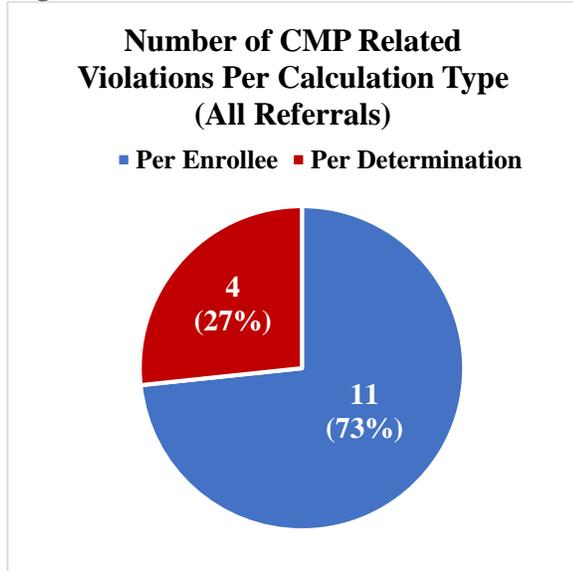
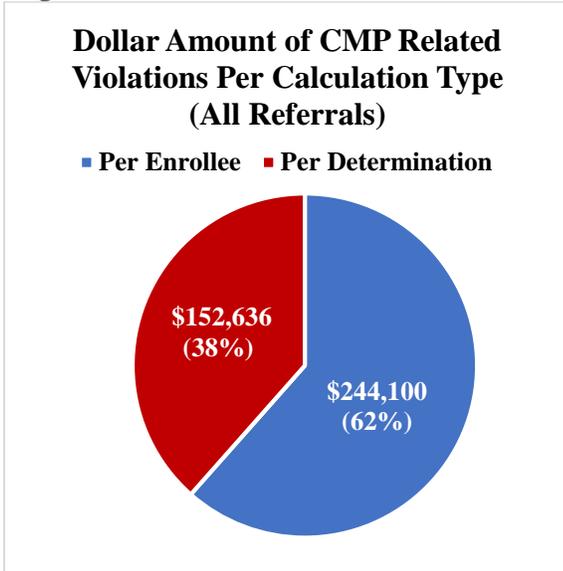


Figure 21



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 2018, there were three intermediate sanctions imposed. These actions were imposed because of non-compliance with CMS’ Medical Loss Ratio (MLR) requirements, state licensure requirements, fiscal soundness requirements, and other program requirements detected on audit. In 2018, three sponsors were released from enrollment sanctions imposed in 2017 and 2018 because they were able to demonstrate correction of their deficiencies. Table 4 lists the sponsors and PACE organizations that were under intermediate sanction during 2018.

⁴ These numbers include CMPs from program audits, financial audits, and PACE administration failures that adversely affected an enrollee or had the substantial likelihood of adversely affecting an enrollee.

Table 4

| Date of Imposition | Organization Name | Basis for Referral | Type of Intermediate Sanction | Date of Intermediate Sanction Release |
|--------------------|--|---|-----------------------------------|---------------------------------------|
| 11/08/2018 | QHP Financial Group, Inc. | Fiscal Soundness and 2018 Program Audit | Enrollment & Marketing Suspension | TBD |
| 09/20/2018 | USABLE Mutual Insurance Company (S5795) | Medical Loss Ratio | Enrollment Suspension | 01/01/2020 |
| 10/12/2018 | Omaha Health Insurance Company | State Licensure | Enrollment Suspension | 10/17/2018 |
| 10/03/2017 | Via Christi Healthcare Outreach for Elders, Inc. | 2017 Focused PACE Audit | Enrollment Suspension | 09/18/2018 |
| 12/20/2017 | Riverside Retirement Services, Inc. | 2017 PACE Audit | Enrollment Suspension | 06/18/2018 |

Via Christi Healthcare Outreach for Elders, Inc., and Riverside Retirement Services, Inc. corrected the operational deficiencies that were the basis for their sanctions and were able to demonstrate compliance by successfully passing validation exercises. CMS released Omaha Health Insurance Company from enrollment suspension after curing its licensure deficiencies. CMS also released USABLE from its enrollment sanction (effective 1/1/2020) after determining that USABLE's 2018 MLR data met the MLR requirements. QHP Financial Group, Inc. remains under intermediate enrollment and marketing sanction and is working to remediate its deficiencies.

Independent Auditor Validation

Depending on the nature of the deficiencies, MA or PDP sponsors under intermediate sanction may be required to select and hire an independent auditor to conduct a validation audit at the sponsor's expense. The independent validation auditor audits the sponsor using CMS' audit protocols, drafts a report that details the findings from their independent audit, and submits the report to CMS. CMS uses the information gathered during the sanction monitoring process and results of the independent audit validation to determine if the sponsor should be released from intermediate sanction. If CMS has serious concerns about the ability of the sponsor to correct its

deficiencies, CMS may choose to validate the sponsor’s corrective actions.

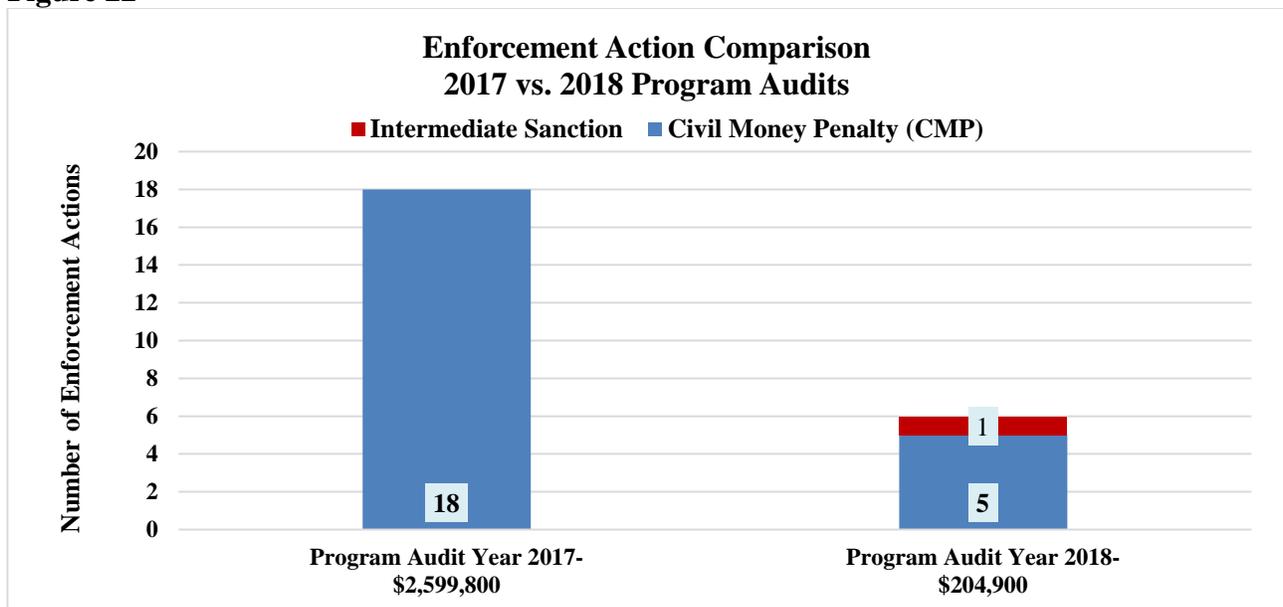
In contrast, PACE sponsors under intermediate sanction must undergo and pass a CMS validation audit. For PACE sponsors subject to intermediate sanction, CMS auditors will conduct the validation audit once the sponsors acquire enough clean data to validate correction of their deficiencies.

ENFORCEMENT ACTIONS RELATED TO 2018 PROGRAM AUDITS

This section provides additional details regarding enforcement actions imposed as a result of 2018 program audits, and offers a comparison of those data to enforcement actions taken based on 2017 program audits. For full details of enforcement actions taken related to 2017 program audits, please see the 2017 Part C and Part D Program Audit and Enforcement Report.⁵

Of the 39 organizations audited during 2018, 5 (13%) received an enforcement action. CMS is continuing to evaluate one of the organizations for an enforcement action. Figure 22 compares the cumulative CMP amounts and types of enforcement actions imposed on sponsors for the 2017 and 2018 program audits.

Figure 22



There were significantly fewer CMPs imposed for 2018 program audits compared to 2017 (i.e., 5 in 2018 vs. 18 in 2017), and the CMP amounts in 2018 were substantially lower than in 2017. The primary reason for both is CMS audited a large number of smaller organizations in 2018 compared to 2017⁶ and did not find many violations with substantial numbers of adversely impacted enrollees as a result of the smaller enrollment.

⁵ <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2017ProgramAuditEnforcementReport.pdf>

⁶ The average enrollment size of sponsors receiving a CMP in 2018 was 14,376 compared to 241,890 in 2017.

Figures 23 and 24 compare the number of FA, CDAG, ODAG, and MMP-SARAG conditions included in the CMP violations for 2017 and 2018 program audits. There were no FA conditions included in 2018 program audit CMPs.

Figure 23

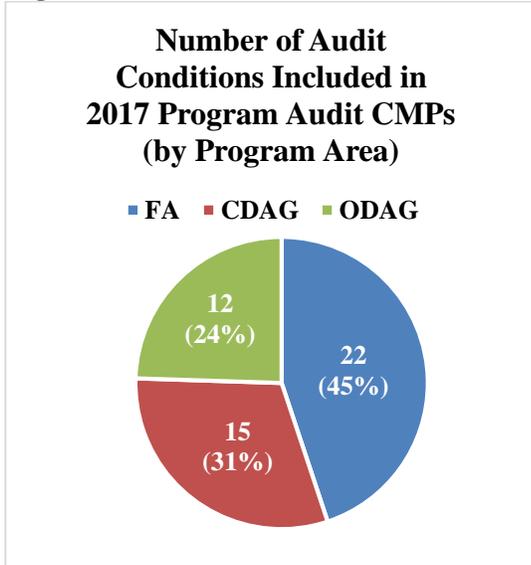
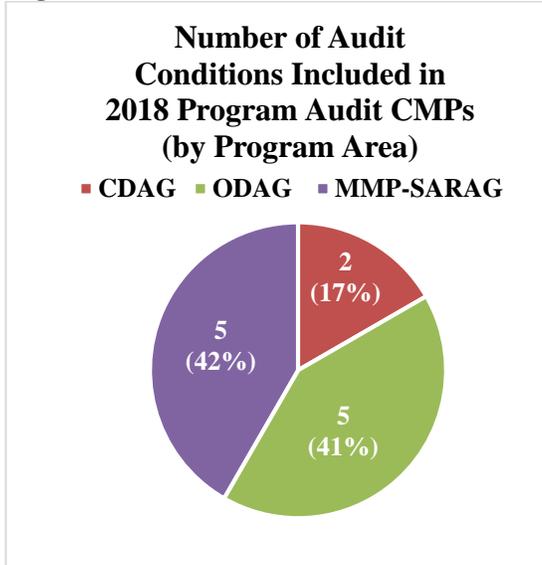


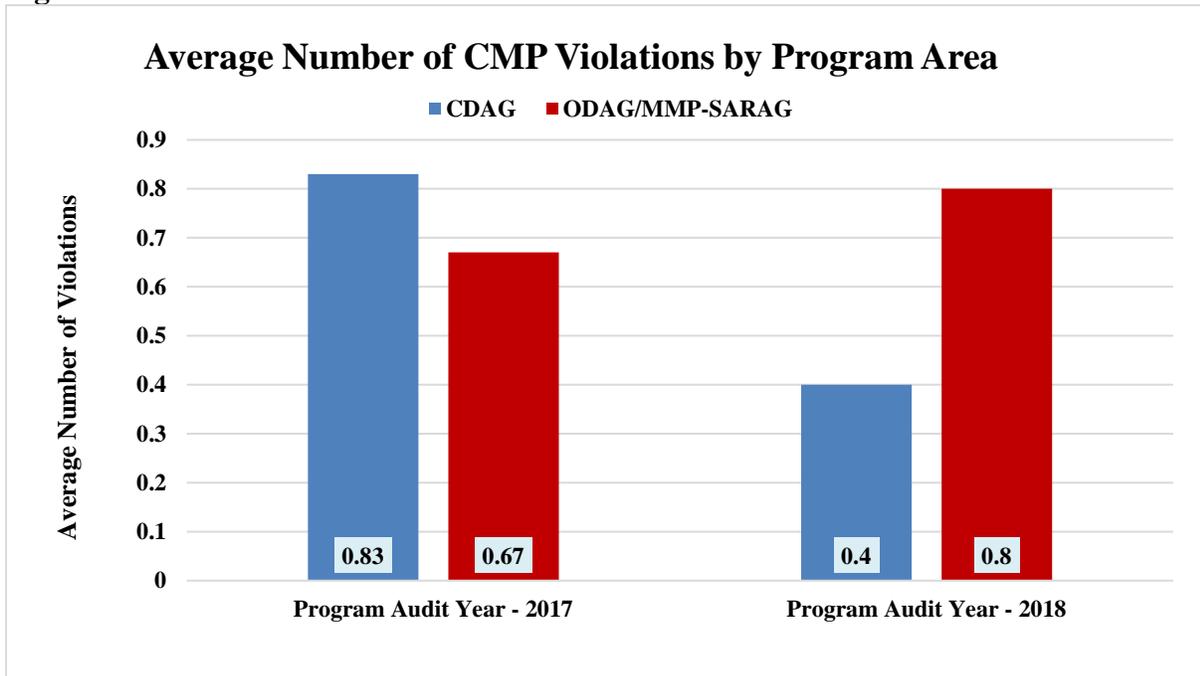
Figure 24



For 2018 program audits, all 5 CMP violations were imposed on a per-enrollee basis (total CMP amount of \$204,900).

Figure 25 shows the average number of CMP violations by program area for 2017 and 2018 program audits. The number of CDAG violations decreased and the number of ODAG/MMP-SARAG violations increased between program audit years 2017 and 2018.

Figure 25



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. From the program audit referrals, one intermediate sanction was imposed during 2018 for systemic operation and financial failures. This action was due to a combination of issues discovered during fiscal soundness monitoring and a 2018 program audit.

ENFORCEMENT ANALYSIS AND PROCESS IMPROVEMENTS

During 2018, CMS continued to improve its enforcement program by giving sponsors additional opportunities to provide information and mitigating evidence for the enforcement division to consider when making its determination. CMS was also able to reduce the number of days it took to issue a CMP following the issuance of the final program audit report (76 days in 2017 vs. 67 days in 2018).

2019 AUDIT PROCESS IMPROVEMENTS

The goal in 2019 is to continue enhancing the consistency among audits and strengthen the expertise of audit teams. All audit findings continue to undergo review and evaluation by program audit consistency teams to ensure a fair and consistent outcome across all audits. Through improved auditor expertise, we are better suited to collaborate with and provide technical assistance to our stakeholders, and aid in improving performance. The following is a list of initiatives and process improvements implemented this year:

- Suspended the Website audit element review from the Formulary and Benefit Administration protocol, as well as the Enrollment Verification audit element review from the SNP-MOC protocol, consistent with changes proposed in the updated PRA package for 2020 program audits; see our proposed edits to CMS-10191, OMB 0938-1000 in <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/Downloads/CMS-10191.zip>.
- Suspended review and collection of Call Logs to assess organizations' oversight of coverage request classification at a higher level during the CPE review.
- Eliminated collection of certain questionnaires at the time of the engagement letter to avoid duplication of information that is generally collected via root cause and impact analyses.
- Refined our sampling methodology and, therefore, clarified that collection of specific data points within certain CPE record layouts are optional as they are no longer necessary for sample selection.
- Posted a Program Audit Frequently Asked Questions (FAQ) document to our program audit website to share key questions and answers related to our audit process and to assist sponsors with universe preparation; see <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/ProgramAuditFAQs.pdf>.
- Combined 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 (https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2019_Program_Audit_Process_Overview.pdf).
- Clarified how CMS quantifies drug and/or enrollee impact to promote transparency within our audit process.
- Updated the threshold for requiring sponsoring organizations to hire an independent auditor in accordance with the Calendar Year 2019 Final Call Letter.

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.