

# FDR Compliance Newsletter

Mercy Care Advantage 4500 E. Cotton Center Blvd. Phoenix, AZ 85040

November 2021 | Issue 2

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- Updates to SAM.gov
- Overseeing your organization's FDRs
- CMS Medicare Part C and D program audit protocols and Enforcement Report

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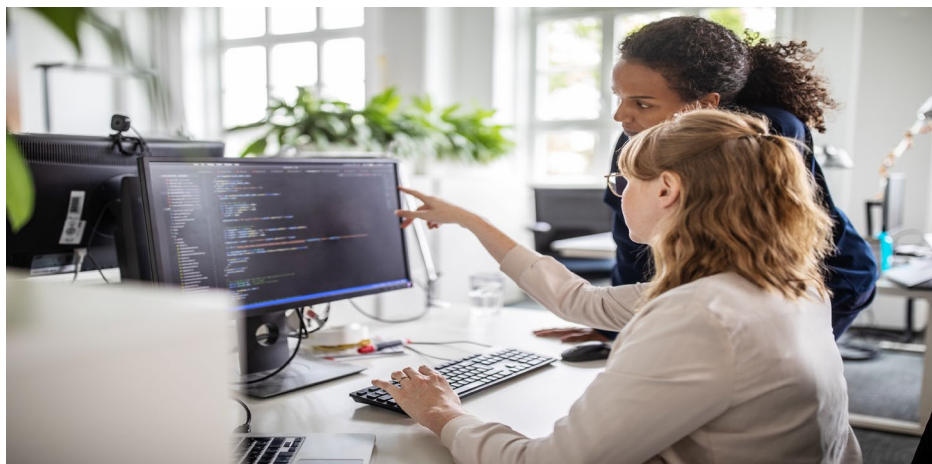
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FDRs can have their own internal processes in place for reporting Fraud Waste & Abuse OR non-compliance, however, instances which impact MCA business should be reported to us immediately using one of the methods below. Compliance concerns can be reported free from retaliation to the MCA Compliance Team at the email address listed above. Or by calling the CVS Health Ethics Line anonymously toll-free at **1-877-287-2040** (24/7) or visit [www.cvshealth.com/ethicsline](http://www.cvshealth.com/ethicsline) to make a report.



## Updates to the SAM.gov website

The General Services Administration (GSA) exclusion list is maintained in the System for Award Management (SAM) database. You can find it on the **SAM.gov** website. If you manually run exclusion screenings using the **SAM.gov** website, you may have recently noticed some changes to the search functionality. If you have questions about using the new functionality, you should reach out to the SAM Service Desk. You can also create a help ticket or start a live chat. The **SAM.gov** Knowledge Base also has some helpful guidance surrounding the new search functionality. Please be sure to review the evidence of completion you are maintaining for screenings on the **SAM.gov** website. Consistent with our previous communications, CVS Health® requires documentation to include a date/timestamp of when the screenings were conducted. When reviewing the exclusion screening evidence you are maintaining, be sure that the documentation clearly includes

the following:

- ✓ The full name of the individual/entity screened
- ✓ The exclusion list the individual was screened against
- ✓ Date/timestamp of completion
- ✓ Results of the screening

If an individual was screened as a potential match and later cleared by a secondary search using their social security number (SSN) or another method, evidence of the secondary screening should be maintained. This evidence should also contain the elements listed above. Be sure you enter only digits for an SSN. Don't use dashes. With the changes made to the SAM.gov website, you may need to update your current process. This ensures that appropriate evidence of exclusion screenings are maintained. Print to PDF or screenshots may be a helpful way to capture the information that you'll need to maintain on file as evidence of screening completion.

## Overseeing your organization's downstream entities

Mercy Care audits and monitors your organization based on your status as a first tier, downstream, and/or related entity (FDR). Similarly, your organization also has the obligation to audit and monitor FDRs that your organization contracts with to perform services for Mercy Care. Here are a few questions and answers to help explain how your organization should be evaluating and overseeing your FDRs.

**Q: How do we determine if a downstream vendor is an FDR or just a vendor?**

**A:** Medicare program requirements apply to FDRs to whom the sponsor has delegated administrative or health care service functions. These functions are relating to the sponsor's Medicare Parts C and D contracts. Chapter 9 of the Prescription Drug Benefit manual and Chapter 21 of the Medicare Managed Care manual, Section 40, outlines areas of consideration when determining if a vendor qualifies as an FDR. The chapter suggests evaluating the following factors when determining FDR status:

- The type of services being performed (many examples of functions that would give rise to FDR status are listed in Section 40)
- The impact of the services on beneficiaries
- The vendor's access to protected health information
- The vendor's decision-making authority
- The vendor's ability to commit fraud, waste or abuse
- The overall risk associated with the vendor

A specific methodology isn't outlined in the chapter. However, your organization should have a process that considers all the components to consistently evaluate the FDR status

of subcontractors performing services on behalf of Mercy Care.

**Q: If my organization determines a vendor is an FDR, what are our oversight obligations?**

**A:** If your evaluation process determines a vendor is a downstream entity for Mercy Care, be sure to let Mercy Care know about this relationship. This includes if any of the FDR services are being performed offshore. Next, ensure there is an executed contractual agreement between your organization and the vendor that contains all CMS-required provisions (42 CFR 423.505(i) and 42 CFR 422.504(i)). You'll also need to ensure that processes are in place for monitoring that the vendor meets compliance and operational requirements, such as:

- Ensuring an oversight policy is in place
- Obtaining compliance attestations
- Conducting monitoring and/or auditing activities of the vendor's compliance program and performance of operational processes

When Mercy Care audits your organization, we'll request evidence of oversight of your FDRs as part of the audit.

**Q: What if oversight of one of our FDRs demonstrates the vendor isn't compliant with a Medicare requirement?**

**A:** Mercy Care is required to hold our organization accountable for non-compliance and require remediation of deficiencies. Your organization must do the same. Section 50.7.2 of Chapter 9 of the Prescription Drug Benefit manual and Chapter 21 of the Medicare Managed Care manual outlines components of Corrective Plans.



## Training changes

**Reminder:** CMS requires that FDRs use CMS's training courses to meet the FDR training requirements.

**Two ways to complete:**

Your employees and Downstream Entities assigned to provide administrative and/or health care services for MCA can access CMS's trainings in one of two ways:

1. Complete the modules on the Medicare Learning network (MLN) website.
2. Download or print CMS's general compliance training and FWA training and incorporate them into your training materials/system.

## Business Continuity Plans (BCPs)

**Reminder:** CMS has set minimum standards for BCPs. BCPs must contain policies and procedures to protect the restoration of business operations following disruptions where business is not able to occur under normal conditions. Mercy Care will routinely validate that contracted FDRs have developed and implemented these new standards. For a complete list of requirements, please review the Final Rule (42 CFR §§422.504(o) and §423.505(p))



## CMS Medicare Part C and D program audit protocols and Enforcement Report

On May 26, 2021, the Centers for Medicare & Medicaid Services (CMS) announced they have released the final audit protocols it uses to conduct the Medicare Part C and Part D program audits and the program audit protocols for Medicare-Medicaid Plans (MMPs). Collectively, these protocols and supporting data collection instruments will be used for Medicare Parts C and D program audits starting in **2022**. They are available for download at: [CMS.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits](https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits)

In addition, in May 2021, CMS also issued the **Annual Program Audit and Enforcement Report**. 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. CMS updates 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. The May report includes results from the program audits conducted in 2020. The highlights are as followed:

### 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 2020 program audits evaluated sponsor compliance in the following program areas based on the contract types offered by the audited sponsors:

- Compliance Program Effectiveness
- Part D Formulary and Benefit Administration
- Part D Coverage Determinations, Appeals, and Grievances
- Part C Organization Determinations, Appeals, and Grievances

CMS audited each sponsor in all program areas applicable to its operation. For example, CMS would not audit a standalone PDP sponsor using the ODAG protocol since it does not offer the MA benefit.

### CURRENT PROGRAM AUDIT LANDSCAPE

CMS does not audit a large number of sponsors each year, but within a three-year period, the sponsors they audit typically represent about 95% of the enrollment of the Medicare Advantage and Part D programs. CMS conducted a relatively small number of scheduled program audits in 2020 due to the Public Health Emergency, bringing the total number of sponsors they audited in 2019 and 2020 to 16, or approximately 7.5% of the sponsors with currently active

### AUDIT RESULTS

The data analyses resulting from the 2020 program audits show the following:

Overall audit scores:

- ✓ The average overall audit score was **0.15** in 2020. *A lower audit score represents better audit performance.*

In 2020, audits were conducted in the following program areas: Compliance Program Effectiveness (CPE), Part D Formulary and Benefit Administration (FA), Part D Coverage Determinations, Appeals and Grievances (CDAG), and Part C Organization Determinations, Appeals and Grievances (ODAG).

- ✓ There were no audit findings for the FA program area.
- ✓ The average audit scores for CPE, FA, CDAG and ODAG were **0.06, 0, 0.22** and **0.30**, respectively.

CMS imposed **6** civil money penalties totaling **\$514,969** and sanctioned **7** sponsors.

**To access the full Program Audit and Enforcement Report, please continue reading below**



**2020 Part C and Part D Program Audit and Enforcement Report**

**Medicare Parts C and D Oversight and  
Enforcement Group**

**Date: May 14, 2021**

*This report is also published online at:*

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

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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 (referred to as sponsors). Regular and consistent auditing of these sponsors provides measurable benefits by:

- Ensuring beneficiaries have appropriate 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 2020.

CMS adjusted its 2020 audit strategy to account for the challenges presented by the COVID-19 public health emergency (PHE). For that reason, we caution readers against drawing conclusions about the overall performance of audited sponsors in 2020 compared to those that were audited in previous years. For additional information on how COVID-19 affected our program audits in 2020, see the Health Plan Management System (HPMS) memo titled, "Reprioritization of PACE, Medicare Parts C and D Program, and Risk Adjustment Data Validation (RADV) Audit Activities," dated March 30, 2020.<sup>1</sup> For additional information on the types of PHE-related flexibilities that CMS offered to sponsors, see the HPMS memo titled, "Information Related to Coronavirus Disease 2019 - COVID-19," dated May 22, 2020.<sup>2</sup>

### **Highlights**

#### ➤ **Audit Results**

The data analyses resulting from the 2020 program audits show the following:

- Overall audit scores:
  - The average overall audit score was 0.15 in 2020.
- Audit scores by program area:
  - In 2020, audits were conducted in the following program areas: Compliance Program Effectiveness (CPE), Part D Formulary and Benefit Administration (FA), Part D Coverage Determinations, Appeals and Grievances (CDAG), and Part C Organization Determinations, Appeals and Grievances (ODAG).

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<sup>1</sup> <https://www.cms.gov/files/document/covid-19-programauditsradv-memo.pdf>

<sup>2</sup> <https://www.cms.gov/files/document/covid-19-updated-guidance-ma-and-part-d-plan-sponsors-52220.pdf>

- There were no audit findings for the FA program area.
- The average audit scores for CPE, FA, CDAG and ODAG were 0.06, 0, 0.22 and 0.30, respectively.

➤ **Enforcement Actions**

- CMS imposed six civil money penalties (CMPs) totaling \$514,969 and sanctioned seven sponsors based on 2020 referrals.

## **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, younger people with disabilities, and people with End Stage Renal Disease. 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, behavioral health care, and long-term services and supports for Medicare-Medicaid beneficiaries 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. 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 2020 audit year. It also discusses the current audit landscape, results of data analyses from the 2020 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 2020 program audits evaluated sponsor compliance in the following program areas based on the contract types offered by the audited sponsors:

- Compliance Program Effectiveness
- Part D Formulary and Benefit Administration
- Part D Coverage Determinations, Appeals, and Grievances
- Part C Organization Determinations, Appeals, and Grievances

CMS audited each sponsor in all program areas applicable to its operation. For example, we would not audit a standalone PDP sponsor using the ODAG protocol since it does not offer the MA benefit.

## **CURRENT PROGRAM AUDIT LANDSCAPE**

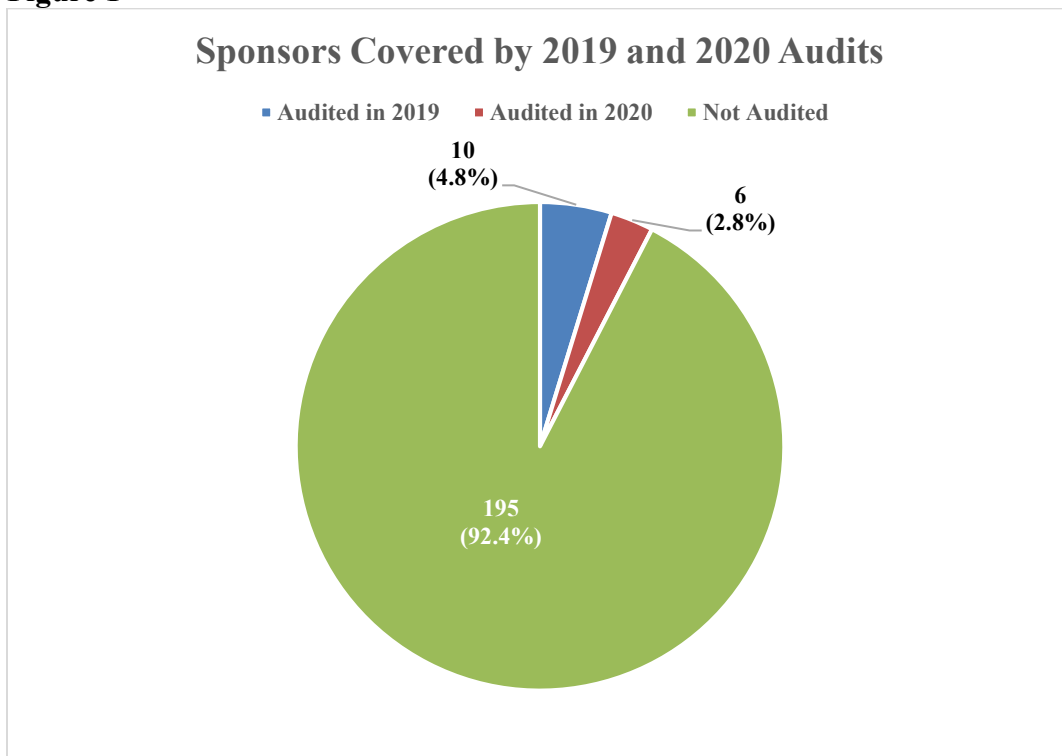
The figures below show the progress of program audits on Parts C and D by percentage of sponsors audited and by enrollment. These figures are based on data as of January 2021 and include coordinated care plan (CCP) contracts, private fee-for-service (PFFS) contracts, demonstration contracts, and standalone PDP contracts. Sponsors offering 1876 contracts are



also included, provided that the sponsors do not operate only 1876 contracts. Figures 1 and 2 represent only those sponsors (and associated enrollments) that still operate Medicare contracts in 2021.

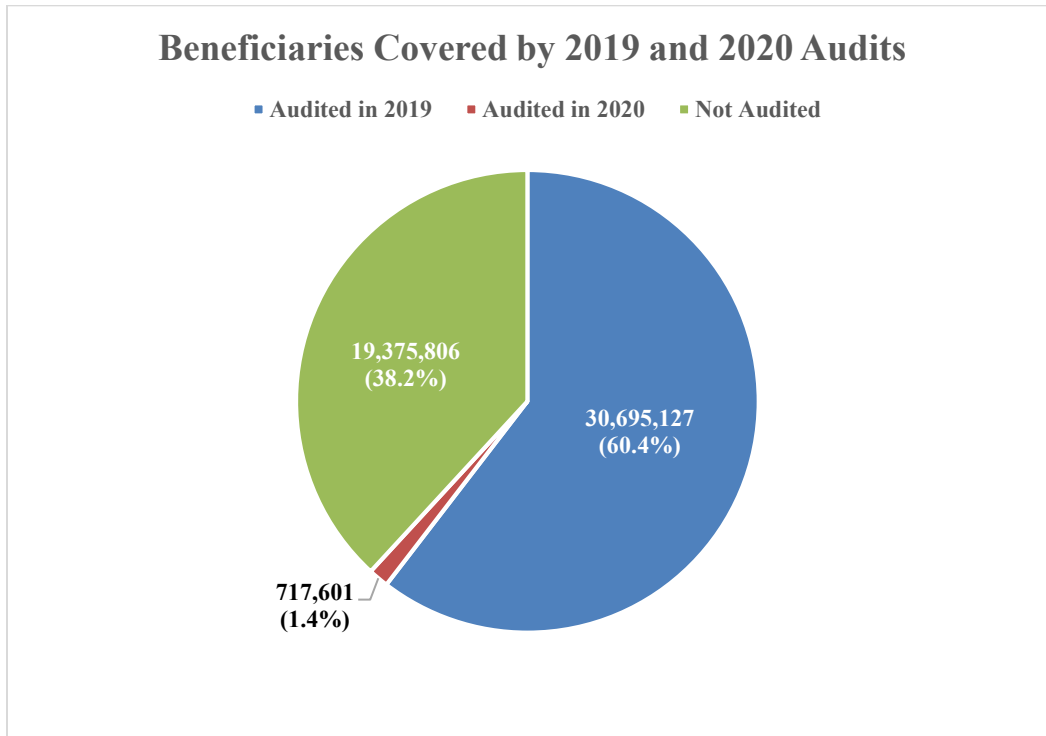
CMS does not audit a large number of sponsors each year, but within a three-year period, the sponsors we audit typically represent about 95% of the enrollment of the Medicare Advantage and Part D programs. CMS conducted a relatively small number of scheduled program audits in 2020 due to the PHE, bringing the total number of sponsors we audited in 2019 and 2020 to 16, or approximately 7.5% of the sponsors with currently active Medicare contracts. Note that we actually conducted 13 separate audits in 2019 but are only reporting on 10 audits in Figure 1 because three of the sponsors we audited in 2019 are no longer active as unique sponsors.

**Figure 1**



Sponsors audited in 2020 covered 1.4% of the Parts C and D enrollment. Audited sponsors in 2019 and 2020 represent approximately 62% of all Parts C and D enrollment.

**Figure 2\***

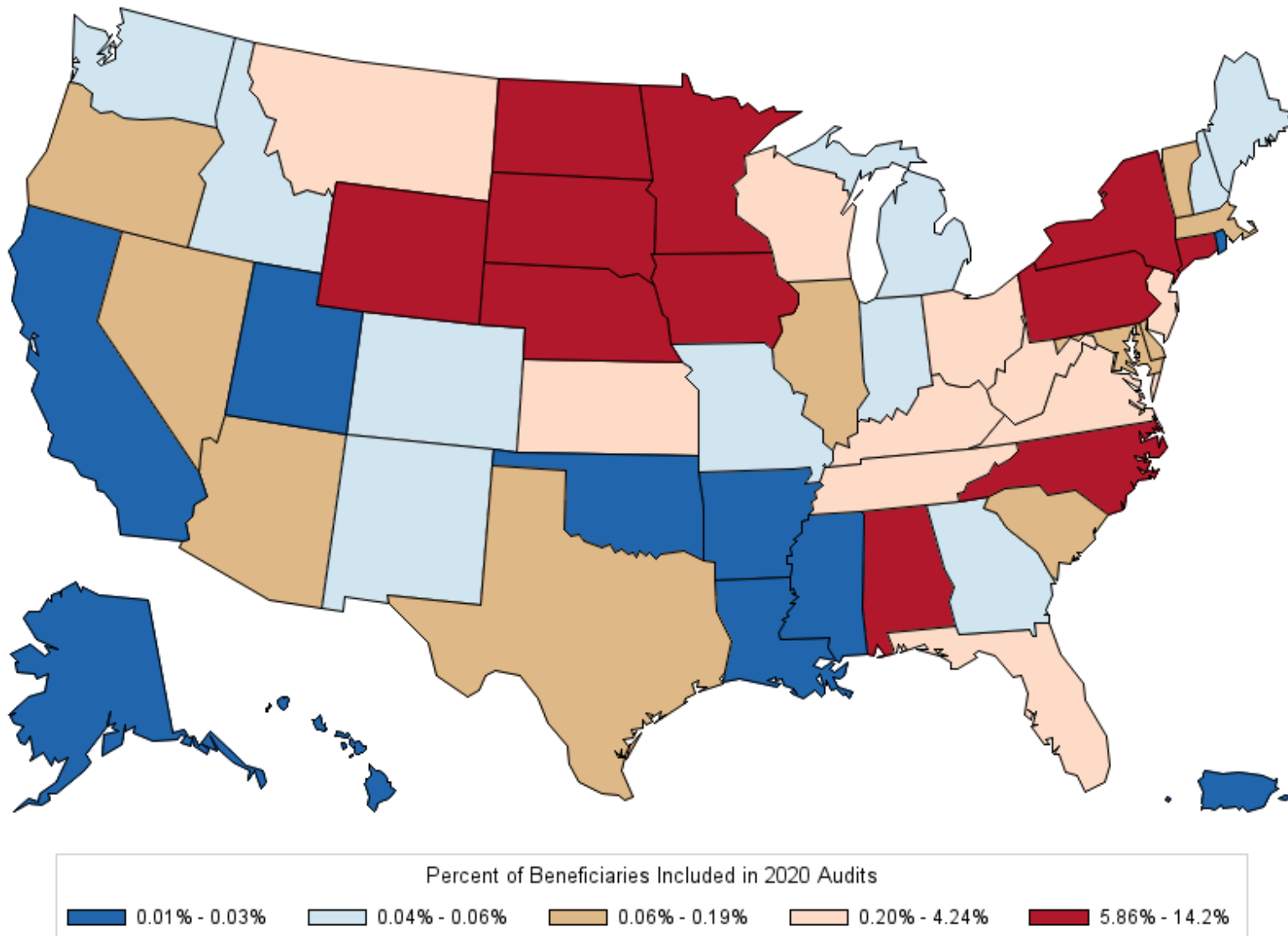


**\*These enrollment data are summed by sponsor at the contract level. All contracts active in 2021 that are associated with sponsors that were audited in 2019 and 2020 are reflected in this chart.**

Figure 3 shows the percentage of Medicare beneficiaries in each state that were covered by the program audits conducted in 2020. The largest percentage of beneficiaries covered in any one state was Alabama with just over 14% (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 2020 program audits. The largest percentage of plans audited in any of these states was in Connecticut and Pennsylvania, where approximately 3.5% of plans were audited in each state.

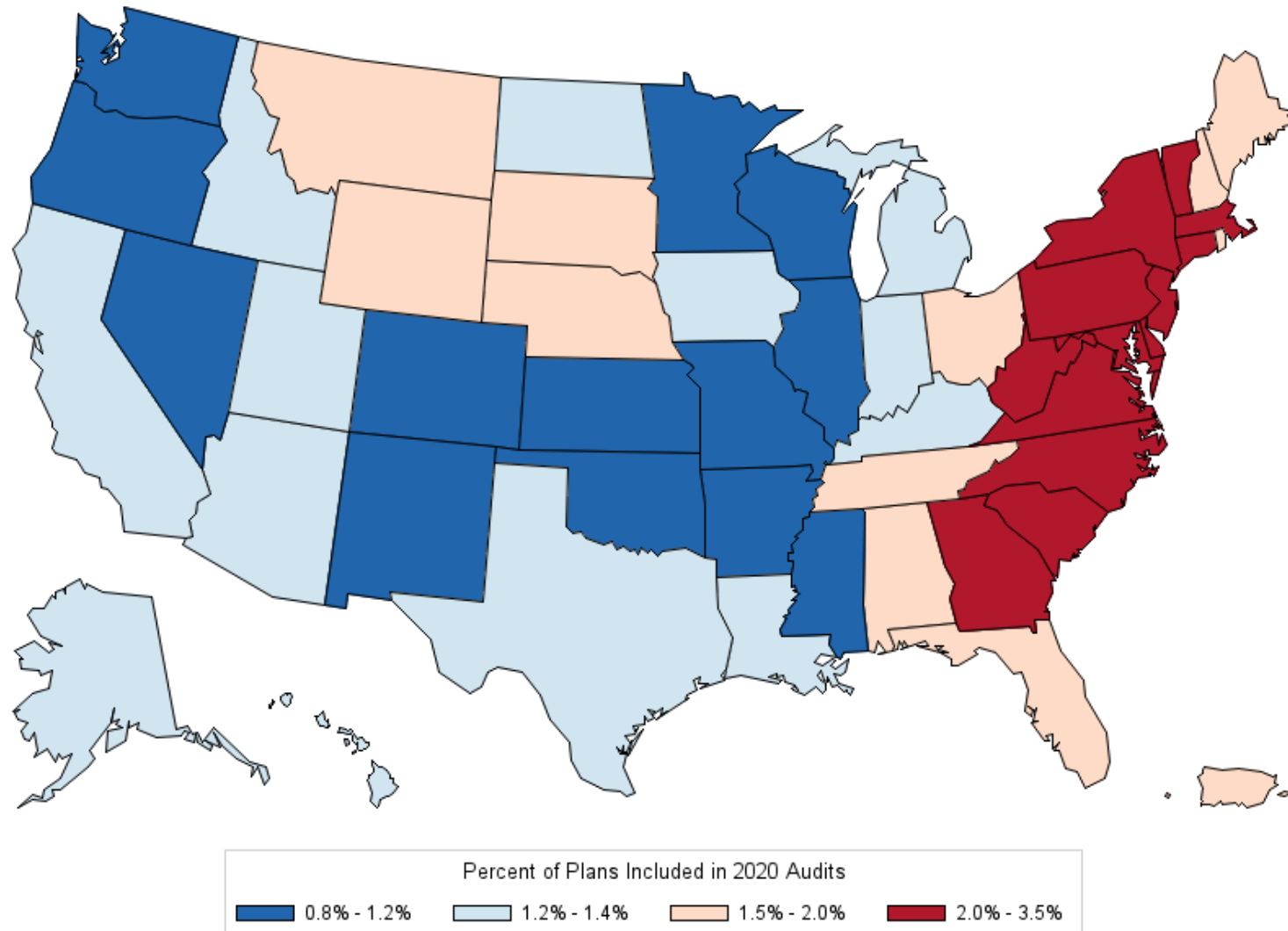
**Figure 3**

**Percentage of Beneficiaries in Each State Included in 2020 Program Audits**



**Figure 4**

**Percentage of Plans in Each State Included in 2020 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. 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 a sponsor 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**





**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. To access the currently-approved audit protocols and related materials, please visit: <https://www.cms.gov/files/zip/2020-medicare-parts-c-and-d-program-audit-protocols.zip> and <https://www.cms.gov/files/zip/2020-mmp-audit-protocols-and-data-requests.zip>.

## AUDIT RESULTS

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:

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

We calculate a score for each audited program area and an overall audit score. The score generally quantifies a sponsor's performance and allows comparisons across sponsors. The figures on the following pages display overall and program-area-specific audit scores for sponsors audited in 2020.

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. This is especially true for the 2020 audit year given the degree to which it was affected by the PHE. For example, the sample size for any average results reported in 2020 is rather small, which makes it difficult to determine how meaningful the results are when compared to the audit results from prior audit years. CMS' 2020 audit approach also took into account the flexibilities that CMS provided to sponsors in order to best provide the Medicare benefit during the PHE, which further complicates any attempt to compare the 2020 audit results to the audit results from prior audit 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.

### **Program Audit Scores**

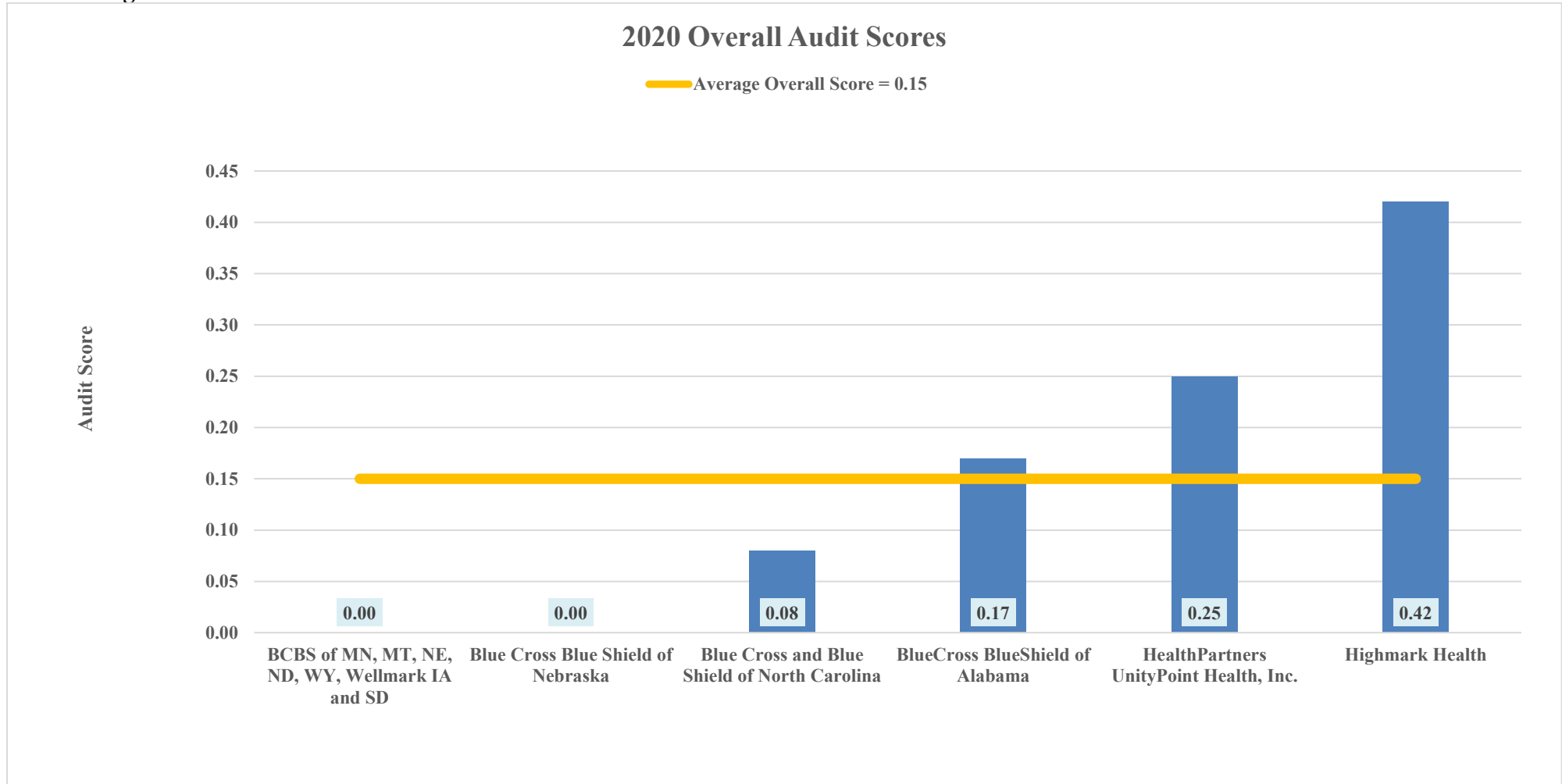
Figures 6-9 array the overall and individual program area audit scores for each program area, except FA. There is no corresponding chart for FA because there were no conditions of non-compliance discovered in FA in 2020. The audit scores are displayed from best (lowest) to worst (highest) score moving from left to right across the graph. The line in each graph represents the average audit score across all audited sponsors.

Of the six CPE audits conducted in 2020, only one instance of non-compliance was cited. In CDAG, two of the six (33%) audits conducted resulted in no conditions of non-compliance, but of the four audits where there were conditions of non-compliance, no single audit had more than one. In ODAG, three of the five (60%) audits conducted resulted in no conditions of non-compliance; for the other two audits, one audit had only one condition of non-compliance, and the other had two.

Table 1 shows 2020 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 have 50,000 or fewer beneficiaries enrolled, medium sponsors have between 50,000 and 250,000 beneficiaries enrolled, and large sponsors have over 250,000 beneficiaries enrolled.

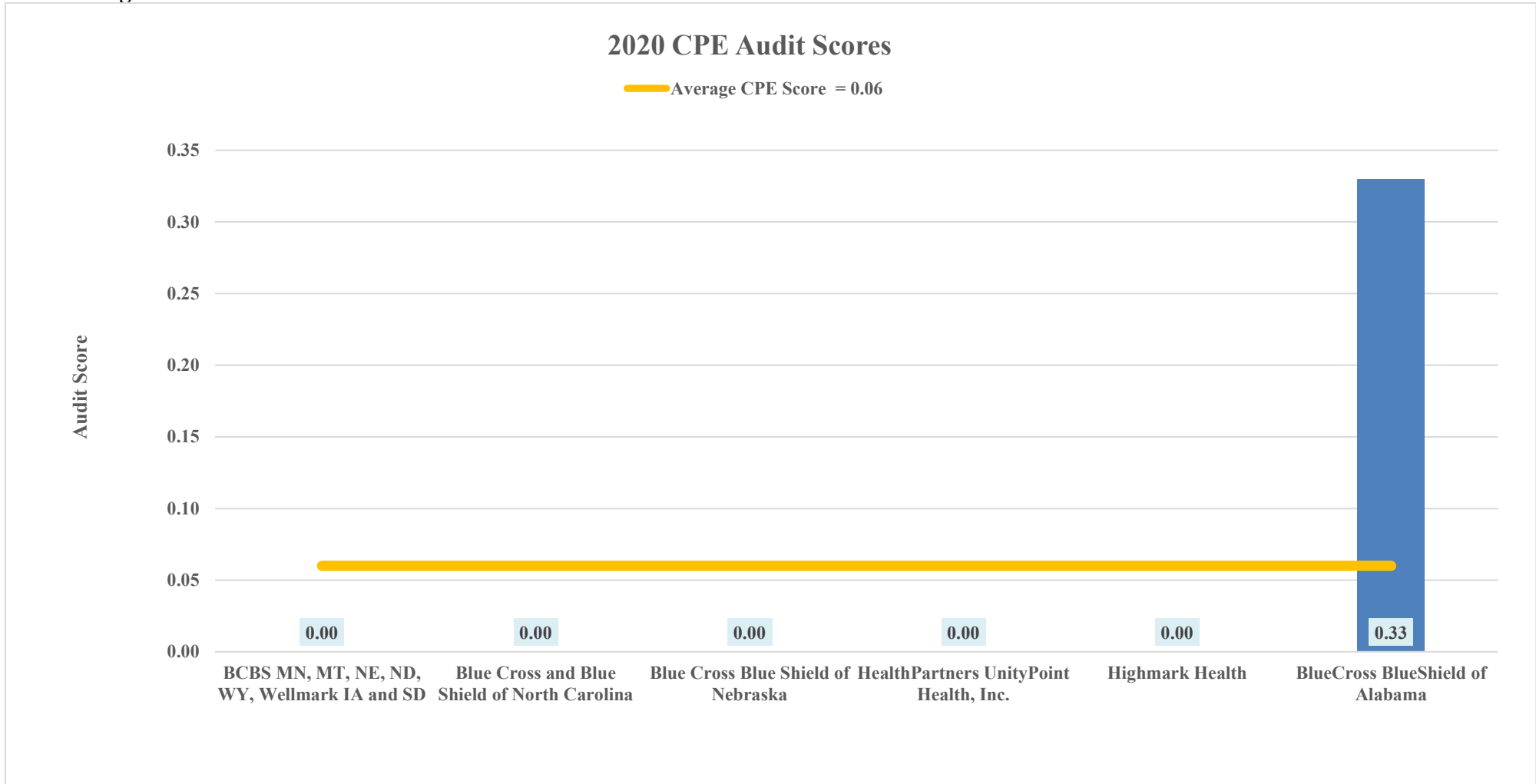
See Table 2 for an overview of the number and percentage of audits that had no conditions of non-compliance in 2020, broken down by program area.

Figure 6\*



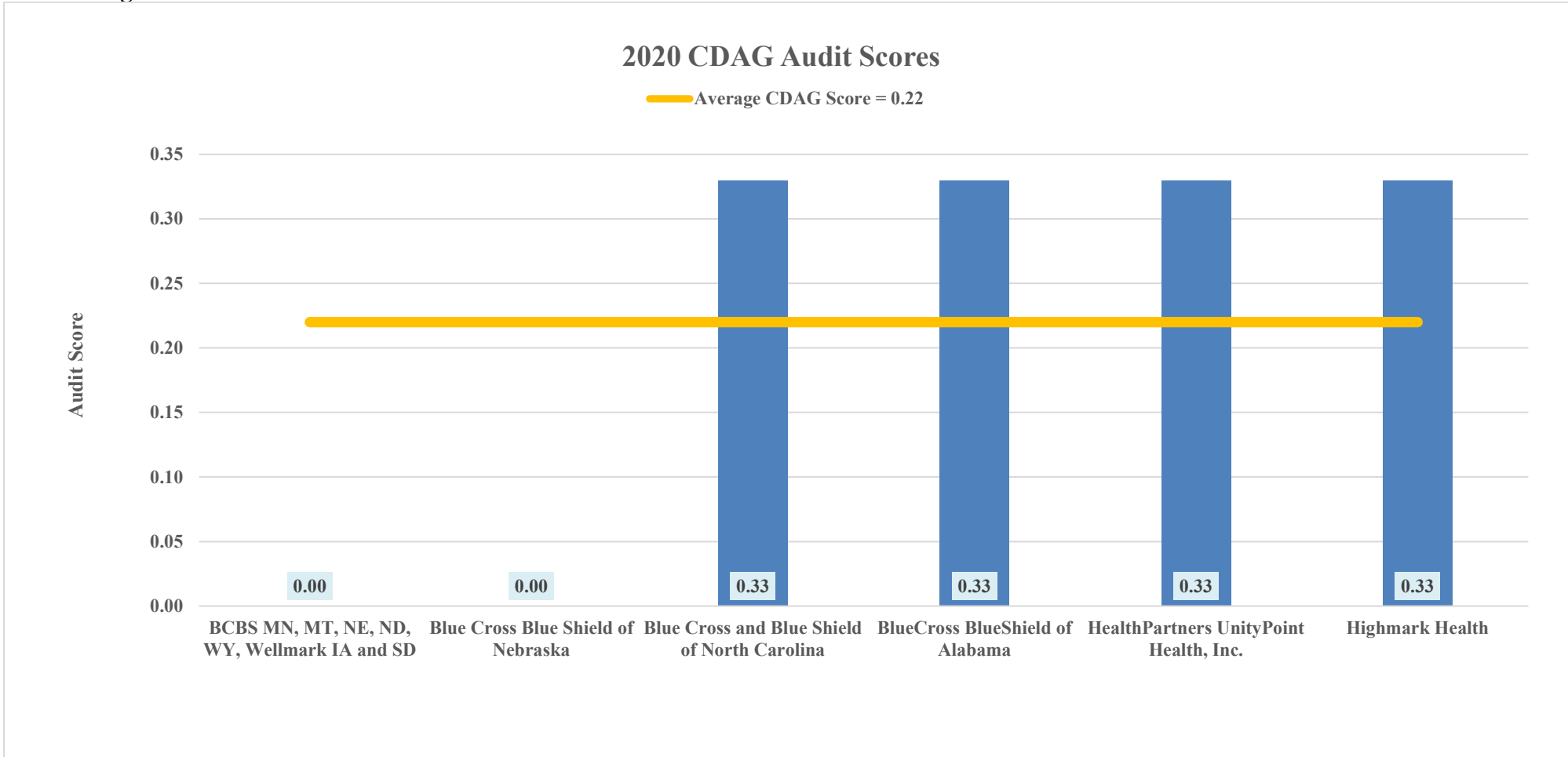
\*A lower audit score represents better audit performance. The average audit score is an unweighted score across all sponsors audited in 2020.

Figure 7\*



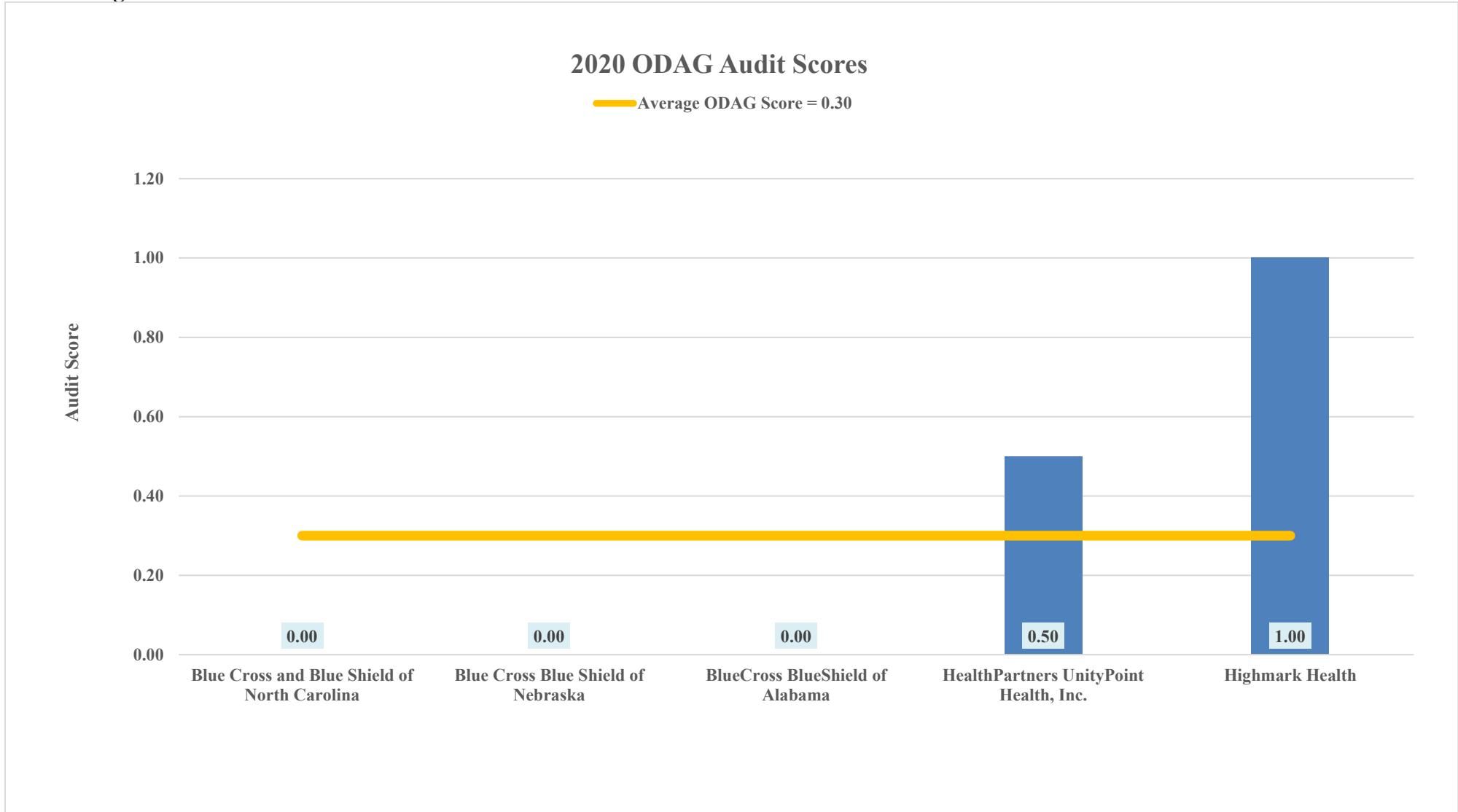
\*A lower audit score represents better audit performance. The average audit score is an unweighted score across all sponsors audited for the CPE program area in 2020.

Figure 8\*



\*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 2020.

Figure 9\*



\*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 2020.



**Table 1\***

Program Area	2020 Average Audit Scores by Enrollment Band		
	<50K Beneficiaries	Between 50K and 250K Beneficiaries	>250K Beneficiaries
<b>Overall</b>	0.13	0.08	0.42
<b>CPE</b>	0	0.11	0
<b>FA</b>	0	0	0
<b>CDAG</b>	0.17	0.22	0.33
<b>ODAG</b>	0.25	0	1
<b>SNP-MOC</b>	N/A*	N/A*	N/A*
<b>MMP-SARAG</b>	N/A*	N/A*	N/A*
<b>MMP-CCQIPE</b>	N/A*	N/A*	N/A*

\*No audits were conducted in 2020 of sponsors that offer Special Needs Plan Model of Care (SNP-MOC), Medicare-Medicaid Plan Service Authorization Requests, Appeals and Grievances (MMP-SARAG), or Medicare-Medicaid Plan Care Coordination and Quality Improvement Program Effectiveness (MMP-CCQIPE) benefits.

**Table 2\***

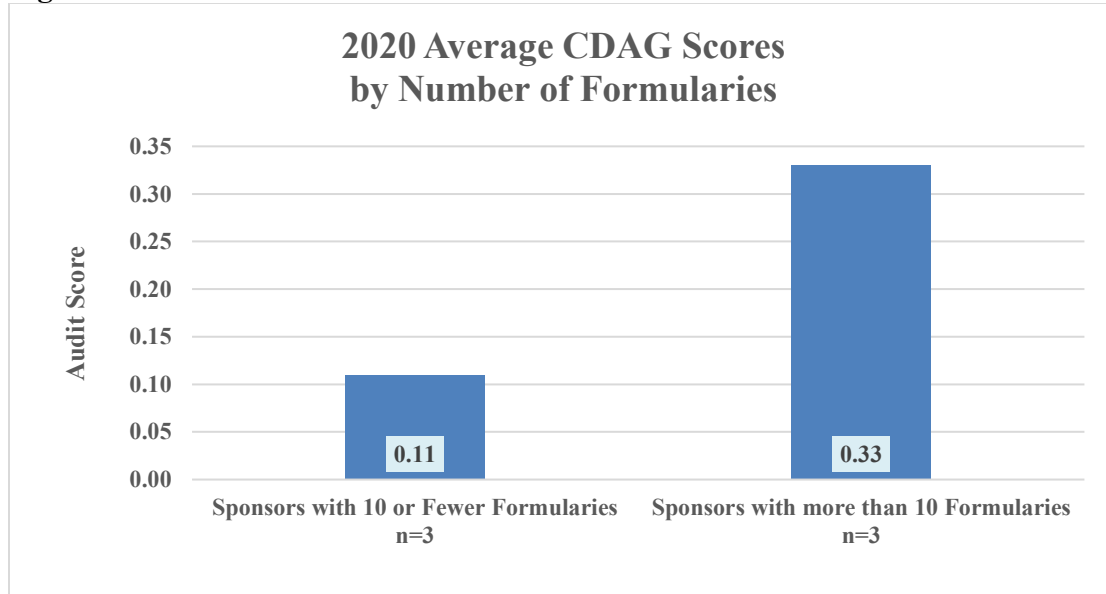
Program Area	Number of Audits without Conditions (2020)	Percentage of Audits without Conditions (2020)
<b>Overall</b>	2	33.33%
<b>CPE</b>	5	83.33%
<b>FA</b>	6	100.00%
<b>CDAG</b>	2	33.33%
<b>ODAG</b>	3	60.00%
<b>SNP-MOC</b>	N/A*	N/A*
<b>MMP-SARAG</b>	N/A*	N/A*
<b>MMP-CCQIPE</b>	N/A*	N/A*

\*No audits were conducted in 2020 of sponsors that offer SNP-MOC, MMP-SARAG, or MMP-CCQIPE benefits.

### CDAG Scores by Number of Formularies

Figure 10 displays the average 2020 CDAG scores across audited sponsors broken into two groups: those that operate 10 or fewer formularies, which comprised half of the sponsors we audited in 2020, and those that operate more than 10 formularies, which comprised the other half of the sponsors we audited in 2020. In the latter group, the number of formularies used ranged from 13 to 40. Sponsors with 10 or fewer formularies performed better on audit in 2020 than sponsors that operated more than 10 formularies, though the performance across both groups was strong. The average number of formularies operated by the sponsors we audited in 2020 was just under 14.

**Figure 10\***



**\*Audit scores are analyzed at the sponsor 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 2020, 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 in calendar year 2020 and early 2021 due to referrals received by CMS in 2020. These referrals encompass actions for violations from program audits, as well as violations discovered through other audits or monitoring efforts.

### General Enforcement Background

CMS has the authority to impose CMPs, intermediate sanctions, and for-cause terminations against MA plans, PDPs, Medicare-Medicaid plans (MMPs), Program 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.<sup>3</sup> All information contained in referrals that involve suspected fraud, waste, and abuse is referred to the Center for Program Integrity.

### ENFORCEMENT ACTIONS IMPOSED BASED ON 2020 REFERRALS

This section provides information on enforcement actions taken in calendar year 2020 and early 2021 due to referrals received by CMS in 2020. For this time period, CMS issued six CMPs and seven intermediate sanctions against sponsors.

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. CMS received 17 referrals separated into the following referral types:

- One-Third Financial Audit failures (29%)
- Dual SNP (D-SNP) Integration deficiencies (23%)
- Medicare Parts C and D Program Audit Validation failures (18%)
- Medical Loss Ratio (MLR) failures (12%)
- Enrollment application failures (6%)
- Part D claims processing failures (6%)

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<sup>3</sup> <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDEnforcementActions->

- State order to cease and desist accepting enrollments (6%)

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

**Table 3**

Referral Type	# of Referrals	# of Referral Closeouts	# of Referrals Under Review	# of Enforcement Actions Taken
One-Third Financial Audits	5	1	0	4
D-SNP Integration	4	0	0	4
Medicare Parts C & D Program Validation Audit	3	2	0	1
Medical Loss Ratio	2	1	0	1
Enrollment	1	0	0	1
Part D Claims Processing	1	1	0	0
State Suspension of Enrollment	1	0	0	1

## CIVIL MONEY PENALTIES

CMS imposed five CMPs for referrals received in 2020 totaling \$514,969 with an average of \$102,994 per CMP. The highest CMP imposed was \$318,975, and the lowest CMP imposed was \$6,784. The following table shows the sponsors that received a CMP based on 2020 referrals:

**Table 4**

Date of Imposition	Sponsor Name	Basis for Referral	Enrollment <sup>4</sup>	CMP Amount
07/21/2020	Care N' Care Insurance Company of North Carolina	2018 Program Validation Audit	15,474	\$71,868
11/17/2020	Anthem Inc.	2017 Financial Audit	513,290	\$318,975
11/17/2020	MetroPlus Health Plan, Inc.	2017 Financial Audit	7,494	\$6,784
11/17/2020	Centene Corporation	2017 Financial Audit	5,412,176	\$16,536
11/17/2020	CarePlus Health Plan, Inc.	2017 Financial Audit	8,321,704	\$100,806

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 beneficiaries impacted by certain violations. Consequently, the CMP amount may be higher for sponsors with larger enrollments or when a violation affected a high number of beneficiaries.

The type of contract(s) involved, as well as the nature and scope of the violation(s), determine the total CMP amount a sponsor receives. CMS applies a standard CMP amount for each deficiency cited in a CMP notice, based on either a per-beneficiary or a per-determination basis. CMPs imposed on a per-beneficiary basis have a quantifiable number of beneficiaries that have

<sup>4</sup> Enrollment reflects actual contracts included in the CMP versus the entire sponsor.

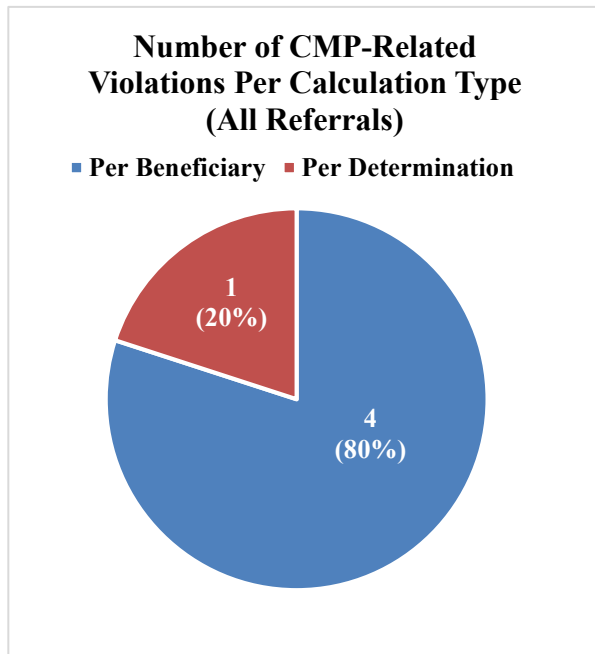
been adversely affected (or have the substantial likelihood of being adversely affected) by a deficiency, while CMPs imposed on a per-determination basis do not.

There were five specific violations cited in the five CMPs:<sup>5</sup>

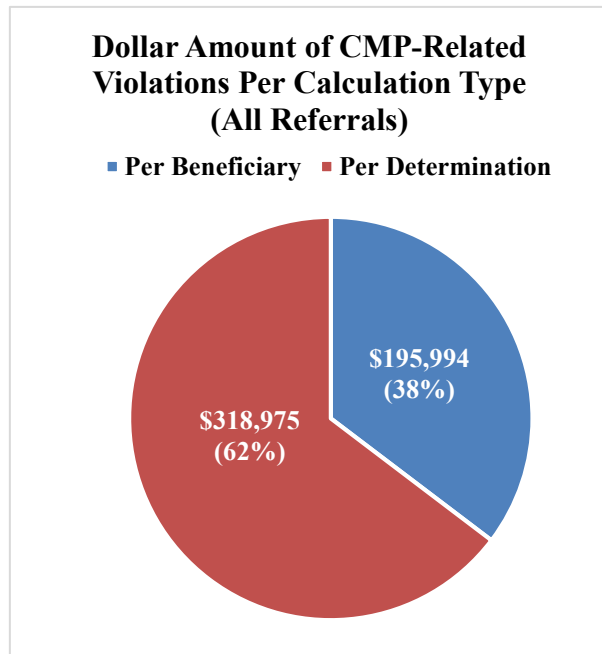
- Four violations were calculated on a per-beneficiary basis resulting in \$195,994
- One violation was calculated on a per-determination basis resulting in \$318,975

For CMPs taken as a result of 2020 referrals, Figure 11 and Figure 12 show the total number of violations and dollar amount of violations by calculation type:

**Figure 11**



**Figure 12**



<sup>5</sup> These numbers include CMPs from program audits and financial audits.

### **Aggravating Factors**

A sponsor's CMP is increased if aggravating factors apply to certain deficiencies. The standard penalty for a deficiency may increase if the violation involved the following:

- Drugs that are used to treat acute conditions that require immediate treatment,
- Beneficiaries 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.

Out of the five violations, CMS applied an aggravating factor penalty to three violations because beneficiaries incurred inappropriate out-of-pocket expenses exceeding \$100. The total aggravating factor penalties amounted to \$23,320, which is 5% of the total CMP amount of \$514,969 imposed for 2020 referrals.

### **Mitigating Factors**

Consistent with our approach in 2019, CMS considered other available evidence indicating that harm to beneficiaries 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 a beneficiary received the requested drug on the same day after an inappropriate rejection occurred at the point of sale, CMS would exclude the beneficiary from the total CMP calculation.

## **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 beneficiaries. In 2020, CMS imposed seven intermediate sanctions. Of the seven sanctions, six actions were imposed because of non-compliance with CMS' requirements with respect to enrollment processing (one action), MLR (one action), and D-SNP integration (four actions). One action was imposed because of a state cease-and-desist order.

Intermediate sanctions remain in place until the deficiencies which formed the basis of the sanction are corrected and are not likely to recur. Out of the seven intermediate sanctions imposed in 2020, two sponsors have corrected their deficiencies and returned to normal enrollment status.

Table 5 lists the sponsors that were sanctioned during 2020.



**Table 5**

Date of Sanction Letter	Effective Date of Sanction	Sponsor Name	Basis for Referral	Type of Intermediate Sanction	Date of Intermediate Sanction Release
01/31/2020	02/01/2020	Group 1001 (Delaware Life Insurance Company)	Enrollment Processing Issues	Enrollment & Marketing Sanction	09/22/2020
07/02/2020	07/03/2020	Vitality Health Plan of California, Inc.	State Cease & Desist Order	Enrollment Suspension	TBD
09/09/2020	01/01/2021	Blue Cross of Idaho Health Services, Inc.	Medical Loss Ratio	Enrollment Suspension	TBD
12/09/2020	01/01/2021	Hamaspik, Inc.	D-SNP Integration Requirements	Enrollment Suspension (D-SNP Only)	2/18/2021
12/09/2020	01/01/2021	MetroPlus Health Plan, Inc.	D-SNP Integration Requirements	Enrollment Suspension (D-SNP Only)	TBD
12/09/2020	01/01/2021	UnitedHealthcare of New York, Inc.	D-SNP Integration Requirements	Enrollment Suspension (D-SNP Only)	TBD
12/09/2020	01/01/2021	Visiting Nurse Association of Central New York	D-SNP Integration Requirements	Enrollment Suspension (D-SNP Only)	TBD

In addition, there was one sponsor sanctioned in 2019 that remained under a sanction during 2020. The sponsor corrected its deficiencies in 2020, returned to normal enrollment status, and continues to conduct post-sanction monitoring and oversight activities.

Table 6 lists the sponsor that was sanctioned during 2019, but corrected its deficiencies and was released from sanction in 2020.

**Table 6**

Date of Sanction Letter	Effective Date of Sanction	Sponsor Name	Basis for Referral	Type of Intermediate Sanction	Date of Intermediate Sanction Release
09/11/2019	01/01/2020	Care Improvement Plus South Central Insurance Company	Medical Loss Ratio	Enrollment Suspension	01/01/2021

## **2021 ENFORCEMENT PROCESS IMPROVEMENTS AND LESSONS LEARNED**

This section includes information about the improvements we made to the enforcement process and the lessons we learned from reviewing enforcement action referrals.

### **Codification of CMP Methodology**

On January 19, 2021, CMS codified in regulation the current methodology for increasing civil money penalties. These regulations took effect on March 22, 2021. To access the current methodology go to <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2019CMPMethodology06212019.pdf>.

### **Increasing Transparency**

MOEG 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. MOEG also continues to conduct outreach with sponsors to discuss and validate plan-submitted impact analyses in order to provide those sponsors 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, 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 were under review;
- Sponsors were given timely notice when CMS decided not to take enforcement actions;
- 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 considered sponsors' comments to the draft audit reports when evaluating referrals.

## Lessons Learned

We also used what we learned from reviewing enforcement action referrals to help sponsors strengthen their overall compliance programs. To benefit the program more broadly, below is a summary of several major observations we made during our analysis of 2020 enforcement referrals.

- **Monitoring for Beneficiary Overcharges**  
CMS recommends that sponsors improve their internal processes for monitoring and refunding (when appropriate) overcharges to beneficiaries by contracted and non-contracted providers. Improved monitoring and analysis of claims denials, co-pays/co-insurance coding, and provider payments (both contracted and non-contracted) could improve a sponsor's ability to identify overcharges that require correction. Sponsors must ensure that beneficiaries are not overcharged and, when they are, refunds are issued to beneficiaries for any incorrectly collected amounts. CMS may impose a CMP on sponsors when beneficiaries have been overcharged or there was a substantial likelihood that beneficiaries were overcharged.
- **Enrollment Processing During the Annual Election Period (AEP)**  
Another area sponsors should focus on is being fully prepared for large enrollment increases during the AEP. Specifically, CMS has found that when sponsors are unprepared for significant volume increases in enrollment, this has led to inappropriate and untimely processing of enrollment requests and untimely enrollment materials. Ultimately, this may result in delays and/or denials in access to medical services and prescription medications. One way to ensure that a sponsor is prepared for a smooth AEP is to test its enrollment system to ensure that it is properly configured to process beneficiary enrollment elections. In addition, it is important for sponsors to be able to monitor and track each step of the enrollment application process from beginning to end to confirm compliance with CMS enrollment processing requirements. To ensure beneficiaries receive support throughout the enrollment process, sponsors should also have a sufficient number of properly trained enrollment and call center customer service staff that are readily available. Sponsors should monitor their call centers to ensure that all enrollment issues are fully addressed. Sponsors must always ensure they have effective oversight of first tier, downstream, and related entity functions that are fundamental to the enrollment process, such as pharmacy benefit manager claims processing and call center management.
- **Financial Solvency and Contracting Requirements**  
Sponsors must also be prepared financially to operate a Medicare Advantage prescription drug plan (MA-PD) or PDP. Federal requirements do not preempt state authority in the areas of licensure and fiscal solvency. When sponsors are out of compliance with these requirements and subject to state actions that limit their ability to enroll new beneficiaries as a result, they are also out of compliance with CMS' requirement for contracted sponsors to accept new enrollments. When sponsors have been sanctioned by states with enrollment freezes, CMS will impose a parallel enrollment sanction on the affected MA or Part D contracts. When a sponsor satisfies the state requirements and the state lifts its

enrollment freeze, CMS will also lift its enrollment sanction. If the sponsor is unable to meet state requirements and further action is taken to either revoke its license or declare it insolvent, CMS may take steps to terminate the contract.

Being prepared, both financially and operationally, is imperative to running a viable MA-PD or PDP organization. Before a sponsor decides to contract with CMS to offer Medicare Advantage or prescription drug benefits, it should ensure that it has the proper resources and funding to offer adequate health and drug benefits for its beneficiaries. This includes providing sufficient scrutiny to actuarial, service area, and risk profile assumptions when developing and submitting bids to CMS each year. These assumptions should be objectively evaluated in conjunction with individual state financial requirements. In addition, any changes in ownership, novation agreements, and service area expansions should be fully vetted with CMS to ensure they are in compliance with CMS regulations.

## **2021 AUDIT PROCESS IMPROVEMENTS**

It is CMS's goal to continually improve and streamline the audit data collection and submission process to the greatest extent possible. Although CMS intended to use the updated protocols proposed under CMS-10717 for its 2021 program audits, the updated protocols are still awaiting Office of Management and Budget (OMB) approval. Delaying implementation of the updated protocols proposed under CMS-10717 will give stakeholders sufficient lead-time to apply and test the updated protocols prior to CMS using them to conduct audits. CMS will use the audit protocols used for the 2020 program audits (Medicare Parts C and D Program Audit and Timeliness Monitoring Data Requests (CMS-10191; OMB control number: 0938-1000)) to conduct the 2021 program audits. That collection request can be found at: <https://www.cms.gov/files/zip/2020-medicare-parts-c-and-d-program-audit-protocols.zip>.

## **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 the sponsor community and external stakeholders in developing new approaches to improve compliance.