

The Part C and Part D Program Audit Annual Report

(For Industry Distribution)

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The Medicare Parts C & D Oversight and Enforcement Group

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INTRODUCTION

The Center for Medicare (CM), Medicare Parts C and D Oversight and Enforcement Group's (MOEG) mission is to evaluate all Medicare Advantage Organizations (MAO) and Prescription Drug Plan (PDP) sponsors' performance in the delivery of health care services and ensure that beneficiaries receive the services for which these sponsors have already been paid. This mission supports the Centers for Medicare and Medicaid Services' (CMS) goals to strengthen program integrity and strengthen consumer protections in the Part C and Part D programs. The primary way in which MOEG strengthens program integrity is by conducting Part C and Part D program audits that test whether sponsors are providing beneficiaries with the services and prescription drugs as required under their plan benefit package. This report provides an introduction to the program audit process, a current snapshot of the program audit landscape, a summary of the 2012 program audit year, and other highlights and noteworthy developments in MOEG's program audit operations.

BACKGROUND

The Part C and Part D programs provide health and prescription drug benefits for eligible individuals 65 years and older and eligible individuals with disabilities. CMS contracts with private companies, herein referred to as "sponsors", to provide health and prescription drug benefits to beneficiaries' enrolled in Medicare Advantage-Prescription Drug (MA-PD), MA-only and standalone PDPs.

As of April 2013, the Part C and Part D programs had a combined enrollment of approximately 37 million beneficiaries. CMS is responsible for administering and conducting oversight of the Part C and Part D programs. Pursuant to 42 CFR §422.504(e) and §423.505(e), CMS may evaluate, through inspection, audit, or other means, that sponsors are in compliance with program requirements. Based on this authority, MOEG conducts annual program audits of sponsors at the parent organization level that provide MA, MA-PD, and PDP offerings to beneficiaries. MOEG does not audit HCCP-1833 Cost plans, but will be auditing 1876 Cost plans in 2013. Also, MOEG coordinates National PACE plan audits with the Consortium for Medicare Health Plan Operations (CMHPO) and the Medicare Drug and Health Plan Contract Administration Group (MCAG).

The Part C and Part D programs operate in a capitated payment model that protects CMS from excessive spending on healthcare services but may also inadvertently create incentives for plans to inappropriately deny or delay medically necessary items and services to enrollees, in an attempt to keep costs down. MOEG's program audits are one way that CMS is reasonably assured that sponsors deliver benefits in accordance with the terms of their contract and plan benefit package. Consequently, the program audits are designed to detect instances when sponsors are inappropriately denying services to beneficiaries and require sponsors to correct identified deficiencies and provide outreach to adversely affected beneficiaries. Audit findings are analyzed for consideration of the imposition of appropriate enforcement actions up to and including contract termination. It is through these audits that CMS can work to ensure the integrity of the Part C and Part D programs and protect the health and safety of Medicare beneficiaries.

THE 2012 PROGRAM AUDITS

This section of the report provides a description of important audit concepts and terminology, shows the current and projected program audit landscape, and summarizes the results of the 2012 program audits.

SCOPE, METHODOLOGY & TERMINOLOGY

In order to conduct a comprehensive audit of a sponsor's operation, the program audits were conducted at the parent organization level. Therefore, all MA-PD and PDP contracts owned and operated by the sponsor were included in the scope of the audit. The audits evaluated sponsor compliance in the following program areas¹:

- Part D Formulary and Benefit Administration
- Part D Coverage Determinations, Appeals, and Grievances (CDAG)
- Part C Organization Determinations, Appeals, and Grievances (ODAG)
- Agent/Broker Oversight
- Enrollment/Disenrollment

¹ Each program area was divided into sub-areas, referred to as "elements", which tested specific requirements under each program area. A full list of program areas and elements is found in Appendix A.

- Late Enrollment Penalty (LEP)
- Compliance Program Effectiveness

Sponsors were audited in all program areas when possible, but in instances when sponsors did not have operations in a program area (e.g. sponsor did not use independent agents/brokers, sponsor was a stand-alone PDP) the program area was omitted from the audit. All program areas were audited virtually via webinar by the audit team, except for Compliance Program Effectiveness, which was evaluated onsite at the sponsor's location.

The auditors used the following audit procedures to detect non-compliant conditions:

- Reviewed, analyzed, and selected targeted samples from data universes submitted by sponsors prior to the webinars and on-site review;
- Reviewed sponsors' data systems, operations, and documentation by conducting webinars and on-site reviews of the targeted samples;
- Applied a failure threshold to determine a result of "Pass" or "Fail" for each set of targeted samples in each area of review; and
- Interviewed sponsor personnel.

The following terminology is critical to understanding the audit results and is defined below:

- **Condition** – an instance of non-compliance detected during the audit that resulted from a sponsor's incorrect policies, systems, operations, or lack of internal controls. Conditions resulted in Recommendations, Corrective Action Required (CAR), or Immediate Corrective Action Required (ICAR) requests.
- **Observation** – a deviation from CMS policy that does not rise to the level of a condition, but may be useful to the sponsor in preventing compliance problems in the future.
- **Recommendation** – a request that a sponsor improve their operations related to the detected condition. This only occurred when a sponsor "passed" the audit element and the condition did not result in beneficiary harm. A "recommendation" request is only applicable to the 2012 audits and will not be used in the 2013 audits.
- **Corrective Action Required (CAR)** – a demand that a sponsor correct the detected condition. This occurred when a sponsor "failed" the audit element or the condition caused beneficiary harm. The sponsor was given 90 days from the date of the issuance of the final report to correct this non-compliant condition.
- **Immediate Corrective Action Required (ICAR)** – a demand that the sponsor correct the detected condition immediately. This occurred when the condition caused significant beneficiary harm, which is defined as policies, procedures, systems, and/or operations that may result in numerous beneficiaries not receiving medical services or prescription drugs. The sponsor had three days from the issuance of the ICAR notice to remediate the condition and provide a corrective action plan. ICARs were issued in the following program areas: Part D Formulary and Benefit Administration; Part D Coverage Determinations, Appeals, and Grievances; and Part C Organization Determinations, Appeals, and Grievances.

AUDIT INNOVATIONS AND PROCESS IMPROVEMENT

As part of an effort to continuously improve, MOEG evaluates the audit process and solicits feedback from sponsors, industry and trade associations, audit staff, regional office staff, and other Center for Medicare components on ways to improve the audit process. As a result of our evaluation and the feedback received, the following improvements and innovations were implemented in 2012:

- Selected sponsors for audit from a variety of performance pools (not only "At-risk" sponsors)
- Expanded the scope of audits to include ODAG, Enrollment/Disenrollment, and Late Enrollment Penalty.
- Formalized the Immediate Corrective Action Request (ICAR) process.
- Imposed enforcement actions as a direct consequence for severe audit deficiencies.
- Refined and shortened the time required for the report writing/issuing process.
- Created and developed a Compliance and Audits Website to host all audit, compliance, and enforcement related content.
- Published the audit protocols and 2 Best Practices and Common Findings memos on the Compliance and Audits Website and issued to the industry via HPMS.
- Implemented the use of webinar technology in the audit process to significantly reduce onsite attendance of the audit teams.

- Conducted Best Practice Reviews of 5 Star sponsors.
- Developed a condition-focused scoring methodology as a means to quantify and compare sponsor performance.

CURRENT PROGRAM AUDIT LANDSCAPE

MOEG began its program audit operation in 2010. It is MOEG's goal to audit every sponsor in the Part C and Part D programs within a reasonable time period. The charts below show the depth of MOEG's program audit operation on the Part C and Part D industry by enrollment, parent organization, contract, and plan benefit package (PBP) perspective².

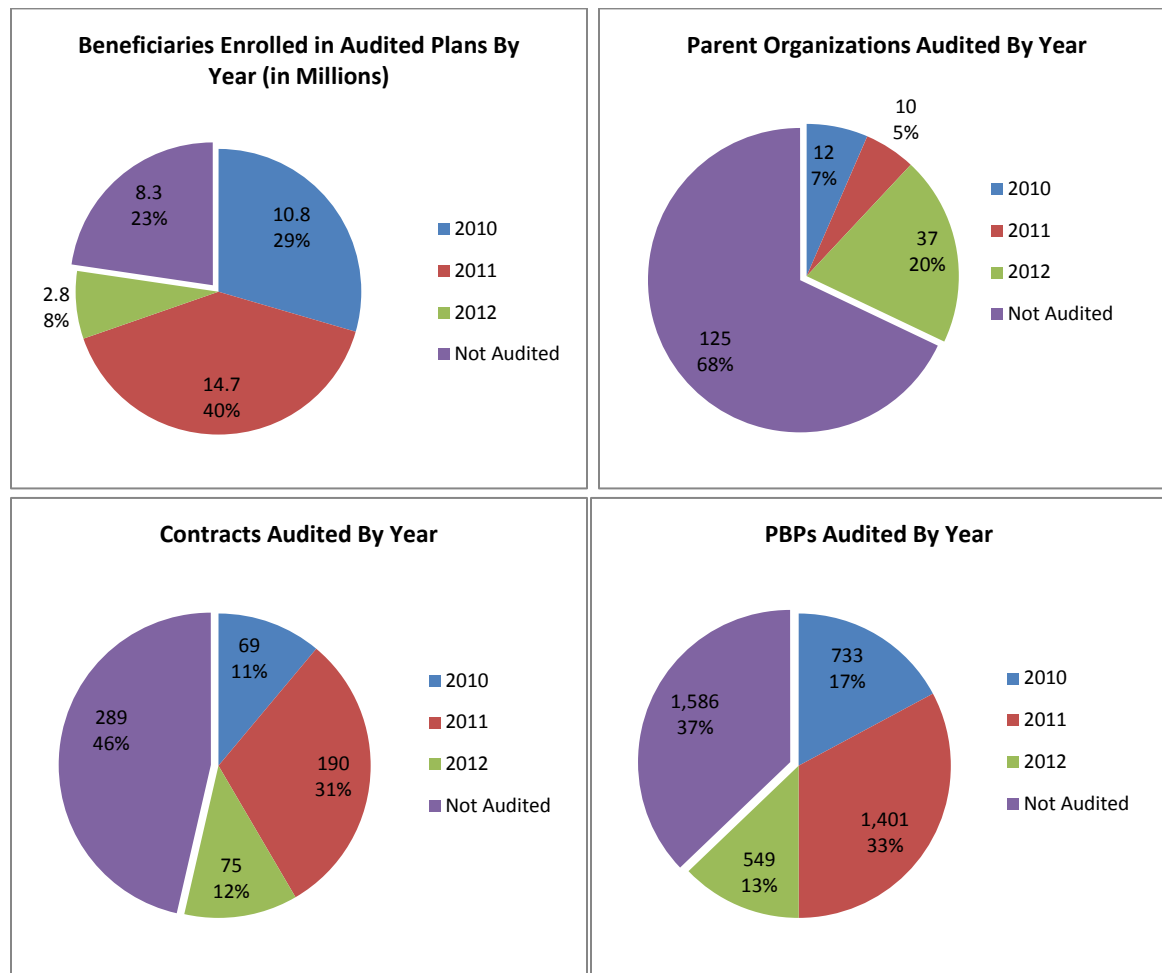
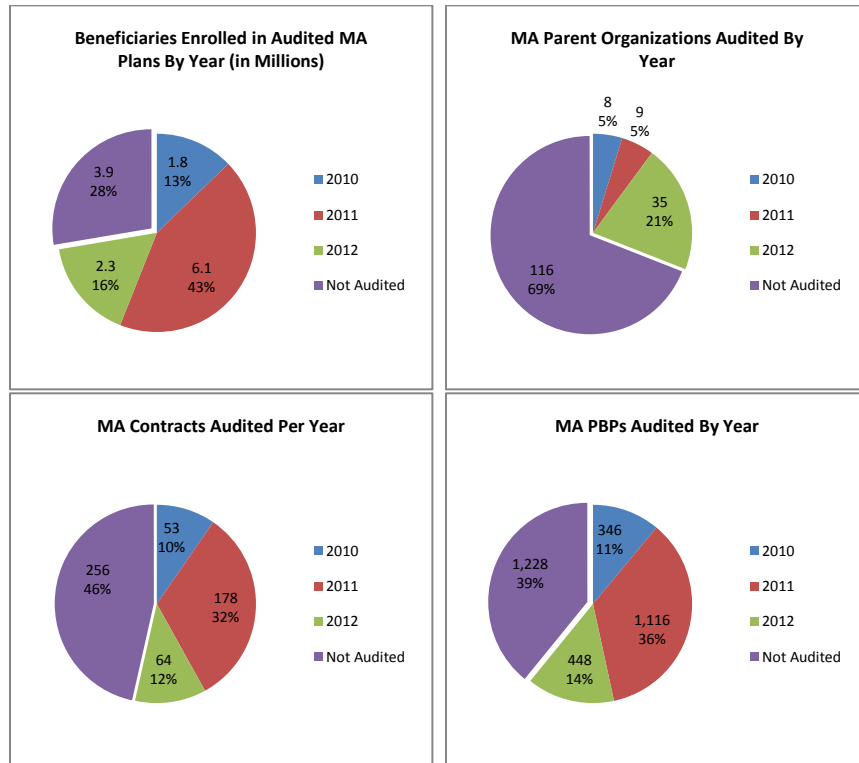


Chart Summary:

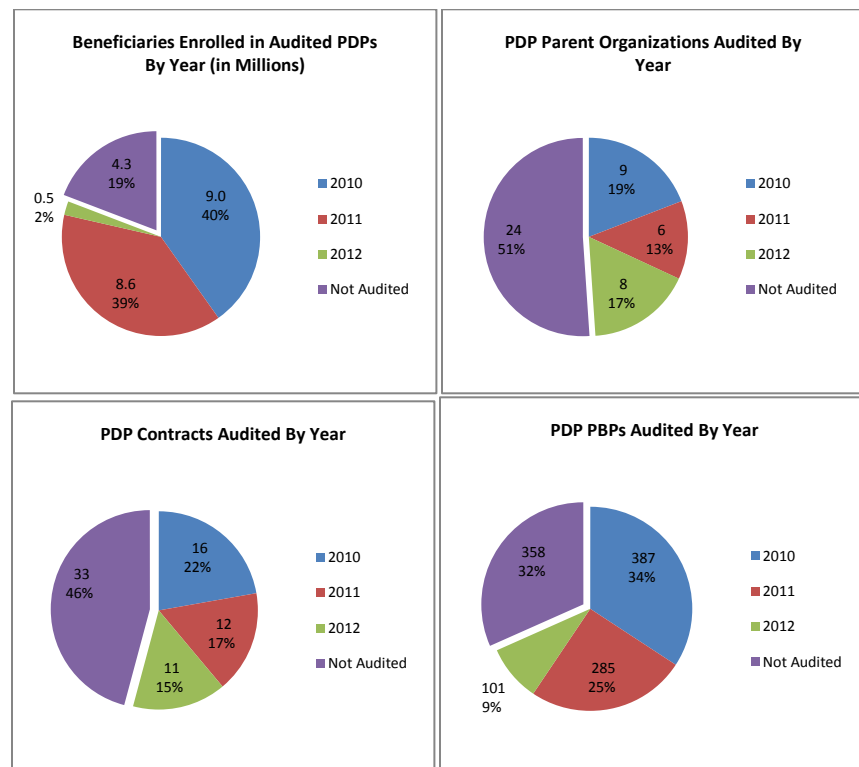
- The variance between the percentage of parent organizations audited and the percentage of enrollment audited reflects MOEG's focused effort to audit sponsors with the largest enrollment in order to ensure that sponsors who impact the most beneficiaries are appropriately providing services to their enrollees.
- Since 2010, MOEG has audited sponsors that account for 77 percent of Part C and Part D enrollment.
- 125 (68%) parent organizations have not been audited and may have problems unknown to CMS.
- More than half of all contracts and plans have been audited since 2010.

² The charts are based on sponsor and enrollment data as of April 2013. Therefore, some parent organizations audited between 2010 and 2012 are no longer in existence due to merger, acquisition, or termination. As a result, the number of parent organizations audited each year is not reflective of the number of audits conducted in that year.

The charts below show MOEG's program audit penetration specifically for MA-PD and MA-only sponsors.



The charts below show MOEG's program audit penetration specifically for PDP sponsors.



PROJECTED PROGRAM AUDIT LANDSCAPE

The following charts show the projected program audit landscape for the 2013 audit year.

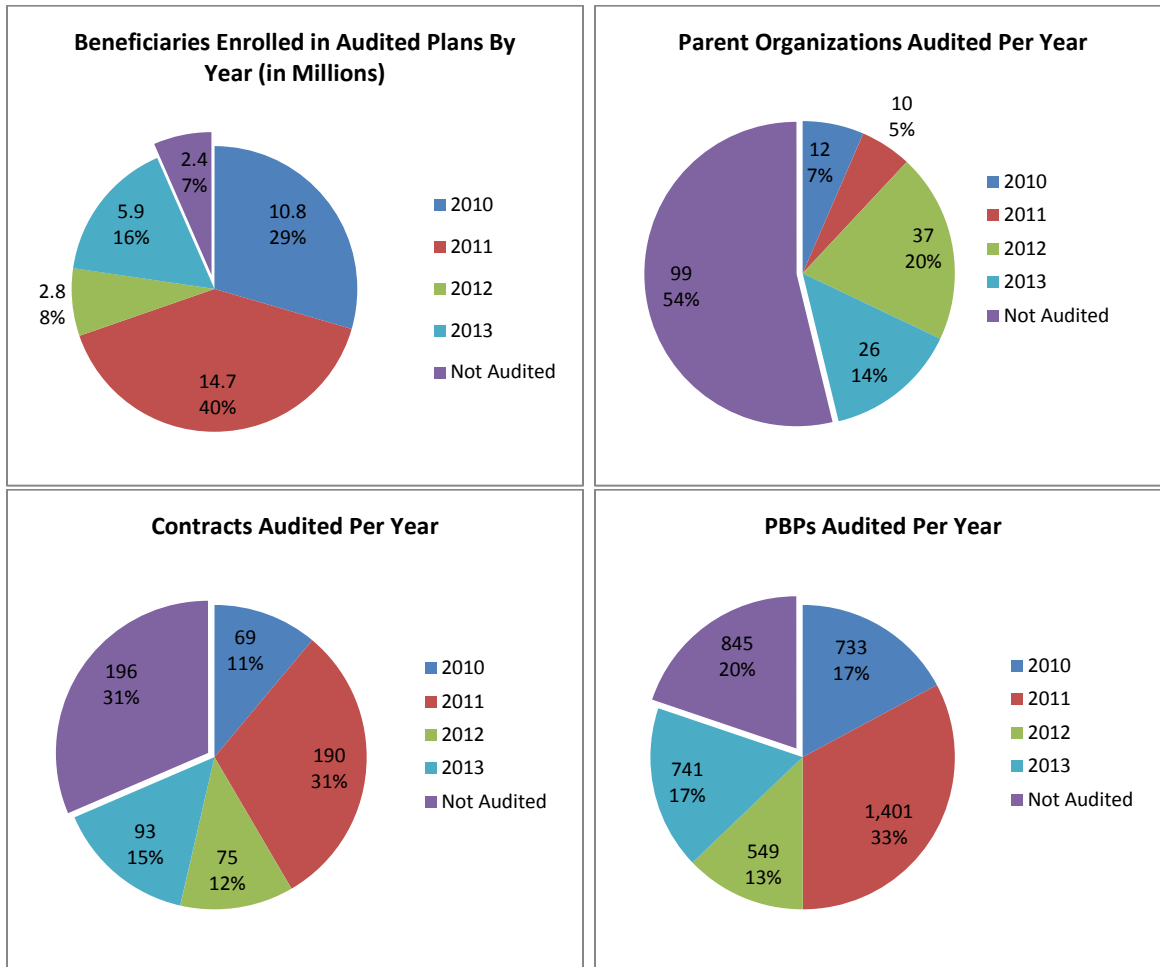


Chart Summary:

- 93 percent of beneficiaries will be enrolled in sponsors that have been audited by CMS by the end of 2013.
- 99 parent organizations, that account for only 7 percent of the beneficiary population, will remain unaudited by the end of 2013.

MOEG considers a sponsor's enrollment size and risk to the program when selecting a sponsor for audit. The top 20 sponsors by enrollment provide benefits to 87 percent of the beneficiaries in the Medicare Advantage and Prescription Drug programs. To date, MOEG has audited 18 of these sponsors and will have audited all 20 sponsors by the end of 2013. In addition, MOEG conducts a risk assessment based on plan data available to CMS to generate a risk score for every parent organization in the Part C and Part D programs. In 2013, MOEG's risk assessment identified 44 "At-risk" sponsors in the top quartile of our assessment. Of those 44 sponsors, 40 sponsors will have received an audit by the end of 2013 and the remaining four will likely be audited in 2014.

The audit process provides MOEG with a reasonable assurance that sponsors are operating in compliance with the program requirements tested during the audits. This assurance is not achieved until the audit process is concluded and the sponsor is released from audit. The duration of the audit process is typically 1-2 years due to a thorough validation process that ensures sponsors correct all deficiencies discovered during audit (see section "Audit Lifecycle" for more information on the audit process). For example, a sponsor audited in 2012 will likely not enter the validation phase of the audit process until sometime in 2013. The charts below provide a view of the current audit status of all audits from 2010 through 2013. It shows the percentage of sponsors who are "Corrected and

Closed”, meaning CMS has a reasonable assurance that the sponsor is in compliance with program requirements tested during the audits, and it shows the percentage of beneficiaries enrolled in those sponsors’ plans.

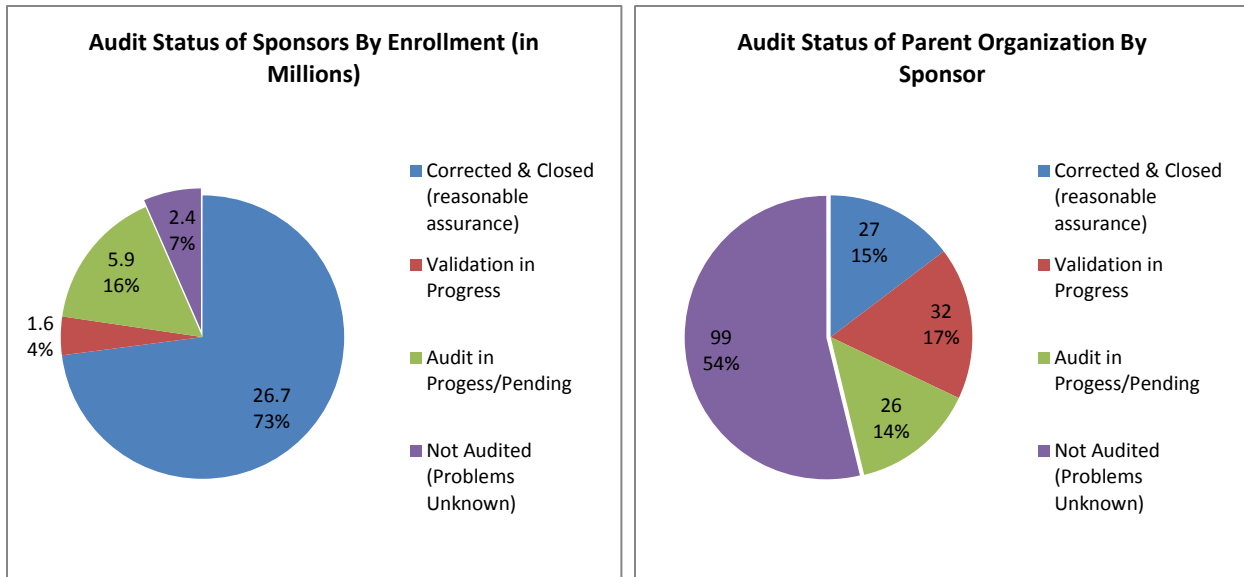


Chart Summary:

- All sponsors audited in 2010, 2011, and five sponsors in 2012 are “Corrected and Closed”.
- Approximately 73 percent of all beneficiaries are enrolled in a plan that CMS has reasonable assurance is operating in compliance with the audit program areas.
- Most of the sponsors audited in 2012 are in validation and all of the sponsors audited in 2013 have audits that are either in progress or pending.

The 7 percent of beneficiaries enrolled in plans that have yet to be audited may be at risk due to unknown performance problems, whereas beneficiaries enrolled in plans that have undergone a program audit are more likely to have corrected, or are in the process of correcting their deficiencies. MOEG will continue to conduct program audits on sponsors that pose the most risk to beneficiaries while ensuring that all sponsors in the Part C and Part D programs have been audited within the next few years.

AUDIT RESULTS

In 2012, MOEG introduced a scoring system that generates an audit score for every sponsor audited based on the number and severity of non-compliant conditions detected in a sponsor’s operations. This new scoring system aligns with MOEG’s shift in audit philosophy which now places more emphasis on the number of systemic conditions discovered during the audit rather than the previously used pass/fail threshold sample case review. In this scoring system, **a lower score represents better performance on the audit** (see Appendix B for the complete scoring methodology). Because the audit score is generated based on the number of non-compliant conditions discovered, the maximum audit score is unlimited. Also, the scoring system is weighted to ensure that conditions that severely impact beneficiary care have a greater impact on the overall score. A score of “0” on the audit would indicate there were no non-compliant conditions discovered on the audit. This scoring system quantifies a sponsor’s performance and allows them to compare their scores to other sponsors in the industry. The chart on page 7 arrays the 2012 audit scores in order of best performance to worst performance.

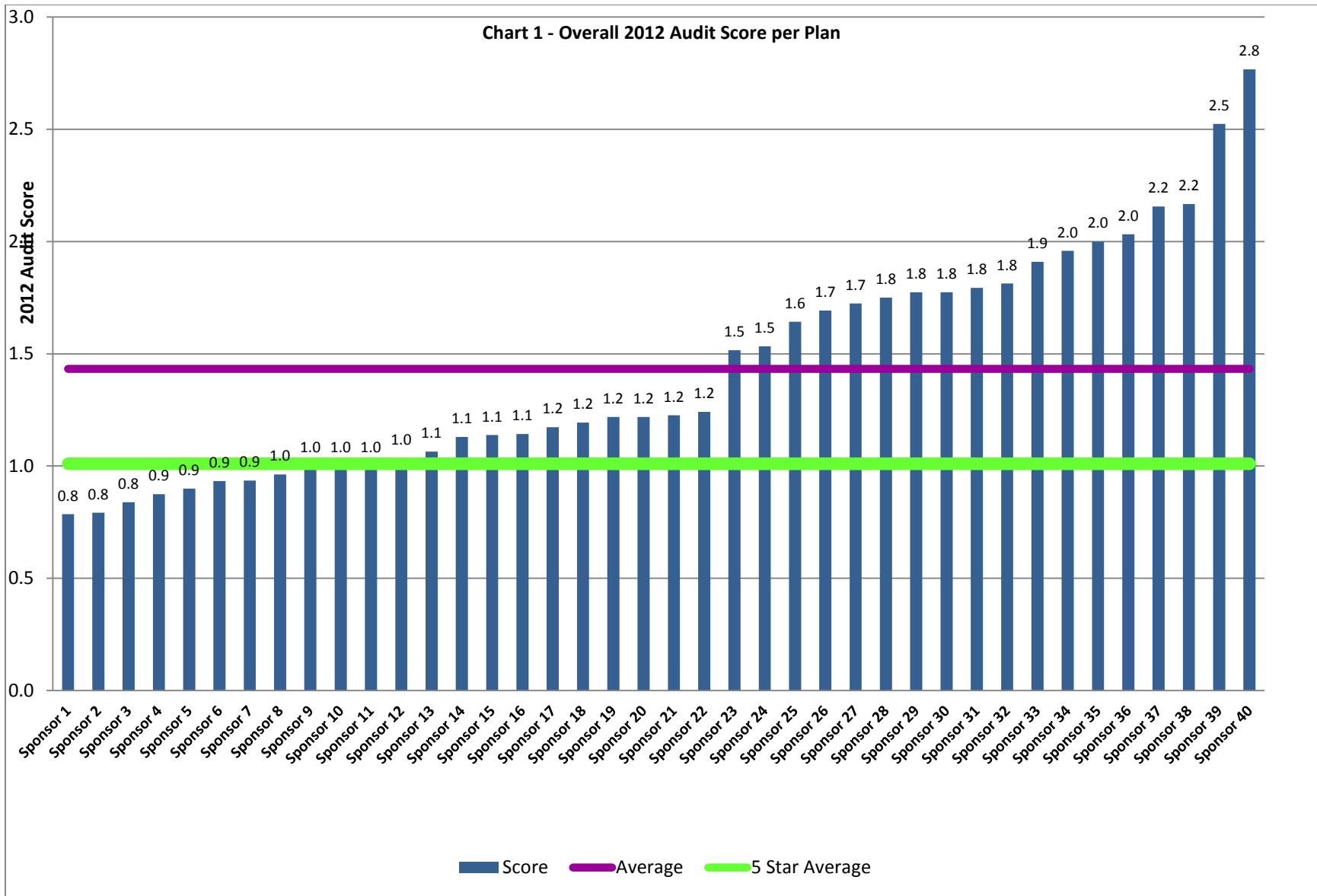


Chart 1 – Overall 2012 Audit Score per Sponsor Summary

- The average audit score across all 40 audits was 1.43, as shown in the purple line above, with scores ranging between 0.79 (best) and 2.77 (worst).
- The average 5 Star score was 1.01 and is shown in the green line above. CMS acknowledges the association between 5 star sponsors and above average performance on the audits, however the program audits do not evaluate and measure performance in areas directly related to a plan’s Star rating.

The 2012 audit results can also be viewed by overall sponsor performance in a given program area. The chart below shows the average sponsor score in each program area of the audit. A lower score represents better audit performance.

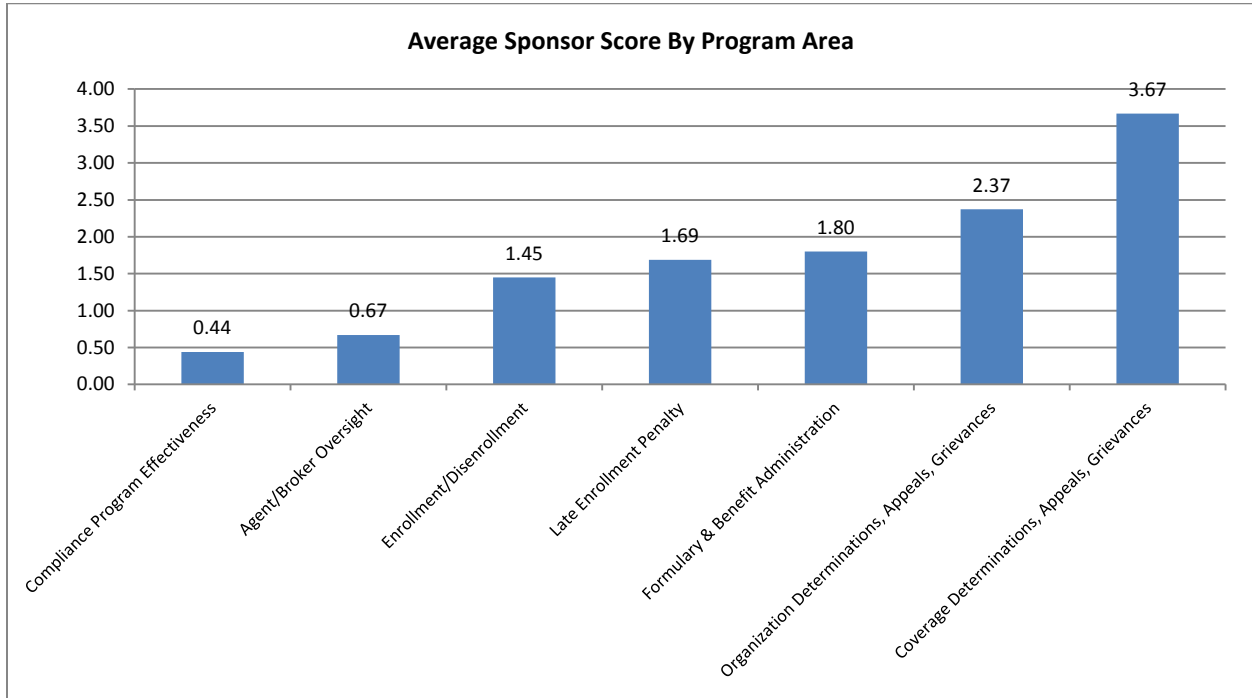


Chart Summary:

- Sponsors struggled the most in the areas of Coverage Determinations, Appeals, and Grievances (CDAG) and Organization Determinations, Appeals, and Grievances (ODAG).

Program area score comparisons to the 2011 audit results cannot be made because the scoring system was not implemented until 2012. However, MOEG can compare program area performance across audit years using the pass/fail threshold system used in 2011, and for the last time, in 2012.

Program Area	Number of Elements tested in Area	2011 - % of Elements Passed	2012 - % of Elements Passed	Percent Difference
Organization Determinations, Appeals, and Grievances	6	N/A	34%	N/A
Coverage Determinations, Appeals, and Grievances	3	35%	41%	+6%
Enrollment/Disenrollment	5	N/A	46%	N/A
Formulary Benefit Administration	3	48%	48%	0%
Late Enrollment Penalty	2	N/A	53%	N/A
Compliance Program Effectiveness	9	33%	71%	+38%
Agent/Broker Oversight	5	61%	72%	+11%
AVERAGE RATE OF ALL AREAS	33	44%	52%	+8%

Table Summary:

- Sponsor improvement was seen in the areas of CDAG, Compliance Program Effectiveness, and Agent/Broker Oversight. The improvement noted in Compliance Program performance was partly due to a change in audit protocol which relaxed the Compliance Program Effectiveness evaluation to allow sponsors an opportunity to fully review the updated Manual guidance published by MOEG in 2012.
- The “N/A” indicates the measure is not applicable because the program area was not tested during that audit year.
- Overall sponsor performance remains low with an overall passage rate of 52 percent.

The chart on the left identifies the number of severe non-compliant conditions that resulted in an Immediate Corrective Action Required (ICAR) request in the program areas of Formulary and Benefit Administration, CDAG, and ODAG. As mentioned, ICAR requests are issued by MOEG when a condition is found that caused, or has the likelihood to cause significant beneficiary harm. The chart to the right shows how many sponsors received an ICAR and what enforcement action, if any, was taken as a result of it.

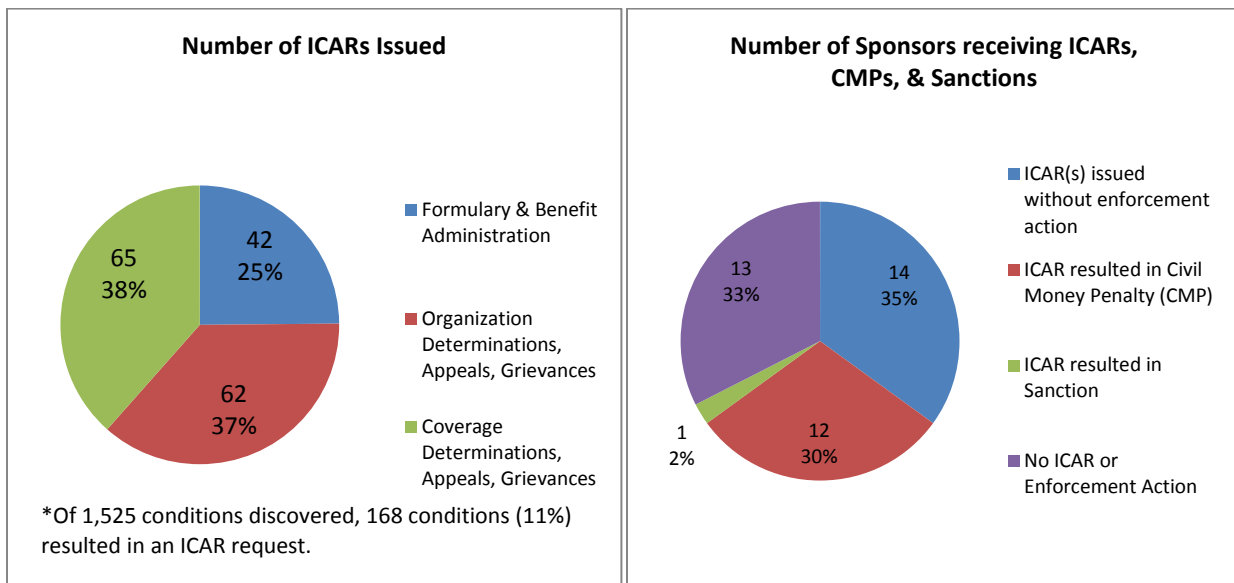


Chart Summary:

- Of the 1,525 conditions identified during audits, 169 ICARs were issued to 27 different sponsors in 2012.
- There was an average of 38 non-compliant conditions detected per audit.
- Of the 27 sponsors that received ICARs in 2012, 12 sponsors received a Civil Money Penalty (CMP) as a result of ICAR conditions.
- MOEG issued \$3,750,000 CMPs in 2012.
- MOEG imposed a sanction (Immediate Suspension of Marketing and Enrollment) on one sponsor.

MOEG AUDIT OPERATIONS

This section of the report summarizes MOEG’s internal program audit operations and its plan to improve the 2013 program audit process.

AUDIT LIFECYCLE

The lifecycle of an audit begins the day a start notice is issued to the sponsor and concludes with the sponsor’s receipt of an audit closeout letter. MOEG made improvements to the efficiency of the audit lifecycle by streamlining processes to reduce the overall length of the cycle and by responding to sponsor feedback to adjust sponsor due dates. The following table shows the audit lifecycles for 2011 and 2012 and where time was either added or reduced to the cycle.

Audit Phase	2011		2012	Difference Between '12 and '11
	Total Days Elapsed	Average Days Per Phase	Average Days Per Phase	
Audit Start Notice Issued	1	1	1	0
Entrance Conference	21	20	27	7
Exit Conference	26	5	12	7
Draft Report Issued	240	214	109	-105
Final Report Issued	267	27	26	-1
Sponsor Submits Corrective Action Required (CAR) Response & Attestation	357	90	90	0
Audit Team Review of CAR Response	404	47	TBD	-
Validation Reviews Conducted	497	93	TBD	-
Audit Closeout Letter Issued	498	1	TBD	-

Table Summary:

- MOEG responded to sponsor feedback that CMS did not allow sponsors enough time from the receipt of the start notice to the entrance conference (when the program area reviews begin) by extending this phase by 7 days. This phase of the audit required sponsors to compile and submit complete and accurate data universes, test webinar and file transfer protocol systems, and participate in calls with CMS audit teams to logistically prepare for the audit.
- MOEG and the sponsors needed an average of 12 days to conduct all of the reviews via webinar and conduct the onsite compliance program review. This 7 day increase was necessary and welcomed by the sponsors due to the number of reviews needed to complete the audit.
- MOEG reduced the time necessary to deliver the draft report by 105 days by streamlining its audit report drafting and issuance processes.

The timeliness of the audit report is critical to the audit lifecycle because a sponsor needs the official documentation to share with the organization and leadership to create change and focus resources on the corrective action plan. Once the corrective action plan is submitted, MOEG reviews the corrective actions and validates that the conditions of non-compliance have been fixed. The time required for the validation process varies by sponsor, but on average it took approximately 140 days to review the CAR response and complete the validation exercises. MOEG continues to work on improving its internal processes to shorten the lifecycle of the program audits, especially in the areas of report issuance and validation.

PLANS FOR 2013 AUDIT PROCESS

MOEG will be focused on the following initiatives to improve the program audit process in 2013:

1. **Early Release of the Audit Protocols** - In previous audit years, MOEG has released audit protocols after commencement of the yearly audits. In 2013, MOEG released the audit protocols prior to the initiation of all 2013 audits.

2. ***Implement a 2-week audit review period*** – MOEG will implement a 2-week audit review period to conduct all webinars and the compliance program review. This approach will lessen the burden on sponsors' compliance staff and allow more flexibility for CMS and the sponsors to conduct a thorough review.
3. ***New HPMS Audit Module*** – MOEG will be implementing the first phases of its HPMS audit module in 2013 and will be working to automate the entire audit process in HPMS by 2014-2015.
4. ***Publicly Post Audit Scores on the Compliance and Audits Website*** – MOEG will be posting the 2012 and 2013 (when available) audit scores on the website along with other comparable information to give sponsors a view of how they compare to the rest of the industry.
5. ***Posting of Q&As on CMS Website*** - Sponsor concerns or questions regarding the audit process will be addressed via a Q&A section on the CMS Website.

APPENDICES

APPENDIX A – Program Areas and Elements Audited in 2012

PROGRAM AREA	ELEMENT
Part D Formulary and Benefit Administration	Formulary Administration
	Transition
	Pharmaceutical and Therapeutics (P&T) Committee ¹
Part D Coverage Determinations, Appeals, and Grievances	Effectuation Timeliness
	Appropriateness of Clinical Decision Making & Compliance with Processing Requirements
	Grievances
Part C Organization Determinations, Appeals, and Grievances	Effectuation Timeliness
	Appropriateness of Clinical Decision Making & Compliance with Processing Requirements
	Grievances
	Dismissals
	Misclassified Grievances
	Complaints
Part C and Part D Compliance Program Effectiveness	Written Policies, Procedures, and Standards of Conduct
	Compliance Officer, Compliance Committee, and Governing Body
	Effective Training and Education
	Effective Lines of Communication
	Enforcement of Well-Publicized Disciplinary Standards
	Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks
	Procedures and Systems for Promptly Responding to Compliance Issues
	Effectiveness Measure
First Tier, Downstream and Related Entities (FDR) – Compliance Program	
Agent/Broker Oversight	Licensure
	Appointment
	Testing and Training
	OEV Calls
	Complaints
Enrollment/Disenrollment	Timely Processing
	Incomplete Enrollment Request
	Denials
	Special Needs Plans (SNP)
	Non-payment of Premium
Late Enrollment Penalty	Creditable Coverage
	IRE Reconsideration Request Timeliness

APPENDIX B – Draft Program Audit Scoring Methodology

The following items are considered when scoring an audit:

- 1) Number of conditions³ identified in the final audit report.
- 2) Remediation required for each condition.
 - a) Only a condition resulting in a recommendation⁴, corrective action required (CAR) or immediate corrective action required (ICAR) are counted toward the score.
 - b) Observations will not be counted in the scoring.
- 3) Number of audit elements tested.

The audit score is calculated by assigning 0 points to observations, 1 point to each recommendation and CAR, 2 points to each ICAR, and dividing the sum of these points by the number of audit elements tested⁵. A lower score is better than a higher score. The following is the formula for calculating the audit score:

$(\# \text{ CARs} + \# \text{ of recommendations}) + (\# \text{ of ICARs} \times 2) / \# \text{ of audited elements tested}$

Assigning a point value of 0, 1, or 2 points, assigns conditions a weight dependent on the severity of the condition. Division by the number of audit elements tested is necessary to account for Sponsors being audited for a varying number of program areas. For example, the 2012 audit elements tested included testing of Agent/Broker which was only relevant to those sponsors utilizing Agents/Brokers.

An overall audit score is calculated, as well as a score for each program area. The overall audit score is calculated by dividing the total points of each of the program areas by the total audit elements tested. Each program area score is calculated by dividing the total points of the given program area by the number of audit elements tested within the program area. Individual sponsor audit scores as well as comparative data across audited sponsors will be posted on the CMS website.

³ A condition is defined as a finding resulting in an audit “Recommendation,” “Corrective Action Required,” or “Immediate Corrective Action Required.” Audit results would be evaluated by the number and type of conditions identified during the audit, rather than the number of sampled cases failed. For example, a sponsor failing 10 cases as a result of 1 condition will have a better score than a sponsor failing 5 sampled cases for 5 different conditions.

⁴ Recommendations only existed in 2012 audit reports.

⁵ There is an exception to this formula for 2012 in that P&T committee is considered as though it was tested regardless of whether it was actually tested. Accordingly, although all 2012 audited sponsors were not audited for the P&T committee review, for purposes of counting the number of audit elements tested, P&T was considered to be tested. In 2013, all program audits will include a P&T committee review.