DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: January 15, 2014

TO: All Medicare Advantage Organizations, Prescription Drug Plan Sponsors, Cost Plans, Employer-Direct and Employer-Only Contracts, and Medicare-Medicaid Plans

FROM: Tracey McCutcheon, M.H.S.A, M.B.A, Acting Director, Medicare Drug Benefit and C & D Data Group

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SUBJECT: 2015 Application Cycle Past Performance Review Methodology Update – FINAL

Each year, the Centers for Medicare & Medicaid Services (CMS) conducts a comprehensive review of the past performance of Medicare Advantage Organizations (MAO), Medicare Prescription Drug Plan (PDP) Sponsors, and Cost Plans.[1] The review methodology is a tool CMS uses to evaluate the performance of all Medicare contractors; these evaluations may also identify organizations with performance so impaired that CMS would prohibit the organization from further expanding its Medicare operations. Specifically, pursuant to 42 C.F.R. § 422.502(b) and § 423.503(b), CMS may deny an organization's application either to offer Medicare benefits under a new contract or in an expanded service area during the subsequent contract year if a review of an organization's past performance finds that the organization has been out of compliance with any requirement.

[1] We note that CMS applies the past performance review methodology to Medicare-Medicaid plans (MMPs) differently than to MAOs, PDP Sponsors, Cost Plans, and Employer Contracts. For more guidance on the applicability of the past performance methodology to MMPs in States implementing Capitated Financial Alignment Demonstrations in 2015, please refer to our January 13, 2014 HPMS guidance memorandum entitled, "Organizations Interested in Participating as Medicare-Medicaid Plans in States Seeking to Implement Capitated Financial Alignment Demonstrations in 2015" (see http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/2015_NewApplicantGuidance.pdf) and our January 14, 2014 guidance memorandum, "Capitated Financial Alignment Demonstration Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2015" (see http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/2015_CurrentMMPAnnualRequirements.pdf). These documents describe the current applicability of the past performance methodology to all MMPs.

CMS has long held the authority to deny applications based on past performance (even if the applicant otherwise meets all application requirements). In December 2010, CMS first published the methodology we used for the 2012 Application Cycle to determine whether an organization's performance was sufficiently non-compliant to form the basis for a CMS decision to deny an application. CMS published a slightly revised version of the methodology in December 2011. In November 2012, CMS provided interested parties the opportunity to comment on the methodology we developed for use during the upcoming calendar year (CY) 2014 application review cycle. CMS provided this opportunity again in November 2013 for the upcoming calendar year (CY) 2015 application review cycle. The purpose of this memorandum is to describe common themes among the comments we received, provide our responses to those comments, and to publish the final 2015 Past Performance Assessment Review methodology, provided in the attachment.

CMS appreciates the comments we received from about a dozen health plan contractors, drug plan sponsors, and other industry representatives. We received several comments that were supportive of our changes to the Past Performance methodology. Most of the remaining comments addressed one of the following categories: performance audits; low performing icon (LPI); timing; transparency; and grace period. Below we describe the nature of the comments in each of these categories and CMS' response, including any changes to the methodology or actions we will be taking.

Additionally, CMS has chosen not to respond to comments on issues that we have already addressed in previous solicitations for comments concerning the methodology which remained unchanged in the document released in November 2013. Organizations can find previously addressed comments regarding the Past Performance Methodology in the HPMS memorandum titled 2014 Application Cycle Past Performance Review Methodology Final, released on January 17, 2013.

- Program Audits

CMS received a variety of comments regarding the newly reworked Performance Audit category (now titled "Program Audits"). This category received a similar amount of attention from commenters in late 2012 when CMS first alerted the industry in the 2014 Past Performance Methodology – Request for Comment that we would be revising the category. As a direct result, CMS delayed implementing the proposed changes for one year due to the volume of comments we received. We thoroughly reviewed those comments and on the basis of that review made further improvements to the Program Audit category prior to implementation this fall. CMS has made no substantive changes to the Program Audits section of the methodology in response to our most recent solicitation of comments. We have, however, made a minor revision to clarify the description of our methodology for calculating the threshold for assigning a negative performance point in this category.

Many of the comments focused on the need to ensure equitable treatment across the spectrum of organizations regardless of their size. CMS considers several factors when selecting organizations for audit each year, including our obligation to audit all sponsors in the program. It is possible that a given sponsor could be selected for audit more than once, as CMS cycles through auditing all sponsors (i.e., CMS determines that the level of risk to Medicare beneficiaries posed by an organization's performance rises to an unacceptable level), but there is no indication that larger organizations are audited more often than smaller ones.

CMS also received comments about the timing of the implementation of the newly reworked program audit category. In particular, commenters expressed concern that scores in the Program Audit category could not be fairly compared since they would span a period during which CMS used two different methodologies. In fact, CMS will apply the new methodology to all audit results during the review period. As we stated in the draft methodology, in calculating an applicant's score in the Performance Audit category, we use the results contained in the final audit reports issued during the 14-month review period, which for the CY 2015 application review cycle will be January 1, 2013, through February 28, 2014. CMS will use the data upon which reports issued during that period were based to calculate the modified past performance scores.

Finally, some commenters asserted that because CMS does not audit all sponsors each year, sponsors that are audited are placed at a disadvantage under the methodology since they face the risk of being assessed a negative performance point in this category while unaudited sponsors do not. CMS' policy of including program audit results in the Past Performance Assessment is consistent with inclusion of the One-Third Financial Audit results as well as the prior methodology's inclusion of the program audits. As with the One-Third Financial Audits, all contracting organizations are audited on a cycle basis, thereby creating the same level of risk to all contracting organizations throughout the course of the audit cycle. We believe these audits provide critical information about an organization's performance which should not be ignored by CMS. Nevertheless, we recognize that it is appropriate to make some accounting for the fact that not every organization is subject to an audit within a given past performance review period. Our establishment of a maximum of only one negative performance point for the absolute weakest performers in the Program Audit category is a reflection, in part, of that accounting.

- Low Performing Icon

In an effort to better capture poor performance, organizations with an LPI designation due to three consecutive years of poor star ratings will receive 3 negative past performance points in the Outstanding Concerns category on the basis that the regulation states that such contracts are subject to termination (§ 423.509(a)(13) and § 422.510(a)(14)). This new requirement generated several comments from organizations. Many organizations questioned the robustness of the Star Ratings in general and whether it was a credible enough measure on which to base the assessment of additional negative past performance points. Other organizations argued that assessing negative performance points for an LPI was tantamount to duplicative counting since the methodology already assessed points on an organization that possessed a star rating below three stars in a given performance cycle. CMS feels that LPI status constitutes a distinct level of poor performance. An LPI organization has demonstrated a propensity for achieving poor star ratings (i.e. below three stars) for three straight years and therefore poses a greater risk to the Medicare program than does a one-year poor performer. As per regulation, CMS will have the authority to terminate such an organization following three years of poor star ratings. Thus, it seems in concert with the regulatory authority to assess additional negative performance points on this basis.

- Transparency

CMS received suggestions of ways in which we can be more transparent in our application of the methodology. We agree with and will begin implementing the suggestion to provide organizations with our calculations of cut-points for determining outliers in the compliance letter

category. Beginning with the next round of assessment results, we will post the 80th and 90th percentile compliance letter thresholds in HPMS in the same location where an organization can locate its full results. We will post the 75th percentile program audit threshold in HPMS in a similar manner.

One organization asked CMS to provide examples of compliance issues which are clearly Part C, Part D, or cross-cutting Part C/D issues. An example of a uniquely Part C issue would involve non- compliance with requirements governing payments to medical providers. An example of a uniquely Part D issue would involve compliance issues surrounding drug adjudication at the point of sale. An example of a cross-cutting Part C/D matter would be compliance issues dealing with enrollment timeliness.

We are declining to make other suggested changes. For instance, CMS will not create a new contracting organization-facing compliance module for the purposes of tracking compliance notices. Organizations already receive copies of all the letters that we maintain in that database, and they may contact their Account Managers with any questions about their compliance letters. Moreover, we continue to encourage organizations to get in touch with CMS about questions or concerns they may have regarding any aspect of their Past Performance Review results. Many organizations have already taken advantage of this opportunity, which has proven useful to both CMS and the organizations.

CMS is further declining to make available the criteria and methodology for every type of compliance notice as some plans have requested. The nature of the compliance assessment process makes granting such a request generally unworkable. CMS may issue a range of compliance notices to document contracting organizations' non-compliance with Medicare program requirements. CMS determines the nature of each instance of non-compliance by identifying and weighing a range of factors, including the duration of the conduct, the significance of the applicable program requirement, and whether the organization reported the conduct to CMS. Because instances of non-compliance usually involve a unique set of facts, our process for determining the severity of compliance notices is based more on the fair application of a broad set of principles to those facts rather than a set methodology. The Medicare statutes, regulations, and guidance already provide sponsors sufficient instruction on how to comply with Part C and D requirements. Organizations are better served by focusing on those instructions to guide their compliance efforts than by seeking information on what CMS considers "permissible" levels of non-compliance.

- Grace Period

CMS received several comments concerning the one-year grace period during which, under the methodology, CMS would not assign to an acquiring organization the negative performance points earned by its acquired organization. Commenters objected to our policy of requiring organizations to alert CMS that they have elected to invoke the need for a grace period due to a recent merger or acquisition. We believe our policy makes sound operational sense. It is the organization that is best suited to know for certain whether it has completed a merger or acquisition within a particular timeframe. Moreover, the benefit to organizations (i.e., the grace period) significantly outweighs any burden the notice requirement may place on them. Therefore, CMS will continue to require organizations to request the grace period exceptions provided for under the methodology.

CMS received several comments that were contracting organization-specific. We decline to address such comments in a document intended for a general audience. Organizations that put forth comments concerning issues unique to their operations should reach out to CMS for clarification.

Once again, we thank organizations for submitting comments. CMS intends to continue publishing our Methodology each fall, and we will seek comments on sections where our approach involves substantive changes.

We are committed to ensuring that CMS contracts with only the strongest and best performing Medicare Advantage Organizations and Prescription Drug Plan Sponsors. The Past Performance Assessment Review enables us, in a systematic and rigorous way, to understand the performance levels of all contracting organizations and to identify organizations that should focus on their current book of business before further expanding.

If you have any questions, please contact Michael Neuman at Michael.Neuman@cms.hhs.gov or 410-786-7069. Thank you.

Attachment:
2015 Application Cycle Past Performance Assessment Review Methodology (Final)

This methodology below describes in detail the approach CMS uses to evaluate the performance of all Medicare C and D contractors, evaluations that may also identify organizations with performance so impaired that CMS would prohibit the organization from further expanding its Medicare operations.

Review Period

CMS clarified in its April 15, 2010 final Part C and D regulations that we limit our performance review each year to the 14-month period leading up to the annual application submission deadline. (As a practical matter, we count the entire calendar month in which applications are due as the 14th month.) The specific 14-month performance period that will be assessed for the 2015 Application Review Cycle is January 1, 2013 through February 28, 2014.[2]

For an instance of non-compliance to be considered in the review, the non-compliance or poor performance must have either occurred *or* been identified during the 14 month period. Thus, we may include in our analysis non-compliance that occurred in prior years but did not come to light or was not addressed until sometime during the review period. Likewise, if the problem occurred during the 14-month period but it was not identified until, for instance, the month following the end of the review period but before we finalize our results, we include the matter in our assessment.

In April 2011, CMS published new regulations stating that in the absence of 14 months' performance history we may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the Part C or Part D programs. (§ 422.502(b)(2) and § 423.503(b)(2)) Therefore, during the 2015 Application Cycle, organizations that commence their Part C and/or Part D operations in 2014 will not be permitted to expand their service areas or product types until they have accumulated at least 14 months of performance experience, which can then be evaluated under this methodology.

Importantly, these provisions only pertain to applying entities that currently operate Part C or Part D contract(s) but have done so for less than 14 months, and further, are unrelated (by virtue of being subsidiaries of the same parent) to any other contracting entity with at least 14 months' experience. So long as a contracting entity or another subsidiary of its parent organization has operated one or more Medicare contracts for the requisite period of time, applications for new contracts or service area expansions submitted by a current contracting entity will not be subject to denial for having less than 14 months experience.

Plan Types

The past performance assessment is conducted at the contract level, and includes contracts that operated at any time during the performance period, even if the contract terminated or non-renewed prior to the end of the performance period. Beginning with the 2015 Application Review Cycle, contracts exclusively offering products into which only employer group or union

[2] Per 42 C.F.R. §§ 422.502(b)(3) and 423.503(b)(3), for organizations that have had a previous Medicare contract terminated or non-renewed by CMS within the 38 months preceding the application submission deadline, the applicable past performance review period will be extended to include that same 38-month period.

members may enroll will be included in our review (these contracts had been excluded in the past). These types of plans represent a growing share of the overall enrollment in Medicare plans and as a result, the contracts under which these plans are offered are increasingly receiving the same level of review by CMS as other types of contracts. Therefore, it is appropriate to begin including them in our past performance assessment. Due to continuing variations in the Program for all-Inclusive Care for the Elderly (PACE) regulations, PACE organizations remain excluded from this analysis. MA-PD organizations receive both a C and D score. Unless otherwise noted, the methodology presented below is identical for both the Part C and Part D reviews.

Performance Categories and Negative Performance Points

For the 2015 Application Cycle, we have established 11 distinct performance categories. We carefully analyze the performance of all contracts in each performance category and assign "negative performance points" to contracts with poor performance in that category. The number of potential negative performance points corresponds to the risk to the program and our beneficiaries from deficient performance in that particular area.

The 11 performance categories that are included in the review for the 2015 application cycle include:

1. **Compliance Letters** (i.e., Notices of Non-Compliance, Warning Letters, and Corrective Action Plans (CAPs))
2. **Performance Metrics** (i.e., the plan performance ratings, sometimes called "star ratings" developed each year and published on the Medicare.gov website)
3. **Multiple Ad Hoc Corrective Action Plans (CAPs)** (i.e., findings of egregious violations that were discovered outside of the audit process, such as through beneficiary complaints)
4. **Ad Hoc CAPs with Beneficiary Impact** (i.e., CAPs where the compliance violation presented a threat to beneficiaries' health (e.g., denial of access to health care services or prescription drugs) or financial condition (e.g., charging of incorrect premiums or cost sharing)
5. **Failure to Maintain Fiscally Sound Operation** (i.e., organizations with financial solvency problems)
6. **One-Third Financial Audits** (i.e., organizations with adverse audit opinions or disclaimed audit reports stemming from a CMS One-Third Financial Audit)
7. **Program Audits** (i.e., poor audit results)
8. **Exclusions** (i.e., exclusion from: receiving auto-enrollees, appearing in Medicare & You, having certain formulary update opportunities, or participating in the Online Enrollment Center)
9. **Enforcement Actions** (i.e., intermediate sanctions and civil money penalties imposed or in place during the performance period)
10. **Terminations and Non-Renewals** (i.e., requests by an organization to rescind a contract with CMS after the annual non-renewal deadline or after the annual marketing and enrollment period has begun, mutual terminations to be effective mid-year, or terminations initiated by CMS)

11. **Outstanding Compliance Concerns Not Otherwise Captured** (i.e., compliance and enforcement actions largely developed but not yet formally issued by CMS)

Detailed Information

1. Compliance Letters

When CMS learns of a performance problem, we issue a compliance notice to the responsible organization. These notices serve to document the problem and, in some instances, request details on how the organization intends to address the problem. There are three key notice types: Notices of Non-Compliance (NONC), Warning Letters, and Ad Hoc Corrective Action Plan (CAP) Requests.

Notices of Non-Compliance are used to document small or isolated problems. Warning Letters are issued either when an organization has already received a NONC, yet the problem persists, or for a first offense for larger or more concerning problems. Unlike NONCs, these letters contain warning language about the potential consequences to the organization should the non-compliant performance continue. We also occasionally issue a Warning Letter with a request for a Business Plan when CMS determines that a plan of action is needed from the organization. The last type of letter, the CAP request, is reserved for persistent problems or very serious concerns that need in-depth and continued monitoring by CMS.

An outlier in this category is defined as an organization that is one of the worst performing organizations, based on a weighted distribution of the number and types of compliance letters received (or for conduct that occurred and for which letters will soon be issued) during the performance period across all organizations (including those that received no letters during the period, but excluding contracts otherwise not included in this analysis, such as PACE contracts). Specifically, a weighted score is calculated for each contract; the following table (Table 1) indicates the weights to be assigned for each type of letter or compliance event.

Table 1: Weights for Each Compliance Letter Type

Compliance Letter Type	Weight	Rationale for Weight
Notice of Non-Compliance	1	Mildest type of letter. Does not contain specific language regarding further compliance escalation or other consequences should the behavior/non-compliance continue.
Warning Letter	3	Formal communication that describes the consequences of continued non-compliance; weighted 3 times greater than notices of non-compliance.
Warning Letter with a Business Plan	4	The matter is serious enough to warrant a written response from the organization but not significant enough to warrant a CAP.
CAP – Ad hoc compliance event	6	Ad hoc CAPs represent the most serious form of compliance notice. Rated at twice the weight of warning letters because the issuance of this type of letter indicates continuing and/or severe, systemic problems.

Example: if a contract received one notice of non-compliance (weight = 1), two warning letters (weight = 3 each, total 6), and an ad hoc CAP (weight = 6), the contract's score would be 13.

After a Compliance Letter score has been calculated for each contract, we then rank the contracts in descending order from highest to lowest score (in the case of the Part D analysis, separately for MA-PD contracts and PDPs). Next, we identify the value (score) at the 90th percentile point and the 80th percentile point.

All contracts with a weighted score at or above the 90th percentile point receive 2 negative performance points in the Compliance Letter category. All contracts with a weighted score at or above the 80th percentile point, but less than the 90th percentile point, receive 1 negative performance point in this category. All other contracts receive 0 negative performance points for the Compliance Letter category.[3]

The Health Plan Management System (HPMS) serves as CMS' definitive system of record for all such compliance notices. Each time a letter is issued the CMS issuing office enters key data elements into HPMS and uploads a copy of the letter. To obtain these data, we extract this information from HPMS. This ensures a complete and accurate data set. All letters issued during the performance period (or shortly after the performance period to the extent that the non-compliance occurred during the performance period) are included in the extract and analysis.[4]

2. Performance Metrics

The most current "star ratings" data as of the end of the 14-month performance period developed by CMS and posted on the Medicare.gov website are used for this analysis. As of the date of this memo, the most recent sponsor quality and performance metrics were calculated in accordance with the CY 2014 Technical Notes made available to the public on the CMS website at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html .[5] An outlier in this category is defined as any contract that received a summary score for Part C or Part D of 2.5 stars or below. The summary score summarizes a contract's performance across domains and underlying individual measures.

[3] For the 14 months between July 2012 and August 2013, Part D thresholds were as follows: 80th percentile – 12/ 90th percentile – 15 (MA-PDs); 80th percentile – 9/90th percentile – 13 (PDPs). For Part C, the thresholds were: 80th percentile – 5/90th percentile – 7. This information is provided to assist organizations monitor their own performance. These percentile values are likely to change when re-calculated for the final performance period of January 2013 through February 2014.

[4] There are three exceptions. The first is that we exclude ad hoc CAPs where the basis of the CAP is the forthcoming expiration of a PDP licensure waiver. These CAPs are issued in anticipation of the expiration of a sponsor's CMS-granted licensure waiver at the end of the current contract year. They provide sponsors with the notice required by regulation that, should the sponsor not obtain a state-granted risk bearing license, CMS would be required to non-renew all or a portion of that organization's PDP sponsor contract at the end of the contract year. Since these CAPs concern anticipated, rather than actual, non-compliance, they will not be included in any evaluation of an organization's Part D contract performance. The second example is that we exclude ad hoc CAPs concerning an organization receiving a star rating of less than three stars for a specific year. Because this methodology includes a separate performance category specifically concerning low star ratings, it would be inappropriate to further include in our analysis CAPs issued as a result of the same problem. Finally, we exclude CAPs stemming from performance audits as these, by definition, are not "ad hoc" CAPs.

[5] In the rare instance that a contract terminated mid-year and therefore does not have a calculated rating for the current year, we use the prior year's rating.

For Part D, there are currently four domains: Drug Plan Customer Service; Member Complaints, Problems Getting Services, and Improvement in the Drug Plan's Performance; Member Experience with Drug Plan; and Drug Pricing and Patient Safety. All told, there are 15 individual measures assigned among the four Part D domains. For Part C, there are five domains: Staying Healthy – Screenings, Tests and Vaccines; Managing Chronic (Long Term) Conditions; Member Experience with Health Plan; Member Complaints, Problems Getting Services, and Improvement in the Health Plan's Performance; and Health Plan Customer Service. Altogether, there are 36 individual measures assigned among the five Part C domains.

A summary score is calculated separately for Part C measures and for Part D measures. Each summary score rating is based on a weighted average of the individual measure stars, with outcomes and intermediate outcomes weighted 3 times as much as process measures, and patient experience and access measures weighted 1.5 times as much as process measures. Consistent good performance is recognized with a higher rating, while sanctions negatively affect star rating results. While ratings of individual measures fall along a 5-star range with no half-star values, summary score ratings include half-stars to provide more differentiation among contracts.

A score of 2.5 stars or below was chosen as the outlier level because a score of "three stars" on any given individual measure is considered an indicator of adequate performance. Therefore a summary score falling below 3 stars indicates poor or "negative outlier" performance.

All outlier contracts in this category receive 2 negative performance points.

3. Multiple Ad Hoc CAPs

Using the dataset developed for the Compliance Letter category, we identify all contracts that received more than one ad hoc compliance CAP during the performance period (or shortly after the performance period to the extent that the non-compliance occurred during the performance period). Ad hoc compliance CAPs are relatively rare and are typically issued only when other forms of intervention have failed to correct a problem and/or the problem was especially egregious. Receiving more than one such CAP during a performance period is a powerful indication of ongoing performance problems. All contracts meeting the criteria in this category receive 1 negative performance point.

4. Ad Hoc CAPs with Beneficiary Impact

Ad hoc compliance CAPs can be issued for numerous reasons. Some CAPs are related, directly or indirectly, to a beneficiary's experience with the services and protections the contracting organization is required to provide, while others are not. An example of a CAP we previously issued that does not present a significant threat to beneficiaries (and therefore no beneficiary impact as defined here) concerns late reporting of financial information to CMS. The non-compliance in this instance involves largely administrative aspects of the Medicare program that, while crucial to the overall administration of the Medicare program, do not relate to beneficiaries' day-to-day use of the Medicare benefit. In contrast, an example of a CAP where there is beneficiary impact concerns proper administration of the organization's beneficiary call center. Other CAP topics that are associated with beneficiary impact and are therefore counted under this category include: 4RX data submissions to CMS, enrollment and disenrollment processing, application of correct low income subsidy (LIS) status for plan members, volume of member complaints logged into CMS' Complaints Tracking Module (CTM), failure to provide appropriate Part D drugs, failure to apply safety edits when processing claims, processing of

member appeals and grievances, marketing abuses, overall failure to appropriately administer the Part D benefit, execution of benefit coverage determinations, and formulary administration.

We extract from HPMS each individual CAP issued during the performance period (or shortly thereafter for conduct that occurred during the performance period) and assess it to determine whether the non-compliance stated in the CAP request should be characterized as conduct that had a beneficiary impact.[6] Because organizations that have experienced such problems represent more of a performance risk, all contracts meeting the criteria in this category receive 1 negative performance point *for each issued CAP* that had beneficiary impact.

5. Failure to Maintain Fiscally Sound Operations

Organizations whose annual financial reports to CMS demonstrate that they do not meet the requirements of 42 C.F.R. §§422.504(a)(14) and 423.505(b)(23) are carefully monitored by CMS. Specifically, CMS more closely monitors organizations when:

1. The entity has a negative net worth (liabilities greater than assets), or
2. A negative net income (net loss) is reported and the amount of that loss is greater than half of the entity's total net worth.

These entities are required to report financial data quarterly to CMS. When, upon review of an independently audited annual report, CMS determines that neither Item 1 nor Item 2 apply to the organization, it is no longer required to submit quarterly financial data to CMS.

Because CMS has a responsibility to ensure our contractors have sufficient funds to allow them to pay providers and otherwise maintain operations, contracts CMS has determined have not met the requirements of 42 C.F.R. §§422.504(a)(14) and 423.505(b)(23) at the time the analysis is conducted receive 1 negative performance point.

6. One-Third Financial Audits

Sections 1857(d)(1) and 1860D-12(b)(3)(C) of the Social Security Act require the Secretary to provide for an annual audit of the financial records (including, but not limited to, data relating to Medicare utilization and costs, including allowable reinsurance and risk corridor costs as well as low income subsidies and other costs and computation of the bid per 42 CFR 423.504(d) and 422.503(d)) of at least one-third of all active MAOs and PDPs. For example, this may include procedures to test Prescription Drug Event (PDE) data, Direct and Indirect Remuneration (DIR) data, bid data, internal controls, etc. All contracts that receive **adverse** audit opinions or **disclaimed** audit reports during the 14 month performance period receive 1 negative performance point. The auditor issues a ***disclaimed*** audit report when it could not form, and consequently refuses to present, an opinion on management's assertion (i.e., the auditor tried to audit an entity but could not complete the work to issue an opinion because of circumstances created by the audited organization). The auditor issues an ***adverse*** audit report when it determines that the financial data is materially misstated (i.e., the information contained is materially incorrect, unreliable, and inaccurate).

These types of audit reports signal a lack of internal controls over the sponsoring organization's operations and/or a serious failure by the sponsoring organization to devote the necessary

[6] CAPs indicate in the body of the letter if the issue was related to beneficiary experience (i.e., will be considered to have beneficiary impact for this purpose).

resources to respond to the auditor's request for documentation. The scope of the one-third financial audits includes: 1) Solvency, 2) Related-Party Transactions, 3) Non Benefit Expense, 4) Part D Costs and Payments (TROOP, Direct and Indirect Remuneration), and 5) Direct Medical.

7. Program Audits

Each year, CMS conducts audits of select Part C and D sponsors to determine the level of performance under their Medicare contracts. At the conclusion of the audit, sponsors receive an audit score based on both the variety and severity of the conditions identified (see http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/HPMS-Memo-Final-Program-Audit-Scoring-Methodology.pdf for more information). For purposes of the Past Performance Assessment, a modified audit score is calculated by utilizing the audit results for each of the following program areas: Part D Formulary and Benefit Administration; Part D Coverage Determinations, Appeals, and Grievances (CDAG); Part C Organizational Determinations, Appeals, and Grievances (ODAG); and Compliance Program Effectiveness. We consider only these 4 core program areas for the modified past performance audit score because they are consistently audited each year and have limited changes to the audit protocols from year-to-year. The modified audit score is then calculated by taking the total number of audit points (determined based on both the number of unique conditions identified and the severity of those conditions) in these 4 areas and dividing those audit points by the total number of audit elements tested (again in the 4 core program areas) to arrive at the Past Performance Audit Score. A lower score is better than a higher score.

In order to determine whether a sponsor will receive a negative past performance point, CMS will determine a threshold in which sponsors exceeding the threshold will receive 1 negative performance point in this category. The threshold will be determined by utilizing cumulative data and establishing the 75th percentile as the threshold. (The date of issuance of the final audit report determines whether an organization's audit results are included in the 14-month performance period.)

8. Exclusions

Medicare offers contracts in good standing certain privileges. These include the display of the organization's marketing information on our web site and in publications, the ability to make certain programmatic updates during the course of a benefit year, and the automatic enrollment of some low income members who have not elected a prescription drug benefit plan and would otherwise be without coverage. Should an organization demonstrate poor performance, CMS may choose to exclude the organization from participation in one or more of these activities. The particular exclusion CMS might select would be tied to the nature of the organization's poor performance. The full list of privileges which could be suspended in such a manner includes:

- Medicare & You Handbook. Each fall, CMS issues Medicare & You Handbooks to all beneficiaries. The Handbook provides information about the different plan choices available to Medicare beneficiaries. Should an organization fail to complete its contracting activities in a timely manner (e.g., fail to sign a contract or have its bid or formulary approved), then we would prevent information related to the incomplete contract(s) from appearing in the Handbook. Should this occur during the performance period, the Medicare & You Handbook exclusions are noted in the performance review with 1 negative performance point. (There are other reasons why a contract may be excluded from appearing in the Handbook, such as

the contracting organization being under a sanction, but to the extent those types of compliance problems are addressed via other performance categories, they are not considered as part of this category.)

- On-Line Enrollment Center (OEC). Most organizations are required to participate in CMS' On-Line Enrollment process, which enables Medicare beneficiaries to submit an enrollment application via the Medicare.gov website. There are a variety of OEC requirements organizations must fulfill, including downloading these enrollments from the website on a daily basis. Contracting organizations that fail to download these enrollments once or twice receive compliance letters for those contracts for which enrollments were not properly processed. Contracts for which organizations fail repeatedly to retrieve enrollments are excluded from participation in the OEC. Contracts that were excluded from the OEC for any length of time falling within the performance period receive 1 negative performance point.
- Formulary Update *(Part D only)*. Organizations have a special opportunity to update newly approved formularies for the upcoming benefit year each summer. On occasion, CMS will deny an organization the opportunity to update its new formulary during the summer due to serious problems CMS has had in working with the contract to receive an acceptable formulary. Should this be the case, CMS assigns 1 negative performance point to any contracts that lose their summer update opportunity.
- Low Income Subsidy (LIS) Reassignments/Auto-enrollees *(Part D only)*. Each month, CMS auto-enrolls low income subsidy beneficiaries (who have not elected a Part D plan on their own) into a randomly selected plan whose premium is low enough to be covered in full by the subsidy amount (known as "benchmark" plans). Each fall, CMS reassigns members into new plans when the old plan's premium in the coming year will be above the benchmark amount. Should a contracting organization whose plans otherwise qualify for such auto-enrollments or reassignees demonstrate poor performance that would jeopardize its ability to accommodate these members, CMS suspends the contract's participation in the auto-enrollment/reassignment process until the problem is cured. Contracts with such a suspension during the performance period, but that subsequently cure their problems, making them eligible to resume receiving these enrollments by the end of the period, receive 2 negative performance points. Contracts that are under a suspension at the end of the performance period receive 3 negative performance points.

9. Enforcement Actions

CMS may impose intermediate sanctions, such as a suspension of an organization's ability to market to or enroll members, if an organization meets one or more of the bases for intermediate sanctions in 42 C.F.R. §422.752(a) and § 423.752(a) or meets one or more of the bases for termination in 42 C.F.R. §422.510(a) and § 423.509(a). Likewise, in addition to or in place of intermediate sanctions, CMS has the authority to impose civil money penalties (CMPs) when an organization meets one or more of the bases for termination in 42 C.F.R. § 422.510(a) and § 423.509(a) and its violations have directly adversely affected or had the substantial likelihood of adversely affecting one or more enrollees. Because these enforcement actions are contract determinations, it is important that we capture these as distinct performance events for the purpose of this review.

Contracts under an intermediate sanction during the performance period but then released from the sanction prior to the end of the performance period receive 3 negative performance points for "immediate" sanctions (i.e., sanctions that become effective on a date specified by CMS and are based on conduct that poses a serious threat to a beneficiary's health and safety) or 2 negative performance points for "non-immediate" sanctions (i.e., sanctions that become effective 15 days after CMS issues notice of the sanction). Contracts under sanction at the conclusion of the performance period (or subsequent to the performance period if the conduct that formed the basis of the sanction occurred during the performance period) receive an additional 4 points, bringing the possible total to 7 negative performance points for immediate sanctions or 6 negative performance points for non-immediate sanctions.

Regarding CMPs, we assess 1 negative performance point for each CMP imposed by CMS on a contract. Should an organization receive more than one CMP during the performance period, the contract receives 1 negative performance point for each distinct CMP.

Of note, both intermediate sanctions and CMPs are subject to potential appeals from the organization on which the sanction or CMP has been imposed. Should an organization win on appeal (thereby fully overturning the sanction or CMP), no points are assessed for CMS' initial determination. Should an appeal be underway at the time of the analysis, the points are counted during the appeals process. If necessary, we will retroactively remove the points and reconsider any decisions that were based on the original point values.[7]

10. Terminations and Non-Renewals

There are three types of contract, or partial contract, terminations of concern to CMS: 1) CMS-imposed, 2) disruptive mutual, and 3) non-disruptive mutual.

CMS will impose a termination as a last resort when an organization meets one or more of the bases for termination in 42 C.F.R. § 422.510(a) and § 423.509(a) such that the organization substantially fails to comply with the terms of its contract, is carrying out its contract in a manner that is inconsistent with the effective and efficient implementation of the Medicare program, or no longer meets the requirement of the Medicare program for being a contracting organization. Under such circumstances, we assign 8 negative performance points to the terminated contract. In some instances, CMS must terminate or non-renew an organization's contract in only a portion of its service area where it no longer meets the plan sponsor qualifications (e.g., organization is no longer licensed as a risk-bearing entity in a particular jurisdiction). CMS will assign 4 negative performance points to these contracts.

In past years, several organizations requested mutual contract terminations (for an entire contract or for a specific portion of the service area) very late in the year based on financial solvency grounds or because their contracted provider networks, necessary to meet provider access requirements, had not been finalized in time for the start of the new benefit year. These are very serious problems and could have been grounds for CMS-imposed contract terminations had CMS not granted the organizations' requests for a mutual contract termination or service area reduction. Such "disruptive terminations" are harmful to beneficiaries, show lack of good faith in contracting with CMS, and put stress on the Part C and D programs by providing less than the

[7] If CMS denied an application based on an enforcement action that was later overturned on appeal, the latest date for a favorable decision to the applicant and a reversal of CMS' decision to deny the application would be the established program-wide last date for signing contracts (typically in late summer).

required 90-day notice to CMS to effectuate a smooth transition. Organizations that experienced such problems after marketing for the upcoming year begins on October 1, or at any time of the year in the case of a mid-year termination, are high-risk organizations. Therefore, these terminated/reduced contracts receive 4 negative performance points. As discussed below, the 4 points are ultimately assessed to the organization that held the terminated contract.

On the other hand, there are some instances where organizations encounter operational and/or financial difficulties, but partner with CMS in order to coordinate and effectuate a smooth transition for beneficiaries with adequate notice. For example, there are organizations that experience such difficulties but may have just missed CMS' non-renewal notification deadline. If the organization demonstrates adequate partnership with CMS, and the mutual termination is not considered immediately disruptive (i.e., occurs prior to the commencement of marketing on October 1, gives beneficiaries and CMS at least 90 days to effectuate a smooth transition to other Part D coverage, and has an effective termination date of the last day of the current contract year, December 31), then CMS assigns 1 negative performance point for such a "non-disruptive" mutual termination.

Table 2 summarizes the point value designations for the various termination types.

Table 2: Summary of Termination Scenarios

Termination Type	**Point Value**
CMS-imposed termination/Non-renewal CMS-imposed partial termination/non-renewal	8 points 4 points
Mutual termination in all cases that are effective mid-year, and also where the termination is effective on December 31, but beneficiaries and CMS have less than 90 days' notice to effectuate a smooth transition or termination.	4 points (Disruptive)
Mid-year mutual terminations that are entered into *after* the non-renewal deadline but before October 1st, and where the termination date is December 31st. In these cases, CMS and beneficiaries have the full 90 days to effectuate a smooth transition.	1 point (Non-Disruptive)

11. Outstanding Significant Compliance Concerns Not Otherwise Captured

Finally, we believe it is important that a thorough past performance analysis account for non-compliance that is a strong indicator of weaknesses in the organization's performance, but which is not otherwise captured in other areas of the past performance analysis. This situation arises only where CMS has identified non-compliance that supports the imposition of an intermediate sanction, civil money penalty, or termination, but the matter has not yet worked its way through CMS's internal enforcement clearance processes. In such a situation, CMS has already developed and verified the facts concerning the scope and severity of non-compliance and only the timing of the agency's internal enforcement processes (e.g., formal sign-off from senior CMS leadership or the issuance of a formal demand letter) is preventing the non-compliance from being included in the organization's past performance profile. In such an instance, it is irresponsible for CMS not to account for the non-compliant conduct as part of our evaluation as

to whether an organization is qualified to expand its Medicare business. Therefore, in this limited circumstance, CMS assigns negative performance points to open significant compliance concerns.

Specifically, organizations for which CMS has an enforcement action pending (e.g., suspension of marketing and enrollment activities or imposition of civil money penalty) receive 2 negative performance points for pending sanctions or 1 point for pending CMPs. Organizations with a "Low Performing Icon" designation due to three consecutive years of poor star ratings receive 3 negative past performance points on the basis that the regulation states that such contracts are subject to termination (§ 423.509(a)(13) and § 422.510(a)(14)). In extremely limited circumstances where a termination is actively in process or where CMS has identified recent and ongoing non-compliance that puts beneficiary health and safety at significant and immediate risk, CMS may assign up to 5 negative performance points.

Summary of Negative Performance Point Values and Calculation of Contract-Level Scores

The results of the analyses described above are then compiled in separate Part C and Part D tracking spreadsheets. A contract is assigned the designated number of negative performance points in each category where it is deemed deficient according to the results of the analysis. Otherwise, the contract receives a score of 0 for the particular category. We sum the results across the performance categories to calculate a total negative performance score. Higher scores indicate evidence of performance problems across multiple and varied and/or high risk dimensions. Table 3 on the following page summarizes the negative performance points associated with each performance area.

Summarizing Results at the Contracting Organization (Legal Entity) Level

While the analyses described above are conducted at the contract level, it is necessary to summarize the results at the legal entity level. Frequently a contracting organization (i.e., a licensed, risk-bearing legal entity) holds multiple contracts with CMS. In turn, some parent organizations own numerous legal entities, each of which hold one or more CMS contracts. We summarize the contract-level performance results at the contracting organization level by assigning to a contracting organization the highest point value assessed for each performance area among all of the contracts held by that organization. The assigned scores for each performance area are then added to produce a total score for that contracting organization. For instance, "ABC Health Plan" holds two Medicare contracts, HXXXX and SXXXX. In reviewing ABC's Part D past performance we find that HXXXX received 1 point for Compliance Letters and 2 points for Performance Metrics, and SXXXX received 1 point for Compliance Letters and 1 point for Formulary Exclusions. To calculate the performance of ABC Health Plan as a whole, we assign that contracting organization the highest number of points any of its contracts received per performance category. In this example, ABC Health Plan would be assigned 1 point for Compliance Letters, 2 points for Performance Metrics, and 1 point for Formulary Exclusions for a total past performance score of 4.

Contracting organizations with high negative performance scores (according to the cut-offs described below) are checked to see if they are applying for an initial contract or a service area expansion. Such applications are denied.

Table 3: Summary of Performance Areas and Negative Performance Points

Performance Area	**Negative Performance Points Value for Contracts Identified as Category Outlier or Meeting Category Criteria**
Compliance Letters	90^{th} – 100^{th} percentile: 2 points 80^{th} – <90^{th} percentile: 1 point
Performance Metrics	2 points
Multiple Ad Hoc CAPs	1 point
Ad Hoc CAPs with Beneficiary Impact	1 point per CAP with beneficiary impact
Failure to Maintain Fiscally Sound Operations	1 point
One-Third Financial Audits (Adverse Opinion or Disclaimed Results)	1 point
Program Audit	1 point
Exclusions • Medicare & You Handbook • On-Line Enrollment Center • Formulary Update • LIS Reassignments/Auto-Enrollees	 1 point 1 point 1 point Subsequently lifted: 2 points Ongoing: 3 points
Enforcement Actions • Intermediate Sanctions • Civil Money Penalties (CMP)	 Immediate: 3 points lifted/7 points ongoing Non-Immediate: 2 points lifted/6 points ongoing 1 point
Terminations	CMS-Imposed: 8 points Disruptive Mutual: 4 points Non-Disruptive Mutual: 1 point
Outstanding Compliance Concerns Not Otherwise Captured	1-5 points

Additionally, we identify applying contracting organizations with no prior contracting history with CMS (i.e., a legal entity brand new to the Medicare program). We determine whether that entity is held by a parent of other Part C or D contracting organizations. In these instances, it is

reasonable in the absence of any actual contract performance by the subsidiary applicant, to impute to the applicant the performance of its sibling organizations as part of CMS' application evaluation. This approach prevents parent organizations whose subsidiaries are poor Part C or D performers from evading CMS' past performance review authority by creating new legal entities to submit Part C or D applications. It also forces parent organizations to direct their attention away from acquiring new Medicare business when their focus should be bringing their current Medicare contract performance up to an acceptable level. Should one or more of the sibling organizations have a high negative performance score, the application from the new legal entity will be denied.

Of note, we wish to clarify the impact of mergers and acquisitions on the past performance review and legal-entity summary result. If a parent organization with existing Part C and/or Part D lines of business purchases a contracting entity or the Part C and/or D contract of another parent organization that has negative performance points, the purchasing parent (upon a formal request to CMS) will be allotted a one-year grace period, calculated from the closing date of the purchase, before any negative performance by the purchased entity or contract will be imputed to the purchasing parent's existing entities. More specifically, negative performance points associated with the purchased entity will not be assigned to the purchasing entity during both the performance period in which the transaction closes and the entire succeeding period. In any event, the negative performance points earned by that contract during the review period will remain with that contract, and will be counted by CMS in response to any request for an expansion of that contract's service area.

Negative Performance Point Thresholds

In determining those organizations that have significant performance problems, we established a contracting organization threshold of 4 negative performance points for Part C and 5 negative performance points for Part D. The difference is due to a larger number of applicable categories where points may be accumulated by Part D sponsors (e.g., formulary or LIS specific categories). It is sufficient to reach the designated threshold for either the Part C or Part D analysis to be considered an overall poor performer.

These cut-offs were established to identify organizations that were outliers in at least one serious performance category (e.g. a current sanction) or in multiple performance categories. While even 1 negative performance point indicates a contract's "outlier" status in an important performance area, we established 4 or 5 points as the minimum total score for identifying those organizations with performance problems significant enough for us to take definitive action, such as denying expansion applications. This allows us to concentrate on those organizations that are either performance outliers in multiple categories or otherwise represent a high risk to the program. That said, we reserve the flexibility to increase the threshold values as necessary to account for shifts in the underlying performance categories and their associated point values to ensure that the analysis continues to identify true outliers.

Communication of Results with Organizations

During the application review process, CMS will provide results to the affected organizations in advance of the issuance of the application Notices of Intent to Deny to provide applicants the opportunity to proactively withdraw their applications. Organizations that choose to pursue their applications receive a Denial Notice and have an opportunity to appeal the decision. In 2011 and

2013 organizations whose applications had been denied on past performance grounds appealed the decisions, thus making CMS' Past Performance Methodology the subject of multiple appeals. Both the CMS Hearings Officer and the CMS Administrator upheld CMS' decisions to deny applications based on the appropriateness of this methodology, and CMS' correct application of the methodology to the application approval and denial process. Formal application denials are made available to the public.

We have been asked in the past whether it would be possible to provide organizations with advance notice of their scores so that low performing organizations could opt not to submit applications in the first instance. Because our analysis is based on performance during the 14 months immediately prior to the submission of applications at the end of February, we cannot provide final scores any earlier. However, as stated previously, organizations should be conducting a continuous self-review of their performance and based on that analysis, can make business decisions about submitting applications given the risk that CMS may deny the application on past performance grounds. Additionally, we make every effort to calculate preliminary scores in the fall, post the results in HPMS for plans to review, and communicate the potential of a denial to organizations with high negative scores that also submit Notices of Intent to Apply.

Public Posting of Past Performance Results

Once final, results of this analysis are posted on CMS' public website at: http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Part-C-and-Part-D-Compliance-Actions.html .