DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

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TO: All Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and 1876 Cost Plans

FROM: Gerard J. Mulcahy, Director
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SUBJECT: Final Program Audit Scoring Methodology

In the March 13, 2013 Health Plan Management System (HPMS) memo titled "Draft Program Audit Scoring Methodology for Public Comment", CMS provided interested parties the opportunity to comment on the proposed methodology. 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 Program Audit Scoring Methodology, provided in Attachment A.

CMS appreciates the comments we received from health and drug plans, industry associations, and stakeholder representatives. We received approximately twenty sets of comments. After careful consideration of each of the comments, the methodology has not been modified. Most of the comments addressed one of the following categories: consistent application of methodology, point value of recommendations, point value of self-reported issues, website publication and inclusion in Star Ratings and Past Performance Reviews. Below we describe the nature of the comments in each of these categories, and CMS' response.

Attachment A includes the final scoring methodology which is based on the number and severity of the conditions of non-compliance identified, thereby more accurately reflecting the range of results of the program audits. CMS will no longer use the number of samples passed or failed to determine compliance. We will rely solely on the number of conditions and the resulting score to compare performance across plan sponsors and years. Attachment B identifies the audit elements in the 2012 and 2013 program audits.

CMS anticipates publishing the 2012 audit results on the CMS website by June 21, 2013. The website format will reflect attachments B, C, D, E, and G of the March 13, 2013 HPMS memo titled "Draft Program Audit Scoring Methodology for Public Comment". The scoring methodology is being applied retroactively to 2012 audits, and therefore, will not impact the current Part C and Part D Star Ratings (Star Ratings) and the Past Performance Assessment Review (Past Performance Reviews). Instead, the 2012 audits will be included in the Star

Ratings and Past Performance Reviews using the same methodology as the 2011 audits.[1] In 2013 and beyond, audit scores calculated with this methodology will be published on the CMS website, as well as incorporated into the Star Ratings and Past Performance Reviews. Further details as to how the audit scores will impact the Star Ratings and the Past Performance Reviews will be provided in upcoming HPMS memos.

1. **Consistent application of methodology –** Numerous organizations expressed the need to classify conditions as an Immediate Corrective Action, Corrective Action, or Observation in a consistent manner. Additionally, numerous organizations requested examples of each condition category.

   CMS concurs that consistency is essential for accurate scoring of the program audits. Accordingly, CMS has defined each of these categories, implemented internal controls, including developing standard operating procedures and several layers of review, to ensure consistent categorization of conditions. CMS also provides sponsors an opportunity to comment on their draft audit report prior to finalizing an audit score.

   Below are definitions of the various condition categories:

   "Immediate Corrective Action Required (ICAR)" - An ICAR is the result of non-compliance with specific requirements that has the potential to cause significant beneficiary harm in the areas of Part D formulary administration (Formulary); Part D coverage determinations, appeals, and grievances (CDAG); Part C organization determinations, appeals, grievances, and dismissals (ODAG). Significant beneficiary harm exists if the non-compliance resulted in the plan's failure to provide medical services or prescription drugs, causing financial distress, or posing a threat to beneficiary health and safety due to non-existent or inadequate policies and procedures, systems, internal controls, operations or staffing. Below are examples of conditions resulting in an ICAR:

   <u>Part D Prescription Drug Formulary Administration</u>

   - Disruption of care for beneficiaries with drugs in the protected classes or other critical medications.
   - Beneficiary access problems related to the use of clinically inappropriate and unapproved utilization management criteria.
   - Transition issues that prohibit beneficiaries from receiving a temporary supply of prescribed Part D drugs when they are eligible for a transition benefit.

   <u>Part D Coverage Determinations, Appeals, and Grievances</u>

[1] The 2011 scoring methodology, as explained in both the Star Ratings and Past Performance Reviews methodologies, was solely dependent on the ratio of passed audit elements in comparison to the total number of audited elements. An audit element was determined to pass or fail depending on whether the number of sampled cases failing exceeded the failure threshold described in the audit protocol (i.e. failure of more than 20% of sampled cases).

- Misclassifying coverage determinations or appeals as grievances or failure to effectuate overturns or approvals.
- Failure to provide appropriate appeal rights.
- Failure to auto-forward cases to the IRE as required.

Part C Organization Determinations, Appeals. and Grievances and Part C Access to Care

- Failure to follow National Coverage Determinations (NCDs)/Local Coverage Determinations (LCDs) or other CMS coverage policy when making coverage decisions on any medical or other health service that is covered by Medicare.
- Misclassifying organization determinations or appeals as grievances or failure to effectuate overturns or approvals.
- Failure to provide appropriate appeal rights.
- Failure to auto-forward adverse reconsideration cases (including cases that are not adjudicated within the required timeframe) to the IRE as required.

"Corrective Action Required (CAR)" – A CAR is the result of a material non-compliance with specific requirements that does not have the potential to cause significant beneficiary harm. A material non-compliance is usually due to non-existent or inadequate policies and procedures, systems, internal controls, operations or staffing. Below are examples of conditions resulting in a CAR:

- Sponsor inappropriately rejected claims for drugs that were required to be dispensed in certain package sizes based on the prescribed dose.
- Failure to make a determination and notify the beneficiary within 72 hours after receiving an expedited organization determination request.
- Failure to establish and implement an effective system for monitoring and auditing its FDRs' compliance with CMS requirements.
- Failure to produce evidence that at least three OEV calls were made and/or that a follow-up enrollment verification letter was sent to the beneficiary.

"Observations" – Observations are either immaterial events of non-compliance with specific requirements or other items that may be useful to management in preventing contract non-compliance in the future. Below are examples of items resulting in an observation:

- Failure to include correct criteria in a coverage determination denial letter due to an isolated human error.
- Failure to effectuate a coverage determination in a timely manner as a result of a human error when entering the prescription drug into the system.
- Failure to appropriately determine coverage under Part B vs. Part D. The error appeared to be an isolated oversight not indicative of a lack of understanding of CMS requirements or a lack of internal controls.
- Failure to conduct an Outbound Enrollment Verification call or send an enrollment verification letter as a result of a non-systemic human error miscoding a new beneficiary enrollment as a like plan to plan change.

2. **Point value of "Recommendations" –** Numerous sponsors suggested that "Recommendations" should have a 0 point value.

   Recommendations were only used in 2012, and will not be used in 2013. CMS conducted a thorough review of each recommendation in 2012 to determine whether it would qualify as a CAR under the new scoring methodology. Consequently, one point was assessed for each recommendation that qualified as a CAR. In 2013 and beyond, audit elements no longer have failure thresholds and all identified conditions will be classified as a CAR, ICAR, or an Observation, regardless of the number of sampled cases failed.

3. **Point value of self-reported issues –** It was suggested that self-reported issues should have a lower point value than those identified as a result of the audit.

   CMS concurs that self-reported issues, validated to have been corrected prior to receipt of the audit engagement letter, will be noted as an observation. Self-reported issues that were not corrected prior to receipt of the engagement letter will be scored in the same manner as unreported items (i.e. CAR, ICAR or Observation, depending on severity).

4. **Website publication and inclusion in Star Ratings and Past Performance Reviews –** There were several comments surrounding the desire to delay public display of audit results as well as to delay inclusion in the Star Ratings and Past Performance Reviews until all sponsors are audited and scored in a consistent manner.

   Publication of audit results aligns with CMS' goal of driving the industry towards improvement, as well as providing enhanced transparency of CMS' oversight activities.

   The audit scoring methodology is a consistent way to reflect the results of the program audits and demonstrates how one plan compares to another. Over time, all sponsors will have audit scores displayed on our website for comparison purposes. CMS is also posting a spreadsheet with each audited sponsor's current status to show when all conditions are corrected and the sponsor is released from audit.

   Star Ratings and Past Performance Review currently include audit results. This will continue by using the new audit score because it is a more accurate depiction of the audit results.

5. Other Clarifications:

a. CMS will note on the CMS website that only audited sponsor scores are listed. Omission of a sponsor from the above list merely indicates that CMS did not yet audit this sponsor. It does not indicate better or worse performance.
b. All scores will remain on the website indefinitely. However, Appendix E of the March 13, 2013 memo will be included on the website to indicate which audits are closed and the issues have been corrected.
c. Along with the comparative data included on the website, it will be noted that sponsors with a higher score, or more audit conditions, indicates worse performance. Accordingly, sponsors with low audit scores, or a fewer number of conditions, should be viewed as a strong performing sponsor.
d. Sponsor audits are at the Parent Organization level regardless of the number of contracts for the given sponsor. The number of contracts in scope for a sponsor does not impact the audit scoring, that is, the number of contracts has no weight in determining the audit score.
e. In 2013 and beyond, scores will be included in the draft audit report and sponsors will have an opportunity to comment prior to issuance of the final audit report.
f. The 2012 audit scores were provided to sponsors audited in 2012 after the draft scoring memo was released.
g. As average annual audit scores shift as the audit year progresses, CMS will only publish audit results annually, at the conclusion of all audits during the given year.
h. The audit score has no bearing on determining whether an enforcement action is warranted, or the level of an enforcement action. Audit conditions will be evaluated for significance and their potential or actual adverse beneficiary impact. Enforcement actions will be determined on the merit of the conditions.
i. Immediate Corrective Actions as well as Corrective Actions identified during the program audit require a sponsor to correct the identified conditions. Once the sponsoring organization attests to correcting the various issues, CMS may engage in validation activities to confirm that correction has occurred. Validation activities are not a second full-scope program audit. Validation is focused on the conditions identified in the audit report. Audit findings will be validated by either reviewing the Corrective Action Plan (CAP) and/or "testing" the corrective action. Accordingly, validation does not result in a validation score. Alternatively, the validation results are used to determine whether the program audit remains open. Once all conditions are validated and corrected, the program audit is closed. Enforcement actions may result from continuous or newly discovered conditions of non-compliance identified during the validation.
j. In 2013 and beyond, CMS will consider self-identified issues that are reported to CMS per the engagement letter instructions and corrected prior to receipt of the audit engagement letter to be observations.

Attachment A

Final Program Audit Scoring Methodology

The following items are considered when scoring an audit:

1) Number of conditions[2] identified in the final audit report.
2) Remediation required for each condition.
   a) Only a condition resulting in a recommendation[3], 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. See Attachment F for a listing of audit elements.

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 tested[4]. A lower score is better than a higher score. The following is the formula for calculating the audit score:

(# CARs + # of recommendations) + (# of ICARs X 2) / # 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. See Attachment B for a listing of 2012 and 2013 audit elements.

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.

[2] 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.

[3] Recommendations only existed in 2012 audit reports.

[4] 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.

Attachment B

2012 and 2013 Audit Elements

Below is a listing of the standard audit elements of the 2012 and 2013 program audits. CMS reserves the right to expand the scope of the audit to include additional program areas and audit elements.

Program Area	Audit Element	2012 Audited Element	2013 Audited Element
Part D Formulary and Benefit Administration	Formulary Administration	X	X
	Transition	X	X
	Website Review		X
	Pharmacy & Therapeutics (P&T) committee	X	X
Part D Coverage Determinations, Appeals, and Grievances	Effectuation Timeliness	X	X
	Clinical Decision Making	X	X
	Grievances	X	X
Part C Organizational Determinations, Appeals, and Grievances	Effectuation Timeliness	X	X
	Clinical Decision Making	X	X
	Grievances	X	X
	Dismissals	X	X
	Access to Care	X	
	Grievances Misclassifications	X	
Agent/Broker	Licensure	X	
	Training/Testing	X	
	Outbound Enrollment Verification Calls (OEV)	X	X
	Complaints	X	
	Appointment	X	
Compliance	Written Policies and Procedures	X	X
	Compliance Officer, Compliance Committee, and High Level Oversight	X	X
	Effective Training and Education	X	X

Program Area	Audit Element	2012 Audited Element	2013 Audited Element
	Effective Lines of Communication	X	X
	Enforcement of Well-Publicized Disciplinary Standards	X	X
	Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks	X	X
	Procedures and Systems for Promptly Responding to Compliance Issues	X	X
	Sponsor Accountability and Oversight of FDRs	X	X
	Effectiveness Measure	X	X
Enrollment/Disenrollment	Timely Processing	X	
	Incomplete Enrollment Request	X	
	Denials	X	
	SNPs	X	
	Non-Payment of Premiums	X	
Late Enrollment Penalty (LEP)	Creditable Coverage	X	
	Timely IRE Processing	X	
	Reconciliation and Identification of LEP Discrepancies Between Sponsoring Organization and CMS Systems	X	
Special Needs Plans – Model of Care Implementation	Population to be Served – Enrollment Verification		X
	Health Risk Assessment (HRA), Interdisciplinary Care Team (ICT), Implementation of the Individualized Care Plan (ICP) and Use of Evidence-Based Clinical Guidelines		X
	Plan Performance Monitoring and Evaluation of the MOC		X
Total		34	24