Revised Civil Money Penalty Methodology: Comments and CMS' Responses

On March 15, 2019, the Centers for Medicare & Medicaid Services (CMS) released the proposed revised methodology to calculate Civil Money Penalties (CMPs) for Medicare Advantage Organizations (MAOs), Prescription Drug Plans (PDPs), Medicare Medicaid Plans (MMPs), Medicare Cost Plans, and Program of All Inclusive Care for the Elderly (PACE) Organizations beginning in 2019. CMS received 48 comments from 9 submitters. CMS thanks all commenters for reviewing the proposed methodology and has taken commenters' concerns and questions into consideration when finalizing the revised methodology. This document summarizes the comments received and CMS' responses to the comments.

1. Topic
   Release and Implementation of the Methodology

   Comments
   CMS received four comments regarding the release and implementation of the methodology. Several commenters required clarification regarding contradictory statements on whether the methodology would be applied to enforcement actions starting with referrals received in 2019 or 2020. Additionally, one commenter asked CMS to confirm that industry stakeholders will be given the opportunity to review and comment on any proposed changes.

   CMS Response
   The final version of the revised methodology has been edited to clarify that CMS intends to apply it to audits, routine monitoring, surveillance activities, or identification of significant instances of non-compliance in 2019. CMS remains committed to publishing any future proposed changes in advance of implementation and providing an opportunity for comment.

2. Topic
   Aggravating Factors: Removal of the Common Conditions Aggravating Factor

   Comments
   CMS received six comments supporting the removal of the common conditions aggravating factor.

   CMS Response
   CMS removed the aggravating factor for CMPs involving violations that are among the top conditions in the Medicare Part C and Part D Program Audit and Enforcement Report.

3. Topic
   Aggravating Factors: New Aggravating Factor

   Comments
   CMS received seven comments related to the proposed new per enrollee aggravating factor "Enrollees never received their Part C medical service or Part D medication." Commenters made several requests in response to this new factor. First, sponsors requested that CMS

define the term "never" in the new aggravating factor or clarify the time frame used to determine the enrollee never received their Part D medication. Second, sponsors asked CMS for additional information about how CMS will implement and apply the new aggravating factor and examples of when and how the factor could be applicable. Lastly, sponsors requested that CMS define the timeframe for "never" in a way that allows a sponsor to submit revised impact analyses up to the final audit report (or later) since the audit period is so short.

CMS Response

The new aggravating factor is utilized when auditors determine there is an inappropriate denial of a Part D medication or Part C medical service that the enrollee has not received up to the point when the impact analysis (IA) is submitted to CMS auditors. CMS believes there is enough time between the dates universes and IAs are provided to CMS for the sponsor to evaluate whether a Part D medication or Part C service was provided after an inappropriate denial.

Additionally, CMS gives sponsors the opportunity to submit additional information during its enforcement analysis that may mitigate the violation. For example, sponsors may supply CMS with revised IAs or additional information after further research that would indicate enrollees received the drugs or services timely or explain why an enrollee not receiving a drug or service was outside the plan sponsor's control (e.g., the plan sponsor did not ensure the drug would be available to the enrollee at the point of sale).

In light of the comments, CMS changed the factor description to: "The Sponsor did not ensure enrollees were provided access to their inappropriately denied Part C medical service or Part D medication."

4. Topic

Aggravating Factors: Untimely or Inaccurate Plan Benefit Information

Comments

CMS received five comments related to the aggravating factor for untimely or inaccurate plan benefit information. Several commenters agreed with CMS' proposal to remove the language related to the Evidence of Coverage (EOC) documents from the aggravating factor. Another commenter requested clarity regarding the removal of the EOC language from both the aggravating factor and standard penalty language and inquired if Annual Notice of Change (ANOC) documents are only an example of plan benefit information or if other plan benefit information may be subject to penalties. Finally, given that the sponsor may not be aware of when the enrollee "receives" the ANOC/errata documents, one commenter requested that CMS change the language in the aggravating factor from the enrollee did not *receive* the documents by December 31st to the sponsor did not *mail* the document by December 31st.

CMS Response

After careful consideration, CMS decided to change the language for the ANOC documents aggravating factor language from "Enrollees did not receive ANOC/errata documents by Dec. 31" to "ANOC/errata documents were not mailed by Dec. 31."

CMS will not include EOCs in the aggravating factor for ANOC/EOC plan benefit information not being mailed by December 31. Please note that removing the EOC example from the standard penalty and aggravating factor for untimely or inaccurate plan benefit information does not preclude CMS from subjecting plans to penalties for violating CMS's requirements for EOCs and other plan benefit information.

5. Topic
Aggravating Factors: Delay or Denial of Prescription Drugs Within One Day to Treat Acute Conditions or Maintain Therapeutic Treatment of Non-Acute Conditions

Comments
CMS received three comments related to the aggravating factor for the delay or denial of prescription drugs within one day. One commenter asked for clarification regarding how CMS will calculate "one day" if the 24 hour standard is not utilized. Two commenters agreed with the use of this aggravating factor and the change of the language from "24 hours" to "one day".

CMS Response
CMS changed the language from "24 hours" to "one day" to further clarify the timeframes used to determine when the aggravating factor will apply since beneficiary impact data from sponsors is provided in days and not hours. For example, if an enrollee presented at their pharmacy and received an inappropriate rejection for an anticonvulsant medication to treat their epilepsy at 5:00pm on day one, but the sponsor was able to resolve the issue and fill the drug by 7:00pm on day two (i.e., the next day), the sponsor would not be assessed an aggravating factor for this inappropriate rejection. The sponsor would only receive the standard penalty amount. However, if the drug was not provided until day three, the sponsor would receive an aggravating factor for this rejection. Therefore, in most cases, a sponsor has more than 24 hours to provide the drug to an enrollee before this aggravating factor would apply. CMS will finalize the change as proposed.

6. Topic
Other Aggravating and Mitigating Factors

Comments
CMS received four general comments related to aggravating and mitigating factors. One commenter urged CMS to only consider aggravating factors in cases where deficiencies are systemic and likely to have adversely affected beneficiaries. Another commenter asked CMS to provide examples of mitigating factors, including but not limited to when CMS' guidance or systems may have contributed to the deficiency, when analyzing cases for an enforcement action. Two commenters asked CMS to provide examples of the application of the prior offense aggravating factor, and if the Transition Monitoring Program Analysis (TMPA) and Formulary Administration Analysis (FAA) audits, which were suspended as of 2019, would be excluded from the CMP calculation.

CMS Response

CMS considers all of the facts and circumstances that led to a deficiency when determining if a CMP is warranted for the deficiency, including the type of benefit that was involved, whether CMS' guidance or systems may have contributed to the deficiency, or whether the issue was systemic. CMS applies the prior offense aggravating factor when it determines that the sponsor received the same finding in the preceding two calendar years. The finding can be cited in a previous audit report, enforcement action, or compliance action. CMS will consider violations cited in TMPA and FAA compliance notices when evaluating formulary conditions in 2019 since the related compliance notices have been issued, but will not consider them after 2020.

7. Topic

Per Determination and Per Enrollee Penalty Adjustment Approach

Comments

CMS received eight comments related to the per enrollee and per determination penalty adjustment approach. Several comments supported CMS' utilization of the cost-of-living multiplier, with updates to the standard penalty amount occurring at the start of a new audit cycle, or no more frequently than every three years. One commenter supported the memorialization of the adjustment of CMP amounts through regulation. Two commenters asked CMS to clarify if the cost-of-living multiplier would apply to either or both the per enrollee standard penalty and aggravating factor amounts. One commenter urged CMS to apply lower OMB cost-of-living multiplier factors if the increases are higher than expected, and also suggested that these factors be communicated to plans on an annual basis via the Call Letter. Finally, one commenter requested clarity on whether the standard penalty amount for the per- determination penalty that would be applicable for "all other violations" of $20,000 per violation, per contract would be increased using the same formula used to increase the per enrollee penalty adjustments.

CMS Response

CMS will finalize utilizing the cost-of-living multiplier as proposed, with updates to the standard penalty amount occurring at the start of a new audit cycle, or no more frequently than every three years beginning in 2019. The cost-of-living multiplier will apply to both the per enrollee standard penalty and aggravating factor amounts.

CMS will also finalize our proposal to memorialize the adjustment of CMP amounts through regulation, and will announce the applicable standard penalties for the upcoming contract year in the Call Letter as suggested. However, CMS does not believe limiting the annual multiplier amount is necessary. CMS will use the OMB multiplier to create a maximum amount of the adjustment, and will retain the discretion to adjust or not apply the CMP annual multiplier when appropriate.

CMS did not specify an approach for calculating increases for the per determination standard penalty and aggravating factor amounts. As suggested by the commenter, CMS will increase the $20,000 per determination and $5,000 aggravating factor penalty amounts utilizing the same formula that is used to increase the per enrollee penalty amounts.

8. Topic
   Per Enrollee Standard Penalty – Inappropriate Delay/Denial of Appeal Rights

   Comments
   CMS received two comments on the proposal to add language related to the inappropriate delay/denial of appeal rights per enrollee standard penalty language. Commenters asked CMS to define and/or provide examples of situations where access to the appeals process was either delayed or impeded.

   CMS Response
   The per enrollee standard penalty for the delay/denial of appeal rights would apply, for example, when a sponsor fails to auto-forward cases to the Independent Review Entity (IRE). In this particular example, CMS cannot assume that denials that were not auto-forwarded were necessarily inappropriate, but the beneficiaries' access to the appeals process was certainly impeded by not sending the denials to the IRE as required. If there are two distinct violations or conditions, a beneficiary can be counted for two different violations (i.e., a per enrollee penalty for the first violation and a per enrollee penalty for the second violation).

9. Topic
   Per Determination Standard Penalty– Programs of All- Inclusive Care for the Elderly (PACE)

   Comments
   CMS received three comments related to the PACE per determination standard penalty. One commenter asked CMS for clarification regarding CMS' authority for applying CMPs for PACE, specifically if CMS would also be applying penalties on a per enrollee basis. CMS received one comment supporting the clarification for the calculation of CMPs for PACE organizations. Lastly, one commenter requested that CMS consider the deficiency and size of the entity on which a CMP is assessed instead of applying the maximum penalty permissible when calculating the per determination penalty for PACE organizations.

   CMS Response
   The regulation at 42 C.F.R. § 460.46 allows CMS to issue per determination CMPs to Medicare PACE organizations but does not permit CMS to issue per-enrollee CMPs. However, the regulation gives CMS the authority to apply a CMP amount that is less than the maximum amount permitted, and CMS will continue applying that flexibility when determining the appropriate penalty amount for a PACE violation

10. Topic
    CMPs for Invalid Data Submissions (IDS)

    Comments
    CMS received two comments about penalties related to IDS. One commenter asked CMS to clarify how CMS intends to determine if an IDS condition had adversely affected enrollees. Another commenter asked CMS if the IDS condition would continue to be related

specifically to universe submissions under program audits, or if it would also be applicable in other instances due to the proposed revision removing the reference to enrollee universes.

CMS Response
Sponsors must provide accurate and complete records and documents (which include enrollee universes) to demonstrate compliance with CMS rules. Additionally, sponsors have a duty to track and maintain certain data to ensure compliance with CMS' requirements. When sponsors are unable to track and maintain data to demonstrate compliant operations, enrollees are at risk of experiencing lapses in coverage, delays in access to care, and/or financial hardship. Therefore, CMS will continue to consider this penalty for IDS violations in both audit and non-audit settings when such violation demonstrates a plan sponsor's inability to ensure compliance with program requirements that may adversely affect beneficiaries.

11. Topic
General Questions about the Methodology

Comments
CMS received four comments about various CMP-related topics. A commenter asked CMS to simplify audit and CMP methodology definitions. One commenter asked CMS to afford sponsors an opportunity to formally present and explain the IA, its contents, and the methodology used to create it. Another commenter welcomed the clarification on the scope of the methodology to include PACE, MMP, and Medicare Cost Plans. Finally, one commenter supported eliminating language that suggested enrollees could be considered physically adversely affected by receiving formulary alternatives.

CMS Response
CMS recognizes the complexities involved in its audit and enforcement programs and strives to promote transparency and simplicity. To that end, CMS releases any proposed updates to the audit protocol and other supporting data collection instruments for comment, and annually releases the Program Audit Process Overview document to provide stakeholders with information about what to expect during a program audit. Additionally, CMS indicated that it will continue to publish its CMP calculation methodology for comment when updates are needed, and will periodically hold conferences and trainings to educate industry partners on Parts C and D program policies and audits.

With respect to IA, CMS may conduct an IA validation to assess whether the IA(s) submitted is reasonable and complete, and will provide sponsors an opportunity to provide CMS with a virtual walkthrough of the IAs for all conditions that move forward for enforcement analysis.

CMS calculates CMPs for MMPs the same as MAOs and PDPs because the bases for issuing CMPs are the same, as provided in the MMP contracts and 42 C.F.R. §417.500, respectively.

CMS will remove the language suggesting enrollees could be considered physically and/or adversely affected by receiving formulary alternatives.