Civil Money Penalty Methodology: Comments and CMS' Responses

On September 13, 2016, the Centers for Medicare & Medicaid Services (CMS) released the proposed methodology to calculate Civil Money Penalties (CMPs) for Medicare Advantage Organizations (MAOs) and Prescription Drug Plans (PDPs) in 2017. CMS received 94 comments from 19 submitters in response, and made a number of changes to the methodology to address the commenters' concerns and questions. This document summarizes the comments received and CMS' responses to the comments.

1. Topic
   Civil Money Penalty Limits

   Comments
   CMS received 13 comments on the proposal to limit the maximum penalty amount a sponsor can receive for each deficiency in a CMP. The commenters' primary concern is the proposed limits have a much greater financial impact on sponsors with a smaller enrollment compared to the impact on sponsors with a larger enrollment. Commenters proposed a number of options to address the disparate impact on smaller sponsors, including adding enrollment bands and lowering the limits for small sponsors, basing the limits on the number of affected enrollees as a percentage of total enrollment, and considering Part C and Part D enrollment separately.

   CMS Response
   As noted in the proposed methodology, CMS applies the penalty limits in order to ensure that CMPs are not excessive when a large portion of a sponsor's enrollment is affected by a deficiency. The limits are very rarely reached in practice, but we agree that the limits should be revised to better address the impact on small sponsors. CMS, therefore, revised the limits by creating seven enrollment bands for sponsors that have less than 500,000 enrollees instead of the two enrollment bands that were proposed. CMS also lowered the maximum penalty amounts that apply to sponsors with less than 250,000 enrollees.

2. Topic
   Mitigating Factors

   Comments
   CMS received 14 comments about the mitigating factors that CMS applies to decrease penalty amounts. Commenters asked CMS to consider additional mitigating factors for per-enrollee penalties (e.g., when CMS guidance is not clear), and suggested adding mitigating factors for per-determination penalties. Commenters also suggested increasing the value of mitigating factors so that they are equal to the aggravating factor penalty amounts.

CMS Response

CMS evaluated these comments in concert with commenters' suggestions to consider all of the facts and circumstances that led to a deficiency when determining if a CMP is warranted for the deficiency. After careful consideration, CMS decided that the "received drugs the same day as the inappropriate denial," and "missed the adjudication timeframe by 24 hours or less" mitigating factors should be considered when determining if a CMP should be imposed for a deficiency rather than as factors that lower the penalty amount for a deficiency. CMS is, therefore, eliminating these mitigating factors from the CMP methodology.

3. Topic

Application of Adverse Impact Standards

Comments

CMS received 11 comments related to CMS' determination that an enrollee was either adversely affected or substantially likely to have been adversely affected by a deficiency. Commenters asked CMS to define and/or provide more examples of situations that result in a "substantial likelihood of adversely affecting" enrollees. Commenters also urged CMS to consider all of the facts and circumstances that led to a deficiency when determining if a CMP is warranted for the deficiency, including whether actual harm occurred, the type of benefit that was involved, and if CMS contributed to the deficiency (e.g., by unclear guidance).

CMS Response

CMS relies on the data that are available at the time of the audit to determine if a sponsor's deficiency either adversely affected, or had the substantial likelihood of adversely affecting an enrollee. A sponsor's deficiency could adversely affect an enrollee physically (e.g., adverse effects as a result of not receiving a medication, experiencing delayed access to a medication, or receiving a formulary alternative) or financially (e.g., by diverting financial resources to pay for improperly denied benefits in order to receive them timely). CMS applies the "adversely affected" and "substantial likelihood of adversely affecting" standards independently. CMS may issue a CMP under the adversely affected standard when it determines that an enrollee was actually adversely affected by the deficiency. Under the substantial likelihood standard, CMS may issue a CMP when it determines that a sponsor's deficiency had the potential to adversely affect an enrollee when the deficiency occurred, even when a sponsor may be able to subsequently show, for example, evidence of a paid claim for the enrollee. Because CMS carefully and independently evaluates the facts and circumstances of each deficiency to determine if either the adversely affected or substantial likelihood of adversely affecting standard was met when the deficiency occurred, we do not believe providing examples of situations that may lead to either situation is particularly useful. Therefore, we removed the examples from the methodology.

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 and

whether CMS' guidance or systems may have contributed to the deficiency. Sponsors should submit evidence that potentially mitigates a deficiency to the CMS component that detected the deficiency. For example, if a deficiency was detected during a CMS program audit, the sponsor should submit the mitigating evidence to CMS in response to the Draft Audit Report. CMS auditors will consider the information and may rely on it to justify removing the condition from the Report. If the deficiency is included in the Final Audit Report, CMS will consider the sponsor's responses to the Draft Audit Report when determining whether the deficiency warrants a CMP or other enforcement action.

4. Topic
CMP Calculations

Comments
CMS received 16 comments on CMS' application of the per-enrollee and per-determination calculations. In particular, commenters asked CMS to explain how CMS decides to apply the per-enrollee or per-determination methodology when calculating a CMP for a condition, and how the beneficiary Impact Analysis (IA) is used for CMP purposes.

CMS Response
CMS calculates the CMP amount for a condition on a per-enrollee basis when the sponsor has provided CMS with an enrollee universe or IA for the condition. The penalty and any aggravating factors are applied only to affected enrollees identified in the universe or IA provided by the sponsor. CMS does not extrapolate the deficiency to all of a sponsor's enrollees. If CMS does not have the enrollee-specific data, it calculates the penalty under the per-determination methodology.

5. Topic
Opportunity to Review a CMP

Comments
Four commenters asked CMS to provide sponsors with an opportunity to review a CMP calculation before it is finalized and raise questions, especially when CMS is considering the application of aggravating and/or mitigating factors to the standard penalty amount.

CMS Response
CMS issues CMPs to sponsors based on referrals from other components within CMS. A referring component typically only makes the referral after discussing the related deficiency with the sponsor, providing the sponsor with an opportunity to respond, and documenting the sponsor's responses. For example, if a deficiency was detected during a routine CMS program audit, the sponsor has the opportunity to submit a response to the Draft Audit Report and provide any information that may explain or mitigate a deficiency. CMS auditors will consider the information and may rely on it to justify removing the condition from the Report. If the deficiency is included in the Final Audit Report, CMS will also consider the

sponsor's responses to the Draft Audit Report when determining whether the deficiency warrants a CMP or other enforcement action. Sponsors should therefore use that opportunity to raise issues and present information to CMS when the sponsors believe it is relevant to CMS' evaluation of a deficiency for CMP purposes. CMS will continue to make itself available to answer questions about the specifics of a CMP after it is issued, and a sponsor may appeal a CMP if the sponsor does not agree with CMS' reasons for imposing it.

6. Topic

Release and Implementation of Methodology

Comments

CMS received six comments about the release and implementation of CMS' CMP methodologies. The commenters asked CMS to release all of the methodologies that CMS uses to calculate CMPs (not just the methodology used to calculate CMPs for program audits), annually publish the CMP methodology for comment, and implement each methodology at the beginning of an audit cycle.

CMS Response

As discussed in the proposed CMP methodology, CMS has a broad statutory and regulatory authority to issue CMPs. CMS is not required to develop or make public any methodology it uses to calculate CMPs, nor do the statue or regulation limit CMS' ability to modify any methodology it develops. Despite having that broad authority, CMS developed and implemented the methodology used to calculate CMPs related to deficiencies identified during CMS program audits because we routinely issue audit-related CMPs and believe a methodology helps to ensure the consistency and fairness of audit-related CMPs. CMS reserves the right to issue other types of CMPs without publishing other methodologies in advance of the issuance. However, if CMS determines that it routinely issues CMPs for other types of deficiencies, it may develop and release additional methodologies to ensure the consistency and fairness of those CMPs.

CMS proposed to apply the CMP methodology to the 2017 program audits. However, because CMS does not expect the audit-related CMP methodology to change from year-to-year, CMS removed all references to 2017 and will apply the methodology to the 2017 program audits and program audits occurring in years after 2017 so long as CMS does not revise the methodology. If CMS revises the methodology, it will publish the proposed changes in advance of implementation and provide an opportunity for comment. Once a revised methodology is finalized, CMS will apply it to program audits that occur in the program year following publication.

7. Topic
Aggravating Factors: Use of Common Findings

Comments
CMS received six comments on its reliance of the Best Practices and Common Conditions memorandum as an aggravating factor. One commenter asked CMS to reconsider applying the common conditions because the commenter believed the list of common conditions is not binding guidance. Commenters also asked CMS to clarify which document published by CMS will contain the list of common findings, and to which audit year the memorandum will apply.

CMS Response
The common conditions are comprised of the most commonly violated program requirements by the cohort of sponsors from a given audit year. The violated requirements are rooted in statute, regulation, and CMS guidance. CMS believes that adding aggravating penalty amounts for the common deficiencies is necessary to further encourage compliance in these areas, but has lowered the "common condition" aggravating penalty amount from $150 to $100 per-enrollee so that it is consistent with the other per-enrollee aggravating factor penalty amounts. CMS also recognizes the need to provide sponsors with sufficient time to implement processes to detect and prevent the common conditions published by CMS. Therefore, CMS will apply the common conditions that were published by CMS two years before the program year being audited. For example, for the 2017 program audits, CMS will apply the common conditions that were announced in the 2015 Annual Report that was published by CMS in August 2015. CMS anticipates that it will continue publishing the common conditions in the Annual Report.

8. Topic
Aggravating Factors

Comments
CMS received five comments about the aggravating factors that CMS applies to increase penalty amounts. Commenters asked CMS to identify the drugs that require access within 24 hours to either treat acute conditions or maintain the therapeutic treatment of non-acute conditions. Commenters also asked CMS how far back it looks to determine if a sponsor was previously cited for an offense, if more than one aggravating factor can apply to a penalty, and if the out-of-pocket expense aggravating factor applies on a claim-by-claim basis or is cumulative over a plan year.

CMS Response
CMS does not maintain a list of the drugs that could require access within 24 hours to either treat acute conditions or maintain the therapeutic treatment of non-acute conditions because the drugs that may meet that criteria change over time. CMS carefully considers each drug

associated with a deficiency and determines if the drug would have met the criteria when the deficiency occurred.

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 or compliance action. CMS updated the methodology to make that point clear.

CMS may apply multiple aggravating factors to a single audit condition.

CMS applies the out-of-pocket expense aggravating factor when the out-of-pocket expense for an enrollee's individual claim exceeds the $100 threshold. The $100 threshold is not calculated on a cumulative basis for an affected enrollee who has multiple claims.

CMS identified two aggravating factors under the per-determination methodology that rely on enrollee-specific data to calculate and impose them. Because CMS does not have enrollee-specific data to rely on under the per-determination penalty methodology, these two aggravating factors cannot be calculated and have been removed from the per-determination methodology. CMS will only apply an aggravating factor under the per-determination methodology when the sponsor was previously cited for the deficiency, or the violation is one of the top common conditions cited in the Annual Report.

9. Topic
CMPs for Invalid Data Submissions (IDS)

Comments
CMS received five comments about penalties related to IDS. The commenters asked CMS to clarify the conditions under which a sponsor would receive a CMP for an IDS finding and the authority that CMS relies on to issue a CMP for an IDS condition.

CMS Response
CMS calculates IDS-related CMPs under the per-determination methodology because the number of affected enrollees cannot be established. CMS issues an IDS-related CMP when a sponsor is not able to create and submit to CMS requested data after three unsuccessful attempts to do so. The per-determination penalty amount will be multiplied by the number of audited contracts. For example, if CMS audits three of a sponsor's contracts and the sponsor receives an IDS condition, the CMP amount for the condition would equal the standard penalty amount multiplied by three.

CMS' authority to issue CMPs to sponsors for the IDS condition is derived from the regulations. Sponsors are required to maintain certain records and documents and submit them to CMS, if requested, in order for CMS to audit and inspect the quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract

(see 42 C.F.R. §§ 422.504(d), (e), and (f)(2)(v), and 423.505(d), (e), and (f)(2)(v)). A sponsor that substantially fails to provide accurate and complete universes violates these requirements and has met the standard for an enforcement action (see 42 C.F.R. §§ 422.510(a)(1) and 423.509(a)(1)). If a sponsor cannot produce accurate universes, CMS is unable to evaluate its operations and the failure may indicate that the sponsor is not adequately conducting its own internal monitoring of operations and enrollees are not receiving the benefits they are entitled to receive in accordance with CMS' rules.

10. Topic
General Questions about the Methodology

Comments
CMS received two general questions and one comment about various CMP-related topics. Commenters asked CMS to clarify which audit areas rely on enrollee universes and how CMS uses the money it collects from CMPs. One commenter recommended that CMS issue CMPs within 180 days of determining that a deficiency exists so that sponsors will quickly resolve identified issues and enrollees receive timely information about sponsors' performance.

CMS Response
CMS relies on enrollee universes when auditing the following program areas: Formulary Administration; Part C Organization Determinations, Appeals, and Grievances; and Part D Coverage Determinations, Appeals, and Grievances.

The funds collected from CMPs are deposited in the Medicare Trust Fund.

CMS posts the all of the CMP notices related to a given program audit year in late February following the program year being audited. For example, in late February 2017, CMS will post all of the CMPs that resulted from the 2016 program audits. Posting the notices in this manner allows beneficiaries to better compare the performance of all audited sponsors. If CMS published the CMP notices as they are issued, beneficiaries may mistakenly conclude that a sponsor who received a CMP early in a year may be performing worse than a sponsor that will be audited later in the same year. Sponsors begin resolving deficiencies as soon as they are discovered by the auditors.

11. Topic
Outside the Scope Comments

Comments
CMS received 11 comments that were outside the scope of the CMP methodology. Some commenters asked CMS to provide more information about the compliance continuum and the impact of CMPs on Star Ratings. Other commenters asked CMS to publish any

compliance trends it notices during program audits and provide more information about the types of deficiencies that have led to enforcement actions.

CMS Response

The commenters' requests are outside the scope of the CMP methodology. However, we referred the Star Ratings and compliance continuum requests to the appropriate CMS staff for consideration. We also note that CMS annually publishes the Part C and Part D Program Audit and Enforcement Report, which provides information about the industry's compliance performance and related enforcement actions (see https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html).