Civil Money Penalty Methodology

Medicare Parts C and D Oversight and Enforcement Group
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Civil Money Penalty Methodology

I. Introduction

On September 13, 2016, the Centers for Medicare & Medicaid Services (CMS) released its proposed methodology for calculating Civil Money Penalties (CMPs) for Medicare Advantage Organizations (MAOs) and Prescription Drug Plans (PDPs) (hereinafter referred to as "sponsors") in 2017. CMS received a number of comments in response, considered all of the comments carefully, and made a number of changes to the methodology to address the commenters' concerns and questions. The methodology discussed in this document is the approach that CMS will use to calculate CMPs beginning in Contract Year (CY) 2017.[1] CMS intends to apply this methodology to CMPs issued in CY 2018 and beyond, so long as CMS does not modify the methodology. If CMS revises the methodology, it will publish any proposed changes in advance of implementation and provide an opportunity for comment. Once a revised methodology is finalized, CMS will apply it to audits that occur in the contract year following publication. The methodology described in this document does not limit CMS' authority to impose any penalty that is permissible under the law.

II. Background

The Medicare Parts C and D Oversight and Enforcement Group (MOEG) evaluates referrals for potential enforcement actions, determines if enforcement actions are warranted, and imposes enforcement actions against sponsors when necessary. As discussed in the Authority section below, CMS' enforcement actions include issuing CMPs, imposing intermediate sanctions (suspension of marketing, enrollment, and/or payment), or terminating contracts.

In CY 2015, 80% of the enforcement actions imposed were CMPs.[2] In addition, 60% of the referrals resulted from Parts C and D program audits conducted by MOEG. Therefore, the methodology discussed in this document will primarily be used to calculate CMPs for deficiencies that are detected during routine program audits. CMS may determine that a different methodology should be used to calculate a recommended CMP for a deficiency that was not detected during a program audit. When a different methodology is applied, CMS will follow the principles outlined in this document as much as practicable.

The methodology used to calculate CMPs has evolved over time. Prior to 2014, the amount of a CMP varied based on a number of factors, including the severity of the deficiency, the extent to which the deficiency was systemic, and the enrollment of the sponsor. CMS implemented a pilot in 2014 that standardized the calculation of CMPs. Under the pilot, CMPs were calculated by applying standard penalty amounts as well as aggravating and mitigating factors that increased or decreased the overall penalty amount.[3] CMS also began calculating CMPs on a "per enrollee" or

[1] CMS will begin applying this methodology to CMPs issued during or after 2017 for non-compliance that occurred during CY 2017, and will apply it to future CY program audits so long as the methodology is not revised by CMS.
[2] See the 2015 Part C and Part D Program Audit and Enforcement Report located here: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html
[3] An aggravating factor is added to the standard penalty when, for example, a sponsor has received the same condition before.

"per determination" basis under the pilot.[4] CMS has continued to use the methodology developed under the pilot to calculate CMPs. The primary differences between the pilot methodology and the methodology discussed in this document are the slight increases in penalty amounts over time in order to encourage better compliance with CMS' rules, and an enrollment-based limit on the maximum CMP amount a sponsor can receive for each deficiency.

III. Authority to Issue CMPs

CMS' ability to issue CMPs derives from its authority to either terminate sponsors under 42 C.F.R §§ 422.510 and 423.509, or sanction sponsors under §§ 422.750, 422.752, 423.750, and 423.752. In lieu of, or in addition to, terminating a contract or issuing sanctions, CMPs can be imposed under §§ 422.752(b) and (c), and 423.752(b) and (c). Because CMPs have been historically issued under termination authority, the CMP methodology discussed in this document relates to that authority.

Pursuant to §§ 422.752(c) and 423.752(c), a CMP can be imposed on a sponsor for any of the criteria under the termination authority in §§ 422.510(a)(1)-(3), and 423.509(a)(1)-(3). The criteria include the sponsor:

1. Failed to substantially carry out the contract;
2. Is carrying out the contract in a manner inconsistent with the efficient and effective administration of 42 C.F.R. parts 422 or 423; or
3. Is no longer substantially meeting the applicable conditions of 42 C.F.R parts 422 or 423.

CMS may determine that one of the three criteria has been met when, for example, a sponsor substantially failed to comply with the requirements of subparts M or V of 42 C.F.R. parts 422 or 423 (see §§ 422.510(a)(4)(ii)-(xii) and 423.509(a)(4)(ii)-(xi) for a complete list of the reasons that may lead to a determination that one of the three criteria above has been met). Once a determination has been made that a sponsor's deficiency meets the requirements for a CMP, the penalty amount is calculated.

IV. Calculation of the CMP Amount

CMS will calculate the CMP amount for each deficiency by applying a standard formula. Under the standard formula, CMS will apply a standard penalty amount (based on whether the deficiency should be calculated on a per enrollee or per determination basis) to the deficiency, and will adjust it for any factors that contributed to the deficiency (i.e., aggravating factors). If a penalty for a deficiency is calculated on a per enrollee basis, the penalty amount will be multiplied by the number of affected enrollees. If the penalty for a deficiency is calculated on a per determination basis, the penalty amount will be multiplied by the number of affected contracts. The total penalty amount will be limited for each deficiency if the sponsor's enrollment exceeds specific thresholds. Each of these concepts are discussed more thoroughly below.

[4] CMS utilizes the per enrollee basis when CMS is able to determine the number of affected enrollees.

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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 by CMS during a routine 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 Final 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.

A. Per Enrollee or Per Determination

Pursuant to §§ 422.760(b)(1) and (2) and 423.760(b)(1) and (2), CMS determines if the penalty for a deficiency should be calculated on a per enrollee or per determination basis. Per enrollee deficiencies have a quantifiable number of enrollees that have been adversely affected (or have the substantial likelihood of being adversely affected), while per determination deficiencies do not have a quantifiable number of enrollees adversely affected. CMS will calculate the CMP amount for a condition on a per enrollee basis when the sponsor has provided CMS with an enrollee universe or Impact Analysis (IA) for the condition. The penalty and any aggravating factors will be applied only to affected enrollees identified in the universe or IA provided by the sponsor. If CMS does not have the enrollee-specific data, it will calculate the penalty under the per determination methodology. Under the per determination methodology, a penalty may be imposed for each deficiency, and the penalties will be imposed at the contract level (i.e., sponsors with multiple contracts may receive per determination penalties for each contract affected by a given deficiency).

B. Beneficiary Impact

If CMS determines that at least one beneficiary was adversely affected (i.e., directly adversely affected or substantially likely to have been adversely affected) by a sponsor's deficiency, a CMP can be issued under the termination authority.

CMS will rely on the data that are available at the time of the audit to determine if a sponsor's deficiency either directly 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 will apply the "adversely affected" and "substantial likelihood of adversely affecting" standards judicially. CMS will issue a CMP under the adversely affected standard when it determines that an enrollee was directly adversely affected by a sponsor's deficiency. CMS also has the authority to determine that a sponsor's deficiency had the potential to adversely affect an enrollee even when a sponsor may be able to subsequently show, for example, evidence of a paid claim for the enrollee because the sponsor's violation could have adversely affected the enrollee.

C. Amount of the CMP

Under §§ 422.760(b)(1) and (2) and 423.760(b)(1) and (2), CMS has the authority to issue a CMP up to the maximum amount permitted under regulation, as adjusted annually,[5] for each affected enrollee or per determination. However, CMS does not apply the maximum penalty amount in all instances because it believes the penalty amounts under the current methodology are sufficient to encourage compliance with CMS' rules. As more sponsors improve their performance, the CMP methodology may be revised to encourage any non-compliant sponsors to improve their performance. The methodology may be adjusted by increasing or decreasing the penalty amounts, and/or basing the penalties on data that are accessible to sponsors (e.g., payment data). When these types of adjustments are proposed, CMS will publish them in advance of implementation and provide an opportunity to comment.

The specific penalty amounts applied by CMS are discussed below.

1. Standard Penalty Amounts

The standard penalty amount is based on the calculation type that is applied (i.e., per enrollee or per determination) and the type of adverse impact that occurred.

Per Enrollee Penalties

- Inappropriate delay/denial of Part C medical services or Part D drugs: $200 per enrollee
- Incorrect premiums charged or unnecessary costs incurred: $200 per enrollee
- Inaccurate or untimely plan benefit information (e.g., ANOC and/or EOC documents) provided: $25 per enrollee

Per Determination Penalties

- Invalid data submission (i.e., failure to develop and/or provide valid enrollee universes): CMS will apply the maximum amount permitted under regulation, as adjusted annually,[6] per violation/per contract
- All other violations: $20,000 per violation/per contract

2. Aggravating Penalty Amounts

Once CMS has calculated the standard penalty amount, it will apply any aggravating factors to it. Aggravating factors will increase the standard penalty amount.

[5] Per the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which amended the Federal Civil Penalties Inflation Adjustment Act of 1990, the maximum monetary penalty amount applicable to 42 C.F.R. §§ 422.760(b) and 423.760(b) will be published annually in 45 C.F.R. part 102.
[6] See footnote 5.

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a. Per Enrollee Aggravating Factors

Inappropriate delay/denial of Part C medical services or Part D drugs

- Delay/denial of drugs that generally require access to prescription drugs within 24 hours in order to either treat acute conditions or maintain the therapeutic treatment of non-acute conditions:[7] $100
- Prior offense:[8] $100 (one prior offense) or $1,000 (two or more prior offenses)
- Missed adjudication time requirement for expedited coverage decisions: $100
- Violation was among the top common conditions listed in the annual Part C and D Program and Enforcement Report (Annual Audit Report):[9] $100

Incorrect premiums charged or unnecessary costs incurred

- Incurred inappropriate out-of-pocket expenses exceeding $100: $100
- Prior offense: $100 (one prior offense) or $1,000 (two or more prior offenses)
- Violation was among the top common conditions listed in the Annual Audit Report:[10] $100

Untimely or inaccurate plan benefit information provided:

- Prior Offense: $15 for each prior offense
- For Annual Notice of Change/Evidence of Coverage (ANOC/EOC) documents: Enrollees did not receive ANOC/EOC/errata documents by Dec. 31: $15

b. Per Determination Aggravating Factors[11]

- Prior offense: $5,000
- Violation was among the top common conditions in the Annual Audit Report:[12] $5,000

[7] CMS will carefully review each drug listed in sponsors' impact analyses to determine if it would have met the aggravating factor criteria when the deficiency occurred.

[8] CMS will apply 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 compliance notice, audit report, or other enforcement action.

[9] CMS will apply the common conditions that were published by CMS in the Annual Report two years before the contract year being audited. For example, for the 2017 program audits, CMS will apply the common conditions contained in the 2015 Annual Report that was published by CMS in August 2015. Annual Reports can be found here: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html.

[10] See footnote 9.

[11] The penalty amounts will be adjusted to align with Section 4(b) of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act). See footnote 5.

[12] See footnote 9.

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3. CMP Calculation Formulas

CMPs will be calculated using the following formulas:

- Per Enrollee:

Standard Penalty X *Number of Enrollees*
+
Aggravating factor(s) X *Number of Enrollees*
Total Penalty for the Violation

- Per Determination:

Standard Penalty X *Number of Contracts*[13]
+
Aggravating factor(s) X *Number of Contracts*
Total Penalty for the Violation

4. Maximum Penalty Amount

a. Enrollment-Based Limit

The CMP amount for each violation is restricted by the application of enrollment-based limits. The following limits apply to per enrollee and per determination penalties:

Enrollment of Parent Organization	CMP Violation Limit	Percent of Enrollment	Percent of Sponsors
Below 1,000	$50,000	0.02%	14%
1,000-4,999	$100,000	0.2%	15%
5,000-19,999	$200,000	1%	27%
20,000-49,999	$300,000	2%	16%
50,000-99,999	$400,000	3%	10%
100,000-249,999	$500,000	7%	10%
250,000-499,999	$1,000,000	6%	3%
500,000-2,999,999	$1,500,000	19%	3%
3,000,000 or more	$2,000,000	61%	2%

b. Per Determination Limit

Pursuant to §§ 422.760(b)(1) and (2) and 423.760(b)(1) and (2), as adjusted annually under 45 C.F.R. part 102,[14] CMS will apply the maximum penalty permissible when calculating a per determination penalty for a single deficiency and will apply that amount to all of a sponsor's contracts that are affected by the deficiency. For example, in 2017, the maximum penalty amount that CMS will be permitted to apply under statute and regulation is $36,794 per determination. If CMS determines that the deficiency is applicable to 10 of a sponsor's contracts, the maximum CMP that can be imposed for the determination in 2017 is $367,940.

[13] The total number of contracts that were impacted by the deficiency.
[14] See footnote 5

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Appendix

Examples of CMP Calculations for a Sponsor with 300,000 Enrollees

Example 1: CMP Calculated on a Per-Enrollee Basis

- ***Standard Penalty***
  - Inappropriate delay/denial of Part D drugs/ Part C services: $200
  - Number of affected enrollees: 2,500
  - Standard penalty subtotal**: $500,000**

- ***Aggravating Factor #1***
  - Violation was among the top conditions in the Annual Audit Report: $100
  - Number of affected enrollees: 2,500
  - Penalty adjustment**: $250,000**

- ***Aggravating Factor #2***
  - Delay/denial of Part D drugs that generally require access to prescription drugs within 24 hours in order to either treat acute conditions or maintain the therapeutic treatment of non-acute conditions: $100
  - Number of affected enrollees: 500
  - Penalty adjustment: **$50,000**

- ***Total CMP Amount: $800,000 ($500,000 + $250,000 + $50,000)***

Example 2: CMP Calculated on a Per-Enrollee Basis and Application of the Enrollment-Based Limit

- ***Standard Penalty***
  - Inappropriate delay/denial of Part C medical services or Part D drugs: $200
  - Number of affected enrollees: 6,000
  - Standard penalty subtotal: **$1,200,000**

- ***Aggravating Factor #1***
  - Violation was among the top conditions in the Annual Audit Report: $100
  - Number of affected enrollees: 6,000
  - Penalty adjustment: **$600,000**

- ***Aggravating Factor #2***
  - Delay/denial of Part D drugs that generally require access to prescription drugs within 24 hours in order to either treat acute conditions or maintain the therapeutic treatment of non-acute conditions: $100
  - Number of affected enrollees: 1,580
  - Penalty adjustment: **$158,000**

- ***Penalty exceeds enrollment-based penalty maximum***
  - Penalty adjustment: **($958,000)**

- ***Total CMP Amount: $1,000,000 ($1,200,000 + $600,000 + $158,000 - $958,000)***

Example 3: CMP Calculated on a Per-Determination Basis

- ***Standard Penalty***
  - Sponsor failed to provide complete, accurate and/or timely audit universes as requested by CMS[15]: $36,794
  - Number of affected contracts: 15
  - Standard penalty subtotal**: $551,910**

- ***Total CMP Amount:*** **$551,910**

[15] This is the maximum per determination penalty amount that CMS can apply in 2017 under the statute and regulations.