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

MEDICARE PARTS C AND D OVERSIGHT AND ENFORCEMENT GROUP

DATE: September 13, 2016

TO: All Medicare Advantage Organizations and Prescription Drug Plan Sponsors

FROM: Gerard J. Mulcahy
Director, Medicare Parts C and D Oversight and Enforcement Group

SUBJECT: Release of the Proposed 2017 Civil Money Penalty Methodology for Comment

Plan sponsors and other Medicare stakeholders have asked the Centers for Medicare & Medicaid Services (CMS) to publish the methodology used to calculate a Civil Money Penalty (CMP) when CMS determines that a CMP is the appropriate enforcement action that should be taken against a sponsor to address identified deficiencies. In the 2017 Call Letter, CMS agreed to publish the CMP methodology and give the public an opportunity to comment before implementing the methodology on January 1, 2017. CMS is therefore releasing the proposed methodology for calculating CMPs for Plan Year (PY) 2017 and providing interested parties with the opportunity to comment before implementation. The proposed methodology is attached to this notice, and can also be downloaded from the "Downloads" section of the following CMS webpage: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDEnforcementActions-.html

If you wish to comment on the 2017 CMP methodology, please submit your comments to the following email address: part_c_part_d_audit@cms.hhs.gov. Please include "2017 CMP Methodology Comments" in the subject line. **Comments must be received by 5PM ET on October 13, 2016.**

Proposed Civil Money Penalty Methodology

2017

Proposed 2017 Civil Money Penalty Methodology

I. Introduction

The methodology discussed in this document is the approach that the Centers for Medicare & Medicaid Services (CMS) proposes to use to calculate Civil Money Penalties (CMPs) for Medicare Advantage Organizations (MAO), Prescription Drug Plans (PDP), Cost plans, and PACE plans (hereinafter referred to as "sponsor") in Plan Year (PY)[1] 2017. A number of sponsors and industry groups asked CMS to provide more information on the approach used to determine CMP amounts and how deficiencies are factored into CMPs. CMS is not required under statute or regulation to establish a CMP methodology or make one public prior to implementation. However, in an effort to increase transparency and emphasize the need for sponsors to develop and maintain compliant Medicare operations, in the 2017 Call Letter, CMS announced its intent to provide the industry with an opportunity to comment on the methodology used to calculate CMPs. CMS is therefore publishing the proposed PY 2017 CMP methodology and soliciting comments. 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) reviews 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 PY 2015, 80% of the enforcement actions 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 is primarily used to calculate recommended 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 wasn't 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 size 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

[1] This methodology will be applied to CMPs issued during or after 2017 for non-compliance that occurred during PY 2017.

[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/Downloads/Part_C_and_Part-_D_Program_Audit_Annual_Reports.zip

decreased the overall penalty amount.[3] CMS also began calculating CMPs on a "per enrollee" or "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 increase 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 determinations under the termination authority in §§ 422.510(a)(1)-(3), and 423.509(a)(1)-(3). The reasons 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 this part; or
3. Is no longer substantially meeting the applicable conditions of 42 C.F.R parts 422 or 423.

One of the three criteria above has been met if the sponsor, for example, 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 is made that a sponsor's deficiency meets the requirements for a CMP, the penalty amount is calculated.

IV. Calculation of CMP Amount

CMS calculates the CMP amount for each deficiency by applying a standard formula. Under the standard formula, CMS applies a standard penalty amount (based on whether the deficiency should be calculated on a per enrollee or per determination basis) to the deficiency, and adjusts it for any factors that either contributed to the harm (i.e., aggravating factors) or mitigated the harm (i.e., mitigating factors). If a penalty for a deficiency is calculated on a per enrollee basis, the penalty amount is multiplied by the number of affected enrollees. If the penalty for a deficiency is calculated on a per determination basis, the penalty amount is multiplied by the number of affected contracts. The total penalty amount is limited for each deficiency if the sponsor's

[3] An aggravating factor is added to the standard penalty when, for example, a sponsor has received the same condition before. A mitigating factor is subtracted from the standard penalty when, for example, a sponsor provides a coverage determination decision to an enrollee within 24 hours after missing the deadline.

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

enrollment exceeds specific thresholds. Each of these concepts are discussed more thoroughly below.

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. Under the per determination methodology, a penalty may be imposed for each deficiency, and the penalties are 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 Harm

If CMS determines that at least one beneficiary was either directly adversely affected (i.e., actual beneficiary harm), or had the substantial likelihood of being adversely affected (i.e., substantial likelihood of beneficiary harm) by a sponsor's deficiency, a CMP can be issued under the termination authority.

Example of Actual Beneficiary Harm: A sponsor fails to provide an appropriate transition process for new enrollees who are prescribed non-formulary Part D drugs that represent ongoing therapy. The enrollees who received the inappropriate denials at the point-of-sale are harmed by not receiving the medications timely, never receiving the medications, or paying increased costs in order to receive the medications at the point-of-sale.

Example of Substantial Likelihood of Harm: A sponsor fails to approve exception requests for the remainder of the plan year as required under § 423.578(c)(3) and (4)(i). The affected enrollees are substantially likely to have been harmed by the delays associated with having to file additional exception requests for medications that were previously approved in the same plan year, switching to alternative medications that may not be as effective as the previously approved medications, or choosing to not re-file the requests and suffering adverse effects of not receiving the medications because the exception process is burdensome.

In general, the types of deficiencies that result in enrollee harm and are likely to merit a CMP include, but are not limited to:

- Inappropriate delay or denial of access to Part C medical services or Part D prescription drugs. These violations are often detected when monitoring and auditing sponsors in the formulary and benefit administration; Part C organization determinations, appeals, grievances (ODAG); and Part D coverage determinations, appeals, grievances (CDAG) program areas.
- Incorrect premiums charged or unnecessary costs incurred by enrollees. These violations occur when a sponsor, for example, does not identify Low Income Subsidy beneficiaries, enrolls beneficiaries in incorrect plans, or improperly processes an enrollee's formulary exception request and the enrollee pays out-of-pocket for the medication.

- Invalid data submission. These violations occur, for example, when a sponsor is not able to provide auditors with enrollee universes in the formulary and benefit administration, Part C ODAG, or Part D CDAG program areas, or provides auditors with inaccurate or incomplete enrollee universes. CMS calculates CMPs for this deficiency on a per determination basis.

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 $25,000[5] for each affected enrollee or determination if the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more enrollees. However, significantly lower penalty amounts are applied because the current amounts sufficiently encourage compliance with CMS' rules. As more sponsors in the industry continue to improve performance, the CMP methodology may be revised to better encourage the remaining non-compliant sponsors to improve 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, the changes will be made available for comment before implementation.

The specific CMP amounts that will apply primarily to audit deficiencies detected in PY 2017 are discussed below.

1. Standard Penalty Amounts

The standard penalty amounts vary based on the calculation type that is applied (i.e., per enrollee or per determination), and the type of enrollee harm identified.

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 provided (e.g., inaccurate or untimely ANOC and/or EOC documents): $25 per enrollee

Per Determination Penalties

- Invalid data submission (i.e., failure to develop and/or provide valid enrollee universes): $25,000 per violation/per contract
- All other violations: $20,000 per violation/per contract

[5] Per the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which amended the Federal Civil Penalties Inflation Adjustment Act of 1990, CMS will annually adjust the maximum monetary penalty for inflation. Therefore, the maximum monetary penalties in §§ 422.760(b) and 423.760(b) are subject to change.

Proposed 2017 Civil Money Penalty Methodology

2. Aggravating and Mitigating Penalty Amounts

Once CMS has calculated the standard penalty amount, it will apply any aggravating and/or mitigating factors to the CMP. Aggravating factors increase the standard penalty, while mitigating factors decrease the standard penalty.

a. Per Enrollee Aggravating and Mitigating Factors

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

- Aggravating factors
  - 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: $100
  - Prior offense:[6] $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 most recent Annual Report or Common Findings and Best Practices memorandum:[7] $150
- Mitigating factors
  - Enrollees received drugs the same day as the inappropriate denial: -$50
  - Missed the adjudication time requirement by 24 hours or less: -$50

Incorrect premiums charged or unnecessary costs incurred

- Aggravating factors
  - 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 most recent Annual Report or Common Findings and Best Practices memorandum: $150

Untimely or inaccurate plan benefit information provided:

- Aggravating factors
  - Prior Offense: $15 for each prior offense
  - For Annual Notice of Change/Evidence of Coverage (ANOC/EOC) documents: Enrollees didn't receive ANOC/EOC/errata documents by Dec. 31: $15
- Mitigating factors
  - For ANOCs/EOCs: ANOC/EOC/errata sent to member by November 14: -$5

[6] Prior offenses include, for example, compliance notices, prior audit report findings, and/or prior enforcement actions within the previous two years.

[7] CMS will rely on the list of top common conditions that was most recently published in either the Annual Report or the Common Findings and Best Practices memorandum. Annual Reports and the Common Findings and Best Practices memorandums can be found here: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html.

b. Per Determination Aggravating and Mitigating Factors[8]

Aggravating factors

- Prior offense: $5,000
- Missed adjudication time requirement for expedited coverage decisions: $5,000
- High prevalence of failed sample cases:[9]
  - 25% to 49% of the sample cases fail: $2,500
  - 50% or more of the sample cases fail: $5,000
  - Violation was among the top common conditions in the most recent Common Findings and Best Practices memorandum: $5,000

3. CMP Calculation Formulas

CMPs are calculated using the following formulas:

Per Enrollee:

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

Per Determination:

Standard Penalty X *Number of Contracts*[10]
+
Aggravating factor(s) X *Number of Contracts*
-
Mitigating factor(s) X *Number of Contracts*
Total Penalty for the Violation

[8] These 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.

[9] Failed sample cases are cases that do not comply with CMS regulations or guidance.

[10] The total number of contracts that were impacted by the deficiency.

Proposed 2017 Civil Money Penalty Methodology

4. Maximum Penalty Amount

a. Enrollment-Based Limit

The CMP amount for each violation is restricted by the application of enrollment-based limits.[11] 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 100,000	$500,000	7%	83%
100,000 – 499,999	$1,000,000	13%	13%
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), the maximum penalty that CMS can issue when calculating a per determination penalty for a single deficiency is $25,000 per contract. For example, if CMS determines that a per determination penalty for a single deficiency is applicable to 10 of a sponsor's contracts, the maximum CMP that can be imposed for that determination for the 10 contracts is $250,000.

[11] The enrollment quartiles were calculated using the enrollment data current as of January 1, 2016. The 193 parent organizations operating MA, MA-PD, and PDP contracts were separated into four quartiles by enrollment size and assigned a CMP cap limit.

Proposed 2017 Civil Money Penalty Methodology

Appendix

Example of a CMP Calculation

SAMPLE VIOLATION # 1 CMP CALCULATION PER ENROLLEE		
Standard Penalty		
Inappropriate delay/denial of Part D drugs/ Part C services	$200	
Number of Enrollees Adversely Effected (or Substantial Likelihood)	500	
Standard Penalty Subtotal		$100,000
Aggravating Factor #1		
Top 5 common condition per the Best Practice/Common Findings memorandum	$150	
Number of Enrollees	500	
Penalty Adjustment		$75,000
Aggravating Factor #2		
Delay/denial beyond 24 hours of drugs used to either treat acute conditions or maintain the therapeutic treatment of non-acute conditions	$100	
Number of Enrollees	264	
Penalty Adjustment		$26,400
Mitigating Factor #1		
Enrollee received the drug the same day as rejection/denial	($50)	
Number of Enrollees	50	
Penalty Adjustment		($2,500)
Total CMP Amount		**$198,900**

Proposed 2017 Civil Money Penalty Methodology

SAMPLE VIOLATION #2 CMP CALCULATION PER DETERMINATION		
Standard Penalty		
Sponsor failed to provide complete, accurate and/or timely audit universes as requested by CMS		$25,000
CMP Amount		$25,000
Number of Contracts	12	
Total CMP Amount		**$300,000**

Total CMP Amount for all Sample Violations	**$498,900**