



MEDICARE PARTS C AND D OVERSIGHT AND ENFORCEMENT GROUP

Date: March 15, 2019

To: All Medicare Advantage Plans, Prescription Drug Plans, Section 1876 Cost Plans, Medicare-Medicaid Plans, and PACE Organizations

From: John A. Scott, Acting Director
Medicare Parts C and D Oversight and Enforcement Group

Subject: Release of the Revised Civil Money Penalty Calculation Methodology for Comment

I. Introduction

The Centers for Medicare & Medicaid Services (CMS) is proposing to update the Civil Money Penalty (CMP) calculation methodology for the 2019 contract year (CY) and considering our methodology for later years. As indicated in the final CMP calculation methodology released on December 15, 2016, CMS will publish any proposed changes to the methodology prior to their utilization and provide an opportunity for comment. The CMP calculation methodology is composed of two parts: 1) how we apply or assess CMPs and 2) how we apply a formula to increase the CMPs from year to year.

CMS is soliciting comments on the proposed changes to the 2019 CMP calculation methodology discussed in section III. The proposed changes to the methodology would be implemented beginning with penalties imposed as a result of enforcement referrals received in CY 2019.

In section IV, CMS solicits comments on a potential formula for adjusting CMPs amounts in 2019 and beyond including the formula itself, the frequency of the adjustments, the vehicle for announcing the adjustments, and the vehicle for memorializing the calculation methodology. We have provided one example for determining the adjustment from year to year and welcome comments on it. We also welcome suggestions for alternative approaches.

II. Background

The CMP methodology is used by CMS to calculate penalties issued to Medicare Advantage Organizations, Part D sponsors, and other Medicare managed care organizations when CMS discovers systemic issues that may lead to beneficiary harm. Although CMS has been issuing CMPs in these programs for over ten years, the methodology used to calculate the CMPs was not made public until December 2016. CMS published a proposed draft of the methodology, solicited and evaluated public comments, and subsequently published a final methodology based

on the comments received.

CMPs are calculated by applying a standard penalty amount to each deficiency. The standard penalty amount is calculated on either a “per enrollee” or “per determination” basis. CMS applies the per enrollee methodology when accurate enrollee data is available. CMS applies the per determination methodology when accurate enrollee data is either not provided by a sponsor or unknown, or when regulations require CMS to do so. Per enrollee penalties are calculated by multiplying the penalty amount by the number of affected enrollees. Per determination penalties are calculated by multiplying the penalty amount by the number of affected contracts. CMS may also increase the standard penalty amount when specific aggravating factors exist. CMS applies CMP limits to ensure an organization’s CMP amount is not excessive compared to its number of enrollees.

III. Clarifications and Proposed Changes Included in the 2019 CMP Calculation Methodology

CMS is including the following clarification and proposed changes to the CMP calculation methodology for CY 2019:

- Clarifying how CMS calculates per determination standard penalties for Programs of All-Inclusive Care for the Elderly (PACE) organizations
- Proposal to add an aggravating factor for enrollees who never received their Part C services or Part D medications due to violations of CMS program requirements
- Proposal to modify the language for two aggravating factors
- Proposal to remove the common condition aggravating factor

Clarifying how CMS Calculates Per Determination Standard Penalties for PACE Organizations

The statute and regulation allow CMS to issue per determination CMPs to a Medicare PACE organization when CMS determines the PACE organization substantially failed to provide participants medically necessary items and PACE services that adversely affected (or had the substantial likelihood of adversely affecting) participants. Under this authority, CMS has been applying up to the maximum penalty permitted under regulation, as adjusted annually for inflation, per violation, per contract for PACE organizations.¹ Our December 2016 methodology did not explicitly describe how CMS calculates per determination penalties for PACE organizations. CMS is therefore clarifying in the methodology that per determination CMPs for PACE organizations are calculated consistent with our statutory and regulatory authority.

Proposed Changes to Per Enrollee Aggravating Factors

CMS proposes adding an aggravating factor when there was an inappropriate denial of a Part C medical service or a Part D medication and the enrollee never received the care or medication. Enrollees who never receive their services or medications are at a much greater risk for adverse harm compared to enrollees whose access was delayed.

¹ CMS issued one per determination CMP to a PACE organization in 2017.

CMS proposes to modify the language for two aggravating factors. First, CMS proposes to modify the language for the aggravating factor related to the delay or denial of prescription drugs for acute conditions by changing “24 hours” to “one day.” Second, CMS proposes to remove the Evidence of Coverage (EOC) from the second aggravating factor related to untimely and inaccurate plan benefit information because the Annual Notice of Change (ANOC) and the EOC have become two independent (stand-alone) documents with different delivery requirements and flexibilities.

CMS also proposes to remove the aggravating factor for violations that are among the top conditions in the Medicare Part C and Part D Program Audit and Enforcement Report.

IV. Adjustments to CMP Amounts

CMS is proposing to adjust the amounts for CMPs using the approach described below. However, we request comments and suggestions on that approach and welcome ideas for alternatives.

CMS also welcomes comments and suggestions on how to memorialize the methodology for adjusting CMP amounts and the frequency for adjusting CMP amounts. CMS is considering establishing the methodology for adjusting CMP amounts in regulation, and by regulation, granting CMS the discretion to adjust CMP amounts no more often than every three years. CMS currently conducts program audits in three-year cycles. Thus, under this potential approach, organizations that are audited within a cycle would be subject to the same penalty level. If CMS lengthened an audit cycle to four or more years, we could continue applying the penalty amounts for the duration of the cycle and would update the amounts before a new cycle begins. If CMS chooses to no longer conduct audits in cycles, CMS would adjust CMP amounts no more often than every three years.

Background

The Federal Civil Penalties Inflation Adjustment Act Improvement Act of 2015 (Sec. 701 of Pub. L. 114-74) requires agencies to adjust the maximum CMP amounts for inflation annually. The Office of Management and Budget (OMB) releases the multiplier agencies must use to calculate penalty increases for the following year.² CMS, however, has the discretion to set CMP amounts below the maximum amount required by law. Prior to 2014, CMS based the overall amount of a CMP 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 by establishing penalty amounts for specific types of violations and applying the amounts consistently among MA organizations and Part D plan sponsors. CMS adopted this framework in the 2017 CMP Methodology and increased the penalty amounts to encourage better compliance with CMS’ rules and account for inflation.

Per Enrollee Penalty Amounts in 2017 and 2018

- Standard Penalty: \$200

² See OMB Memorandum M-19-04 for the 2019 inflation adjustment multiplier. Available at: https://www.whitehouse.gov/wp-content/uploads/2017/11/m_19_04.pdf

- Aggravating Factors: \$100
- Untimely/Inaccurate Beneficiary Communications Standard Penalty: \$25
- Untimely/Inaccurate Beneficiary Communications Aggravating Factor: \$15

Proposed Per Enrollee Penalty Amounts for 2019-2021

- Standard Penalty: \$212
- Aggravating Factors: \$106
- Untimely/Inaccurate Beneficiary Communications Standard Penalty: \$27
- Untimely/Inaccurate Beneficiary Communications Aggravating Factor: \$16

Proposed Approach for Increasing the Penalty Amounts

CMS could increase the standard penalty amount by multiplying the penalty amount by the cost-of-living multiplier published annually by OMB.³ CMS would track the accrual of the standard penalty amounts each year, but would update the standard penalty amount no more often than every three years. When the standard penalty amount is updated, CMS will increase the penalty by the amounts that would have applied if CMS had multiplied the standard penalty amount by the cost-of-living multiplier each year.

The following table shows how CMS used this approach to calculate the proposed CMP amounts for 2019. The same methodology would be applied for subsequent 3-year audit periods, beginning in 2022.

Table 1: Proposed CMP Standard Penalty adjustment for 2019

Adjustment Year	OMB Multiplier	Starting Standard Penalty (Accrual)	Standard Penalty After Adjustment (Accrual)	Applied Standard Penalty Each Year
2017*	1.01636	\$200	\$203	\$200
2018*	1.02041	\$203	\$207	\$200
2019	1.02522	\$207	\$212	\$212

*These amount are not the actual amounts for 2017-2018. See the background section above for the amounts that applied in 2017-2018. This table illustrates how CMS would apply the OMB multiplier to calculate the 2019 standard penalty of \$212.

Table 2: Proposed CMP Aggravating Factors and Untimely or Inaccurate Material Penalty adjustments

³ Per OMB Memoranda M-19-04, *Implementation of Penalty Inflation Adjustments for 2019, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015*, published December 14, 2018, the cost-of-living adjustment multiplier for 2019 is 1.02522.

Adjustment Year	Applied Standard Penalty	Aggravating Factor (AF)	Untimely or Inaccurate Materials Penalty	Untimely or Inaccurate Materials AF	Applied Other Penalties & AFs Each Year
2017	\$200	\$100	\$25	\$15	\$100 / \$25 / \$15
2019	\$212	\$106	\$27	\$16	\$106 / \$27 / \$16

V. Submission of Comments

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 revised CMP methodology, please submit your comments to the following email address: part_c_part_d_audit@cms.hhs.gov. Please include “2019 CMP Methodology Comments” in the subject line. **Comments must be received by 11:59PM ET on April 15, 2019.**

CMS hopes to publish a final methodology within 30 days of the comment deadline.