



[BILLING CODE 4120-01-P]

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 402**

**Office of the Secretary**

**45 CFR Part 102**

**[CMS-6061-P]**

**RIN 0938-AT86**

**Medicare Program; Medicare Secondary Payer and Certain Civil Money Penalties**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would specify how and when CMS must calculate and impose civil money penalties (CMPs) when group health plan (GHP) and non-group health plan (NGHP) responsible reporting entities (RREs) fail to meet their Medicare Secondary Payer (MSP) reporting obligations in any one or more of the following ways: when RREs fail to register and report as required by MSP reporting requirements; when RREs report as required, but report in a manner that exceeds error tolerances established by the Secretary of the Department of Health and Human Services (the Secretary); when RREs contradict the information the RREs have reported when CMS attempts to recover its payments from these RREs. This proposed rule would also establish CMP amounts and circumstances under which CMPs would and would not be imposed.

**DATES:** Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [insert date 60 days after date of publication in the **Federal Register**].

**ADDRESSES:** In commenting, please refer to file code CMS-6061-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed).

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-6061-P,  
P.O. Box 8013,  
Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,

Attention: CMS-6061-P,  
Mail Stop C4-26-05,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

**FOR FURTHER INFORMATION CONTACT:** Jacqueline Cipa, (410) 786-3259.

**SUPPLEMENTARY INFORMATION:**

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that website to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

## **I. Background**

### **A. Imposition of Civil Money Penalties (CMPs) – Legislative Overview**

In 1981, the Congress added section 1128A to the Social Security Act (the Act) (section 2105 of Pub. L. 97-35) to authorize the Secretary of Health and Human Services (the Secretary) to impose civil money penalties (CMPs) and assessments on certain health care facilities, health care practitioners, and other suppliers for noncompliance with rules of the Medicare and Medicaid programs. CMPs and assessments provide an enforcement tool for agencies to use to ensure compliance with statutory and regulatory requirements. These administrative penalties may be imposed in addition to potential criminal or civil penalties.

Since 1981, the Congress has increased both the number and the types of circumstances under which the Secretary may impose CMPs. Some CMP authorities address fraud, misrepresentation, or falsification, while others address noncompliance with programmatic or regulatory requirements. The Secretary has delegated the authority for certain provisions to either the Office of Inspector General (OIG) or Centers for Medicare & Medicaid Services (CMS). (See the October 20, 1994 notice, titled “Office of Inspector General; Health Care Financing Administration; Statement of Organization, Functions, and Delegations of Authority,” (58 FR 52967).) A summary of these CMP changes are discussed in this section of this proposed rule.

### **B. Legislative History**

In 1980, the Congress added section 1862(b) of the Act, which defined when Medicare is the secondary payer to certain primary plans. These provisions are known as

the Medicare Secondary Payer (MSP) provisions of the Act.

Section 1862(b) of the Act prohibits Medicare from making payment if payment has been made, or can reasonably be expected to be made by any of the following primary plans:

- Group Health Plans (GHPs).
- Workers' compensation plans.
- Liability insurance (including self-insurance).
- No-fault insurance.

Medicare may make conditional payments, subject to Medicare payment rules, in situations where workers' compensation, liability insurance (including self-insurance), or no-fault insurance has not made payment or cannot be expected to make payment promptly. See section 1862(b)(2)(A) of the Act. Any conditional payments that Medicare makes are subject to reimbursement from the primary plan. See section 1862(b)(2)(B) of the Act.

### C. Legislative Provisions Regarding Mandatory Reporting Requirements

To enhance enforcement of the MSP provisions, section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110-173) added paragraphs (7) and (8) to section 1862(b) of the Act. These paragraphs established new mandatory reporting requirements regarding Medicare beneficiaries who have coverage under GHP arrangements as well as for Medicare beneficiaries who receive settlements, judgments, awards or other payment from liability insurance (including self-insurance), no-fault insurance, or workers' compensation (collectively referred to as Non-Group

Health Plan, or NGHP). Sections 1862(b)(7)(A) and 1862(b)(8)(F) of the Act define those parties responsible for this reporting (collectively referred to as RREs); they are generally identified as group health insurers or third party administrators or both as well as NGHP applicable plans. RREs are currently required to submit coverage information for Medicare beneficiaries on a quarterly basis through an electronic file submission process that may vary depending upon the number of beneficiary records being reported or updated. This coverage information primarily consists of enough identifying information to uniquely identify the Medicare beneficiary and confirm their beneficiary status, as well as information about the nature of the coverage (such as GHP or NGHP, coverage effective dates, policy limits, settlement amounts, and so forth). These section 111 of MMSEA reporting provisions do not eliminate any other existing statutory provisions or regulations. Further, these reporting provisions include authority for Medicare to impose CMPs against entities that fail to comply with the section 111 of MMSEA reporting requirements under section 1862(b)(7) or (b)(8) of the Act, and required that GHPs and NGHPs that fail to comply with these reporting requirements shall be subject to a CMP of up to \$1,000 for each calendar day of noncompliance.

In 2013, Congress enacted the Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 (the SMART Act, at SSA section 1862(b), and codified at 42 U.S.C. 1395(y)(b)(2). The SMART Act amended section 1862(b)(8)(E) of the Act, which includes the section 111 of MMSEA reporting requirements and describes the enforcement provisions for NGHPs that fail to comply with the reporting requirements. The SMART Act revised section 1862(b)(8)(E) of the

Act to state that NGHP applicable plans that fail to comply with the reporting requirements *may* be subject to a civil money penalty of *up to* \$1,000 for each calendar day of reporting noncompliance required of NGHP applicable plans under section 1862(b)(8)(E) of the Act. The SMART Act also added section 1862(b)(8)(I) of the Act, which specifically required rulemaking actions regarding the enforcement of CMP provisions under section 1862(b)(8)(E) of the Act.

We note that the SMART Act did not amend any CMP provisions for GHP arrangements that have reporting obligations under section 1862(b)(7) of the Act. Such GHP arrangements remain subject to *mandatory* CMPs of \$1,000 per calendar day of noncompliance and per individual for whom submission of information was required. In addition, the SMART Act directed rulemaking for NGHP applicable plans regarding the imposition and non-imposition of CMPs.

We further note that the statutory language speaks to “individuals,” though there are situations described that are specifically applicable to Medicare beneficiaries; we have attempted to be consistent with the usage of this statutory terminology but use the term “beneficiary” where it is more appropriate.

#### D. Summary of Public Comments Received on the December 11, 2013 Advanced Notice of Proposed Rulemaking (ANPRM)

In accordance with the rulemaking directed by the SMART Act, on December 11, 2013 (78 FR 75304), we published an advance notice of proposed rulemaking (ANPRM) titled “Medicare Secondary Payer and Certain Civil Money Penalties.” The December 2013 ANPRM solicited public comment on specific practices

for which CMPs may or may not be imposed for failure to comply with MSP reporting requirements for certain GHP and NGHP arrangements.

We received 34 timely pieces of correspondence in response to the December 2013 ANPRM. In this section of the proposed rule, we provide an analysis of the public comments received by subject area, with a focus on the most common issues raised, and briefly discuss how we propose to address the issues raised by commenters in response to the 2013 ANPRM in this proposed rule.

#### 1. CMPs and “Good Faith Efforts” to Obtain Information to Report

Commenters suggested that CMS refrain from imposing CMPs where NGHPs with reporting obligations under section 1862(b)(8) of the Act make “good faith efforts” to obtain required information from individuals who are unwilling or unable to provide it. Some “good faith efforts” suggested included the following: (1) CMS could accept documentation signed by the individual stating that he, or she is either not a Medicare beneficiary, or will not provide the NGHP entity with his or her Social Security Number (SSN) (full SSN or last 5 digits); and (2) CMS could accept a judicial order establishing that the individual is not required to provide his or her Medicare Beneficiary Identifier (MBI) or SSN to the NGHP entity. We note that concerns about “good faith efforts” were received from the NGHP industry and not the GHP industry, which we believe is reflective of fundamental differences between the two industries and the relationships between those plans and the individuals in question. Our understanding is that NGHP applicable plans may be in an adversarial relationship at times with the reportable individual, whereas the reportable individual is typically the client of a GHP.



In response to the comments, we are proposing that we would not assess CMPs against NGHP entities where those entities make efforts as defined in this proposed rule to obtain necessary reporting information. NGHP entities would document their records with their efforts to obtain this reporting information, as we would retain the right to audit such documentation.

## 2. Determining Noncompliance

Most commenters suggested that “noncompliance” with CMS’s reporting requirements include failure to--(1) report when an entity is required to report; (2) report all Medicare beneficiaries who are/were plan participants (GHP) or claimants (NGHP); and (3) report when medical care was either claimed or released (as a part of a settlement, judgment, award, or other payment). We generally agree with the suggested concepts and have incorporated them into section II. of this proposed rule involving these reporting requirements.

## 3. Amounts of CMPs

A number of commenters recommended developing a “sliding scale” or “tiered” CMP approach, based upon the requirement of the responsible reporting entity (RRE) to obtain the necessary reporting information from these entities. We considered the possibility of incorporating penalty tiers for NGHP entities that have reporting obligations under section 1862(b)(8) of the Act. However, we are not proposing to rely on the intent of the NGHP entity reporting. Instead, we are proposing that we would assign CMP amounts based on the number of times, meaning individuals, a particular

entity fails to report, or fails to report correctly. We solicit comment on this proposal, as explained in section II. of this proposed rule.

#### 4. Proposed "Safe Harbors"

Many commenters suggested that CMS should establish a series of “safe harbors” that would preclude the assessment of a CMP. We note that multiple commenters were concerned about non-compliance due to technical issues and wished to define these myriad situations as “safe harbors.” In section II. of this proposed rule, we are proposing to employ tolerances related to submissions that contain certain types of errors or mistakes to address these comments, and to only consider performance against those tolerances over time so that a few poor submissions do not necessarily result in the imposition of a CMP. Multiple commenters were also concerned about their ability to obtain all of the required information for reporting and requested safe harbors for non-compliance due to non-cooperation on the part of the reportable individual. This situation has been addressed under “good faith efforts” in this section.

#### 5. Develop an Appeals Process

A number of commenters suggested that CMS should develop a formal appeals process to provide entities with reporting obligations a formal structure in which to appeal any notice of a pending or imposed CMP. We would expect that this proposed rule, once finalized, would comport with the appeals process as prescribed by 42 CFR 402.19 and set forth under 42 CFR part 1005. In broad terms, parties subject to CMP would receive formal written notice at the time penalty is proposed. The recipient would have the right to request a hearing with an Administrative Law Judge (ALJ) within

60 calendar days of receipt. Any party may appeal the initial decision of the ALJ to the Departmental Appeals Board (DAB) within 30 calendar days. The DAB's decision becomes binding 60 calendar days following service of the DAB's decision, absent petition for judicial review

#### 6. Rule is Prospective

Many commenters suggested that the rule should be enforced prospectively only. We agree and would evaluate compliance based only upon files submitted by the RRE on or after the effective date of any final rule.

#### 7. Statute of Limitations

Many commenters requested a statute of limitations on the imposition of CMPs. We agree and will apply the 5-year statute of limitations as required by 28 U.S.C. 2462. Under 28 U.S.C. 2462, we may only impose a CMP within 5 years from the date when the non-compliance was identified by CMS. An explanation and example of how this proposed statute of limitations would work for each of the three proposed types of CMPs is provided in this section of this rule.

For failure to report, the noncompliance occurs on every day of non-reporting after the required timeframe for reporting has elapsed:

If an RRE fails to report any beneficiary record as required beginning in 2023, and CMS identifies this non-compliance in 2024 but fails to take action until 2030, then no CMP would be imposed.

For responses to recovery efforts contradicting reporting, the noncompliance occurs when the response is received by CMS:

If in 2023 an RRE reported ongoing primary payment responsibility for a given beneficiary and then responded to recovery efforts 1 year later, in 2024, with an assertion that coverage for that beneficiary was actually terminated prior to the issuance of the recovery demand letter. If CMS fails to impose a CMP for this noncompliance within 5 years (no later than 2029), then no CMP would be imposed for this incident of noncompliance.

For situations where the reporter exceeds the error tolerance threshold, the noncompliance occurs at the end of the fourth consecutive reporting period over the 20 percent threshold (out of eight consecutive reporting periods):

If an RRE exceeds the error tolerance threshold in all four reporting periods of 2023 and then never exceeds the threshold again, it would normally be subject to a CMP. But if CMS fails to impose a CMP for this noncompliance within 5 years (no later than 2028), then no CMP would be imposed for this noncompliance.

We do appreciate the concerns raised by commenters and wish to reiterate that CMPs would only be imposed on a prospective basis.

#### 8. Informal and Formal Notice

Many commenters requested that CMS explain how it will provide notice to entities regarding pending or imposed CMPs and how much information will be included.

We would expect to communicate with the entity informally before issuing formal notice regarding a CMP. Informal communications would depend upon the nature of the non-compliance. Regarding the potential imposition of CMPs on other grounds, CMS anticipates utilizing an informal (that is, prior to formal enforcement actions) written

“pre-notice” process that would allow the RRE the opportunity to present mitigating evidence before the imposition of a CMP. Once we determine that a CMP will be imposed, we would provide formal notice to the entity in writing in accordance with 42 CFR 402.7, which would contain information on the reason for the assessment of a CMP, the amount of the CMP, and next steps for the entity, including appeal rights.

For example, we expect to continue to utilize the current messaging procedures around file errors described in the MMSEA Section 111 User Guides, which entail indicators on response files, emails, and phone calls depending upon the nature and severity of the error. RREs thus would remain informed about the performance of their quarterly file submissions. Upon the third submission out of seven consecutive reporting periods that exceeds error tolerances, the RRE would receive an “informal notice” that consists of a written warning letter (which requires no response, but is intended to warn the RRE that a subsequent submission that exceeds tolerances would result in potential CMP imposition). Upon the fourth submission out of eight consecutive reporting periods that exceeds error tolerances (and any additional triggering submissions), the RRE would receive another “informal” written notice of non-compliance indicating the nature of the non-compliance and the determination of the potential amount of the CMP, with 30 calendar days to respond with any mitigating information prior to the issuance of a notice of proposed determination in accordance with 42 CFR 402.7.

In the event that a CMP may be imposed for lack of timely reporting, CMS would issue an informal written notice of non-compliance, identifying the nature of the non-compliance and the determination of the potential amount of the CMP. The RRE

would again have 30 calendar days to respond with mitigating information before the issuance of a written notice in accordance with 42 CFR 402.7.

Recovery demand letters would be revised to include information regarding the potential for CMPs should an RRE contradict its own reporting in the recovery process. If an RRE submits a dispute or redetermination request in response to the recovery process that appears to directly contradict its own reporting, an informal written notice of non-compliance identifying the nature of the non-compliance and the determination of the potential amount of the CMP would be issued to the RRE. The RRE would again have 30 calendar days to respond with mitigating information before the issuance of a written notice in accordance with 42 CFR 402.7.

#### 9. Suspension of CMP Imposition Where Programmatic Changes are Required

Commenters suggested that CMS consider suspending the imposition of CMPs, where changes to mandatory reporting procedure require RREs to make significant revisions to the systems used to prepare the data for reporting.

We would expect to continue to provide at least 6 months' (180 calendar days) notice regarding any changes in policy or procedure associated with section 111 of MMSEA required reporting to allow reporting entities adequate time to react. We would not assess any CMPs associated with a specific policy or procedural change for a minimum of two reporting periods following the implementation of that policy or procedural change.

## 10. Duplicative Reporting and CMPs

Commenters suggested that CMS should not impose CMPs in situations where required information has already been reported to another agency or entity, such as the Department of Labor, or in situations where multiple entities have obligations to report the same information to CMS and one entity has already reported.

The reporting requirements established under sections 1862(b)(7) and (b)(8) of the Act imposed certain unique requirements on specific entities to report data to CMS for the purposes of identifying those situations where another party has primary payment responsibility. These reporting requirements were imposed under the Act, regardless of whether another agency or entity requires the same or similar data (and such data must also be reported to CMS in the manner and form specified by the Secretary). The current OMB control number assigned to this information collection effort, as required under the Paperwork Reduction Act, is 0938-1074.

## 11. Correct Coordination of Benefits and Recovery

Commenters suggested that CMS not impose CMPs when CMS has been able to coordinate benefits correctly or CMS has otherwise been able to recover.

The obligations to report under section 1862(b)(7) and (b)(8) of the Act are separate and distinct from any other obligation with respect to MSP. The fact that we may be able to correctly coordinate benefits and pursue recovery does not negate the obligations established under section 1862(b)(7) and (b)(8) of the Act.

## **II. Provisions of Proposed Regulations**

We have reviewed the public comments in response to our December 11, 2013 ANPRM (78 FR 75304), and other policy considerations as discussed in section I.D. of this proposed rule. Accordingly, we are proposing specific criteria for when CMPs would be imposed and proposing specific criteria for when CMPs would not be imposed, in circumstances when a GHP or an NGHP entity fails to comply (either on its own or through a reporting agent) with MSP reporting requirements specified under section 1862(b)(7) and (b)(8) of the Act. We note that the proposed CMPs would be levied in addition to any MSP reimbursement obligations.

Further, we proposed to amend the amount of these CMPs, as set forth under 45 CFR 102.3 (Penalty adjustment and table).

### A. CMP Bases and Scope

Section 402.1 describes the basis for imposition CMPs against parties who violate the provisions of the Act. We propose to add regulatory language under § 402.1(c), which would identify situations in which GHP entities and NGHP entities with RREs would be subject to CMPs under sections 1862(b)(7) and (b)(8) of the Act. To accomplish this regulatory addition, we are proposing the following regulatory revisions in §402.1:

- Removing paragraph (c)(20).
- Redesignating paragraph (c)(21) as paragraph (c)(20).
- Redesignating paragraphs (c)(22) through (34) as paragraphs (c)(23) through (35).



- Adding new paragraphs (c)(21) and (22).

Section 402.105(b) establishes the amount of penalties assessed against parties who violate the provisions of the Act. The proposed regulation at § 402.105(b)(2) would establish the amount of penalties imposed against GHPs, and the proposed regulation at § 402.105(b)(3) would establish the amount of penalties imposed against NGHPs. The regulatory provisions proposed would amend § 402.105(b) by revising paragraph (b)(2) and adding a new paragraph (b)(3). The proposed regulatory changes would establish the amount of CMPs imposed in these situations.

In addition, we have revised the regulations at 45 CFR 102.3 to establish the updated amounts for all CMPs at issue in these and the impacted proposed regulations. The table in this section sets forth the changes described for these amounts.

#### B. CMP Imposition and Amounts

The proposed regulations at § 402.1(c) would identify circumstances where GHP entities and NGHP entities with RREs would be subject to CMPs for violation of sections 1862(b)(7) and (b)(8) of the Act. We may become aware of these violations through various means. Currently self-referral is the most common means by which RREs that have failed to properly register and report are identified, which we expect to continue. Following publication of the final rule, we will enhance monitoring of recovery process disputes and appeals that contradict reported data, as well as monitoring of the reported data and performance over time to identify reporting that exceeds error tolerances. The proposed regulations at § 402.105(b) would clarify how we would calculate CMP amounts for GHP and NGHP entities that have reporting obligations under sections

1862(b)(7) and (b)(8) of the Act. Furthermore, the proposed § 402.1(c) would identify situations where GHP and NGHP RREs would not be subject to CMPs for violation of section 1862(b)(7) and (b)(8) of the Act.

Under section 1862(b)(7) of the Act, a GHP RRE shall be subject to a CMP of \$1,000 as adjusted annually under 45 CFR part 102 (currently \$1,569 as of January 17, 2020; please see 85 FR 2869) for each calendar day of noncompliance for each individual for which the required information should have been submitted. Under section 1862(b)(8) of the Act, an NGHP RRE may be subject to a CMP of up to \$1,000 (as adjusted annually under 45 CFR part 102) for each calendar day of noncompliance for each individual for which the required information should have been submitted. These CMPs would be in addition to any other penalties prescribed by law, and in addition to any MSP claim under section 1862(b) of the Act with respect to an individual.

#### 1. Imposition of a CMP

We would impose a CMP in the following situations:

- If an RRE fails to report any GHP beneficiary record within the required timeframe (no more than 1 calendar year after GHP coverage effective date or the Medicare beneficiary's entitlement date, whichever is later). The penalty would be calculated on a daily basis, based on the actual number of individual beneficiaries' records that the entity submitted untimely (that is, beyond the required timeframe after the GHP MSP effective date). The penalty would be \$1,000 (as adjusted annually under 45 CFR part 102) for each calendar day of noncompliance for each individual for which the required information should have been submitted, as counted from the day after the

last day of the RRE's assigned reporting window where the information should have been submitted through the day that CMS received the information, up to a maximum penalty of \$365,000 (as adjusted annually under 45 CFR part 102, currently \$572,685) per individual per year.

- If an RRE fails to report any NGHP beneficiary record within the required timeframe (no more than 1 year of the date of the settlement, judgment, award, or other payment (also referred to as the Total Payment Obligation to Claimant (TPOC))). The penalty would be calculated on a daily basis, based on the actual number of individual beneficiaries' records that the entity submitted untimely (that is, in excess of the required timeframe after the TPOC date). The penalty would be up to \$1,000 (as adjusted annually under 45 CFR part 102) for each calendar day of noncompliance for each individual for which the required information should have been submitted, as counted from the day after the last day of the RRE's assigned reporting window where the information should have been submitted through the day that CMS received the information, up to a maximum penalty of \$365,000 (as adjusted annually under 45 CFR part 102) per individual per year.

- If a GHP's or NGHP's response to CMS recovery efforts contradicts the entity's section 111 of MMSEA reporting. For example, if an RRE reported and repeatedly affirmed ongoing primary payment responsibility for a given beneficiary, then responded to recovery efforts with the assertion that coverage for that beneficiary actually terminated 2 years prior to the issuance of the recovery demand letter. The penalty would be calculated based on the number of calendar days that the entity failed to appropriately

report updates to beneficiary records, as required for accurate and timely reporting under section 111 of MMSEA. For a GHP, the penalty would be \$1,000 (as adjusted annually under 45 CFR part 102) for each calendar day of noncompliance for each individual for which the required information should have been submitted. For an NGHP, the penalty would be up to \$1,000 (as adjusted annually under 45 CFR part 102) per calendar day of noncompliance for each individual, for a maximum annual penalty of \$365,000 (as adjusted annually under 45 CFR part 102) for each individual for which the required information should have been submitted.

- If a GHP or NGHP entity has reported, and exceeds any error tolerance(s) threshold established by the Secretary in any 4 out of 8 consecutive reporting periods. We propose that the initial and maximum error tolerance threshold would be 20 percent (representing errors that prevent 20 percent or more of the beneficiary records from being processed), with any reduction in that tolerance to be published for notice and comment in advance of implementation. We intend for this tolerance to be applied as an absolute percentage of the records submitted in a given reporting cycle; we welcome feedback on this proposed methodology and threshold. The errors that would be used to determine whether the error tolerance is met must also be defined in advance of implementation of the final rule; we are only considering those significant errors which prevent a file or individual beneficiary record from processing. These errors are defined in the Section 111 User Guides, but we welcome the public's feedback. We would maintain the current notification process in place where RREs receive notice via response file and direct

outreach (email and, in more serious cases, telephone call) when there are errors with their file submissions.

Although the Act indicates that CMPs are calculated based on the number of days of RRE noncompliance, RREs do not report on a daily basis and so non-conformance in this situation cannot be defined on a daily basis. Therefore under this proposed rule, an RRE is considered to be out of compliance for the entire reporting period when the RRE exceeds the error tolerance threshold. A reporting period is defined as one quarter (defined as 90 calendar days for the purposes of standardizing quarters). For a GHP entity, the penalty would be imposed if the GHP entity was determined to have exceeded the error tolerances(s) in the entity's fourth above-tolerance submission out of any eight consecutive reporting periods. The penalty would be \$1,000 (as adjusted annually under 45 CFR part 102) for each calendar day of noncompliance for each individual for which the required information should have been submitted. An RRE is considered to be out of compliance for the entire reporting period when the error tolerance is exceeded; as previously noted, a reporting period is currently defined as one quarter (standardized to 90 calendar days). Therefore, the penalty for a non-compliant GHP would be \$90,000 (as adjusted, currently \$141,210) for each individual for which the required information should have been submitted, per reporting period where a CMP may be imposed.

For an NGHP entity, a CMP would be imposed on a tiered approach if the NGHP entity exceeded the error tolerance(s) in the entity's fourth above-tolerance submission. As with GHP entities, an NGHP entity is considered to be out of compliance for the entire reporting period when the error tolerance is exceeded; a reporting period is defined

as one quarter, standardized to 90 calendar days. For the first level of this penalty (reflecting the fourth submission exceeding error tolerances in any of the previous eight consecutive reporting periods), we would impose a penalty of one quarter, or 25 percent, of the maximum penalty per individual record per calendar day of non-compliance (this maximum penalty is currently defined as \$1,000, as adjusted annually under 45 CFR part 102) after the required date of submission (last calendar day of the NGHP's reporting period), based upon the number of beneficiaries whose records exceeded any error tolerance(s) established by the Secretary. In effect, \$250 (as adjusted, currently \$392) per calendar day, over the 90 calendar days of non-compliance for the full reporting period, per individual record. If the NGHP entity fails to comply again in the next consecutive reporting period, the amount of the penalty would increase to one half, or 50 percent, of the maximum penalty (currently defined as \$1000, as adjusted annually under 45 CFR part 102) per beneficiary per calendar day of non-compliance. In effect, \$500 (as adjusted, currently \$785) per calendar day, over the 90 calendar days of non-compliance for the full reporting period, per individual record. If the NGHP entity fails to comply again in the next consecutive reporting period, the amount would increase again to three-quarters, or 75 percent, of the maximum penalty (currently defined as \$1,000, as adjusted annually under 45 CFR part 102), and so on, up to the maximum penalty of \$1,000 (as adjusted annually under 45 CFR part 102) per beneficiary per calendar day of non-compliance (in effect, \$90,000 as adjusted, over the 90 calendar days of non-compliance for the full reporting period, per individual record). However, the potential penalty amount for the next penalty-eligible file would be reduced by one quarter (25

percent) of the maximum penalty of \$1,000 (as adjusted annually under 45 CFR part 102) per individual record per calendar day of non-compliance for each immediately consecutive subsequent quarter of compliance where an NGHP entity reports after the assessment of a penalty and the entity remains below any error tolerances. Such reductions may accumulate for each subsequent reporting period where the entity remains below the error tolerance until the entity is once again at the minimum penalty of one quarter, or 25 percent, of the maximum penalty per individual record per calendar day of non-compliance.

The following chart depicts how the concept of “any 4 out of the most recent 8 consecutive reporting periods” would work. CMP amounts are used for illustration purposes only; all amounts should be assumed to be adjusted annually.

| Example | Year 1 |    |    |    | Year 2 |    |    |    | Year 3 |    |    |    | CMP Imposed                   |
|---------|--------|----|----|----|--------|----|----|----|--------|----|----|----|-------------------------------|
|         | Q1     | Q2 | Q3 | Q4 | Q1     | Q2 | Q3 | Q4 | Q1     | Q2 | Q3 | Q4 |                               |
| 1       | E      | E  | G  | E  | G      | G  | G  | E  | G      | G  | E  | G  | Q4 of Year 2                  |
| 2       | E      | E  | G  | G  | G      | G  | E  | G  | G      | G  | E  | E  | No                            |
| 3       | *      | *  | *  | *  | E      | G  | E  | G  | G      | G  | G  | E  | No                            |
| 4       | *      | *  | *  | E  | E      | G  | G  | E  | G      | G  | E  | E  | Q3 and Q4 of Year 3           |
| 5       | *      | E  | G  | E  | G      | E  | G  | E  | G      | E  | G  | G  | Q4 of Year 2 and Q2 of Year 3 |

**KEY:** \* = No File

E = Error Tolerance Exceeded

G = Good File

The following explanations correlate to the examples depicted in this chart.

Example 1. CMP Imposed: Error tolerances exceeded in 4 out of 8 quarters as of year 2, quarter 4. As of year 3, quarter 3, there are only three out of eight quarters where submissions exceeded error tolerances, so no additional CMP would be imposed.

Example 2. No CMP Imposed: In no 8 sequential quarters were error tolerances exceeded 4 or more times.

Example 3. No CMP Imposed: In no 8 sequential quarters were error tolerances exceeded 4 or more times.

Example 4. CMP Imposed: Error tolerances were exceeded in 4 out of 8 quarters as of year 3, quarter 3. The subsequent submission (year 3, quarter 4) also exceeded error tolerances. According to the assessments proposed for GHP reporting entities, a GHP RRE would be assessed a CMP of \$1,000 per calendar day for each individual for whom information should have been submitted. According to the tiered approach proposed for NGHP reporting entities discussed later, an NGHP RRE would be assessed a CMP of \$250 per calendar day per for quarter 3 and \$500 per beneficiary above the tolerance per calendar day for quarter 4.

Example 5. CMP Imposed: Error tolerances were exceeded in 4 out of 7 quarters by year 2, quarter 4. According to the assessments proposed for GHP reporting entities, a GHP RRE would be assessed a CMP of \$1,000 per calendar day for each individual for whom information should have been submitted. According to the tiered approach proposed for NGHP reporting entities discussed later, an NGHP RRE would be assessed a CMP of \$250 per calendar day per individual for whom information should have been submitted. Error tolerances were again exceeded in year 3, quarter 2. Because error tolerances were not exceeded in year 3, quarter 1, an NGHP RRE would only be assessed a CMP of \$250 per calendar day per individual for whom information should have been submitted for year 3, quarter 2 instead of \$500.

The following examples demonstrate how the concept of exceeding error tolerances in “any 4 out of 8 consecutive reporting periods” would work:



Example 1: The RRE, ABC Insurer, submitted a file for each quarter in Year 1 of its required submissions. For Year 1, quarters 1 and 2, ABC Insurer submitted files where the file submissions entirely failed processing (100 percent error rate), and thus the quarterly submissions exceeded the error rate tolerance. In quarter 3 of Year 1, ABC Insurer submitted a file with no serious errors that prevented the files from being processed. However, severe file errors again occurred in quarter 4 and 25 percent of its records failed. These errors were corrected by the RRE for the first quarter of Year 2. ABC Insurer continued to submit error-free files for quarter 2 and quarter 3 of Year 2. However, in quarter 4 of Year 2, 50 percent of the submitted records failed. CMS would impose a CMP because the error tolerances exceeded four out of the eight quarterly reporting periods as of quarter 4 of Year 2.

Example 2: In the first two quarters of Year 1, Acme Insurance submitted files with errors that prevented 30 percent of the records from processing (exceeding error tolerances for quarter 1 and quarter 2). The file submissions for the last two quarters of Year 1 and quarters 1 through 3 of Year 2 did not have any significant errors and did not exceed tolerances. However, quarter 4 of Year 2 saw a recurrence of serious errors and Acme Insurance again exceeded the error tolerance with 25 percent of its records failing to process. Quarters 1 and 2 of Year 3 did not exceed tolerances, but the third and fourth quarters of Year 3 again saw Acme Insurance exceed the error tolerance with 30 percent and 20 percent of its records failing to process, respectively. CMS would not impose a CMP as in no continuous eight reporting periods did Acme Insurance exceed error tolerance four or more times.

We are proposing a maximum 20 percent per file submission error tolerance. Any future modification to this error tolerance threshold will be subject to notice and comment. We would not consider submission errors that fall below this tolerance in determining the imposition of a potential CMP; we would continue to provide the response file that allows submitters to be aware of their performance. We have evaluated the historical error rates from RRE submissions and have determined that the vast majority of submitters are able to meet or exceed this initial minimum acceptable performance level. The 20 percent per file tolerance for errors would only include those errors and condition flags that are within the entities' direct control and cause CMS to be unable to process the individual beneficiary records or entire file submissions. The errors that would be used to determine whether the error tolerance is met shall also be defined a minimum of 6 months in advance of imposition of any CMP (after publication of the final rule) in the reporting User Guides and will be subject to notice and comment. We would only consider those significant errors which prevent a file or individual beneficiary record from processing, such as failure to provide an individual's last name or valid date of birth, or failure to provide a matching Tax Identification Number. Less serious errors, such as internal CMS processing errors, will continue to be noted on the response files, but will not be considered in determining compliance. We currently interact with RREs to inform them of errors with file submissions, between response files to email notifications to, in more severe situations, direct telephone outreach. Following publication of the final rule, we would implement a monitoring system but would continue to review submissions each reporting period to determine whether the entity has

continued to exceed error tolerance(s) and preserve the notification apparatus currently in place. GHP and NGHP entities will continue to have penalties assessed for each reporting period, until the entity submits a file that does not exceed any error tolerance(s).

## 2. No CMP Imposed

We would not impose a CMP in the following situations, where all of the applicable conditions are met:

- If a RRE reports any GHP beneficiary record that is reported on a quarterly submission timeframe within the required timeframe (not to exceed 1 year after the GHP effective date), or any NGHP beneficiary record that is submitted within the required timeframe (not to exceed 1 year after the TPOC date).
- If an RRE complies with any TPOC reporting thresholds or any other reporting exclusions published in CMS's MMSEA Section 111 User Guides or otherwise granted by CMS. Note that these thresholds are not defined in the regulatory text as TPOC reporting thresholds are currently subject to change on an annual basis per 42 U.S.C. 1395(y)(b)(9)(i). CMS also elects to impose operational thresholds for reporting, such as the current \$5,000 threshold for Health Reimbursement Arrangements.
- If a GHP entity or NGHP entity does not exceed any error tolerance(s) in any four out of eight consecutive reporting periods.
- If an NGHP entity fails to report required information because the NGHP entity was unable to obtain information necessary for reporting from the reportable individual, including an individual's last name, first name, date of birth, gender, MBI, or SSN (or the last 5 digits of the SSN), and the responsible applicable plan has made and

maintained records of its good faith effort to obtain this information by taking *all* of the following steps:

++ The NGHP has communicated the need for this information to the individual and his or her attorney or other representative and requested the information from the individual and his or her attorney or other representative at least twice by mail and at least once by phone or other means of contact such as electronic mail in the absence of a response to the mailings.

++ The NGHP certifies that it has not received a response in writing, or has received a response in writing that the individual will not provide his or her MBI or SSN (or last 5 digits of his or her SSN).

++ The NGHP has documented its records to reflect its efforts to obtain the MBI or SSN (or the last 5 digits of the SSN) and the reason for the failure to collect this information.

The NGHP entity should maintain records of these good faith efforts (such as dates and types of communications with the individual) in order to be produced as mitigating evidence should CMS contemplate the imposition of a CMP. Such records must be maintained for a period of 5 years. The current OMB control number assigned to this information collection effort, as required under the Paperwork Reduction Act, is 0938-1074.

We solicit comments on our proposed approaches to imposing and not imposing CMPs, including our proposed methods of calculating CMP amounts, and our proposed error tolerance rates. Our proposed approach to imposing CMPs was developed to give

entities meaningful opportunities to resolve most reporting issues, without the immediate risk that a CMP would be imposed.

### **III. Collection of Information Requirements**

This document does not impose any new information collection and recordkeeping requirements that have not already been reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

### **IV. Responses to Comments**

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

### **V. Regulatory Impact Statement**

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (CRA) (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A detailed regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). Estimating the economic effects of this rule presents a significant challenge under current circumstances. At this point in time, the reporting program has not yet reached a level of maturity where we have definitively identified any additional RREs that have failed to register and report as required. We have purposely selected an error tolerance threshold (20 percent) that is achievable for all current RREs based on recent performance, and thus would not impose any CMPs based on current performance. However, we do not yet have eight consecutive reporting periods of data, and, as such, we are not able to currently model the potential imposition of CMPs on this basis at this time. We also do not have the systems in place at this time to monitor when entities contradict their reported data in response to CMS MSP recovery efforts. At this point in time, we do not expect to collect CMPs totaling \$100 million or more in any given year, nor do we expect this rule to have any other economic effects that meet or exceed that threshold. Therefore, this rule is not considered a major rule under the CRA. We note that we are currently implementing monitoring systems that will allow us to better model future reporting violations and CMP imposition. Therefore, when we are ready to develop the final rule we expect to have available a significantly increased array of relevant data. As a result, we commit to providing a detailed analysis

of the costs and benefits of this rule at that time. We also invite feedback from the public that would assist us in determining the quantifiable costs and benefits of this proposed rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$7.0 million to \$35.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We consider a rule to have a significant impact on a substantial number of small entities if it has at least a 3-percent impact of revenue on at least 5 percent of small entities. Affected entities with reporting responsibilities have been required to comply with sections 1862(b)(7) and (b)(8) of the Act since these provisions were added to the Act in 2007. This proposed rule is intended to define how CMPs would be imposed as a consequence of non-compliance with these statutory obligations, and thus does not present any additional burden beyond the review of the rule. As discussed later in this section, the total cost impact of reviewing this rule by all 20,855 currently registered RREs, regardless of size, is estimated to be \$6,842,437, or \$328 per entity. This falls below the standard definition of “significance” of 3 or more of small entity revenue. As a result, we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 for the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately \$154 million. This proposed rule has no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. It has been determined that this proposed rule is not a “significant regulatory action” and thus does not trigger the previously discussed



requirements of Executive Order 13771.

We used the current number of GHP RREs (1,039) and NGHP RREs (19,816) to determine the total number of impacted entities (20,855). We recognize that this is a slight overestimate, as a single corporate parent may have multiple associated RREs. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

Using the May 2018 wage information from the U.S. Department of Labor Bureau of Labor Statistics for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$109.36 per hour, based on doubling the mean hourly wage of \$54.68 to include overhead and fringe benefits (see <https://www.bls.gov/oes/current/oes119111.htm>). We assume that one individual associated with each of the 20,855 impacted entities will read the rule. Assuming an average reading speed, we estimate that it would take approximately 3 hours for the staff to review this proposed rule. For each entity that reviews the rule, the estimated cost is \$328.08 (3 hours x \$109.36). Therefore, we estimate that the total cost of reviewing this proposed rule is \$6,842,437 ( $\$328.08 \times 20,855$ ).

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

## List of Subjects

### 42 CFR Part 402

Assessments, Civil money penalties, Exclusions.

### 45 CFR Part 102

Administrative practice and procedure, Penalties.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

## **PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS**

1. The authority citation for part 402 is revised to read as follows:

**Authority:** 42 U.S.C. 1302 and 1395hh.

2. Section 402.1 is amended--

a. In paragraph (c) introductory text by removing the reference "(c)(34) of this section" and adding in its place the reference "(c)(35) of this section";

b. By removing paragraph (c)(20);

c. By redesignating paragraph (c)(21) as paragraph (c)(20);

d. By redesignating paragraphs (c)(22) through (34) as paragraphs (c)(23) through (35); and

e. By adding new paragraphs (c)(21) and (22).

The additions read as follows:

### **§402.1 Basis and scope.**

\* \* \* \* \*

(c) \* \* \*

(21) Section 1862(b)(7)(B)—Except for the situation described in paragraphs (c)(21)(iv)(A) and (B) of this section, any entity that has a reporting obligation under section 1862(b)(7) of the Act (“reporting entity”) reports, but fails to comply with the reporting instructions in the following situations:

(i) Fails to report any beneficiary record within 1 year from the group health plan (GHP) coverage effective date or the Medicare beneficiary’s entitlement date.

(ii) Contradicts its reporting under section 1862(b)(7) of the Act in response to CMS recovery efforts.

(iii) Has reported and exceeds any error tolerance(s) threshold established by the Secretary in any 4 out of 8 consecutive reporting periods.

(iv) A civil money penalty (CMP) is not imposed if--

(A) It is associated with a specific policy or procedural change is not imposed for a minimum of two reporting periods following the implementation of that policy or procedural change; or

(B) The entity complies with any reporting thresholds or any other reporting exclusions.

(22) Section 1862(b)(8)(E)—An applicable plan has a reporting obligation under section 1862(b)(8) of the Act (“applicable plan”), but fails to comply with the reporting instructions in the following situations:

(i) Except for the situations described in paragraphs (c)(22)(iv)(A) through (C) of this section, fails to report any beneficiary record within 1 year from the date of the settlement, judgment, award, or other payment.

(ii) Contradicts its reporting under section 1862(b)(8) of the Act in response to CMS recovery efforts.

(iii) Has reported, and exceeds any error tolerance(s) threshold established by the Secretary (not to exceed 20 percent) in any 4 out of 8 (or less) consecutive reporting periods.

(iv) A CMP is not imposed in the following situations:

(A) If a non-group health plan (NGHP) applicable plan fails to report required information as a result of the applicable plan's inability to obtain an individual's last name, first name, date of birth, gender, Medicare Beneficiary Identifier (MBI), Social Security Number (SSN), or the last 5 digits of the SSN, and the applicable plan has made a good faith effort to obtain this information by meeting all of the following:

(1) Communicating the need for this information to the individual and his or her attorney or other representative.

(2) Requesting the information from the individual and his or her attorney or other representative at least twice by mail and at least once by phone or other means of contact.

(3) Has not received a response or has received a response in writing that the individual refuses to provide his or her MBI or SSN or a truncated form of the MBI or SSN.

(4) Has documented its efforts to obtain the MBI or SSN (or the last 5 digits of the SSN).

(B) A CMP is not imposed if an NGHP applicable plan complies with any reporting thresholds or any other reporting exclusions.

(C) A CMP associated with a specific policy or procedural change is not imposed for a minimum of two reporting periods following the implementation of that policy or procedural change.

\* \* \* \* \*

3. Section 402.105 is amended by revising paragraphs (b)(2) and adding paragraph (b)(3) to read as follows:

**§402.105 Amount of penalty.**

\* \* \* \* \*

(b) \* \* \* \*

(2) For entities with reporting obligations under section 1862(b)(7) of the Act (“reporting entity”) as follows:

(i) A reporting entity fails to report any beneficiary record within the specified period from the latter of the GHP coverage effective date or the Medicare beneficiary’s entitlement date. The penalty is--

(A) Calculated on a daily basis, based on the actual number of beneficiary records that the entity submitted more than 1 year after the GHP Medicare Secondary Payer (MSP) effective date; and

(B) \$1,000 as adjusted annually under 45 CFR part 102 for each calendar day of noncompliance for each individual for which the required information should have been

submitted, up to a maximum penalty of \$365,000 as adjusted annually under 45 CFR part 102 per individual per year.

(ii) A reporting entity's response to CMS recovery efforts contradicts the entity's reporting under section 1862(b)(7) of the Act. The penalty is--

(A) Calculated based on the number of calendar days that the entity failed to appropriately report updates to beneficiary records, as required for accurate and timely reporting; and

(B) \$1,000 as adjusted annually under 45 CFR part 102 for each calendar day of noncompliance for each individual for which the required information should have been submitted.

(iii) A reporting entity has reported, and exceeds any error tolerance(s) threshold established by the Secretary (not to exceed 20 percent) in any 4 out of 8 (or less) consecutive reporting periods. The penalty is--

(A) Based upon the number of beneficiary records on the fourth submission that exceed any such error tolerance(s); and

(B) \$1,000 as adjusted annually under 45 CFR part 102 for each calendar day of noncompliance for each individual for which the required information should have been submitted.

(3) For entities with reporting obligations under section 1862(b)(8) ("applicable plan") of the Act as follows:

(i) An applicable plan fails to report any NGHP beneficiary record within the specified period from the date of the settlement, judgment, award, or other payment. The penalty is--

(A) Calculated on a daily basis, based on the actual number of beneficiary records that the entity submitted more than 1 year after the Total Payment Obligation to Claimant (TPOC) date; and

(B) Up to \$1,000 as adjusted annually under 45 CFR part 102 for each calendar day of noncompliance for each individual for which the required information should have been submitted, up to a maximum penalty of \$365,000 as adjusted annually under 45 CFR part 102 per individual per year.

(ii) An applicable plan's response to CMS recovery efforts contradicts the entity's reporting under section 1862(b)(8) of the Act. The penalty is--

(A) Calculated based on the number of calendar days that the entity failed to appropriately report updates to beneficiary records, as required for accurate and timely reporting; and

(B) Up to \$1,000 as adjusted annually under 45 CFR part 102 per calendar day of noncompliance, for a maximum penalty of \$365,000 as adjusted annually under 45 CFR part 102.

(iii) An applicable plan has reported, and exceeds any error tolerance(s) threshold established by the Secretary (not to exceed 20 percent) in any 4 out of 8 consecutive reporting periods. The penalty is calculated using the following tiered approach, based on the number of calendar days that the applicable plan exceeded the error tolerance(s) in

the entity's fourth above-tolerance submission.

(A) Initial penalty amount. For the first penalty, CMS imposes a penalty of one-quarter (25 percent) of the maximum penalty per beneficiary per calendar day of non-compliance after the required date of submission (last calendar day of the applicable plan's reporting period), based upon the number of beneficiaries whose records exceeded any error tolerance(s) established by the Secretary.

(B) Subsequent penalty amounts. For the second and subsequent penalties, CMS increases the penalty specified in paragraph (b)(3)(iii)(A) of this section in increments of one-quarter (25 percent) of the maximum penalty for applicable plans that fail to comply in consecutive reporting periods to a maximum of \$1,000 as adjusted annually under 45 CFR part 102 per beneficiary per calendar day of non-compliance.

(C) Reduction in penalty amount. If the applicable plan reports after the assessment of a penalty and the entity remains below any error tolerances, the penalty amount for the next penalty eligible file is reduced by increments of one-quarter (25 percent) of the maximum penalty per beneficiary per calendar day of non-compliance per consecutive subsequent quarter of compliance, to the minimum penalty of one-quarter (25 percent) of the maximum penalty per beneficiary per calendar day of non-compliance.

\* \* \* \* \*



For the reasons specified in the preamble, the Department of Health and Human Services proposes to amend 45 CFR part 102 as specified below:

**PART 102—ADJUSTMENT OF CIVIL MONETARY PENALTIES FOR INFLATION**

4. The authority for part 102 continues to read as follows:

**Authority:** Public Law 101-410, Sec. 701 of Public Law 114-74, 31 U.S.C. 3801-3812.

5. Section 102.3 is amended in the table by:

a. Revising the entries “1395m(k)(6),” “1395m(l)(6),” “1395y(b)(6)(B),” and “1395y(b)(7)(B)(i);”

b. Adding an entry for “1395y(b)(8)(E)(i)” in alphanumeric order; and

c. Revising the entries for “1395pp(h),” “1395ss(a)(2),” “1395ss(p)(8),” “1395ss(p)(9)(C),” “1395ss(q)(5)(C),” “1395ss(r)(6)(A),” “1395ss(s)(4),” and “1395ss(t)(2).”

The revisions and addition read as follows:

**§ 102.3 Penalty adjustment and table.**

\* \* \* \* \*

**Table 1 to §102.3—Civil Monetary Penalty Authorities Administered by HHS**

**Agencies and Penalty Amounts**

January 17, 2020

|                          | CFR <sup>1</sup>                   | HHS Agency | Description <sup>2</sup>  | Date of last statutorily established penalty figure <sup>3</sup> | 2019 Maximum adjusted penalty (\$) | 2020 Maximum adjusted penalty (\$) <sup>4</sup> |
|--------------------------|------------------------------------|------------|---|--|------------------------------------|---|
| *****                    |                                    |            |   |  |                                    |   |
| 42 U.S.C                 |                                    |            |   |  |                                    |   |
| *****                    |                                    |            |   |  |                                    |   |
| 1395m(k)(6) <sup>5</sup> | 42 CFR 402.1(c)(32), 402.105(d)(3) | CMS        | Penalty for any person or entity who knowingly and willfully bills or collects for any outpatient therapy services or comprehensive outpatient rehabilitation services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(k)(6) and 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)) | 2019   | 15,975                             | 16,257  |
| 1395m(l)(6) <sup>5</sup> | 42 CFR 402.1(c)(33), 402.105(d)(4) | CMS        | Penalty for any supplier of ambulance services who knowingly and willfully fills or collects for any services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(b)(18)(B), which is assessed according to 1320a-7a(a))   | 2019   | 15,15,975                          | 16,257  |
| *****                    |                                    |            |   |  |                                    |   |
| 1395y(b)(6)(B)           | 42 CFR 402.1(c)(20), 402.105(a)    | CMS        | Penalty for any entity that knowingly, willfully, and repeatedly fails to complete a claim form relating to the availability of other health benefits in accordance with statute or provides inaccurate information relating to such on the claim form  | 2019   | 3,383                              | 3,443   |
| 1395y(b)(7)(B)(i)        | 42 CFR 402.1(c)(21), 402.105(a)    | CMS        | Penalty for any entity serving as insurer, third party administrator, or fiduciary for a group health plan that fails to provide information that identifies situations where the group health plan is or was a primary plan to Medicare to the HHS Secretary   | 2019   | 1,211                              | 1,232   |
| *****                    |                                    |            |   |  |                                    |   |
| 1395y(b)(8)(E)(i)        | 42 CFR 402.1(c)(22), 402.105(a)(E) | CMS        | Penalty for any entity serving as insurer, third party administrator, or fiduciary for a non-group health plan that fails to provide information that identifies situations where the group health plan is or was a primary plan to Medicare to the HHS Secretary   | 2019   | 1,211                              | 1,232   |
| *****                    |                                    |            |   |  |                                    |   |

|                        | CFR <sup>1</sup>                        | HHS Agency | Description <sup>2</sup>   | Date of last statutorily established penalty figure <sup>3</sup> | 2019 Maximum adjusted penalty (\$) | 2020 Maximum adjusted penalty (\$) <sup>4</sup> |
|------------------------|---|------------|--|--|------------------------------------|---|
| 1395pp(h) <sup>5</sup> | 42 CFR 402.1(c)(24), 402.105(d)(2)(xv)  | CMS        | Penalty for any durable medical equipment supplier, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries under certain conditions. (42 U.S.C. 1395(m)(18) sanctions apply here in the same manner, which is under 1395u(j)(2) and 1320a-7a(a)) | 2019   | 15,975                             | 16,257  |
| 1395ss(a)(2)           | 42 CFR 402.1(c)(25), 405.105(f)(1)      | CMS        | Penalty for any person that issues a Medicare supplemental policy that has not been approved by the State regulatory program or does not meet Federal standards after a statutorily defined effective date   | 2019   | 54,832                             | 55,799  |
| * * * * *              |   |            |  |  |                                    |   |
| 1395ss(p)(8)           | 42 CFR 402.1(c)(26), 402.105(e)         | CMS        | Penalty for any person that sells or issues Medicare supplemental policies after a given date that fail to conform to the NAIC or Federal standards established by statute   | 2019   | 28,413                             | 28,914  |
|                        | 42 CFR 402.1(c)(26), 405.105(f)(2)      | CMS        | Penalty for any person that sells or issues Medicare supplemental policies after a given date that fail to conform to the NAIC or Federal standards established by statute   | 2019   | 47,357                             | 48,192  |
| 1395ss(p)(9)(C)        | 42 CFR 402.1(c)(27), 402.105(e)         | CMS        | Penalty for any person that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits  | 2019   | 28,413                             | 28,914  |
|                        | 42 CFR 402.1(c)(27), 405.105(f)(3), (4) |            | Penalty for any person that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits  | 2019   | 47,357                             | 48,192  |
| 1395ss(q)(5)(C)        | 42 CFR 402.1(c)(28), 405.105(f)(5)      | CMS        | Penalty for any person that fails to suspend the policy of a policyholder made eligible for medical assistance or automatically reinstates the policy of a policyholder who has lost eligibility for medical assistance, under certain circumstances   | 2019   | 47,357                             | 48,192  |
| 1395ss(r)(6)(A)        | 42 CFR 402.1(c)(29), 405.105(f)(6)      | CMS        | Penalty for any person that fails to provide refunds or credits as required by section 1882(r)(1)(B)   | 2019   | 47,357                             | 48,192  |

|              | CFR <sup>1</sup>                   | HHS Agency | Description <sup>2</sup>   | Date of last statutorily established penalty figure <sup>3</sup> | 2019 Maximum adjusted penalty (\$) | 2020 Maximum adjusted penalty (\$) <sup>4</sup> |
|--------------|------------------------------------|------------|--|--|------------------------------------|---|
| 1395ss(s)(4) | 42 CFR 402.1(c)(30), 405.105(c)    | CMS        | Penalty for any issuer of a Medicare supplemental policy that does not waive listed time periods if they were already satisfied under a proceeding Medicare supplemental policy, or denies a policy, or conditions the issuances or effectiveness of the policy, or discriminates in the pricing of the policy base on health status or other specified criteria | 2019   | 20,104                             | 20,459  |
| 1395ss(t)(2) | 42 CFR 402.1(c)(31), 405.105(f)(7) | CMS        | Penalty for any issuer of a Medicare supplemental policy that fails to fulfill listed responsibilities   | 2019   | 47,357                             | 48,192  |
| * * * * *    |                                    |            |  |  |                                    |   |

<sup>1</sup>Some HHS components have not promulgated regulations regarding their civil monetary penalty-specific statutory authorities.

<sup>2</sup>The description is not intended to be a comprehensive explanation of the underlying violation; the statute and corresponding regulation, if applicable, should be consulted.

<sup>3</sup>Statutory or Inflation Act Adjustment.

<sup>4</sup>The cost of living multiplier for 2018, based on the CPI-U for the month of October 2017, not seasonally adjusted, is 1.02041, as indicated in OMB Memorandum M-18-03, "Implementation of Penalty Inflation Adjustments for 2018, Pursuant to the Federal Civil Penalties Adjustment Act Improvements Act of 2015" (December 15, 2017).

<sup>5</sup>The cost of living multiplier for 2020, based on the Consumer Price Index for all Urban Consumers (CPI-U) for the month of October 2019, not seasonally adjusted, is 1.01764, as indicated in OMB Memorandum M-20-05, "Implementation of Penalty Inflation Adjustments for 2019, Pursuant to the Federal Civil Penalties Adjustment Act Improvements Act of 2015" (December 16, 2019).

**Dated:** August 12, 2019.

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**Seema Verma,**  
Administrator,  
Centers for Medicare & Medicaid Services.

**Dated:** December 12, 2019.

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**Alex Azar,**  
Secretary,  
Department of Health and Human Services.