MARC
Medicare Advocacy Recovery Coalition

April 20, 2020

via www.regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS–6061-P
P.O. Box 8013
Baltimore, MD 21244–8013

Re: CMS-6061-P; MEDICARE SECONDARY PAYER AND CERTAIN CIVIL MONETARY PENALTIES (RIN 0938-AT86)

Dear Administrator Verma:

The Medicare Advocacy Recovery Coalition (MARC or the Coalition) is pleased to provide comments on the February 18, 2020, Proposed Rule related to the assessment of penalties under the MSP reporting regime established by Section 111 of the MMSEA (the "Section 111"), as modified by Section 203 of the Medicare IVIG and Strengthening Medicare and Repaying Taxpayers Act of 2012 (the SMART Act). 85 Fed. Reg. 8793 (Feb. 18, 2020). As reflected in the comments below, MARC appreciates the Agency's efforts to propose a regulation that would clarify when penalties will be assessed in specific circumstances. In proposing rigid penalties for technical reporting errors, however, rather than adopting existing and applicable Civil Monetary Penalty (CMP) regulations that define the criteria that the Office of Inspector General (OIG) and other enforcement agencies must consider in assessing or pursuing collection of CMPs, CMS has failed to implement Congressional direction.

Moreover, the Proposed Rule is unduly focused on penalizing entities that are reporting, rather than those who intentionally refuse to report. Given these fundamental flaws in the proposed regulation, MARC calls upon CMS to withdraw the proposed rule and to issue a new proposal, explicitly incorporating the standards of 42 C.F.R. § 1003.140, or proposing analogous "sliding scale" standards for the assessment of penalties and refocusing the proposal towards those who are not reporting, rather than penalize technical and non-substantive reporting field mistakes made in good faith.

MARC also has numerous other comments on the Proposed Rule, and why they are arbitrary, capricious, and contrary to law. First, the proposed penalties will violate the Eighth Amendment of the United States Constitution, and if applied to technical violations of CMS reporting requirements, would violate the Supreme Court's recent ruling in *Allina Health v. Azar*, and the MSP statute itself. Second, and as noted above, the proposal fails to follow Congressional direction and implement the sliding scale standard already in CMP regulations, and is illegally maintaining the $1,000 penalty limit explicitly modified by Congress. Third,

the proposed penalty regulation related to retroactive terminations of "Ongoing Responsibility for Medicals" (ORM) fields is unreasonable and unworkable. Fourth, the proposed penalties for erroneous reporting resulting in a 20% claim rejection rate is similarly arbitrary and capricious. Fifth, the proposed "safe harbor" for nonreporting when a beneficiary refuses to provide necessary information is unduly restrictive and intrusive to beneficiaries, and should be modified. Sixth, CMS adopts the incorrect statute of limitations for penalty collection purposes. And finally, we comment on several other aspects of the proposed rule, including the one year enforcement period.

In Section I, below, we provide a brief description of the MARC Coalition, and our Membership. Section II provides background on the Section 111 Reporting process, including details on how companies across the country have managed the Reporting requirements, and the unique nature of those requirements in the insurance and self-insured system today. Section III provides specific comments on the Proposed Rule, covering the issues addressed in the above paragraph. Finally, in Section IV, we conclude with specific recommendations related to the Proposed Rule.

I. About MARC

The MARC Coalition was formed in September 2008 by a group of leading stakeholders to advocate on behalf of beneficiaries and interested stakeholders for improvement of the MSP system. MARC's membership represents virtually every sector of the regulated community affected by the secondary payer laws, including plaintiff and defense attorneys, brokers, insureds, insurers, insurance and other trade associations, self-insureds, MSP compliance vendors, and third-party administrators. MARC and its member companies are committed to achieving an efficient and effective MSP system that protects beneficiaries and the Trust Fund, while providing a rational and useable system for all stakeholders. Our members are involved with every aspect of the MSP process, and many of our members handle countless cases that involve conditional payments.

MARC's comments below reflect the membership's extensive experience with the current MSP regulations, and the impact they have on the real world settlement of payments and the return of conditional payment amounts to the Trust Fund. They also reflect the Coalition's intimate involvement with the development and enactment of the SMART Act, our ongoing engagement with CMS regarding the implementation and modification to the ORM process, and our expertise in the Section 111 process. Most importantly, the comments reflect the Coalition Members' desire to ensure that the Agency's proposed Section 111 penalty regime incentivizes all Responsible Reporting Entities ("RRE") to correctly report claims, and punishes wrong-doers, rather than those entities attempting in good faith to meet their reporting obligations.

II. The Section 111 Reporting Process

a. RREs are Strangers to the Medicare Program and the Section 111 Process is Alien to Non-Group Health Plan Claims Systems.

CMPs are pervasive across the health care system, and are assessed against a variety of providers, manufacturers, and others who submit claims to the federal health care programs. Given that each of these entities has a relationship with the federal health care programs by either being paid, or having their products paid for, through Medicare, it is appropriate that their violations of law should be subject to CMPs. In contrast to all these individuals and entities, however, Non-Group Health Plans (NGHPs) have *no* relationship to the federal healthcare programs – they do not submit claims, are not reimbursed, and have no other financial or business connection to the Medicare program. Instead, they are only connected to Medicare by the coincidence that infrequently they may resolve a liability, workers compensation, or no fault claim with a Medicare beneficiary. For that reason, it is arbitrary and capricious for the Agency to expect that reporting entities will understand and master the intricacies of Medicare law, regulation and data to the degree that Medicare has assumed in the Proposed Rule.

CMS has assumed that NGHPs are experts in the myriad amounts of data exchanged by physicians, hospitals, and the Medicare program, and that the insurers and self-insureds manage this type of data in every claim that they encounter. The opposite is true – NGHP encounters with Medicare beneficiaries are rare, and their need to collect the data elements required by CMS for reporting is also rare. Based upon actual 2013-2019 claims data, only 15-16% of individuals "queried" into the Section 111 system were identified by Medicare as beneficiaries.[1] For the Agency to propose that it will penalize RREs $1,000 per claim for a system that the Agency knows 85% of the time will not even involve a Medicare beneficiary is by definition arbitrary and capricious.

Another example of how RREs are strangers to the Medicare program relates to the roughly 125 data fields uniquely required by Medicare in reporting beneficiary settlements, judgments and awards, and particularly the reporting of a critical data element known as the International Classification of Disease (ICD) codes. This system of over 70,000 codes (referred to as ICD-9 and ICD-10 codes) is often misreported by hospitals and physicians, who must use the codes for every patient they treat. Yet, because CMS (and even Group Health Plans) widely uses ICD codes, it chose to require NGHPs to report ICD codes as well. NGHPs and the claims adjusters who handle individual claims, however, being strangers to the Medicare program, do not typically use ICD codes for claims resolution – particularly for liability and no fault (auto) claims. Moreover, the reporting requires RREs to include codes as alleged in broad and vague pleadings, regardless of whether the settlement, judgment, award or other payment is based upon that alleged, and often unfounded and unfunded, injury. Again, proposing to penalize RREs for reporting violations related to a code set that insurers and self-insureds rarely use (and that even providers and CMS, who use them all the time, cannot master) is also arbitrary and capricious.

[1] A survey of over 3.3 million claims resolved between 2013-2019 indicates that only 15% of workers compensation, 16% of no fault, and 15% of liability reports actually involved a Medicare beneficiary (data on file with author), meaning 85% of claims subject to the "query" phase of the reporting process are wasted effort. This suggests that CMS should be reconsidering the waste involved for both the Agency and for NGHPs in collecting data for the Section 111 reporting process, rather than proposing penalties for technical reporting violations that 85% of the time have no impact on the program.

Similarly, CMS has created a system for reporting "ongoing responsibility for medical" (ORM) claims. This may be the system that CMS believes (incorrectly) will result in no claim being accidentally paid by the Agency, but it is completely foreign to NGHPs, and there is no other context in which RREs monitor the tens of millions of claims that are filed each year (for multiple years) to determine whether the "ongoing responsibility for medicals" have terminated. Again, being strangers to Medicare, there would be no reason for NGHPs to do so, and insurers and self-insured entities do not do so for other reasons. While such a system may be convenient for CMS, proposing to penalize NGHPs who have no relationship with the Medicare program for systems that they never use is both arbitrary and capricious.

b. The Reporting Process Rarely Leads to CMS Recoveries

As explained above, 85% of claims initially reported through the query system result in no further activity as they do not involve Medicare beneficiaries. These cases should not be subject to any penalty for late reporting. In addition, however, even settlements, judgement and awards involving Medicare beneficiaries rarely result in any "conditional payment" cases or collections from CMS. A survey of approximately 5,000 settlements, judgments or awards in 2019 involving Medicare beneficiaries indicates that only 5% of such cases resulted in a Conditional Payment Letter (CPL) being issued by CMS. Many of those CPLs were for unrelated care, subsequently only 1% of the cases resulted in reimbursement of any conditional payment to the federal government.[2] MARC appreciates that in addition to repayment of conditional payments CMS believes the reporting of cases *prevents* the Agency from paying claims. The Agency has never published reliable statistics demonstrating the actual avoidance of payment that would have only occurred but for a Section 111 report.

Congress did not enact Section 111 of the MMSEA because reporting had any intrinsic value in and of itself. The only purpose for reporting was to allow CMS to know when a primary plan was available, so that the Agency could recover conditional payments and avoid payments that are others' responsibilities.[3] As demonstrated above, the reporting process is vastly overbroad, and requires reporting remarkable amounts of information about millions of settlements, judgments, and awards that will never result in recovery or avoidance of a conditional payment. No penalty should be assessed for any report (whether submitted containing errors or not submitted in the first instance), unless the Agency can demonstrate that it failed to receive reimbursement or avoid a payment due to the lack of a report.

III. Comments on the Proposed Rule

a. The Proposed Rule Violates the U.S. Constitution, Congress's Plain Language, and Recent Supreme Court Case Law.

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[2] *See also* Helland & Click, *Medicare Secondary Payer and Payer Delay*, 15:2 Jour. Of Empirical Studies 356, n.33 (June 2018), citing Helland & Kipperman, *Recovery Under the Medicare Secondary Payer Act: Impact of Reporting Thresholds*, Occasional Paper, RAND Institute for Civil Justice (2011), at 24, n 29 (noting that Medicare normally recovers only 15% of what it initially demands in workers compensation cases).

[3] *See House Ways & Means Greenbook,* Legislative History of MMSEA (purpose of Section 111 was to "secure from the plan sponsor and plan participants information necessary to identify situations where the group health plan is or has been a primary plan to the Medicare program"), available at https://greenbook-waysandmeans.house.gov/2012-green-book/chapter-2-medicare/legislative-history#anchor7;

i. The Proposed Penalties Violate the Constitution.

The Proposed Rule addresses penalties for "process" violations – failing to report the myriad of data fields related to a settlement, judgment, payment or other award – and not the substantive obligation to reimburse the Trust Fund for conditional payments. Given that only reporting is at issue, CMS must limit reporting penalties to ensure that they are proportional to the potential repayment (or avoided payment). Such limitations must be explicitly set out in the regulation to avoid Constitutional "excessive fine" violations.

The Eighth Amendment provides: "Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U. S. Const., Amdt. 8. The proposed $141,210 per quarter (as adjusted for inflation) penalties at issue here clearly violate that requirement. For example, the Supreme Court in *United States v. Bajakajian*, 524 U.S. 321 (1998), rejected the government's penalty of $357,000 (through forfeiture of the currency at issue) for failure to report the export of currency over $10,000. Finding the penalty disproportionate to the reporting violation, the Court held that "[t]he touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality: The amount of the forfeiture must bear some relationship to the gravity of the offense that it is designed to punish." 524 U.S. at 334. Particularly given that the impact of the reporting violations at issue in the case was particularly "…minimal [given that] [f]ailure to report his currency affected only one party, the Government . . .", *id.* At 339, and considering that the maximum penalty under the U.S. Sentencing Guidelines was $5,000, the Court rejected the penalty as unconstitutional.

As proposed, the penalty rule will violate the Constitution. For example, one large volume RRE reviewed 17,076 "open ORM" claims that were reported to CMS in 2017 which, under the Proposed Rule, would have trigger a "violation" for retroactive termination of the ORM. Using the penalty formula in the Proposed Rule (of the $1,569 penalty per day from the date of retroactive termination through the date the ORM was terminated) would result in penalties of over $35 billion dollars for this one RRE alone, and that is just for just 2017. This level of penalties is clearly Unconstitutional and wildly disproportionate to any harm to the program.[4]

CMS must explicitly incorporate into the Final Rule a penalty limit based upon proportionality given that the Supreme Court's analysis applies with equal force here. Congress has set an upper limit on the penalties that can be assessed for failure to reimburse the Trust Fund for conditional payments at double the amount owed. 42 U.S.C. 1395y(b)(3). It would be unconstitutional if a penalty assessed for failure to simply report the settlement were not proportionate to this amount. Thus, we urge the Agency to amend the Final Rule to include regulatory text setting the upper limit of any penalty to the amount of the underlying conditional payment related to the injury or illness (as defined in 42 C.F.R. 411.37).[5]

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[4] Data on file with author. Of the 17,076 cases, CMS never disputed that the RRE had correctly retroactively terminated ORM, and of all the cases at issue CMS recovered a mere $308,000 from 120 of the over 17,000 cases. . Even if CMS assessed penalties only on those 120 claims those would amount to $179,000,000, over 500 times the amount at issue.

[5] We also urge CMS in the Final Rule to establish clear regulatory authority to waive civil monetary penalties, in whole or in part, as appropriate. Nothing in the regulation should limit the authority of the Agency to settle any issue

In addition, we also urge CMS to modify the penalty proposal to eliminate penalties for the 90 day period during which RREs are unable to update reporting records or otherwise modify records. As the Agency acknowledges, RREs are provided a single reporting window once each quarter to submit reports. Thus, under the penalty regime in the proposed rule, a violation in one quarter does not trigger a $1,000 penalty (adjusted); it in fact triggers a $90,000 penalty (adjusted) until the next quarterly reporting window. Absent a change, the Proposed Rule will be unconstitutional for this second reason as well.

ii. The Proposed Rule is in Violation of the MSP Statute.

The Proposed Rule also is in violation of law because it fails to implement the fundamental change in the penalty regime enacted by Congress in the SMART Act of 2012. As originally enacted in 2007, reporting penalties were to be assessed as a mandatory "$1,000 for each day of noncompliance for each individual for which the information under such subparagraph should have been submitted." MMSEA Section 111, P.L. 110-173 (Dec. 29, 2007). In the 2012 SMART Act, however, Congress changed the language of the statute to both eliminate the mandatory $1,000 nature of the penalty and limit the penalty any RRE could be forced to pay to $1,000 per day, rather than $1,000 per day per claim. Following amendment, the statute now reads: "An applicable plan that fails to comply with the requirements under subparagraph (A) with respect to any claimant may be subject to a civil money penalty of up to $1,000 for each day of noncompliance with respect to each claimant." 42 U.S.C. § 1395y(b)(8)(E)(i). Thus, any RRE is only subject to a maximum penalty of $1,000 per day of reporting non-compliance irrespective of the number of claims not reported on a particular day.[6]

iii. The Proposed Rule is in Violation of the Section 1395hh.

The Proposed Rule also is in violation of the Medicare statute itself. More specifically, although the penalty rule is the subject of this notice and comment rulemaking, the underlying reporting requirements that form the substantive "violations" upon which penalties can be assessed have never been subject to notice and comment rulemaking, in violation of 42 U.S.C.§ 1395hh. That statute provides: "[n]o rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1)."

While CMS was permitted to "implement" the section 111 reporting requirements by "program instruction or otherwise," 42 U.S.C. § 1395y(b)(8)(H), implementation is far different from

or case or to compromise any civil monetary penalty at any time.

[6] CMS tries to rephrase the law as follows: an NGHP RRE may be subject to a CMP of up to $1,000…for each calendar day of noncompliance for each individual for which the required information should have been submitted." 85 Fed. Reg. at 9707 col. 3 and proposed section 402.405(b)(2)(B). The statute, however, does not include the phrase "for each individual for which the required information should have been submitted." Rather, it limits the penalty to any RRE to up to $1,000 per day, period.

enforcement. Thus, until the reporting requirements and standards are promulgated by notice and comment rulemaking pursuant to the Medicare statute and the Administrative Procedures Act, any penalties based upon technical violations or reporting requirements in the Section 111 Reporting Manual are in violation of law.

The Supreme Court in *Allina Health v. Azar,* 139 S.Ct. 1804 (2019), recently considered this issue, and held that the Agency's Medicare enforcement action against Allina was barred because the Agency was seeking to enforce a program requirement that was not subject to public notice and a 60-day comment period. The Supreme Court made clear that its ruling was applicable to any "rule, requirement, or other statement of policy ... that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals…" 42 U.S.C. § 1395hh(a)(2). The Section 111 Reporting requirements that CMS seeks to enforce through this penalty clearly meet the requirements of the *Allina* test. As such, they are not enforceable until promulgated through notice and comment rulemaking themselves.

SUMMARY RECOMMENDATION: Proposed Section 402.105(b)(3)(B) must be amended to:

(a) add explicit limits to ensure that the penalty is proportionate to the violation, and does not exceed the amount of the conditional payment in dispute or $50 if no conditional payments are in dispute, and

(b) remove references to penalties for "for each individual for which the required information should have been submitted" and to instead limit penalties to up to $1,000 per day per RRE, irrespective of the number of claimants involved.

Further, the standards of the Section 111 Reporting Manual cannot be enforced until promulgated through notice and comment rulemaking.

b. The Proposed Rule Must Incorporate CMP Sliding Scale Factors

The Proposed Rule is also flawed in that it fails to incorporate (directly or by reference) the sliding scale penalty factors found in 42 C.F.R. § 402.111. The regulation (reproduced in full at Appendix A) is a fundamental basis of CMPs generally, and in brief provides for consideration of the follow:

- The nature of the information given and the circumstances under which it was presented or given;
- The degree of culpability, history of prior offenses, and financial condition of the person submitting the information;
- The resources available to the person submitting the information;
- Such other matters as justice may require;
- Any aggravating circumstances, including whether the events occurred over a lengthy period of time, and whether the circumstances indicate a pattern;
- The amounts at issue;

- The existence of prior civil monetary penalties;
- The total number of reports, and whether they were related to claims less than $1,000; and
- Whether the reporting was the result of an unintentional and unrecognized error in the process and whether corrective steps were taken promptly after discovering the error.

It is difficult to understand why CMS did not propose to incorporate these basic elements of the CMP regulation into the Proposed Rule, which should be a critical component of a Section 111 penalty regime. Indeed, to not include such regulations will undermine the very reporting policies the Agency claims to encourage.

A simple example demonstrates the point. Company A has expended millions of dollars to comply with Section 111 reporting requirements since 2008, and has been reporting tens of thousands of claims since 2011. Company B has flouted the system and has never reported at all. Under the proposed regulation, Company A bears a far higher risk of penalty because there may be the occasional error in the data it reports. Company B, because it never reported, faces a lower risk of penalties, and even if it is caught, the penalty for A and B will be the same $1,000. It is obvious that this is both a violation of what Congress intended as well as poor policy.

Another example also demonstrates how the Proposed Rule works against the very policies of good data reporting that CMS should want to promote. Often insurers take over other entities that are in "runoff" (the equivalent of bankruptcy for an insurer). If insurer X, who historically has an excellent reporting history, takes over insurer Y's runoff, and discovers that insurer Y never reported under Section 111, it makes no sense under the Proposed Rule for insurer X to begin reporting and face $1,000 penalties notwithstanding its good faith efforts to comply. Instead, under the proposed rule insurer X would be better off not reporting Y's claims at all in the hope that CMS will never learn about the claims.

Congress clearly required a sliding scale standard when it modified the penalty provisions through the SMART Act to require "up to" $1,000 per day of penalty. For CMS to impose a $1,000 per day penalty when Congress explicitly changed that language is a direct statutory violation. We appreciate that CMS may have relied upon the specific references in the penalty provisions to "subsections (e) and (k) of section 1320a–7a of this title" as a limitation on applying the CMP regulations containing the sliding scale factors. But, nothing in the statute prohibits CMS from incorporating the sliding scale provisions into the penalty regulations,[7] and the explicit reference of "up to" $1,000 plainly indicates that Congress intended these sliding scale factors to apply.

SUMMARY RECOMMENDATION: We urge CMS to explicitly incorporate the factors in 42 C.F.R. § 402.111 into the Section 111 Penalty Regulation at Section 402.105.

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[7] When Congress did not want something to apply, it plainly stated so. The phrase "shall not apply" appears five times in Section 1395y alone.

c. The Proposed Penalties for Retroactive ORM Termination Are Flawed.

We also urge CMS to withdraw proposed section 402.1(c)(22)(ii), which would impose penalties for modifications of reports in response to CMS collection efforts. As explained in the preamble, CMS intends this regulation to apply to ORM reports, which sometimes are retroactively closed in response to CMS conditional payment repayment requests (CPLs). 85 Fed. Reg. at 9798 col. 1. However, we believe that CMS has misunderstood how ORM claims are monitored and when they are closed.

There are two different methodologies employed by RREs to terminate ORMs reports.[8] Some RREs have attempted to build automated systems that seek to track certain events such as expiration of statutes of limitations to terminate ORM claims. These systems, of course, are only as good as they were programmed, and as reliable as the data entered into the reporting systems. Because CMS has not issued any consistent guidance on when ORM can be terminated, each insurer's system is designed to a different set of parameters. In addition to these "automated" efforts, however, many RREs have chosen not to automate, but only to manually terminate ORM when the circumstances permit. These RREs will typically administratively close a claim file after the last payment or other event, and will not touch the file again to terminate ORM (or for any other reason) unless a new event (such as receipt of an MSP CPL demand) occurs.

We appreciate that CMS in proposing the new regulation assumed that all RREs employ automated systems to terminate ORM, but that is not the case. Further, as explained above, the ORM process is unique to the MSP system, and is never otherwise employed by NGHPs for any other purpose. It is impossible for adjusters working for companies with a manual ORM termination process to check every open ORM claim file every quarter to determine if some event may have occurred (such as the death of a beneficiary) that triggers ORM termination. Given that CMS has tightly restricted the conditions under which ORM can be terminated, the Agency has created a system where millions of claims remain in the CMS system as open ORM. Now, having built a flawed ORM system (about which MARC advised CMS over five years ago) preventing RREs from closing ORM, CMS now proposes to penalize RREs for not terminating ORM. This proposal is arbitrary and capricious.

Even in the most effective and accurate automated ORM termination system, it is inevitable that some claims will need to be retroactively terminated when CMS is pursuing collections. For example, multiple statutes of limitations could be applicable to a workers compensation claim (for example, where the employer in State A with a workplace in state B is responsible for an employee injury while driving a truck in State C and each of the three states has a different limitation periods on workers compensation claims). An adjuster in such an instance could easily put an incorrect termination date into the system, which would only be discovered when reviewing the file in response to a CPL. These mistakes are made in good faith and should never trigger a Section 111 penalty.

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[88] These comments will not address the conditions under which CMS allows RREs to terminate ORM. MARC for years has urged the Agency to modify its ORM termination criteria. The Agency has refused to do so, resulting in the RREs having to leave ORM open to meet CMS Manual requirements.

CMS has not proposed to penalize *bad faith* retroactive ORM terminations to avoid liability in response to a conditional payment demand – it has proposed to penalize *all* retroactive reporting corrections when CPLs are pending. Given that the Agency and its contractors make thousands of mistakes every month in navigating MSP claims (incorrectly sending claims to the Treasury, incorrectly sending demand letters to wrong addresses, and incorrectly seeking recovery for unrelated care, to name but three categories), it is arbitrary and capricious for the Agency to penalize corrections to reports when collection efforts are underway. This is particularly true for entities that manually terminate ORM, and which have no other way to reopen the numerous pending ORM files each quarter to check the various conditions under which ORM may be terminated. This proposed "gotcha" regulation is simply inappropriate.

Given that ORM is a unique Medicare process and that the Agency has rejected terminating files following administrative closure by the RRE, it is more than appropriate that ORM be permitted to be terminated in response to a recovery demand. We appreciate that it may be frustrating to the Agency and its contractors to encounter retroactive ORM termination on cases in recovery, but it is no less frustrating than RREs needing to report and then terminate ORM in the first instance. The proposed regulation must be withdrawn as arbitrary and capricious.

SUMMARY RECOMMENDATION: We urge CMS to withdraw proposed section 402.1(c)(22)(ii).

d. The Proposed Penalties for Based Upon Error Rate Thresholds Must be Revised

The Agency has also proposed in section 402.1(c)(22)(iii) to issue penalties to RREs who fail to accurately report 80% of their claims in four out of eight quarters. While MARC appreciates that CMS has attempted to set an appropriate erroneous reporting threshold that will capture few RREs, there are common instances where this threshold may be triggered which we believe are not the focus of the Agency's proposed policy. More specifically, there are a number of "low volume" RREs who may report 5 or 10 claims a quarter, where it might be quite easy to trip the error tolerances listed in the proposed regulation.[9] Many of these low volume reporters involve RREs with little experience in the reporting system, long-tail complex environment or toxic tort exposure claims that are infrequently resolved or settled, or insurer runoff situations (explained above).

Further, the proposal does not accommodate the numerous so-called "killer fields" – those Section 111 reporting fields that frequently cause a record to be rejected by CMS. Such fields include fields 64-76 seeking information about the beneficiary's representative counsel (including the counsel's phone number, address and zip code), and fields 18-36 related to ICD codes, including certain "invalid cause of injury" codes which when rejected by CMS cause the entire record to reject (even though reporting of the fields is optional).[10] Other fields

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[9] Further, the Proposed Rule fails to describe how the four out of eight quarters threshold would apply for RREs who use Direct Data Entry and thereby do not undertake quarterly reporting. We assume no penalty would apply.

[10] Although CMS publishes a list of valid and invalid ICD codes for companies to utilize, there are codes on the "valid" list that routinely caused reports to be rejected. RREs should be permitted to rely upon published

which commonly cause file rejection include field 15 ("Alleged Cause of Injury, Incident, or Illness"), which is critical information for the report, but for which the CMS system has not been appropriately designed. While the Preamble suggests that CMS will only consider "significant errors which prevent a file or individual beneficiary record from processing," 85 Fed. Reg. at 8798 col. 1, based upon information in the Section 111 User Guide, the proposed regulatory text does not include that qualification, and does not take into consideration the "frequently erroneously reported" claims. The proposal must define "significant errors" which prevent "processing" and accommodate for these and other fields that cause frequent report rejection.

MARC has previously commented that the Section 111 Reporting system is "overbuilt" and requires RREs to submit far more data than is necessary for the Agency to identify a conditional payment situation, and CMS should be focused on reducing the overall number of Section 111 data fields. Given the high number of data fields currently required, however, there is a relatively high risk that on any given field a small data entry error could cause the entire file to be rejected. Before CMS imposes penalties for data entry errors, CMS should identify the core fields that are needed in order to begin the conditional payment calculation and recovery process and identify ORM.

No CMPs should be assessed if there are errors or incomplete information in other fields. It falls on the Agency, as much as on the regulated community, to create a reporting system that is appropriately limited in scope and scale, and that can be implemented by the regulated community. For the Agency to now propose that it will penalize RREs for reporting errors triggered by codes the Agency knows (or should know) RREs are unable to accurately report is per se arbitrary and capricious.

SUMMARY RECOMMENDATION: Given the above, we request that CMS amend proposed section 402.1(c)(22)(iii) to have it apply only to RREs reporting a minimum of 1,000 reports each quarter. Further the regulation should be amended to explicitly limit the error threshold to misreporting of the 20 most significant data fields required by CMS to identify a conditional payment situation and which are currently not subject to high error rates.

e. The Proposed "Safe Harbor" for Data Collection from Beneficiaries Who Refuse to Provide Information Should Be Modified

We appreciate the proposed regulation's exemption from penalties for those situations where a beneficiary refuses to provide needed information to an RRE for reporting. *See* Proposed section 402.1(c)(22)(iv)(A). It is obviously appropriate not to penalize an RRE if they are unable to

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information from CMS and not be penalized when reports reject based upon codes CMS indicated were valid. We acknowledge that CMS appears to be acting on this issue. For example, for several years ICD codes I252 and code K222 would routinely cause reports to be rejected. When brought to CMS's attention, it corrected the 2020 ICD code lists. The burden, however, should not be on RREs to correct CMS information. And surely no penalty should be assessed for report rejections based upon ICD codes on the CMS "valid" list.

collect the very information that Medicare requires be reported due to no fault of the RRE. That being said, we are concerned that the requirement that an RRE seek this information twice in writing and a third time by other means such as telephone is too burdensome on RREs and on beneficiaries.[11]

First, beneficiaries will become angry and frustrated when repeatedly asked for the same information after they have made clear that they will not provide it. This could trigger complaints against RREs for privacy law violations, violations of insurance laws, and other consumer protection statutes, as has happened in the past. Second, the insurance industry in general is shifting towards reducing the number of "touches" that insurers and claims professionals are having with claimants, and this CMS rule directly contravenes that effort. And third, where a beneficiary is represented by counsel, the settling party is not permitted to speak directly to the beneficiary and can only contact beneficiary's counsel.

CMS should eliminate a mandatory minimum number of communications with beneficiaries, and instead simply require that the RRE make good faith efforts under the circumstances of the particular claimant to secure the necessary information for reporting. In some instances a single communication will make clear that the claimant will not be providing information, and in others it may take more than three attempts to secure the information. We recommend that CMS list it's "three contact" standard in the Final Rule preamble as a helpful guide to what the Agency will be looking for when attempting to collect the needed information.

SUMMARY RECOMMENDATION: We request that CMS eliminate section 402.1(c)(22)(iv)(A)(2), and that it simply reference the "three contact" (to the beneficiary or their counsel) standard in the preamble to the Final Rule as an example of the type of effort CMS expects from an RRE in normal circumstances.

We also request that CMS add a Safe Harbor that should exempt from penalties cases where: (1) a beneficiary is enrolled, whether directly or through beneficiary's counsel, in a mass tort MSP resolution program; or (2) when a claim has been resolved through a bankruptcy trust where the approved plan includes Section 111 reporting.

f. CMS Must Adopt a Three Year Statute of Limitations

CMS proposes to apply a five year statute of limitations to its penalty collection activities, based upon 28 U.S.C. § 2462. The applicable statute of limitations, however, should be three years, as memorialized by Congress through the SMART Act. 42 U.S.C. § 1395y(b)(2)(B)(3).[12] It would

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[11] Not only does the Proposed Rule require these frequently unnecessary communications, but it also requires RREs to maintain documentation of these communications for the entirety of the limitations period. In so doing, the Proposed Rule imposes significant recordkeeping and compliance costs on RREs. To comply with the Proposed Rule, RREs must develop new systems and processes to track, store, and categorize what could be up to tens of thousands of individual communications each year. The Proposed Rule ignores these recordkeeping and compliance costs entirely. MARC suggests that these costs are yet further reason why the Proposed Rule should focus on compliance with standard practices and procedures, rather than demonstrations of individual communications, to avoid the imposition of penalties.

[12] *See generally MSP Recovery Claims v. Farmers Ins. Exch.,* 2019 U.S. Dist. LEXIS 106417 (C.D. Cal. June 12, 2019); *Collins v. Wellcare Healthcare Plans, Inc.,* 73 F. Supp. 3d 653 (E.D. La. 2014) (generally applying three year

be odd if Congress, in clearly defining the statute of limitations for government recovery actions, did not also intend to apply the same limitations period for penalties associated with late reporting. As such, a three year limitations period, rather than a five year limitations period, must apply.

In addition, the preamble to the Final Rule should clarify that the limitations period runs from the first date of non-reporting. *See Gabelli v. SEC,* 568 U.S. 442 (2013) (clarifying that the government does not enjoy a "discovery rule" or any statute of repose for penalty recovery actions).

g. Other Comments on the Proposed Rule

There are several other aspects of the Proposed Rule which MARC supports, or which are missing from the proposed rule which MARC requests be added to the Final Rule. First, MARC agrees that the proposed penalties should only be applied prospectively for claims resolved with settlement, judgment, award or other payment with TPOC dates after the Final Rule, and that penalties should not be applied retroactively.

Second, MARC agrees that a one year compliance period should be afforded to any RRE for any individual report. To the extent that the Agency identifies a reporting gap or error during this period, we urge CMS to notify the RRE of the error and allow the RRE to correct any reporting error.

Third, MARC supports the proposed six month enforcement moratorium in response to any agency change in policy. Particularly given that RREs are only allowed a one week window per quarter to report claims, it will take at least two quarters for RREs to implement Agency policy changes (which may come out between an RRE's reporting windows). We urge the Agency to consider extending this implementation period by one year, as it often takes IT time to implement Agency reporting changes. Finally, we appreciate the Agency's commitment to "informal communication" and a "pre-notice process" prior to actually assessing penalties, as articulated in the preamble. We urge the Agency to emphasize and expand on these issues in the Final Rule.

In addition, we urge CMS to add specific regulations (or Final Rule preamble text) clarifying that penalties will be suspended: (1) for reporting delays due to natural disasters and other significant business interruption events (including, but not limited to, COVID-19); (2) for reporting mistakes due to incorrect information received from CMS in a "query response"; or (3) where information indicates that a settlement may be below the reporting threshold, but subsequent updated information (having to do with ongoing payments for medicals) places a claim above the threshold and triggers report submission.

IV. Conclusion

We appreciate, and support, the Agency's historic philosophy that the goal of the Section 111 Reporting program should not be enforcement, but rather "establishing an effective data

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statute of limitations to all aspects of MSP statute).

exchange process that works well . . ." Transcript, CMS NGHP Town Hall Teleconference, May 9, 2009 at 61.[13] CMS has historically repeated this commitment, including sharing the sentiment in 2020. To some extent, the Proposed Rule can be read as a further commitment to this principle. On the other hand, the Proposed Rule also appears to be a withdrawal from this principle, and instead a retreat to penalizing technical errors by RREs engaged in good faith efforts to comply with a flawed reporting system.

From the outset of the creation of the Reporting system, CMS refused to adopt standard coordination of benefit practices and retain the needed professional staff to examine claims and coordinate benefits. Instead, CMS tried to automate the benefits coordination system by utilizing a computer-driven "Grouper" that would compare reported ICD codes and assess demands for conditional payments and requiring reports of "ORM" to flag beneficiary files for denial of payment. The "Grouper" software and ORM systems today remain deeply flawed, generating significant erroneous demand information. Yet, the Proposed Rule continues to build upon this "automation" approach, proposing to penalize RREs for data reporting mistakes, rather than focusing on the purpose of reporting penalties, which is to incentivize notification to the Agency of settlements, judgments and awards in the first instance.

Most revealing are the Agency's statements in the Proposed Rule preamble that it does not have the ability to identify "any additional RREs that have failed to register and report as required." 85 Fed. Reg. at 8800, col. 3. Of course, the penalty regulations should be focused on exactly those entities not reporting. Instead, the Agency has defaulted to measuring statistics, rather than compliance – a system that will punish those trying to comply while incentivizing those who are not complying to continue to do so.

We are troubled by the Agency's statement that it is "not proposing to rely on the intent of the NGHP entity reporting. Instead, we [CMS] 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." 85 Fed. Reg. at 8795 col. 3. This technical "gotcha" penalty regime will not encourage entities who are not reporting to start, or advance the quality of current reports. Instead, it will penalize those RREs who have operated in good faith trying to meet a technically demanding set of reporting requirements that bear no relationship to what NGHPs actually do or how they work.

The Proposed Rule must be amended consistent with the above recommendations. For both the legal and policy reasons explained above, we urge the Agency to withdraw the proposal, and re-propose a rule that is aligned with the law and which will encourage compliance. In the alternative, we urge the Agency to promulgate a Final Rule that incorporates the changes identified in this letter. We appreciate the Agency's consideration of these comments, and welcome any further questions that the Agency may have. Please contact David Farber, counsel

[13] Available at: http://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Mandatory-Insurer-Reporting-For-Non-Group-Health-Plans/Archive/Downloads/April9NGHPTranscript.pdf; see also Transcript, April 9, 2009 at 61 ("we are not interested in CMPs, we're interested in establishing an effective data exchange process that works well and that's what our goal is"), available at: http://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Mandatory-Insurer-Reporting-For-Non-Group-Health-Plans/Archive/Downloads/April9NGHPTranscript.pdf

to the Coalition, at 202.626.2941 or dfarber@kslaw.com if you have any questions or request any further information regarding these comments.

Respectfully submitted,

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APPENDIX A
Text of 42 C.F.R. § 402.111

(a) Basic factors. In determining the amount of any penalty or assessment, CMS or OIG takes into account the following:

(1) The nature of the claim, request for payment, or information given and the circumstances under which it was presented or given.

(2) The degree of culpability, history of prior offenses, and financial condition of the person submitting the claim or request for payment or giving the information.

(3) The resources available to the person submitting the claim or request for payment or giving the information.

(4) Such other matters as justice may require.

(b) Criteria to be considered. As guidelines for taking into account the factors listed in paragraph (a) of this section, CMS or OIG considers the following circumstances:

(1) Aggravating circumstances of the incident. An aggravating circumstance is any of the following:

(i) The services or incidents were of several types, occurring over a lengthy period of time.

(ii) There were many of these services or incidents or the nature and circumstances indicate a pattern of claims or requests for payment for these services or a pattern of incidents.

(iii) The amount claimed or requested for these services was substantial.

(iv) Before the incident or presentation of any claim or request for payment subject to imposition of a civil money penalty, the respondent was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services.

(v) There is proof that a respondent engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to government programs or in connection with the delivery of a health care service. (The statute of limitations governing civil money penalty proceedings does not apply to proof of other wrongful conduct as an aggravating circumstance.)

(2) Mitigating circumstances. The following circumstances are mitigating circumstances:

(i) All the services or incidents subject to a civil money penalty were few in number and of the same type, occurred within a short period of time, and the total amount claimed or requested for the services was less than $1,000.

(ii) The claim or request for payment for the service was the result of an unintentional and unrecognized error in the process of presenting claims or requesting payment and the respondent took corrective steps promptly after discovering the error.

(iii) Imposition of the penalty or assessment without reduction would jeopardize the ability of the respondent to continue as a health care provider.

(3) Other matters as justice may require. Other circumstances of an aggravating or

mitigating nature are taken into account if, in the interests of justice, they require either a reduction of the penalty or assessment or an increase in order to ensure the achievement of the purposes of this part.

(c) Effect of aggravating or mitigating circumstances. In determining the amount of the penalty and assessment to be imposed for every service or incident subject to a determination under § 402.1(c) -

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment is set at an amount sufficiently below the maximum permitted by §§ 402.105(a) and 402.107 to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment is set at an amount at or sufficiently close to the maximum permitted by §§ 402.105(a) and 402.107 to reflect that fact.

(d) (1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(2) The amount imposed is not less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including but not limited to the costs attributable to the investigation, prosecution, and administrative review of the case.

(3) Nothing in this section limits the authority of CMS or OIG to settle any issue or case as provided by § 402.19 or to compromise any penalty and assessment as provided by § 402.115.