Medicare Advocacy Recovery Coalition

February 7, 2014

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

Re: CMS-6061-ANPRM; MEDICARE SECONDARY PAYER AND CERTAIN CIVIL MONETARY PENALTIES

Dear Administrator Tavenner:

The Medicare Advocacy Recovery Coalition (MARC or the Coalition) is pleased to provide comments on the December 11, 2013, Advance Notice of Proposed Rulemaking addressing implementation of Title II of the Medicare IVIG and Strengthening Medicare and Repaying Taxpayers Act of 2012 (the SMART Act), and specifically implementation of Section 203 of the Act related to the assessment of penalties under the MSP reporting regime established by Section 111 of the MMSEA (the "Section 111" reporting process). 78 Fed. Reg. 75304 (Dec. 11, 2013). MARC thanks the Agency for taking the necessary steps to implement the SMART Act, and encourages CMS to promptly issue a Proposed Rule as quickly as possible based upon these comments and the comments of others so that the regulated community understands how the Agency proposes to implement the Section 111 process. Although the Coalition is disappointed that the Agency failed to publish the ANPRM within 60 days of the SMART Act's enactment, as required by the law, MARC appreciates the opportunity to share its thoughts with the Agency at this time, and looks forward to the completion of a final rule with safe harbors within the coming months.

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. Most importantly, the comments reflect the Coalition Members' desire to clarify the Section 111 process so that all Responsible Reporting Entities ("RRE"), their agents, counsel and advisers, and all others involved in the MSP process know their obligations and can comply with the law.

I. Delegation of Authority

Prior to addressing the issues raised in the ANPRM, MARC urges the Agency to promulgate a notice delegating enforcement authority for Section 111 penalties to the appropriate Agency. The Secretary is obligated to delegate authority for the enforcement of Civil Monetary Penalties (CMP) to an appropriate agency. *See e.g.* 59 Fed. Reg. 52967 (Sept. 12, 2008), 76 Fed. Reg. 13618 (March 14, 2011) (delegating CMP authority). MARC specifically requests that the Secretary delegate her enforcement authority to the office of the Department General Counsel. We believe that the complexity of the MSP program, the unique nature of the claims process, the expertise within the Agency, and the reliance by CMS upon contractors and the benefits coordination process, all support the Department's General Counsel office having a direct role in the implementation of the Section 111 enforcement process.

As the Agency is aware, Section 111 was enacted into law in December 2007, and was to be implemented in July 2009 for non-group health plans (NGHPs). While the Agency appropriately deferred implementation of the NGHP program, the program has been operational since January 2011. We appreciate, and support, the Agency's notion that the goal of the program should not be enforcement, but rather "establishing an effective data exchange process that works well . . ." Transcript, CMS NGHP Town Hall Teleconference, May 9, 2009 at 61.[1] MARC suggests that transparency around the Agency's implementation plans will assist in that regard. Whomever the Secretary chooses, we urge that the delegation occur as soon as possible.

Summary: We Urge CMS to publish a Delegation of Authority Notification delegating enforcement of Section 111 to the HHS Office of General Counsel.

II. Timing of ANPRM

As noted above, the Coalition is disappointed that the ANPRM was not issued until December 11, 2013. As CMS is aware, Congress was particularly interested in the Agency promptly establishing safe harbors around the Section 111 program, and for that reason Section 203 of the

[1] 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

SMART Act required the ANPRM to be issued by March 10, 2013. We are aware that CMS approved the notice on May 28, 2013, and that the Secretary signed the notice on July 30, 2013. Yet, the proposal was not issued until December 11, 2013. In light of the timetable mandated by Congress, we urge the Agency to assimilate the comments it receives into a proposed rule as soon as possible and publish that proposal in the Federal Register so that the rulemaking can be finalized soon.

Summary: We request that CMS expedite the formal rulemaking procedure, and publish a Notice of Proposed Rulemaking, as soon as possible.

III. Comments on definition of "Noncompliance."

The Agency has specifically requested recommendations on how to interpret the word "noncompliance" in the context of the phrase "for each day of noncompliance with respect to each claimant." In our view, noncompliance in the context of the phrase has two distinct meanings. In context, it modifies the former text of the MMSEA which assessed penalties per claim per day per RRE, and now permits penalties of "up to" $1,000 per day for RRE, irrespective of the number of claims that RRE may be obligated to report. We recommend that CMS make this clear in its proposed rule.

The second meaning is with regard to the substantive definition of the term non-compliance. Our review of applicable federal laws and regulations has not revealed any specific regulatory definition of the term. Further, the limited User Guide guidance issued by CMS in 2010 related to defining compliance in the context of RRE registration and data testing is unworkable as a definition for purposes of the regulation. Rather, the agency must look at the individual circumstances of a particular RRE, including the RRE's size, complexity, frequency of reporting, and other facts, in determining what constitutes "non-compliance." Our comments below expand further on this "sliding scale" definition, which focuses on the circumstance of the individual company involved and the absence of any safe harbor or other mitigating factors such as self-correction, opportunity to cure, or other similar efforts.[2]

We also urge CMS to clarify that an act or omission should not be deemed to constitute noncompliance if CMS guidance that has been published in the User Guide or posted in Alerts, which are effective as of the date of the relevant act or omission, are contrary to MSP statute or regulations. More specifically, RREs should not be deemed non-compliant for failing to adhere to oral guidance offered in Town Hall meeting transcripts that conflicts with MSP law or published/posted CMS guidance.

We urge CMS, in choosing a definition, to also define the elements and criteria which will serve as mitigating factors. For example, if multiple RREs are obligated to report a claim, and at least one has done so, the others should not be deemed to be out of compliance for not reporting

[2] We urge CMS not to adopt prior guidance developed by the HHS Office of Inspector General for health care providers and other direct participants in the Medicare system. *See*, e.g., 63 Fed. Reg. 70138 (Dec. 18, 1998). These elements as a measure of MSP compliance are not appropriate given that they were developed by OIG for business entities that are normally involved in the Medicare program. They are not functional for businesses that rarely engage with Medicare but touch the program only by the coincidence of their MSP obligations.

information already in the Agency's possession. Similarly, a non-repetitive negligent failure to file a report, when that RRE is normally compliant, should not meet the definition of noncompliance.

IV. Mechanisms and Criteria to Employ in Evaluating Whether and When to Impose Civil Monetary Penalties

The MARC Coalition urges the Agency to develop clear mechanisms and explicit criteria that it will employ when determining whether and when to impose CMPs. Only by setting forth clear rules and expectations can CMS enable the regulated community to understand precisely what is, and is not, expected. At the same time, the Agency also needs to recognize the nature of the subject matter at issue – reporting settlements and other payments. We identify this issue in that Section 111 is a "process" issue, rather than involving a substantive obligation to reimburse the Trust Fund for conditional payments, and thus many of the existing Medicare and other guides to compliance and enforcement are not particularly applicable in these situations. As CMS is aware, the "Section 111" provisions (42 U.S.C. § 1395y(b)(8)(E)(i)) apply section 1320a-7a(a) subsections (e) and (k) to the civil penalties (including the penalties in section 203 of the SMART Act), which in turn includes numerous provisions referencing "knowing" violations and "patterns or practices" of violations. Indeed, the criteria set out in 42 C.F.R. § 1003, and specifically the eight criteria set for in 1003.106(a), modified for purposes of MSP reporting, provide an appropriate guide, as follows:

> (i) The nature of the wrongdoing;
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> (ii) The degree of culpability of the person against whom a civil money penalty is proposed;
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> (iii) The history of prior offenses of the person against whom a civil money penalty is proposed;
>
> (iv) The financial condition of the person against whom a civil money penalty is proposed;
>
> (v) The completeness and timeliness of any remedial action by the person against whom a civil money penalty is proposed;
>
> (vi) The amount of the underlying conditional payment at issue subject to the violation;
>
> (vii) The financial interest of the reporting entity in the conditional payment amount; and
>
> (viii) Such other matters as justice may require.

MARC also wishes to emphasize that while clear rules and explicit criteria will be important, there are a massive number of RREs and potential RREs, across a wide variety of companies large and small in varied industries, to which these rules will apply. To be very clear, these rules will not just apply to insurers, and the Agency needs to consider and measure its proposed criteria against how they will be applied to large and small self-insured entities ranging from Fortune 500 companies to small businesses on "Main Street." (Our comments in Section V, below, address how the Agency's Rules should be applied.) The Agency must allow room for

fact based determinations on a case by case basis taking into consideration the individual circumstances of the RRE at issue.

A. Mechanisms – Notice and Opportunity to Cure: We have set out below a series of proposed "Safe Harbors" that effectively incorporate a series of operative principles that the Agency should employ. As to the "mechanisms," however, we believe that no penalty should be assessed until an RRE has received notice of a potential violation and has been given an appropriate 90-day opportunity to cure the alleged deficiency. For purposes of this rulemaking, notice should be direct notice to a responsible corporate officer of the RRE, rather than just mailing a notification to the address for the RRE within the files of the CMS contractor.

We place emphasis on this particular point as a result of the experience of numerous RREs over the last three years with Treasury Offset Program (TOP) recoveries for purported "final" claims for which they never received notice. Upon inquiry, the RRE learned that the CMS contractor had sent a notice to an RRE district office or retail location simply because that was the address in the MSPRC file. Such misdirected mailings should not constitute notice for the TOP program, and they should not constitute notice for the penalty process. Thus, the Agency's proposal must make clear that notice should be sent to the RRE "authorized representative," as designated on the RRE registration, with a copy to the RRE Agent of Record, if any (or, if an entity is not registered as an RRE, then the responsible corporate officer of the company against which a penalty is proposed to be assessed).

Similarly, the opportunity to cure must be meaningful. Given that reporting is only a "procedural" obligation, sufficient time should be afforded to any RRE (or potential RRE) to gather facts and information needed to report. To the extent that the RRE has a good faith belief that it has met one of the safe harbors to be established, there must be sufficient time for the RRE to present its views as to why reporting is not needed or why it is otherwise exempt. We recommend at least a 90-day period be used, subject to extension as circumstances warrant.

B. Criteria to Employ: Beyond the principles and concepts in the proposed safe harbors, set forth below, there are several blanket rules that the Agency can readily adopt to appropriately assess penalties against those attempting to avoid the Section 111 process, rather than impose technical fines against those striving for good faith compliance. For example, the Agency must use a sliding scale of penalty based upon the individual culpability of the alleged violator – that is precisely what Congress intended when it amended the Section 111 language to insert the words "up to" before the proposed penalty cap of $1,000 per day.

In addition, there are several types of Section 111 reports that should never be the subject of penalty enforcement. Such reports include updated "Ongoing Responsibility for Medicals" ("ORM") reports when at least one ORM report has previously been filed and is currently in the CMS database. Similarly, penalties should be suspended during major transitions of data reporting fields which may result in data reporting errors (such as the impending conversion from ICD-9 to ICD-10), transition or modification of reporting thresholds, implementation of the "mass tort" program, the impending transition from one CMS contractor to another (or otherwise modifying its systems), or a company's change from one reporting agent to another. Finally,

compliance flags should never be used as a proxy or vehicle for assessing civil monetary penalties.

V. Methods to Determine the Dollar Amount of a CMP for Each day of NGHP RRE Noncompliance

MARC urges CMS to adopt a sliding scale of penalties, measured against intentionality, proportionality, the repetitive nature of the RRE's noncompliance. However, before addressing substantive considerations, MARC addresses legal and Constitutional considerations that the Agency must account for in setting its methodology.

A. Legal Considerations: As previously noted, at issue are penalties for a "process" violation – failing to report a settlement, judgment, payment or other award. The substantive obligation to reimburse the Trust Fund for conditional payments is not at issue in this Rulemaking. That being said, the amount of potential repayment must be a factor that the Agency need consider before setting any penalty amount. For example, it would be wholly inappropriate to assess a $50,000 penalty for failing to report a claim that, at its maximum (and even if doubled), would result in a reimbursement to the Trust Fund of $2,500. A penalty of twenty times the underlying obligation exceeds Constitutional limits on CMPs.

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 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. Finding that the impact of the reporting violations at issue was particularly "…minimal [given that] [f]ailure to report his currency affected only one party, the Government . . .", *id.* At 339, and that the maximum penalty under the U.S. Sentencing Guidelines was $5,000, the Court rejected the penalty as unconstitutional.

The same analysis should apply 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 in excess of this amount. Thus, we urge CMS to explicitly set the upper limit of any penalty at two times the amount of the underlying conditional payment related to the injury or illness (as defined in 42 C.F.R. 411.37), except in cases of willful and intentional non-compliance (as qualified by the criteria in subsection B, immediately below). (For those situations where a report was due but there is no conditional payment, the maximum penalty should be set at no greater than $50 or less, as there has been no harm to the government.) Along the same lines, we urge CMS to establish clear regulatory authority to waive civil monetary penalties, in whole or in part, to the extent that the payment of the penalty would be excessive relative to the violation. Nothing in the regulation should limit the authority of CMS to settle any issue or case or to compromise any civil monetary penalty at any time.

B. Substantive Considerations – Intent, Proportionality, Repeat Violators, and Other Factors: As to the question of intent, the subjective state of mind and actions of the RRE should be used to evaluate whether an RRE intended to avoid compliance, or whether the RRE was simply uninformed of its reporting obligations. While MARC appreciates that a failure to understand or comply with the law should not be a defense, the Agency needs to appreciate that literally every business in the United States, from the country's largest companies to the "mom and pop" restaurant, is subject to reporting compliance. Until and unless the Agency is able to mount a sustained public relations campaign surrounding reporting (and MARC respectfully suggests that Agency resources would be far better spent on numerous other efforts) there is simply no manner in which many "Main Street" businesses will be able to master the complexities of the Section 111 Reporting process. Again, MARC offers this not as an excuse, but as an element for CMS to account for in applying its sliding scale penalty formulation. Conversely, if evidence suggests that an RRE was aware of its obligations and intentionally or recklessly ignored them, that too should be considered in the sliding scale penalty formulation.

Proportionality is also important. Penalties for a single failure to report in the context of hundreds (or thousands) of other reports should be minimal. There may also be instances where failing to report thousands of claims over a sustained period of time may not be deserving of a penalty. Proportionality is not only required in measuring penalties for one RRE against another RRE, but also in measuring the amount of a penalty assessed against a large RRE with a history of compliance against instances of failures to report.

The repetitive nature of the noncompliance is also an important factor for evaluation. Again, repetitive noncompliance may be a factor of the business line that the RRE is involved in, and may also be a factor of computer issues, data transmission problems, data collection difficulties in the RRE's industry, or other similar factors. Further, CMS is already aware that many RREs use agents to meet their reporting requirements, and it may be the case that an Agent has inadvertently failed to report a payment or series of payments. While MARC appreciates that RREs need to be responsible for the agents that they utilize, and that an agent's failures are not a wholesale defense for an RRE, this circumstance should be evaluated by the Agency as a mitigating factor in the assessment and calculation of a CMP for failure to report. However, given the nature of reporting, which for many entities takes place on a continuous basis as claims settle day after day, the fact that a reporting lapse is ongoing, and is therefore repetitive, should not be considered in assessing penalties.

Mitigation is also an important factor. As noted above, the RRE's efforts to mitigate both the failure that led to the proposed penalty, as well as the RRE's efforts to mitigate future lapses, must be taken into account in setting a penalty amount. Clearly RREs who take immediate mitigating actions and set up good faith efforts to avoid future lapses should face a far reduced penalty amount than entities that ignore the law and fail to take corrective actions beyond curing the reports that underlie the proposed penalty.

CMS should also permit RREs to assert affirmative defenses, such as allowing an RRE to establish that it did not have knowledge of the violation and by exercising reasonable diligence, would not have known that the violation occurred; or that the violation is due to circumstances that would make it unreasonable for the RRE, despite the exercise of ordinary business care and

prudence, to comply with the reporting requirements violated and is not due to willful neglect, and was corrected within a reasonable period of time based on the nature and extent of the cause of the failure to comply.

Finally, MARC urges CMS to promulgate a safe harbor clarifying that any penalties will only accrue for settlements and judgments, and associated reports required, after the date of the final regulation. It would be unfair to assess penalties retroactively under rules that had not yet been promulgated. Thus, any penalties should apply prospectively only.

VI. Methods and Criteria to Determine "Good Faith Efforts" For Purposes of Civil Monetary Penalty Assessment

The ANPRM also seeks methods and criteria by which CMS can determine "good faith efforts" of compliance for CMP purposes. MARC understands this request as seeking specific "safe harbor" proposals under which an entity meeting the requirements could avoid penalties altogether. Consistent with the proposal that MARC shared with CMS in 2012, MARC proposes that the Agency adopt the following safe harbors:

A. Safe Harbors related to the Reporting File and Submission Process

1. Good Faith Efforts To Collect Information: Industry is making every effort to gather all of the information that CMS requests for the Section 111 reporting file. However, there are situations in which RREs cannot obtain all of the needed data. Safe Harbor protection should be extended to an RRE if the individual is a Medicare beneficiary, and the beneficiary or representative refuses to provide a SSN/HICN.

RREs continue to struggle with obtaining Social Security Numbers (SSNs) and/or Health Insurance Claims Numbers (HICNs) from beneficiaries and other claimants who are extremely reticent to provide this information. *See, e.g. Hackley v. Garofano*, 2010 Conn. Super. LEXIS 1669 (Sup. Ct. Ct. July 1, 2010) (example of settlement being unwound by court due to reluctance of claimant to provide social security numbers for reporting purposes). MARC recommends that safe harbor protection should be afforded where an RRE makes a good faith effort to identify the claimant as a Medicare beneficiary but is unable to do so, including but not limited to where the claimant submits a signed document (not necessarily an affidavit or the CMS model language) that he/she is not a Medicare beneficiary and is unwilling to provide a SSN. With regard to the current CMS model request form, MARC recommends adding language that would urge claimants (even if not beneficiaries) to provide their HICN or SSN so that their beneficiary status can be monitored until their claim is resolved.

MARC also recommends safe harbor protection where a RRE has documentation indicating that it has made multiple attempts to collect a SSN/HICN from a claimant who refuses to provide the information or to sign a written document so stating. Such documentation should be allowed to include evidence of receipt-of-mail, notes in a claim file documenting phone conversations, or personal contact with the claimant during which the claimant states that he or she is not a Medicare beneficiary and refuses to provide a HICN or SSN. Permitted documentation could also include a letter from an attorney on behalf of a claimant denying that the claimant is a beneficiary and refusing to provide a HICN or SSN.

In cases involving ongoing responsibility for medical treatment (ORM), MARC recommends that if a claimant refuses to provide his or her HICN or SSN, and the RRE documents that refusal through one of the avenues addressed above, then the RRE should be protected from an ongoing responsibility to periodically query the system to assess whether the individual is a Medicare beneficiary. If the RRE is unable to obtain this information from the claimant, they will be unable to submit the required query.

2. Rejected Files: There are also instances where RREs have submitted data they know to be accurate, such as their Taxpayer Identification Number (TIN), but have still had the claim rejected based upon that information. If a claim is erroneously rejected on the basis of accurate information, the RRE should not face any penalty for delayed reporting.

3. Data Entry Errors: We have previously noted that MARC believes that it is possible to reduce the overall number of data fields reported to CMS while still providing all of the information that CMS will need to accurately assess a conditional payment amount and pursue a conditional payment recovery or identify ORM. Given the high number of data fields currently required, there is a relatively high risk that on any given field a small data entry error could cause the entire file to be rejected. MARC recommends that CMS identify the core fields that are needed in order to begin the conditional payment calculation and recovery process and identify ORM. If there are errors or incomplete information in other fields, MARC suggests that no CMPs should attach because such fields are not material. From an operational perspective, MARC suggests that CMS accept all claims where material information is provided on the claim and flag the missing or incorrect data fields for correction by the submitting RRE. This would allow the claim to move forward toward processing while the RRE finalizes the ancillary information.

We also note that there may be instances of natural disasters and other significant business interruption events (either at an RRE or at CMS) that may prevent data reporting. No penalties should be assessed during such periods.

4. Reliance on Incorrect Query Information: RREs should be able to rely on the results they obtain through CMS' HICN/SSN query system. MARC recommends that in instances where the RRE has relied on information provided by CMS in response to a monthly query regarding whether an individual is a Medicare beneficiary, it should not be penalized if the query returned incorrect information. Towards this end, it would also increase reporting accuracy if CMS could provide dates of eligibility and/or benefit termination as part of the query system.

Similarly, there are instances 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 reporting threshold and requires submission of a report. No penalties should accrue in such situations for the period of time before the RRE becomes aware of the updated information, and good faith documentation that an RRE had a valid belief that a settlement or judgment was below the reporting threshold should serve as a safe harbor. Further, RREs should not be penalized if the query fails to identify the claimant as a Medicare beneficiary where the RRE relies on information provided by the claimant and it has no reason to suspect that such information is incorrect.

B. Safe Harbors Based Upon Certain Judicial Actions

1. Court Orders Enforcing Settlement Without SSN/HICN: Since enactment of Section 111, the Medicare Secondary Payer process has been the subject of significant judicial review and activity. In some of these cases, RREs have been placed in a difficult position of trying to comply with the Section 111 reporting process despite a judge's determination that a plaintiff does not need to provide certain information. As we noted above, many individuals are extremely reluctant to provide their SSN or HICN to a party they feel has caused their injury. There are cases where either the judge specifically declines to require the plaintiff to provide his or her SSN or HICN or where a jury verdict is awarded to the plaintiff and the judge does not specifically require the plaintiff to provide this information. In these situations, RREs should receive safe harbor protection.

2. Release of Funds: There have also been cases where a judge has specifically required a RRE to release its payment to a claimant despite the claimant's refusal to provide data to the RRE for the purpose of the Section 111 reporting process. In these situations, the RRE is powerless to obtain the information it needs to be compliant. MARC recommends that a safe harbor should be available in these circumstances.

C. Safe Harbors Related to Certain Categories of Cases and Claims: We understand that CMS remains a part of the process of resolving how large class-action mass-tort cases should be addressed for the purpose of Section 111 reporting. MARC recommends that until such time as the policy for these cases has been resolved and it is clear what entity will be the RRE, penalties should not be assessed for any failure to report. As CMS develops its approach to such mass-tort claims, MARC recommends that CMS consider that the full list of claimants in these cases is often not identified until long after settlement. In these situations, RREs should have a longer period of time to submit the claim report, and that the date on which the claim must be submitted should be tied to when the claimant was identified rather than the date of settlement. (In this regard, the guidance around "timeliness" in the CMS User Guide, Ch. 3, Section 6.5, should be incorporated into the safe harbor provisions.)

1. Emotional Distress and Other Claims that Do Not Involve Actual Medical Treatment: There are also certain types of claims that, by their nature, do not involve any actual injury other than allegations of "infliction of emotional distress." Such claims can also include medical monitoring claims where no actual medical treatment is provided. These claims are rarely indicative of any actual personal injury claims and typically do not have any associated treatment or medical care. Yet, such claims are often present in a case. These categories of cases, including employment practices (including employment discrimination and wrongful termination claims), insurance bad faith (alleged violations of insurance code for alleged unfair claims handling) claims, shareholder disputes, loss of consortium, and contract claims, should be categorically non-reportable, barring an actual showing of medical care.

2. Homeowner/Property Damage Only Claims: Similarly, homeowner's policy claims, or property damage only claims, by their nature, do not involve any actual injury. While the Agency has made clear that these claims and settlements thereof should not be reported, the threat of a penalty leads compliant companies away from taking any risk that a broad "release" in a settlement (which typically always includes release of bodily injury claims, even when none

were alleged or asserted) might trigger a reporting obligation. Rather, claimants add these claims to bolster their request for damages. These categories of cases should be categorically non-reportable, barring an actual showing that medical care was received.

3. State Law Limitations: We also recommend that CMS adopt a safe harbor in instances when state law does not permit recovery of medical expenses. For example, Medicare recognizes that in certain states no medical recovery is permitted if a beneficiary is deceased before a settlement is reached or other payment can be made. *See* Medicare Secondary Payer Manual 50.5.4.1.1 - Wrongful Death Statutes.[3] (We appreciate that family members may retain claims against potential tortfeasors, but such claims are not for medical expenses, and thus cannot be the subject of conditional payment claims. Further, these state laws do not limit the United States' ability to bring a direct action for recovery of medical expenses under 42 U.S.C. 1395y(b)(3), but such claims do not implicate Section 111 reporting requirements.) Thus, in cases where a beneficiary dies prior to a settlement or judgment, no reporting should be required.

4. Statute of Limitations: Finally, we urge CMS to adopt a clear limitations period beyond which no penalty claims will be assessed. Consistent with the Agency's views in other regulatory penalty regimes, we request that CMS issue clear proposed regulations stating that CMS will not exercise its CMP authority unless a complaint is filed on or within the three year period beginning on the date that CMS receives notice from the RRE of settlement, judgment, award or other payment relating to an injury under 42 U.S.C. 1395y(b)(8). This three year limitation period is consistent with Congressional intent in the SMART Act, as well as with other law.

D. Safe Harbors Related to Process Changes Allowing RREs to Correct Errors: In addition to the above specific safe harbors, MARC suggests that CMS consider providing RREs an opportunity to cure any errors identified during the initial reporting period before penalties would be incurred. If CMS identifies error flags on a data file, we recommend that the RRE be alerted as to those errors and have a certain amount of time, possibly one to two reporting quarters, to correct those deficiencies. This would allow RREs to correct these fields and provide CMS with the data it has requested before penalties would begin to accrue. The initial submission would achieve the goal of ensuring that CMS is aware of the settlement, even if there are some errors that will need to be addressed. Allowing the initial claim to go through will permit the RRE to correct these minor errors while still ensuring that CMS has the most essential information.

If there are any errors or missing fields in a report, CMS often rejects the claims and sends it back to the RRE. It has been the case that the RRE cannot re-submit a corrected file until its next reporting window, and although current guidance allows an opportunity to update a report before the next reporting window, that policy could change in the future and could create situations in which the RRE must wait 90 days for the next opportunity to correct the file. MARC recommends that CMS allow RREs to have the opportunity to correct errors before the

[3] Available at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/msp105c07.pdf at page 113-14.

next reporting window and that any proposed or final rule make clear that penalties should not begin accruing until the RRE has had an opportunity to correct any errors or deficiencies.

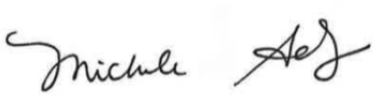
MARC also suggests that for claims where CMS has already processed a conditional payment and the RRE has made a direct payment following a Final Demand Letter, penalties should not accrue as a result of Section 111 reporting process. Claims that have already been resolved and resulted in a reimbursement to CMS should not be the subject of further penalties unless there is an incidence of knowing and intentional failure to report or an RRE's reckless disregard of the reporting requirements.

* * *

Conclusion: MARC urges the Agency to promulgate a Notice of Proposed Rulemaking as soon as possible, to include an explicit delegation of enforcement authority to the CMS General Counsel, define the needed terms as required by the SMART Act, and include the proposed safe harbor provisions set forth above.

We appreciate the Agency's consideration of these comments, and we welcome any further questions that the Agency may have related to the SMART Act and its implementation. Please contact David Farber, counsel 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,



Michele L. Adams, Chair
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