April 20, 2020

Via www.regulations.gov

The Honorable Seema Verma
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

Dear Administrator Verma:

DRI – *The Voice of the Defense Bar*, greatly appreciates the opportunity to comment on the February 18, 2020, Proposed Penalty Rule under the Section 111 reporting requirements of the Medicare Secondary Payer laws. The proposed rule, published at 85 Fed. Reg. 8793 (Feb. 18, 2020), would impose substantial penalties upon thousands of companies and municipalities across the country for technical reporting mistakes.

We believe that the proposal is far too sweeping and overly broad and will inappropriately penalize companies that have invested significant sums of money, time and effort to attempt to comply with Medicare's expansive, detailed and ever-changing reporting requirements. We are particularly troubled that the proposed rule does not explicitly incorporate the mitigating factors found in existing regulation, and appears to be focused on technical reporting accuracy, rather than good faith efforts to comply with the reporting requirements. Furthermore, the safe harbor provisions cannot be accomplished where a beneficiary is represented by an attorney and are lacking in specificity. The safe harbor provisions fail to consider the implications Section 111 reporting requirements have for resolutions in mass torts. We urge the Agency to significantly amend the proposal before finalizing any regulation.

Background

As background, DRI is an international organization of defense attorneys, corporate counsel and corporations. DRI is recognized as a thought leader and an advocate for the defense bar and its clients at the national and state level, as well as in Europe. With more than 19,000 members, DRI provides members and their clients with access to world-class education, legal resources and numerous marketing and networking opportunities that facilitate career and law firm growth. For more information, log on to www.dri.org.

DRI's Center for Public Policy specifically created an MSP Task Force to help educate its members and their clients on all MSP issues, with the goal of ensuring that the Medicare Trust Funds are reimbursed the appropriate amount, and insurance companies as well as self-insured entities are educated on reporting requirements. Members of the MSP Task Force actively handle matters involving MSP issues and educate the legal community on these issues.

Before commenting on the specific provisions of the proposed rule, we wish to put our efforts, and those of our clients, in context. Prior to implementation of the mandatory reporting requirements, many of our non-group health plan ("NGHP") clients were unfamiliar with the codes that CMS insists they report. For example, they do not generally deal with ICD-9 and 10 codes in the resolution of the claim, nor would they track Medicare Claim Numbers. NGHPs do not otherwise collect much of the information that CMS requires for both identifying individuals as beneficiaries, or, if they are beneficiaries, submitting full Section 111 reports. The ongoing reporting of medical ("ORM") process is foreign to adjusters and DRI as it only exists for purposes of the Medicare program. While the industry has asked Medicare to create a reporting system that liability, workers compensation, and no-fault insurers can actually implement, the Agency has not given sufficient consideration to what insurers and self-insureds (and their adjusters) do and how they work, and has instead created a reporting system as if NGHPs were hospitals and group health insurers (which they are not).

Now in the Proposed Rule, CMS proposes to penalize NGHPs for either not collecting or inaccurately reporting information that prior to the mandatory reporting requirement they never collected as they had no relevance to their business. The Section 111 process generally, and this proposed rule specifically, contradict the Administration's commitment to reducing regulation, and to putting people over paperwork. Instead, the proposed rule puts paperwork over people, and proposes to penalize companies who have done the right thing and invested considerable amounts to meet Medicare reporting standards that were never the subject of thorough notice and comment rulemaking. It leaves the safe harbor provision required by the SMART Act unreachable by many NGHPs, particularly when a beneficiary is represented by counsel. In our view, the Proposed Rule is untenable.

Rather than focusing on penalties for technical reporting mistakes, we urge the Agency to withdraw the rule, simplify the reporting system so that NGHPs can accurately report with the information they normally collect, eliminate duplicative reporting and provide safe harbors for those striving to comply. After taking these steps, the Agency should propose a penalty rule that focuses on how Medicare will catch and penalize those ignoring the law, rather than companies like our clients who are trying their best to comply. Such action would be fair and proportionate to the obligations that CMS has inappropriately placed on NGHPs through the Section 111 Reporting Manual.

In addition to our comments above, we offer the following comments on specific provisions of the proposal:

I. Legal Considerations.

The proposed rule, if implemented, would result in penalties of hundreds of thousands of dollars

on entities that have failed to report, or have incorrectly reported, claims for which there may be very little owed to the Agency, or involve claims for which few, if any, Medicare payments were ever avoided. The proposed penalties lack any proportion to the underlying amounts at issue, which we understand raises serious legal concerns. We also understand that the ways in which CMS has chosen to implement the penalty process violates the Medicare law's notice and comment requirements and the MSP law as well. We incorporate by reference the MARC Coalition's analysis and comments on the legal issues, as well as the other points raised in MARC's comment letter.

II. Absence of Sliding Scale Factors

The Proposed Rule is also flawed in that it fails to incorporate (directly or by reference) the sliding scale penalty factors that are key to any civil monetary penalty regime. As CMS acknowledges, the industry's comments during the Advanced Notice of Proposed Rulemaking specifically urged the Agency to incorporate such sliding scale factors, as Congress intended when it modified the penalty provisions to limit penalties to "up to" specified amounts. CMS has failed to offer any reason to not do so. We urge the Agency to include in the Final Rule specific good faith provisions (such as those found in 42 C.F.R. § 402.111) that address:

(1) The nature of the reporting error and the circumstances under which a report was or was not made;
(2) The degree of culpability, history of prior offenses, and financial condition of the person obligated to report;
(3) The resources available to the person obligated to report;
(4) Such other matters as justice may require, including the circumstances of the incident such as the period of time involved, whether a pattern of conduct is involved, the amount at issue, prior history of the reporting entity, and evidence of intentionality;
(5) Mitigating circumstances including the number of reports at issue, whether the reporting issue was the result of an unintentional and unrecognized error in the process of presenting reports, whether the reporting entity took corrective steps promptly after discovering the error, and 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.

We believe that including these factors in the final regulation would not only correct an unfairness in the proposed rule, but it would also encourage the reporting policies that CMS wants to advance.

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.

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

CMS has 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. We appreciate that CMS has set an appropriate erroneous reporting threshold that will capture few RREs, yet we remain concerned that this proposal will inadvertently penalize "low volume" reporters, and may implicate certain ICD-10 codes that are repeatedly rejected by CMS as erroneous even when, to the best of Reporting Entities' knowledge, they are accurate. Further, the Proposed Rule does not address how the four out of eight quarters threshold would apply for RREs who use Direct Data Entry and thereby do not undertake quarterly reporting. Presumably, no penalty would apply. We recommend a minimum claim threshold be added to this proposal, and that only "material" fields be used to calculate the 20% field rejection rate.

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.

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

The Proposed Rule includes an exemption for those situations where a beneficiary refuses to provide needed information to an RRE for reporting. We appreciate and support this proposal but recommend that the Agency not be proscriptive in the number of "touches" that a reporting entity must make (and how they must be made). As written, the Proposed Rule requires a defendant to contact a beneficiary and his/her representative. This is not a workable rule when a beneficiary's representative is an attorney.

As set forth in ABA Model Rules of Professional Conduct, which have been adopted by almost every state bar, per Rule 4.2, "a lawyer shall not communicate about the subject of the representation with a person the lawyer knows to be represented by another lawyer in the matter, unless the lawyer has the consent of the other lawyer or is authorized to do so by law…" While this outreach might arguably be an "authorization by law," requiring opposing counsel to reach out to a represented individual to obtain reporting data – including a social security number – would be wholly inconsistent with manner of practice in representing parties adverse to one another as well as seen as an extreme invasion of privacy.

The easy fix to this situation is to change the Proposed Rule to read in 22(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 representative, or in the event the individual is represented by an attorney it is sufficient to communicate with his or her attorney ~~or other representative~~.

(2) Requesting the information from the individual and his or her representative, or his or her attorney, ~~and his or her attorney or other representative~~ at least twice by mail and at least once by phone or other means of contact. Upon receipt of a documented response, all three contacts need not occur.

(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, including reporting exclusions identified in correspondence from the Secretary such as group resolution programs.

(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.

(D) A NGHP's funds are administered by a bankruptcy trust established under the United States Bankruptcy Code such that the NGHP has no involvement in the disbursement of funds to individuals and the Bankruptcy Trust itself is required to report settlements as per Order of the Bankruptcy Court.

RECOMMENDATION: We request that CMS modify the "safe harbor" section of the Proposed Rule.

V. 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). In addition, the preamble to the Final Rule should clarify that the limitations period runs from the first date of non-reporting.

RECOMMENDATION: CMS explicitly state a three-year statute of limitations by modifying 42 C.F.R. § 402.105(b)(3)(i) to read, "An applicable plan fails to report any NGHP beneficiary record within three years from the date of the settlement, judgment award or other payment. The penalty is . . ."

VI. CMS Should Withdraw the Proposed Penalties for Retroactive ORM Termination.

The Agency proposes to issue penalties for each day an ORM report is kept open if the Agency seeks a conditional payment recovery and the NGHP discovers that the ORM report should have been terminated earlier. This is grossly unfair and runs the risk of creating

penalties of hundreds of thousands (or even millions) of dollars for claims involving small amounts of money. More specifically, under the Agency's proposal, a retroactive ORM termination going back two years would result in over a million dollars of penalty. Again, this is practice grossly unfair, arbitrary, capricious and a violation of law. We urge CMS to withdraw this proposal immediately.

As CMS knows, its ORM policies have never been fair or workable. The MARC Coalition has advised CMS of this fact for over five years. Yet, CMS has not updated its ORM Termination policies, which only provide as follows.

> An ORM termination date should not be submitted as long as the ORM is subject to reopening or otherwise subject to an additional request for payment. An ORM termination date should only be submitted if one of the following criteria has been met:
>
> - Where there is no practical likelihood of associated future medical treatment, RREs may submit a termination date for ORM if it maintains a statement (hard copy or electronic) signed by the beneficiary's treating physician that no additional medical items and/or services associated with the claimed injuries will be required;
> - Where the insurer's responsibility for ORM has been terminated under applicable state law associated with the insurance contract;
> - Where the insurer's responsibility for ORM has been terminated per the terms of the pertinent insurance contract, such as maximum coverage benefits.[1]

The CMS standard that a treating physician provide a letter is completely unworkable, in that doctors exceedingly rarely write such letters, even years after the last treatment related to an accident or injury has been made. Moreover, in some states such as Illinois, a defendant cannot communicate with a plaintiff's treating physician, making such a requirement an unachievable ask. *Petrillo v. Syntex Laboratories, Inc.*, 148 Ill.App.3d 581 (1st Dist. 1986). In sum, CMS has not provided the appropriate standards that would allow NGHPs to terminate ORM when they administratively close claims files.

Some companies try to set "automated" ORM termination systems, while others have a manual process when an event occurs requiring reopening of an administratively closed file. Either way, the CMS parameters for closing ORM are inappropriately narrow. Now the Agency proposes penalizing parties who appropriately look back to close ORM. This is per se arbitrary and capricious. For these reasons, the ORM penalty proposal must be withdrawn.

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

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[1] *See* NGHP Reporting Manual (version 5.8, last updated January 2020), Section 6.3.2, available at: https://www.cms.gov/files/document/mmsea-111-january-31-2020-nghp-user-guide-version-58-chapter-iii-policy-guidance.pdf

VII. CMS Must Allow a Safe Harbor for NGHPs Whose Funds Are Administered by Asbestos Bankruptcy Trusts

Asbestos litigation has driven over a hundred companies into bankruptcy, with most establishing a litigation trust, under Section 524(g) of the Bankruptcy Code or establishing a qualified settlement fund under Section 468B. Funds from insurers/NGHPs contribute to these trust, either when a company does a buy-back of its policies and those monies in turn fund a trust, or by the NGHP directly funding during its insured's bankruptcy process.

The Section 111 NGHP Reporting Manual has consistently stated that when the insured "acts without recourse to its insurance," then the insured is responsible for the Section 111 reporting related to those actions.[2] Further, the NGHP Reporting Manual directs that "[t]o the extent that settlement, judgment, award, or other payment to or on behalf of the inured party is funded from the assets of the entity in liquidation, the entity in liquidation is the RRE."[3](emphasis in original)

These directives lead one to conclude that where a Bankruptcy Trust is created, it is the Trust Administrator's duty to ensure that reporting and reimbursement occur. However, due to prior directives from the Secretary of Health and Human Services, Trusts have concluded that they are not RREs.[4] When NGHPs are involved in the formation of Trusts, albeit with minimal input over the process, they insist that the Trust include in its responsibilities that the Trust report payments issued to beneficiaries and reimburse Medicare from those payments when appropriate.

RECOMMENDATION: §402.1 should include in (22)(iv) a CMP is not imposed in the following situations: When a NGHP applicable plan's funds are issued by a Bankruptcy Trust that has court approved provisions requiring the Trustee to provide MMSEA Reporting and reimbursement to Medicare.

VIII. CMS Must Allow a Safe Harbor Where a NGHP Resolves a Case with a Medicare Beneficiary Whose Exposure, Ingestion, Inhalation and Implantation Ends Before December 5, 1980

December 5, 1980 is the effective date of the MSP provisions.[5] Thus, exposure, ingestion, inhalation and implantation cases where the exposure, ingestion, inhalation occurred only entirely before December 5, 1980 and implantation cases where the implant was removed before December 5, 1980 are matters in which Medicare is the primary payer. As such, settlements,

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[2] *See* NGHP Reporting Manual (version 5.8, last updated January 2020), Ch. III, Ch. 6.1.3, available at: https://www.cms.gov/files/document/mmsea-111-january-31-2020-nghp-user-guide-version-58-chapter-iii-policy-guidance.pdf

[3] See NGHP Reporting Manual (version 5.8, last updated January 2020), in Ch. III, Ch. 6.1.6, available at: https://www.cms.gov/files/document/mmsea-111-january-31-2020-nghp-user-guide-version-58-chapter-iii-policy-guidance.pdf

[4] *See attached*, Ex. 1, Sebelius Letter, Nov. 2, 2009.

[5] *See* NGHP Reporting Manual (version 5.8, last updated January 2020), Ch. III, pg. 4-1, available at: https://www.cms.gov/files/document/mmsea-111-january-31-2020-nghp-user-guide-version-58-chapter-iii-policy-guidance.pdf

judgments, awards and other payments involving pre-1980 occurrences are exempt from Section III reporting requirements.[6] Despite this inclusion in the NGHP Reporting Manual, there remains concern among NGHPs that the CMS directive is unclear. As a result, NGHPs overreport these cases, drawing unnecessarily upon CMS resources as matters are opened and then need to be administratively closed.

RECOMMENDATION: §402.1 should include in (22)(iv) a CMP is not imposed in the following situations: (D) The NGHP does not report a settlement, judgment, award or other payment where the date of incident as defined by CMS was prior to December 5, 1980 as alleged, evidenced and released.

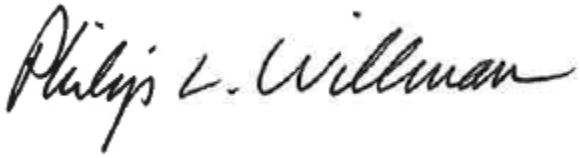
IX. Other Comments

There are several other comments we wish to share. First, we agree that the proposed penalties should only be applied prospectively from the date of the Final Rule, and that all proposed penalties apply only after a one-year compliance period from the date a report was first due. Second, we also support the six-month enforcement moratorium in response to any agency change in policy, which will allow us the time to implement Agency changes.

X. Conclusion

DRI appreciates the opportunity to be heard in the development of the Civil Money Penalty process related to compliance with the Medicare Secondary Payer Act. DRI invites CMS to follow up with any questions it may have and looks forward to collaborating with CMS on this and other MSP issues. Please contact the undersigned or the Chair of DRI's MSP Task Force, Catherine E. Goldhaber at cgoldhaber@hpylaw.com, if you have any questions or request additional information regarding these comments.

Thank you,



Philip L. Willman
DRI President

[6] *See* NGHP Reporting Manual (version 5.8, last updated January 2020), Ch. III, pg. 6-22, available at: https://www.cms.gov/files/document/mmsea-111-january-31-2020-nghp-user-guide-version-58-chapter-iii-policy-guidance.pdf

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