

Medicare Muscles Up

Complying with Medicare "Section 111" Mandatory Reporting

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Section 111 of the Medicare, Medicaid and SCHIP Extension Act requires entities that resolve certain claims with Medicare beneficiaries to report details of the settlement to the federal government. These reporting obligations—and the \$1,000 per day, per claim penalty for non-compliance—are not limited to insurers. Defendants subject to Section 111 should incorporate the reporting requirements into the claim evaluation and settlement process and take proactive steps to minimize exposure to penalties and liabilities.

Medicare's Interest

Medicare is the federally funded health insurance program for individuals 65 years of age or older and individuals of all ages who meet other eligibility standards, such as disability. As the program's costs have increased, the federal government has taken steps to limit Medicare's expenditures when another entity has primary payment responsibility for a beneficiary's medical expenses.

For example, Medicare can "conditionally" pay medical expenses of a beneficiary injured by a third party, but may recover those expenses from the beneficiary's settlement with a third party. In these situations, Medicare is the "secondary payer" and can assert the "Medicare lien" against the settlement. Medicare also has existing statutory and regulatory authority to recover secondary payments from anyone who receives the settlement (such as the beneficiary or his/her lawyer) or is responsible for making the settlement (including the settling defendant or its insurer). See 42 U.S.C. § 1395y(b)(2)(B); 42 C.F.R. §§ 411.24 & 411.37. The Section 111 reporting requirements enhance Medicare's ability to identify "secondary payer" circumstances and recover conditional payments by forcing third-party payers to self-disclose settlements, payments and other awards with or to Medicare beneficiaries.

Reporting Basics

The agency that administers Medicare and runs the reporting program (the Centers for Medicare

and Medicaid Services, "CMS") labels the party with the reporting duty as the Responsibly Reporting Entity (RRE).

A. Reporting Responsibility.

Section 111 applies to "liability insurance (including self-insurance), no fault insurance, and workers' compensation" plans and arrangements. 42 U.S.C. § 1395y(b)(8)(F). "Self-insurance" can be demonstrated by a failure to obtain insurance; for example, where a product liability defendant settles without resort to insurance. See CMS Alert, "Who Must Report" (Feb. 24, 2010) at 11, at www.cms.hhs.gov/MandatoryInsRep/Downloads/NGHPAlertRREsWhoMustReport.pdf. However, CMS broadly interprets "self-insurance" to also include entities that "carr[y] their own risk" through a deductible or co-pay on a liability insurance policy. *Id.* at 11. Therefore, even if an entity has liability insurance, a deductible payment is considered "self-insurance" for purposes of Section 111. As CMS notes, "such deductibles and co-payments constitute liability self-insurance, and require reporting by the self-insured entities." *Id.* at 12.

CMS's latest Section 111 guidance, issued in late February 2010, eases the reporting burden for most insureds. The insurer must report the deductible and any amount in excess of the deductible "where the [insured's] self-insurance in question is a deductible." *Id.* at 4. Accordingly, in a settlement arrangement where the insured is responsible for only a deductible, the insurer has the reporting obligation. However, an insured may need to report if it pays a settlement without recourse to insurance or "without informing its insurer." *Id.* at 5. CMS has not clarified what actions constitute "informing" the insurer for purposes of Section 111.

Additionally, the insured may need to report settlements directly paid to a claimant if the insured is subsequently reimbursed from its insurer under a policy that has responsibility beyond a certain limit, such as excess insurance. In fronting policies, the reporting duty

generally attaches to the party that pays the settlement to the claimant.

Defendants (or their insurers) subject to joint and several liability must report the entire settlement, not only their allocated portion. CMS has issued additional guidance for self-insurance pools, entities in liquidation or bankruptcy, and subrogation claims, among other arrangements.

CMS has released additional rules for reporting coverage under group health plans (GHP) and assuming ongoing responsibility for medical expenses (ORM), most commonly in the workers' compensation context. GHP and ORM reporting are beyond the scope of this article.

B. Claimant's Medicare Status.

The reporting rules apply if the claimant is a Medicare beneficiary at the time of settlement; accordingly, RREs "must implement a procedure in their claims review process to determine whether an injured party is a Medicare beneficiary." See MMSEA Section 111 Medicare Secondary Payer Mandatory Reporting (Non-Group Health Plan) User Guide Version 3.0 (February 22, 2010) ("User Guide"), at www.cms.hhs.gov/mandatoryinsrep. Upon submission of a Social Security or Medicare Health Insurance Claim Number (HICN), the CMS Coordination of Benefits Contractor (COBC) will reply with whether the claimant matches to an individual in the Medicare database. CMS identifies this exchange as the "query" process. Federal confidentiality and privacy obligations restrict use of this exchange.

CMS has offered model language as a safe harbor to demonstrate compliance if a plaintiff refuses to provide his/her Social Security number or HICN for reporting purpose. (These identifiers also must be reported.) Medicare will deem a RRE compliant if the claimant signs the form acknowledging his/her refusal to provide the identifiers. The safe harbor is of limited practical use since compliance requires the claimant to acknowledge a possible violation of Medicare coordination of benefits regulations. Moreover, the safe harbor also does not apply

if the RRE knows the claimant is a beneficiary. See CMS Alert, August 24, 2009, at www.cms.hhs.gov/MandatoryInsRep. CMS recognizes that this potential scenario puts RREs at risk of noncompliance through no fault of their own, and has repeatedly indicated it will release additional guidance on the safe harbor form.

C. Date of Settlement.

Settlements, judgments, awards or other payments (collectively, “settlements”) finalized on or after October 1, 2010, must be reported. Reporting duties arise when the settlement is signed or approved by a court.

D. Settlement Amount. Liability (non-workers’ compensation) settlements finalized before December 31, 2011, that are less than \$5,000 are exempt from reporting. The threshold decreases to \$2,000 between January and December 2012 and to \$600 between January and December 2013. CMS can ignore stipulations by litigants that apportion the settlement proceeds between medicals and

non-medicals—even where a court has approved the allocation. User Guide at 85–86.

E. Nature of Claim or Release.

A settlement of a claim for medical expenses, or one that releases liability for medicals or has “the effect of releasing medicals,” is subject to the reporting rules. User Guide at 85–86. Reporting cannot be avoided by joint agreements that the settlement does not cover medical expenses.

The reporting obligations are likely to extend beyond settlements of expressly alleged personal injury claims. CMS has suggested that any settlement that releases a defendant from potential liability for medical expenses may need to be reported, even in non-personal injury lawsuits. CMS concedes this issue is “unresolved” and is considering issuing additional guidance; however, the timetable for clarification is unclear.

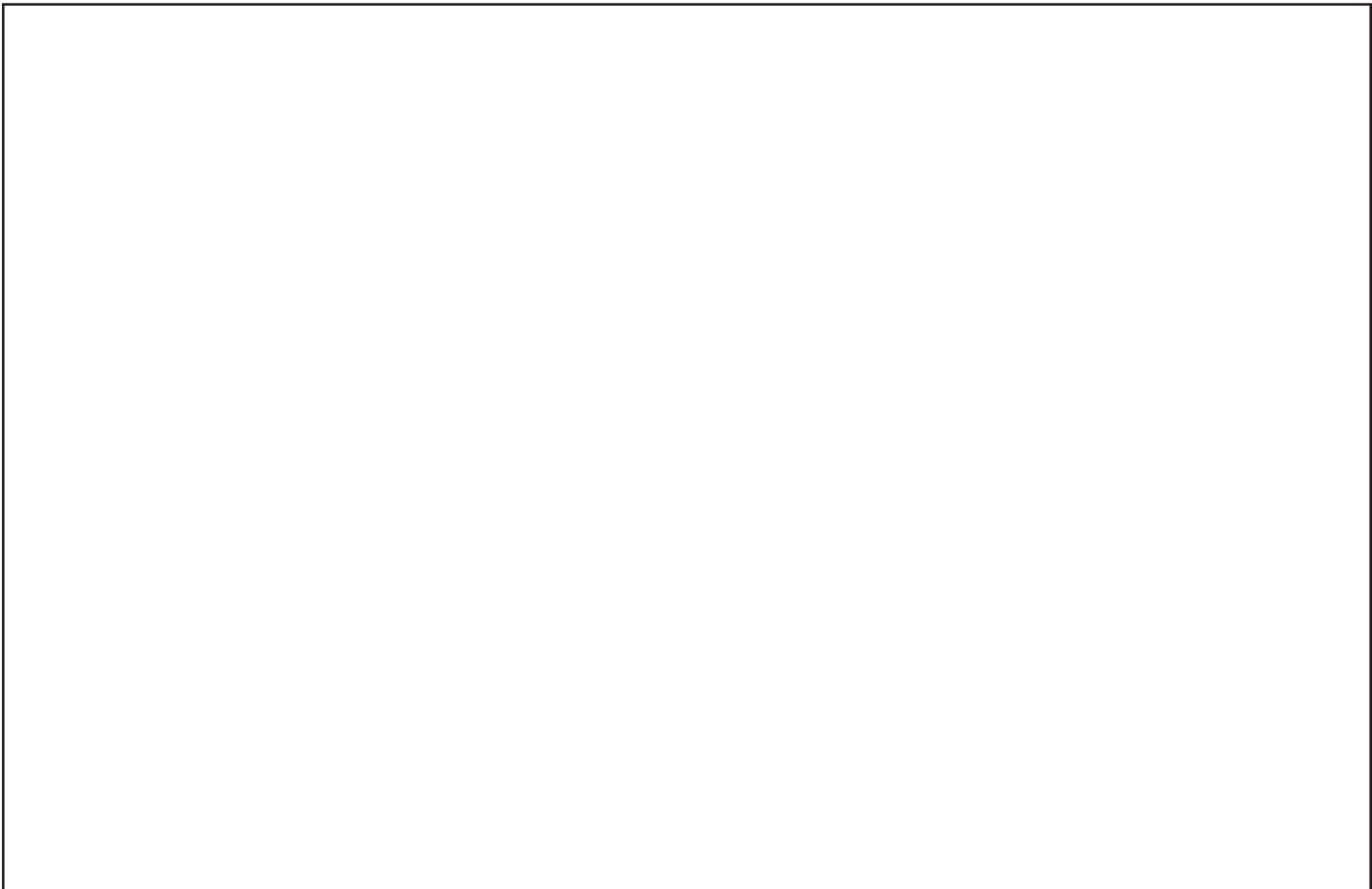
F. Date of Accident. RREs generally are not required to report settlements where the “date of incident” (DOI) was prior to December 5, 1980.

CMS defines the DOI as the date of the accident for “an automobile wreck or other accident.” However,

[f]or claims involving exposure (including, for example, occupational disease and any associated cumulative injury) the DOI is the date of first exposure. For claims involving ingestion (for example, a recalled drug), it is the date of first ingestion. For claims involving implants, it is the date of the implant (or date of the first implant if there are multiple implants).

User Guide at 124. An important and ill-defined exception extends the scope of reportable “exposure” events specifically asbestos allegations:

For claims involving “exposure,” [the December 5, 1980, cutoff] means that there was no exposure on or after December 5, 1980, alleged, established, and/or released. If any exposure for December 5, 1980 or a subsequent date was claimed



and/or released, then Medicare has a potential recovery claim and the RRE must report for Section 111 purposes.

User Guide at 86 (emphasis added). The controlling factor is the date of alleged physical exposure to the asbestos, not manifestation of injury.

CMS has suggested that a typical general release that addresses liability for exposure “from all time,” including potential (but not alleged) exposure after 1980, may trigger reporting obligations. CMS recognizes this concern and may issue additional guidance on how to specify the dates of exposure, especially for asbestos claims. Importantly, CMS is not bound by stipulations or affidavits that attempt to narrow the dates of exposure.

Privacy and Confidentiality Issues

The Section 111 reporting process includes multiple exchanges of information between the RRE and the COBC, including plaintiff’s date of birth, address, Social Security number and descriptions of the

alleged injury and other medical details. Accordingly, RREs and their insureds or insurers must recognize the confidentiality and privacy issues implicated by Section 111 reporting.

A. Data Use Agreements.

During Section 111 registration, RREs must sign a Data Use Agreement (DUA) with the federal government that requires implementation of safeguards to protect data confidentiality and limits the use, access and disclosure of the reported information. RREs must let CMS access the premises where the Medicare data is kept to inspect arrangements regarding compliance with the DUA’s security requirements, and must advise personnel who have access to the data of the “administrative, civil and criminal penalties for noncompliance contained in applicable Federal laws.” User Guide at 113. RREs should accordingly take specific steps to ensure that policies and training programs address the requirements of the DUA. Similarly, CMS advises RREs to be cognizant of the “evolv-

ing body of federal and state law and regulation” addressing the collection and use of Social Security numbers. Supporting Statement, Section 111 of the Medicare, Medicaid, and SCHIP Extension Act (Attachment B) (August 1, 2008), at www.cms.hhs.gov/mandatoryinsrep Contracts with third party vendors (such as consultants used to assist in reporting) should incorporate the information security safeguards required by the DUA and applicable state and federal laws.

B. Settlement Confidentiality.

Section 111 mandates disclosure of the settlement amount regardless of any confidentiality agreement between the litigants. CMS contends that it is entitled to the settlement information, including amount, since Section 111 serves a coordination of benefits purpose. See 42 C.F.R. § 411.24(a); CMS MMSEA Section 111 Teleconference Transcript at 34 (Jan. 22, 2009), at www.cms.hhs.gov/MandatoryInsRep/Downloads/Jan22Transcript.pdf. It seems unlike



ly that such information would be released under the Freedom of Information Act (FOIA) due to the FOIA exemption for requests that intrude on personal privacy. *See* 5 U.S.C. § 552(b)(6) (2000). CMS has noted that federal privacy restrictions would likely preclude disclosure of information on individual settlements. *See* CMS Section 111 Teleconference, December 15, 2009, at 69-70, at www.cms.hhs.gov/MandatoryInsRep. However, it is unclear whether federal privacy limitations would prohibit disclosure of de-identified, aggregated settlement information—for example, the total amount settled by a defendant in a given year or for a specific alleged product defect. CMS contends that logistical challenges render such disclosure unlikely since the information is not organized in aggregated form.

Health Care Providers

Section 111 reporting poses unique problems for health care providers. In addition to lawsuit settlements, CMS has indicated that hospitals may need to report write-offs and other risk management or goodwill gestures. Hospitals write off bills for a variety of reasons, such as to allay patient concerns, frequently before any thought is given to legal action. Similarly, CMS has suggested that reporting obligations may apply to a clinical trial sponsor's agreement to pay for medical expenses related to the trial.

For example, a hospital-defendant would need to consider whether a settlement for a slip and fall on its premises would be reportable. Separately, if the claimant is a patient, any write-off or goodwill reduction of the associated medical bills may also be reportable. In February 2010, CMS noted that write-offs and clinical trial agreements would not need to be reported “until forthcoming guidance is published.” CMS Alert, “Risk Management” (Feb. 24, 2010), at www.cms.hhs.gov/MandatoryInsRep/Downloads/NGHPAlertRiskMgmt022410.pdf. However, CMS cryptically added that in the interim such claims or payments should be iden-

tified so that they “can be reported as prescribed by the general Section 111 requirements and the further guidance.” Accordingly, RREs should, at the least, implement processes to track clinical trials and write-offs that may be subject to Section 111 reporting.

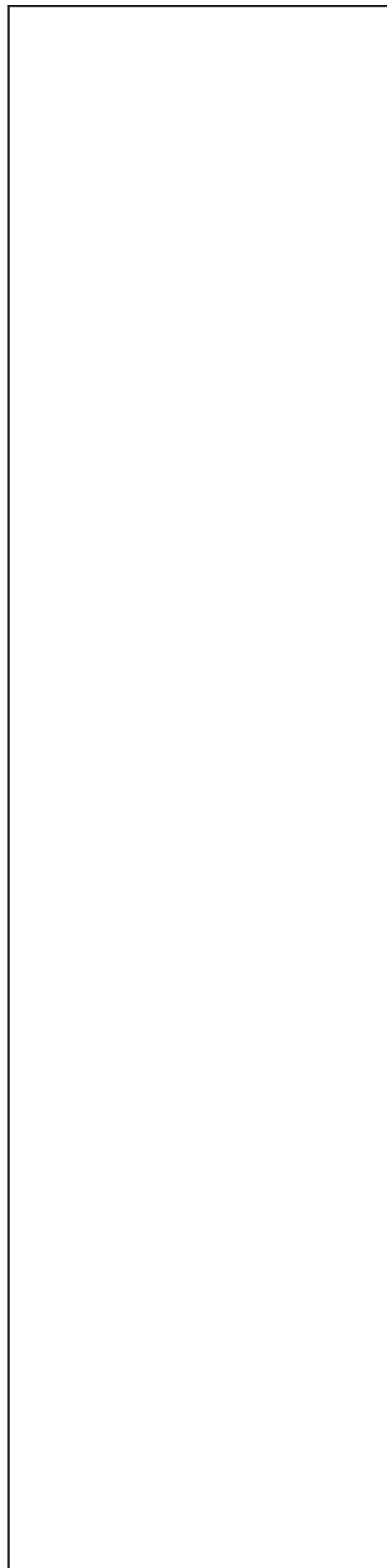
Additionally, health care providers (like other RREs) should ensure that data exchanged with the COBC is safeguarded in a manner consistent with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) and its attendant regulations, *see* 45 C.F.R. Part 160 *et seq.*, as well as the recent Health Information Technology for Economic and Clinical Health Act, enacted as part of the American Recovery and Reinvestment Act. Providers that utilize third-party vendors to assist with reporting should incorporate the DUA's requirements into the vendor contract and/or Business Associate Agreement. To the extent applicable to the RRE, the Section 111 disclosure is likely “required by law” pursuant to HIPAA's disclosure provisions. *See* 45 C.F.R. § 164.512(a).

Finally, health care providers are at a disadvantage relative to other RREs since such providers are in a unique position to know the claimant's Medicare status. As noted, the model language safe harbor does not apply if the RRE has actual knowledge that the claimant is a Medicare beneficiary. As such, health care providers that have a claimant's HICN or otherwise know the claimant's Medicare status cannot take advantage of the reporting safe harbor.

Compliance Guidelines and Recommendations

In February 2010, CMS issued guidelines that identify time-sensitive actions “to avoid the possibility of becoming non-compliant with the Section 111 requirements” and presumably the potential of \$1,000 per day penalties. CMS Alert, “NGHP RRE Compliance” (Feb. 24, 2010), at www.cms.hhs.gov/MandatoryInsRep/Downloads/NGHPComplianceAlert022410.pdf.

In general, an RRE “will be com-



pliant with its Section 111 reporting requirements” if it timely (1) registers for reporting, (2) engages in and completes the testing phase and (3) begins and continues to submit Section 111 reports starting in the first quarter 2011. *Id.* at 1. RREs that cannot meet these deadlines must communicate with the COBC and receive approval for alternate schedules. These guidelines suggest leniency for good faith efforts to comply, but provide little leeway for entities that do not timely register or acknowledge the deadlines.

CMS requires RREs that have a “reasonable expectation of having claims to report” to “register in enough time to allow a full calendar quarter for ... testing” prior to reporting. *Id.* at 2. Accordingly, RREs that have an expectation of reportable events should register by September 30, 2010, to allow a calendar quarter for testing prior to the first quarter 2011 start date for reporting. CMS does not currently provide an exception for RREs that expect a low volume of reportable events per year,

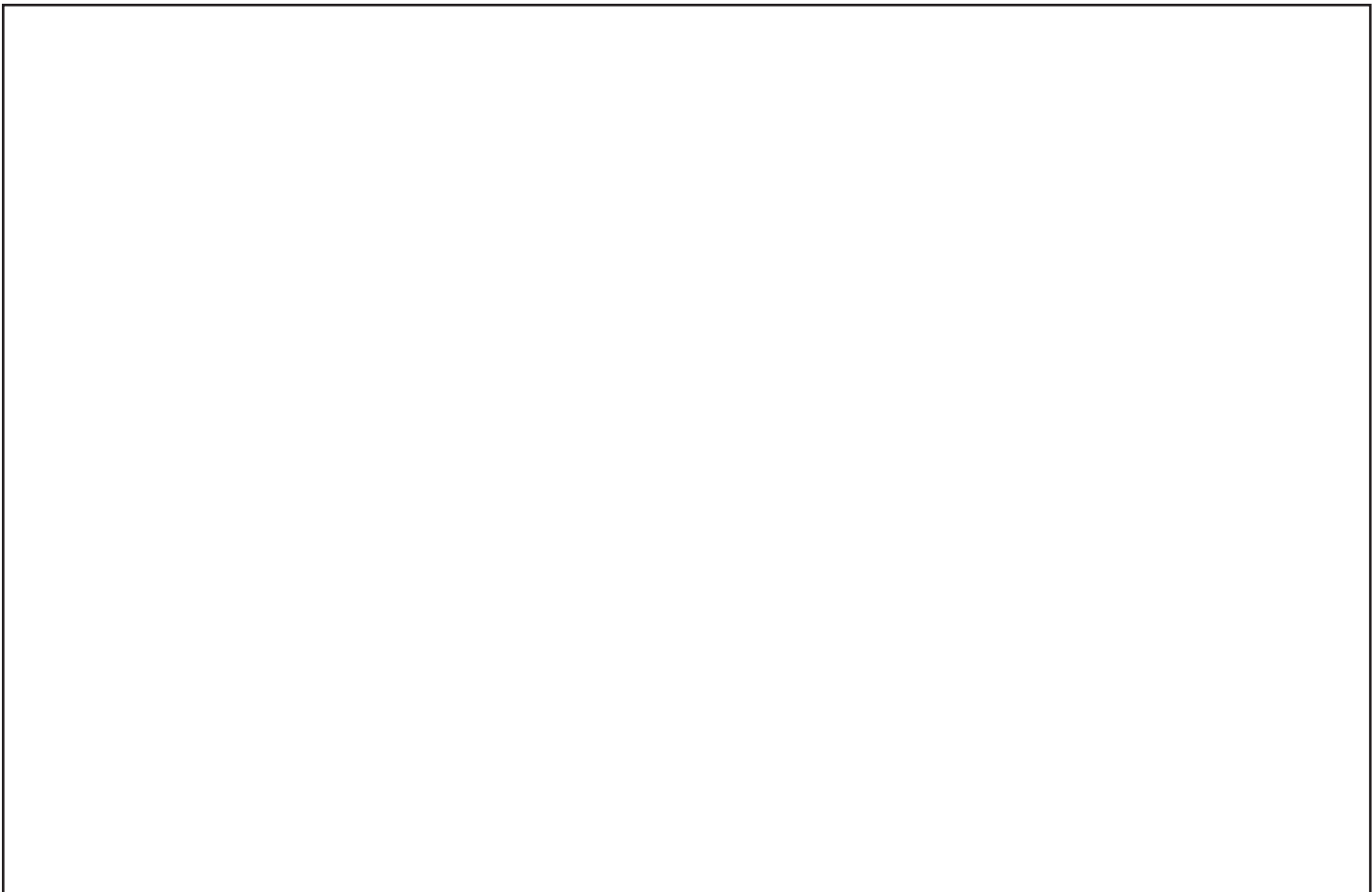
although it has indicated that a less burdensome option may be offered in future guidance.

The first Section 111 reports are due between January 1 and March 30, 2011, and must include information on settlements signed on or after October 1, 2010. RREs must electronically submit the reports every quarter beginning in a pre-assigned seven-day window of the first quarter of 2011. Each report includes more than 100 data fields with details on the RRE, claimant, alleged injury and accident, and settlement (including amount). Section 111 registration, testing and reporting involves information technology issues since reports are submitted electronically; therefore, IT departments should be consulted in developing a Section 111 program. RREs can also contract with third-party vendors to administer reporting, which may be cost-efficient in light of the resources that may be necessary for compliance.

A RRE that fails to comply with the Section 111 reporting requirements is subject to a civil money

penalty of \$1,000 per day of non-compliance, per claim. CMS noted in 2008 that guidelines for penalty assessment would be issued prior to enforcement, but as of March 2010, no such guidelines had been released. CMS has suggested that penalty deliberations would take into account whether an RRE “ma[de] the effort” to comply with the reporting requirements. CMS MMSEA Section 111 Teleconference Transcript at 45 (Feb. 25, 2009), *at* www.cms.hhs.gov/MandatoryInsRep/Downloads/Feb252009NGHPTranscript.pdf.

To minimize CMS scrutiny and related potential liabilities, RREs should incorporate the Section 111 query process, model language form and reporting requirements into the claims evaluation and resolution process and revise release and settlement documents to reflect the reporting obligations, including allocation of responsibility for penalties. Although not required by Section 111, developing fact sheets to confirm reportable information with claimants or their counsel may be useful to resolve future disagree-



ments over accuracy—especially if Medicare commences recovery efforts based on the report. Contracts with third-party vendors who assist with reporting (if any) should allocate financial responsibility for penalties imposed due to the third party's acts or omissions or violations of applicable privacy and confidentiality obligations.

Medicare Liens and Recovery Efforts

Section 111 does not change Medicare's existing authority under the Medicare Secondary Payer (MSP) program to recover conditional payments from anyone who is responsible for paying the settlement, or who receives the settlement. Medicare can also recover double damages from the primary payer if forced to file a recovery lawsuit. 42 C.F.R. § 411.24(c)(2). In certain circumstances, settling defendants could pay three times—once to the claimant and twice to Medicare. Section 111 reporting merely provides notice to Medicare of settlements and does not alter the lien

recovery process.

The Section 111 materials and CMS-hosted teleconferences have carefully avoided substantive analysis of lien-related issues. However, since the purpose of Section 111 reporting is to alert CMS of potential recovery situations, it is reasonable to assume that lien enforcement and recovery activities will increase. CMS may have already started: In 2009, the federal government filed two high profile MSP recovery lawsuits against a plaintiff's attorney, and against settling defendants, their insurers and the plaintiffs' attorneys, respectively. See *United States v. Harris*, C/A No. 5:08-102 (N.D. W.Va. Mar. 26, 2009); *United States v. Stricker*, C/A No. 1:09-02423-KOB (N.D. Ala. Dec. 2, 2009). To further complicate matters, legislation introduced in Congress on March 9, 2010, would alter the MSP lien recovery process and Section 111 penalty structure. See Medicare Secondary Payer Enhancement Act of 2010 (H.R. 4796). Although the issue of Medicare liens and set-asides is

beyond the scope of this article, Section 111 reinforces the necessity for both settling defendants and plaintiff's counsel to appropriately address the issue of Medicare's interests in the settlement process.

Conclusion

Among other actions, insureds and other potential RREs should determine the applicability of Section 111's requirements; take steps to satisfy the compliance deadlines; review policies, training programs and contracts to fulfill the DUA's requirements and ensure compliance with existing confidentiality obligations; and amend settlement and release documents to address Section 111 requirements. Interested parties should monitor CMS's Section 111 Web site, www.cms.hhs.gov/mandatoryinsrep, for further developments and guidance.

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