

DRUG & DEVICE BULLETIN



JUNE 11, 2009

Pharmaceutical & Medical Device

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For additional information on SHB's Pharmaceutical & Medical Device Litigation capabilities, please contact

Harvey Kaplan
Division Chair
816-559-2214
hkapan@shb.com



Marie Woodbury
Division Managing Partner
816-559-2236
mwoodbury@shb.com



MEDICARE REPORTING REQUIREMENTS WILL AFFECT CORPORATE LITIGATION DEFENDANTS

The Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA) created new reporting requirements for corporate defendants, including pharmaceutical companies, that make payments through either settlement or final judgment to Medicare-eligible individuals. These new reporting requirements will go into effect soon and will likely require prompt action by corporate defendants.

Tort Defendants Qualify as Responsible Reporting Entities Under the Law

Section 111 of the MMSEA, codified at 42 U.S.C. § 1395y(b)(8)), requires a "Responsible Reporting Entity" (RRE) to report payments made to a person eligible for Medicare, whether those payments are made to settle a claim or to satisfy a judgment.

Section 111 applies to any payments made under any "applicable plan," which is defined to include "Liability insurance (including self-insurance)." 42 U.S.C. 1395y(b)(8)(F). Liability insurance "means insurance (including a self-insured plan) that provides payment based on legal liability for injury or illness or damage to property." 42 C.F.R. Part 411.50.

A tort defendant qualifies as an RRE. We recommend that all potential corporate defendants review this new law to determine if registration as an RRE is required.

Registration and Reporting Obligations Have 2009 and 2010 Timelines

An RRE must register electronically with the Centers for Medicare and Medicaid Services (CMS) between May 1 and September 30, 2009.

Payments made by an RRE to a Medicare-eligible claimant on or after January 1, 2010, are subject to the new reporting requirements.

An RRE is responsible for testing its enrollment with the CMS system between January 1 and March 31, 2010.

Reports are submitted quarterly during a pre-determined seven-day reporting window, with the first report due during the second quarter of 2010. Each RRE's reporting window will be assigned by CMS after registration.

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How Responsible Reporting Entities Meet Registration Obligations

An RRE can register at www.Section111.cms.hhs.gov. Each RRE will be assigned a unique identification number (RRE ID). Instructions on registering are available at www.cms.hhs.gov/MandatoryInsRep/Downloads/RegistrationOverview.pdf.

How Responsible Reporting Entities Learn if Claimants Are Medicare Eligible—The CMS Query

An RRE is responsible for determining whether a claimant is or is not Medicare eligible. An RRE may query CMS to determine eligibility as often as once a month. Each query must include either the claimant's SSN or Health Insurance Claim Number (HICN) and: 1) first initial of first name; 2) last name; 3) date of birth; and 4) gender. CMS will then determine whether the claimant is Medicare eligible and respond to the querying RRE within 14 days. If the claimant is not Medicare eligible at the time of the query, an RRE is responsible for re-querying the claimant's Medicare eligibility before making any payment.

How the Reporting Requirements Are Fulfilled to Avoid \$1,000 Per Day Penalties

If the claimant is not Medicare eligible, no reporting requirement exists.

As to all Medicare-eligible claimants, reporting must be made for all settlements, awards or judgments, or other payments in which "medicals" are claimed and/or released, regardless of allocation by the parties or a determination of "no medicals" by a court. Reports must be made regardless of any admission or denial of liability. The law does not appear to provide any way to avoid reporting or to shift the reporting obligation to the claimant or claimant's counsel.

Each report will include data in at least the following areas: 1) claimant information; 2) injury/incident information; 3) self insurance/plan information; 4) claimant's attorney or representative information; and 5) settlement, judgment, award, or other payment information. Appendix A to the CMS User's Guide, available at the link below, sets out in detail the 194 specific pieces of information that may be submitted. Many such pieces of information are required, including the payment amount.

Failure to comply with the reporting requirement triggers a \$1,000 per day fine per claimant.

Reporting neither constitutes nor affects in any way Medicare lien-resolution requirements or existing notice requirements applicable to claimants, and the \$1,000 per day fine is in addition to potential penalties under the Medicare Secondary Payer Statute.

Reporting is made to the Secretary of Health and Human Services via the Coordination of Benefits Secure Website (COBSW) located at www.Section111.cms.hhs.gov.

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Signed Authorization to Obtain Information from Claimants to Query CMS is Recommended

The information needed to conduct a query process must be obtained from the claimant through discovery or otherwise. Requiring the claimant to sign an authorization permitting the RRE to obtain information from CMS and the Social Security Administration (Social Security Form SSA-3288, available at <http://www.ssa.gov/online/ssa-3288.pdf>) is advisable.

What to Include in a Release

A release should include specific indemnity against a Medicare claim. Defendants may want to require claimants to provide a signed release from Medicare in favor of the RRE prior to payment.

Where to Go for Guidance and More Information

Additional information can be obtained from CMS at <http://www.cms.hhs.gov/MandatoryInsRep/>.

CMS has also put out a User's Guide, including a supplement, which are available at:

<http://www.cms.hhs.gov/MandatoryInsRep/Downloads/NGHPUserGuide031609.pdf>

<http://www.cms.hhs.gov/MandatoryInsRep/Downloads/NGHPV10UserGuide051109.pdf>