

ALERT

Section 111 Bulletin: CMS Solicits Industry Comments During "Mass Torts" Working Group Call and Promises to Fast-Track Guidance

April 15, 2011

On April 14, 2011, the Centers for Medicare & Medicaid Services (CMS) held a conference call with the Section 111 "Mass Torts" working group, comprised primarily of stakeholders from the insurance industry and plaintiffs' counsel. The call continued dialogue begun last fall over a possible reporting exception for certain claims involving exposure, ingestion or implantation that implicate the December 5, 1980 effective date of the Medicare Secondary Payer statute.

Acknowledging that the process has moved slowly thus far, CMS promised to "fast track" consideration of a reporting exception and to meet every four to six weeks until it finalizes guidance. CMS clarified that its goal is to find a way through guidance to provide that nonspecific allegations or broad general releases would not require Responsible Reporting Entities (RREs) to report payment of claims if evidence shows that no exposure occurred on or after December 5, 1980. RREs would, nevertheless, need to keep such evidence on file should CMS question Medicare's primary payer responsibility, though CMS stated it does not anticipate conducting audits without a suggestion of RRE abuse of the exception. Serious questions remain, however, regarding the evidentiary standard for proving the absence of post-December 4, 1980 exposure. CMS also stated its intent that responsibility for establishing the absence of exposure would fall on the claimant rather than the defendant.

CMS and working group participants discussed a wide variety of topics during the call, including:

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- Reporting of claims that allege only an increased risk of bodily injury, rather than any actual illness or incurrence of medical expenses;
- Exposure in the form of mere presence as opposed to disturbing or manipulating a toxic item;
- Date of first exposure as controlling the application of reporting responsibilities;
- Physical exposure, rather than legal exposure, as controlling reporting obligations;
- The "incontrovertible evidence" standard proposed by CMS (likely to become "uncontroverted evidence");
- Which party will be responsible for proving whether exposure, ingestion or implantation occurred on or after December 5, 1980, and the practical concerns of the industry with regard to that burden;
- Due diligence requirements for RREs; and
- Mass torts issues unique to multiple defendants (not multiple insurers) with joint and several liability.

CMS solicited comments on many of the topics above, but in particular requested further input on the following issues:

- How the proposed rules will work for claims involving ingestion of drugs and pharmaceuticals;
- How the proposed evidentiary standard, and CMS's requirement that no contradictory evidence exist in the record, would work in practice and what types of evidence (such as interrogatories or deposition testimony) should and should not be considered definitive for purposes of the rule; and
- Criteria for establishing the non-existence of exposure on or after December 5, 1980, which CMS referred to as an "alternate positive."

CMS stated that comments on the draft language and topics discussed during the call should be sent to the Agency by next Friday, April 22, 2011, and that it plans to release an updated draft of the proposed guidance in the next four to six weeks. We invite you to contact us if you are interested in submitting comments to CMS.

Our Section 111 Team routinely covers the Section 111 NGHP teleconferences held monthly by CMS, and we send periodic Alerts to our clients addressing notable town hall discussions and other Section 111 developments. We also maintain a searchable electronic database of town hall transcripts back to October 2008. Please let us know if you would like more information about any of the Section 111 topics discussed in this Alert.