

# AN HCCA WEB CONFERENCE

## Understanding the CMS Medicare Secondary Payer Clinical Trial Billing Alert

July 29, 2010 • 12:00 PM CT (90 minutes)



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On June 10, 2010, the Centers for Medicare & Medicaid Services (CMS) posted long standing promised guidance (in the form of an Alert) regarding the Medicare Secondary Payer (MSP) reporting obligations that apply in the context of clinical research studies under Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Section 111). In the Alert, CMS states that it considers payments by sponsors of clinical trials for injuries or complications arising out of clinical trials to be “self-insurance,” which must be reported pursuant to the Section 111 requirements. This is the first time that CMS has stated in formal guidance that the MSP laws apply to injuries or complications arising in clinical research. What does this mean to sponsors? What does this mean for research sites? How does this affect the contracting process? The answers to these and other questions will be addressed in this informative webinar.

- Brief overview of the CMS Clinical Trial Billing Policy (the CTP)
- Issues arising in sponsor and site contracting related to payment for routine care, research injuries, etc.
- Overview of the CMS MSP laws, including the Section 111 reporting requirements.
- What is CMS’ position on the “Legal Obligation to Pay” and sample contract language?
  - Effect of the “Lutz Letter” on MSP in a clinical research context
  - Effect of the new CMS Clinical Trial Alert
- What now? How does Section 111 affect research sites? Sponsors? PIs?
- Questions



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