Strafford

Presenting a live 90-minute webinar with interactive Q&A

Medicare Secondary Payer Rules and Clinical Trials

Navigating MSP Rules and Reporting Requirements for Research Sponsors and Clinical Sites and Best Practices for Contracting

WEDNESDAY, AUGUST 8, 2012

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

Eve M. Brunts, Partner, **Ropes & Gray**, Boston

David Piatt, Managing Partner, **Piatt Consulting and Medicare Consul Services**, Albuquerque, N.M.

The audio portion of the conference may be accessed via the telephone or by using your computer's speakers. Please refer to the instructions emailed to registrants for additional information. If you have any questions, please contact **Customer Service at 1-800-926-7926 ext. 10**.

Medicare Secondary Payer Rules: Clinical Trials
Additional Handout

Strafford Webinar

August 8, 2012

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MSP Reporting Requirements: Clinical Trial Agreement

- Obligation of clinical site to disclose information to research sponsor for Section 111 reporting obligations should be addressed in clinical trial agreement
- Clinical trial agreement may require information to be provided when a subject is injured (to assess Medicare status) and when payment is made or when responsibility otherwise assumed (to meet reporting obligation)
- Requests by sponsor vary and some seek to impose additional obligations. Examples:
  - Permit the sponsor to review all research-related injuries before claims are submitted to Medicare to assess whether the sponsor has a payment obligation?
  - Require the subject/clinical site to comply with information requirements or administrative process as a condition of payment for research-related injuries?
- Sample “middle ground” language provided

MSP Reporting Requirements: Clinical Trial Agreement

Sample Basic Language

Institution and Principal Investigator acknowledge that, pursuant to Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007, Sponsor may have an obligation to confirm the status of and submit certain reports to the Centers for Medicare & Medicaid Services with respect to Medicare beneficiaries who participate in the Study. Subject to applicable law, Institution and Principal Investigator therefore agree to provide to Sponsor or an agent of Sponsor information relating to Subjects, including but not limited to, name, social security number, date of birth, gender, and Medicare identification number and to otherwise cooperate with Sponsor, all as reasonably necessary for Sponsor to meet its Section 111 reporting obligations. Sponsor agrees that Sponsor and its representatives will only use and disclose any such information provided as reasonably necessary to meet the Section 111 reporting obligations.

MSP Reporting Requirements: Informed Consent Form

- Informed consent form should address the disclosure to research sponsor to meet Section 111 reporting requirements
- Key points
  - Collection of information by sponsor (or someone acting on sponsor's behalf)
  - Identification of information collected
  - Reason the information is being collected
  - Information collected will be shared with third parties (including CMS)
- Sample "middle ground" language provided for informed consent form
- Note: HIPAA research authorization language should be consistent

MSP Reporting Requirements: Informed Consent Form

Sample Basic Language

Federal law requires Sponsor to inform the Centers for Medicare & Medicaid Services (the agency responsible for administration of the Medicare program) when Sponsor is going to pay for treatment of an injury to a Medicare beneficiary. Sponsor or its representatives may need to collect certain personal information about you such as your name, date of birth, gender, social security number, and Medicare identification number (if you have one). Sponsor needs this information in order to comply with a Medicare reporting obligation. This information may be collected directly from you, or from researchers, physicians, or other health care providers who treated your problem or injury. This information and also information about your injury or other health problem may be shared with others, including Sponsor representatives, Sponsor's insurance company, and the Centers for Medicare & Medicaid Services.