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Congratulations, Laura!

an interview with Laura Burke — our 15,000th member

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by Kelly M. Willenberg, MBA, BSN, CHRC, CHC, CCRP

Medicare Secondary Payer obligations for sponsor

Kelly M. Willenberg *(Kelly@kellywillenberg.com) is President and CEO of Kelly Willenberg, LLC in Chesnee, SC.*

As more pharmaceutical companies are reporting injuries arising from clinical trials that involve Medicare beneficiaries, the industry is adjusting and trial sites are becoming more accustomed to fulfilling requests for test subjects' personal information.

Willenberg

Section 111 of the Medicare, Medicaid and SCHIP Extension Act (MMSEA) of 2007 requires trial sponsors to: (1) determine whether an injured party is entitled to Medicare benefits; and if they are, then (2) they must report their acceptance of their responsibility to make ongoing medical payments related to treating the injury. Although the penalties for not reporting are heavier than the Sunshine Act ($1,000 per day per unreported beneficiary), implementation costs are much lower, and the actual fiscal responsibility taken on by the sponsor can be controlled. For instance, sponsors generally adjudicate the injuries reported by the sites by only considering related adverse events and then only those events that were not the fault of the test subject, failure to follow protocol, etc., as dictated by their clinical trial agreement with the site.

Actually, collecting the patient personal data required to be reported may be the hardest part of reporting. The conflict arises when Medicare wants to know who suffered the injury and sponsors don't want to destroy the double-blind nature of the test by collecting that information. Sponsors generally hire a Section 111 Reporting Agent to act on their behalf. Sponsors provide non-identifying information to the agent (e.g., study ID, site ID, patient ID) and then the agent contacts the site to collect the first name, last name, DOB, gender, and Social Security number of the test subjects. Site personnel have been trained to protect that information, so agents spend a lot of time reassuring the site that the disclosure is legal and warranted. Medicare recently made that easier by requiring only the last five digits of the Social Security number in order to determine if a test subject is enrolled in Medicare.

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In an interview, David Piatt of Medicare Consul Services said, "Pharmas are adding language to their CTAs [clinical trial agreements] requiring sites to support Section 111 collection efforts and, after contacting thousands of sites, I can say the word is spreading. Clinical sites are tuning in and becoming more cooperative."

Despite Medical secondary payers' checkered history, CMS issued formal guidance in their Non-Group Health Plan (NGHP) User Guide, backed by hefty penalties. Sponsors are stepping up their efforts to comply, and sites are getting on board.