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How early childhood experiences shaped a career in Compliance

an interview with Janie McKinney

Compliance Coordinator & IRB Coordinator
Washington Regional Medical Center

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

The ABCs of AEs

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Clinical drug and device trials depend upon nurse and study coordinators to report complications or adverse events (AEs) once a patient begins receiving active treatment. The FDA's MedWatch program monitors drug safety with accurate reporting by the frontline healthcare providers. This process demands diligence in capturing the information in a timely manner.

Willenberg

When recording the adverse event, is it imperative that detailed, specific information is reported. Reporting events that occur under an Investigational New Drug (IND) application is mandatory and reports are submitted separately to the FDA as specified in the regulations. These are required to be submitted to the Institutional Review Board as well. The key is to specify the timing of the problem, lab values, and all signs and symptoms the patient has during the episode.

The other piece that should be considered by the study team is the cost of treating an adverse event. If the sponsor agrees to cover the cost of treating adverse events, these must be tracked, and many times, they can be invoiced after the event occurs. Many sites fail to report these to government payers, as billable with codes and modifiers, if the Sponsor is not paying the charges. The site may be pulling the charges from the claim for the patient and moving it to a research account, but never recouping the cost.

An open line of communication can enhance this process. Whether you rely on a clinical trial management system (CTMS), a flag when patients are admitted, or old-fashioned word of mouth, these must be not only tracked for regulatory purposes, but also for billing compliance purposes and contractual obligations.

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Some sites use an alert when patients are treated in an Emergency Room. This can help to identify the adverse events. Conveying this to patients and their families during an informed consent process can aid in making sure that the study team knows when a patient receives treatment anywhere, that may or may not be study-related, even if it is not at their facility or by their doctor.

An operational framework will help establish a process flow for reporting these events to MedWatch, the IRB, and the billing team. Above all, remember that if you tell a patient in a consent form that the sponsor covers adverse events, you cannot bill a payer for those services. The costs of tracking these events to ensure that they are not billed can be time-consuming and difficult.