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Keeping organizations compliant, secure, and safe

an interview with Emmy Matthews

Sales Consultant, Legal & Regulatory Solutions U.S.
Wolters Kluwer

See page 16

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

Cracking the code

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Many sites face the burden of trying to decipher subject injury when it occurs to a clinical trial patient. Monitoring for subject injury in a study can be rather intense. Add in the burden of the timing of screening tests and variations of time for points-of-care for payment by a study Sponsor on that rare occasion, and the burden is intense, depending on technology and resources.

Willenberg

Eliminating conditional payment clauses from Sponsor agreements will take away the question of when an injury occurs. Sponsor covers injury, period! When a number of contractors and Dr. Rosemarie Hakim, a senior research advisor in the Coverage and Analysis Group of the Center for Clinical Standards and Quality at CMS, were asked last year if they cared about this issue, their answer was a resounding "YES."

However, in working with Sponsors, they too are trying to figure out if covering the costs of an item or service is okay if the injury is related to the study. Knowing that Medicare wants the best "deal" makes this even more difficult. What should happen when it is merely a varying time point or outside of a protocol scheduled window? The answer can be complex.

What happens when one patient requires a repeat CT scan for screening that all of the patients had during their course of conventional care, but for one patient, it falls outside of the screening window and must be repeated? Sponsors usually agree to cover the cost of the repeated test, so the site does not to have to cover or absorb the cost. This CT is not reimbursable by the payer, so it should not be billed out on a claim. Some sites struggle with this concept, but others do not and manage the payment from the Sponsor. How do you manage this at a site level? Dealing with different plans, payers, and benefits for each patient's commercial insurance requires more than quick decision-making when it occurs. Knowing the "combination" for *each* patient's payer is necessary.

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Sponsors and sites must work together to get this right in Medicare's eyes. It would be beneficial for CMS and the Medicare Contractor Medical Directors to give us the combination to the safe regarding this complex billing issue. If they would help us with cracking the code, we would all have a less difficult time deciding *when* and *if* a Sponsor can cover a cost for a clinical trial subject when an unexpected time point occurs, and there is a thoughtful process on the decision made.