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Without Flags, Hospitals May Be Overpaid for Patients in Research

By Nina Youngstrom

When Medicare beneficiaries come to academic medical centers and community hospitals that have research underway, a flag in the registration or billing system should identify them as participants in a study. That will suspend the claims for their services until they're reviewed, one by one, to determine whether hospitals should bill Medicare or the clinical trial sponsor—and take them a big step closer to compliance with national coverage determination (NCD) 310.1, which is known as the clinical trial policy (CTP).

"If hospitals don't have a way to flag them, there's no hope for billing correctly," says Lisa Murtha, senior managing director of Ankura Consulting Group in Philadelphia. "If that fails, everything else down the line fails."

Failure to flag patients in studies is one reason hospitals may have overpayments stemming from the CTP, which opened Medicare coffers for "routine costs" in qualifying clinical trials and diagnosis and treatment of complications.

"We find organizations bill Medicare for things that should have been billed to the sponsor," Murtha says. Partly that's because the CTP is hard to put into practice. "The government says too bad, so sad, you will have to bill correctly."

Meanwhile, risk is mounting around claims submitted to Medicare Advantage (MA) plans for services provided to enrollees in clinical trials. Hospitals are required to submit the claims to original (fee-for-service) Medicare even when they treat MA enrollees who participate in research. For whatever reason, this is either misunderstood or the underlying billing processes are unreliable, she says. "You would think the claims would reject [from MA plans], but sometimes the claims go through."

The linchpin of NCD 310.1 compliance is a coverage analysis process, Murtha says. The coverage analysis is a clearly documented process to identify which charges are billable and which are invoiceable to the sponsor. "Research organizations are obligated now to understand in advance of billing any services what is billable to Medicare versus what is paid by the sponsor or what is not billable to anyone," she says. "The only way to show the organization has done its homework is with a documented coverage analysis."

She also recommends a billing grid to track the items and services line by line and a review of NCDs and local coverage determinations (LCDs) to ensure only allowable services are billed to Medicare (see boxes below). "That's a critical first step," she says. "You have to do it for every charge on a study. It's a very arduous process."