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Hospital Settles Case Over ICD Battery Replacement; Medical Necessity Cases Are 'Evolving'

By Nina Youngstrom

When Stacy Gerber Ward was an assistant U.S. attorney in Wisconsin in 2002, she investigated a cardiologist for implanting cardiac stents imported from a foreign country that weren't approved by the Food and Drug Administration (FDA) for use in humans, but "there was great reticence" in her office about pursuing questions of medical necessity as health care fraud. Times have changed, however, and "that reticence has evaporated," said Ward, now with von Briesen & Roper. The Department of Justice (DOJ) is now all-in on lack of medical necessity as a False Claims Act (FCA) violation although the premise has been "hotly contested."

"There's been quite a bit of litigation in this area," especially when there's a risk of patient harm, Ward said Sept. 14 at a webinar sponsored by the Health Care Compliance Association.[1]

Apparently, the message has gotten out because some providers cut to the chase with self-disclosures. Hot off the presses: New York-Presbyterian/Queens Hospital agreed to pay $2.5 million to settle false claims allegations over the medically unnecessary replacement of pulse generator batteries for implantable cardioverter defibrillators (ICDs) by a former physician, the U.S. Attorney's Office for the Eastern District of New York said Sept. 14.[2] The settlement stemmed from the hospital's self-disclosure to the HHS Office of Inspector General. According to the settlement, the government alleged the hospital submitted Medicare and Medicaid claims for replacing ICD batteries that weren't medically necessary and "posed risks to patients" from Jan. 14, 2009, through July 9, 2014.[3] Because the physician at the heart of the settlement—who was previously affiliated with New York-Presbyterian/Queens Hospital— allegedly repeatedly replaced ICD batteries when they were still functional, he "subjected his patients to unneeded and risky surgical procedures," a press release said.

Depending on the fact pattern, cases over medical necessity can be hard to prove because there's a degree of subjectivity, Ward said. For example, in the case she handled as an assistant U.S. attorney, "one of the doctor's key themes in his defense was that, despite the fact that he was using stents that had not been approved by the FDA, he was saving lives and that it should fall within the physician's judgment to select an appropriate device for his patients."