

Report on Medicare Compliance Volume 30, Number 34. September 27, 2021 Prosecutor: Provider-Based Notice Noncompliance Is 'Easy to Assess'

By Nina Youngstrom

A provider-based department's failure to comply with Medicare's patient notification requirements is a straightforward proposition for a prosecutor looking at allegations in a False Claims Act case, at least compared to other aspects of the provider-based regulation.

"The notice requirements from an enforcement perspective are clear and easy to assess," said Jessica Matthews, an assistant U.S. attorney with the U.S. Attorney's Office in Colorado, Sept. 21 at the Fraud and Compliance Forum sponsored by the American Health Law Association (AHLA). Allegedly violating them was one driver of the University of Miami (UM) \$22 million false claims settlement in May.^[1] "You don't have to dig into financial and clinical integration" or other more complicated provider-based department (PBD) requirements, said Matthews, who was a prosecutor on the UM case while working at the U.S. Attorney's Office for the Southern District of Florida. But as anyone from the Department of Justice (DOJ) would say, to cross the threshold to a False Claims Act violation requires proof of scienter (knowledge) and materiality, she noted. "Those are two limiting factors."

The UM lawsuit was set in motion by four whistleblowers in three complaints that also included allegations of lab overbilling for transplant patients. Some were "C-suite relators," Matthews said. Jonathan Lord, M.D., the only whistleblower to allege violations of provider-based requirements, was UM's chief compliance officer and chief operating officer; another whistleblower was vice president of medical administration. "There were a number of concerning compliance allegations, which signaled to DOJ there was a noncompliance culture at UHealth," as the University of Miami Health System is referred to now, she said. For example, it was alleged people who raised issues about the medical necessity of tests were ignored and complaints were buried. Also, "there was an overlay of political issues," Matthews said. Former HHS Secretary Donna Shalala was CEO of UM at the time the whistleblowers filed the complaints, and she headed HHS when the provider-based rules were promulgated, Matthews said. Shalala "had issued a lot of statements about strong compliance requirements."

According to the provider-based regulation, when a Medicare beneficiary is treated in a hospital outpatient department that's not on the main campus and the beneficiary will have to pay a copay for both the outpatient visit and the physician service, the hospital must: "provide written notice to the beneficiary, before the delivery of services, of (A) The amount of the beneficiary's potential financial liability; or (B) If the exact type and extent of care needed are not known, an explanation that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider-based, an estimate based on typical or average charges for visits to the facility, and a statement that the patient's actual liability will depend upon the actual services furnished by the hospital."^[2]

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