

Report on Medicare Compliance Volume 31, Number 14. April 18, 2022 DOJ Intervenes in FCA Case Over Hospital Alliance With Doctors; 340B Drugs Are an Issue

By Nina Youngstrom

The Department of Justice (DOJ) said April 11 it has intervened in a whistleblower lawsuit against Methodist Le Bonheur Healthcare (MLH) in Memphis, Tennessee, and Methodist Healthcare Memphis Hospitals (collectively, Methodist) that was set in motion by the former president of an MLH hospital and a former MLH board member. Methodist is accused of violating the Anti-Kickback Statute (AKS) and False Claims Act (FCA) by paying West Clinic P.C., which owns outpatient oncology clinics, for patient referrals through compensation and management arrangements entered into in its quest to build a cancer center “without walls,” according to the U.S. Attorney’s Office for the Middle District of Tennessee.^[1] West, which is known as West Cancer Center, isn’t named in the complaint.

In addition to challenging the motive of the alliance, DOJ alleged that Methodist planned to increase its access to 340B drug discounts by acquiring West’s cancer clinics, an unusual allegation in an FCA lawsuit.

Methodist bought the assets of West and entered into arrangements to lease its nonphysician employees and compensate physicians for their professional and management services from 2012 through 2018, paying West \$300 million. There were no plans for Methodist to employ the physicians. “Notwithstanding the contracts and the requirements therein that purported to provide a lawful way for Methodist to pay West in exchange for referrals, the conduct of Methodist and West show that those agreements were largely meaningless paper,” DOJ alleged in its April 11 complaint.^[2]

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The whistleblowers are Jeffrey Liebman, former president of Methodist University Hospital, and David M. Stern, M.D., former MLH board member and member of the executive cancer council and the steering committee for the West Cancer Center. They raised concerns about aspects of the alliance, according to the whistleblowers’ third amended complaint.^[3] For example, when Stern learned that West physicians would share in Methodist’s 340B “drug profits” for chemotherapy and oral cancer medications, he told then-Methodist CEO Gary Shorb that “it was very unusual for 340B drug profits to be used to increase physicians’ incomes,” the complaint alleged. “Dr. Stern repeatedly objected to the use of 340B drug profits to fund payments to West physicians as inappropriate and excessive. Dr. Stern argued that the 340B drug profits should be used for indigent care, cancer research, and for the development of an NCI-designated cancer center in Memphis. Dr. Stern was repeatedly rebuffed” by Shorb and then-Methodist Chief Financial Officer Chris McLean.

But DOJ will have a hard time proving its case “unless they have a true smoking gun,” said attorney Andrew Ruskin, with K&L Gates in Washington, D.C. He doesn’t see any in the complaint. “Clearly there was a lot of desire to do this the right way” (e.g., Methodist getting fair market valuations for the physician compensation). Ruskin added that he finds it “offensive” that the complaints talk about 340B drug savings “as evidence of trying to” pay off the physicians. “Hospitals come together with other hospitals and with physicians to recognize savings through synergies and efficiencies all the time. How is the fact you are trying to save money on drugs different from other efficiencies? It bothers me because it’s a buzzword, and they shouldn’t use buzzwords to try

to pique someone's interest when the case is otherwise in weak territory.”

The complexity of any alliance, with multiple arrangements, heightens the compliance risk, said attorney Bob Wade, with Barnes & Thornburg LLP in South Bend, Indiana. From a compliance perspective, “all the links in the chain have to be separately analyzed and managed,” he said. “There needs to be a compliance process where you have oversight of all the services rendered so you don’t have services bleeding over from one compensation arrangement to another.”

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