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DOJ Alleges Fresenius Clinics Did Unnecessary Procedures; Compliance Raised Concerns

By Nina Youngstrom

The Department of Justice (DOJ) said July 13 it has intervened in a whistleblower complaint against Fresenius Vascular Care Inc. (FVC) alleging medically unnecessary procedures were performed on patients with end-stage renal disease (ESRD) at nine of its clinics in New York.^[1] With or without referrals from nephrologists and dialysis clinics, the Fresenius vascular access centers (VACs) allegedly did fistulagrams and angioplasties and held contests with prizes for new patient referrals, according to the False Claims Act (FCA) complaint in intervention.^[2] Although the compliance department warned against the allegedly medically unnecessary procedures, DOJ said they continued.

“It is traditional profits over care,” alleged Jeanne Markey, an attorney for the whistleblowers, both nephrologists who referred patients to Fresenius VACs. John Pepe, a physician at Staten Island University Hospital, and Richard Sherman, professor Emeritus at Rutgers University Medical School, were not employed by Fresenius, Markey said. “Often, it’s an insider who becomes aware of [alleged misconduct] but that was not the case.”

Fresenius denied the allegations and will “vigorously defend the litigation,” it said in a statement.

ESRD patients have dialysis three times a week, typically in an outpatient center, and Medicare requires an interdisciplinary team to monitor vascular access. If there’s a potential obstruction that could prevent dialysis from effectively cleaning the blood, a nephrologist may refer the patient to a VAC. According to the complaint, Fresenius’ alleged “scheme” centered on clinically timed evaluations (CTEs). They began with the first visit to a VAC for a fistulagram, which involves penetrating the patient’s skin and blood vessels with a needle and catheter and using imaging to visualize blood flow. Depending on the extent of the blockage, the interventionalist (a physician) performs an angioplasty, which requires a catheter insertion and insertion of a balloon to expand a vessel and restore blood flow.

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