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Tenn. Health System Settles FCA Case for $7.25M Without CIA; OIG Pursues Far Fewer CIAs

By Nina Youngstrom

Methodist Le Bonheur Healthcare and Methodist Healthcare-Memphis Hospitals have paid $7.25 million to settle false claims allegations stemming from sweetheart deals with West Clinic PLLC, the U.S. Attorney's Office for the Middle District of Tennessee said Jan. 4.[1] According to the allegations in the False Claims Act (FCA) complaint, Methodist bought the assets of West Clinic, leased its nonphysician employees and compensated physicians for their professional and management services without employing them, partly to induce their referrals.[2] Methodist denied the allegations and didn't admit liability in the settlement.[3]

As was the case with other recent FCA settlements—including ChristianaCare Health Service's $47.1 million settlement[4] and Exagen's $653,143 settlement[5] —Methodist's doesn't include a corporate integrity agreement (CIA).

"Given Methodist's views that the underlying arrangements had been structured appropriately and that its affiliation with West Clinic greatly improved cancer care in Memphis, Methodist declined to move forward with any settlement that would include a CIA," said attorney Brian Roark, who represents Methodist.

For varying reasons, CIAs are far less common than they used to be while at the same time more tailored to the misconduct alleged in the FCA complaint. Sometimes health care organizations refuse to enter into CIAs, but often the HHS Office of Inspector General (OIG) doesn't require them.

"OIG has over time narrowed the scope of the cases for which they're seeking a CIA," Gregory Demske, former chief counsel to the HHS Inspector General, tells *RMC*. Two decades ago, OIG pursued CIAs in every FCA settlement, but ultimately OIG decided this "was not the best use of its resources or the resources of entities it was settling with," said Demske, with Goodwin Procter LLP in Washington, D.C.

In fact, last year, there was no CIA in 181 FCA settlements, he said, while a CIA popped up in 29. The numbers have been fairly consistent over the past few years. "It shows you there's a fairly narrow slice of cases where OIG is pursuing a CIA," Demske noted. "You can't have a CIA in every case and have the capability to do as many enforcement actions as you'd like."

In two 2023 FCA settlements where health care organizations refused CIAs, OIG assigned them to the "heightened scrutiny" category of its Fraud Risk Spectrum, which ranges from exclusion to no integrity obligations because of a self-disclosure.[6] The two are (1) University of Pittsburgh Medical Center, University of Pittsburgh Physicians and James Luketich, M.D. and (2) Nostrum Laboratories Inc., and Nirmal Mulye, Ph.D. A total of seven are under heightened scrutiny.

CIAs are a desirable alternative to exclusion, which is a death sentence for some organizations—notably facilities like hospitals and health systems. But the reality is OIG is reluctant to exclude hospitals—especially safety net hospitals—because of potential harm to community health services, said attorney Gabriel Imperato, with Nelson

Mullins in Fort Lauderdale, Florida. Because they're unlikely to be excluded, hospitals negotiating an FCA settlement may consider refusing to agree to a CIA, he noted. That could land them in the heightened scrutiny category, where "they will face more direct oversight by OIG." Another possibility is health care organizations agree to a CIA "and after a year or two, there may be reasons OIG would modify the CIA and make it less burdensome," Imperato said.

However, before rebuffing a CIA, health care organizations should consider the broader picture and the upside of a CIA, he said. "It requires an organization to implement the infrastructure of a compliance program and sometimes indirect oversight" by an independent review organization (IRO) versus direct oversight by OIG with the heightened scrutiny designation, Imperato said. "It's a matter of weighing the pros and cons of either option." CIAs also push organizations to fix whatever problems got them into trouble in the first place. Because they're under the OIG's watchful eye for five years (or so), senior leaders who perhaps weren't compliance champions in the past aren't in a position to ignore leadership for compliance oversight, Imperato explained. "You may be better off getting under a CIA. Otherwise you may experience a repeat of the problem that created the need for a CIA and potentially jeopardize management job security."

He raised the question of whether IROs—an essential part of CIAs—could be in jeopardy because of a forthcoming decision from the U.S. Supreme Court about so-called Chevron deference. The way it stands, courts generally are required to defer to interpretations by agencies like CMS or OIG when a statute is ambiguous. That precedent is being challenged in *Loper Bright Enterprises vs. Raimondo* now before the Supreme Court.[7] The case came to the Supremes based on challenges from fishermen in New Jersey and Rhode Island who objected to a 2020 regulation that requires them to have observers with them to prevent overfishing where the fishermen must pay for the observers. "The IRO strikes me as an analogous situation because the requirement to hire an IRO paid for by the organization is the kind of situation that may be more difficult to implement administratively should the Supreme Court erode the Chevron doctrine," Imperato said.

Demske noted that there's no great mystery around OIG's decision-making process for exclusions versus CIAs because it was spelled out in a 2016 document.[8] OIG expects entities to have a compliance program, so they don't score points for having one—but failing to have one counts against them. And a mature and robust compliance program can factor in, Demske said. "For example, OIG says it will give credit to an entity that has a history of significant good faith self-disclosures of overpayments or fraud matters," he explained. "Regardless of an entity's policies and procedures, OIG considers such disclosures as the strongest evidence of an effective compliance program." That's reflected in OIG's new *General Compliance Program Guidance*, which states: "How an entity responds when it finds a violation resulting in a substantial overpayment or serious misconduct sets apart those that have a strong compliance program from those with a compliance program that is more form than substance."[9]

DOJ Alleged Methodist Paid Kickbacks

According to the FCA settlement with Methodist Le Bonheur Healthcare (MLH) in Memphis and Methodist Healthcare Memphis Hospitals (collectively, Methodist), the government has claims against the health system arising from its alleged submission of false claims resulting from "improper financial relationships between Methodist and West, including kickbacks that Methodist paid to West as part of the affiliation," one purpose of which was to induce referrals, from Dec. 1, 2011, through Feb. 23, 2019. The affiliation ended in 2019.

Roark, the attorney for Methodist, told *RMC* that its view is the government's kickback allegations lack merit. Methodist "paid compensation to West Clinic based on guidance from valuation firms regarding fair market value. The government developed no proof that the compensation was not fair market value or that the compensation paid caused West Clinic to refer any patient to Methodist. West Clinic physicians testified

uniformly that they referred patients to Methodist because it was the best place for their patients to receive care. That the government alleged single damages of $350 million but settled for $7.25 million is reflective of the ultimate merit of the allegations."

The FCA case against Methodist was set in motion by whistleblowers 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 (which is how West Clinic was known).

The U.S. Department of Justice (DOJ) intervened in 2022. Methodist was accused of violating the Anti-Kickback Statute (AKS) and FCA by paying West Clinic—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 DOJ's complaint in intervention. West Clinic wasn't named in DOJ's complaint.

Methodist bought West's assets and entered into arrangements to lease its nonphysician employees and compensate physicians for their professional and management services, paying West $300 million. There allegedly 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.

According to the DOJ complaint, West was attractive to Methodist, which didn't have a dedicated inpatient cancer unit or outpatient cancer clinics as of 2011, while West had the largest market share of cancer patients in the Memphis area, but lacked radiation oncology, surgical oncology (apart from breast surgeons) and pathology. So, they joined forces from 2012 through 2018, with "visions of becoming a nationally accredited program," the complaint alleged. But "there was never any formal agreement between Methodist and West that documented a legal partnership."

Methodist Got Fair Market Value Opinions

Instead, they executed an asset purchase agreement, leased employee agreement, professional services agreement and management services agreement. With its December 2011 asset purchase agreement, Methodist bought certain tangible and intangible assets of West, including most equipment, inventory and offices in West's outpatient cancer treatment locations in Tennessee and one in Mississippi for $10.5 million. They became Methodist outpatient departments on Jan. 1, 2012.

The agreement stated that Methodist had obtained a fair market value (FMV) opinion on the purchase price, which didn't factor in the volume or value of referrals. Methodist—which serves Medicaid and indigent patients—also was able to "capitalize on" the 340B drug discount program through the new outpatient sites, according to the complaint.

Methodist also leased West's 193 nonphysician employees and separately compensated physicians under the professional services arrangement based on their work relative value units (wRVUs). "An initial FMV opinion was obtained in early October 2011 to determine the rates per wRVUs based on physician specialty and group level," the complaint said. The opinion didn't reflect benefits, however, and a new valuation wasn't obtained until 2016. The physicians also were paid for their management services under the management services/performance improvement agreement (MSA), which required them to provide management services for the inpatient and outpatient adult oncology service line at six Methodist facilities and the cancer centers. Methodist also made a separate, for-profit $7 million investment in West-affiliated ACORN Research LLC, the complaint alleged.

"Methodist's internal documents show that it expected revenues to increase from $1.25 billion to $1.45 billion with the West transaction," the complaint alleged.

Talk of a 'Partnership'

Methodist and West also repeatedly referred to the West Cancer Center as a "partnership" even though West had sold its assets to Methodist and was required to provide services to the hospitals through the other agreements, DOJ alleged. "Had a legal partnership been formalized, it likely would have run afoul of HHS guidance as to such arrangements, which may violate the AKS and/or the Stark Law," the complaint alleged.

Both Methodist and West continued to think of the West cancer centers "as still being West," the complaint alleged. In fact, West employees who were leased full time to Methodist provided services to West for business unrelated to Methodist.

"The contracts are key to Methodist being able to bill Medicare for the outpatient services and obtain the 340B Program discounts. If the contracts are a fiction, Medicare should not have reimbursed Methodist for the outpatient claims, and Methodist never would have been able to realize the profits from the 340B Program," the complaint alleged. "If the contracts were real, then Methodist gave West rent-free space and paid for the salaries of West's employees to perform work to further the business of West."

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1 U.S. Department of Justice, U.S. Attorney's Office for the Middle District of Tennessee, "Memphis-Based Methodist Le Bonheur Healthcare and Methodist Healthcare-Memphis Hospitals Pay $7.25 Million to Settle Allegations that They Violated the False Claims Act," news release, January 4, 2024, https://bit.ly/48ZL5g2.
2 Complaint, United States ex rel. v. Methodist, Case No.: 3:17-cv-00902 (M.D. Tenn. April 11, 2022), https://bit.ly/3xx0uVM.
3 Settlement Agreement, United States ex rel. v. Methodist, Case No.: 3:17-cv-00902 (M.D. Tenn., 2024), https://bit.ly/48YXJfj.
4 Nina Youngstrom, "ChristianaCare Settles FCA Case Over APPs for $47M; Former CCO Alleged He Was 'Shut Down'," *Report on Medicare Compliance* 33, no. 1 (January 8, 2024), https://bit.ly/3HrsIFf.
5 Nina Youngstrom, "Exagen Settles FCA Case for Restitution, Paid Physicians Specimen Fees Despite OIG Alert," *Report on Medicare Compliance* 32, no. 38 (October 23, 2023), https://bit.ly/3u3B1Us.
6 U.S. Department of Health and Human Services, Office of Inspector General, "Fraud Risk and Heightened Scrutiny," accessed January 18, 2024, https://bit.ly/492qJTH.
7 SCOTUSBlog, "Loper Bright Enterprises v. Raimondo," accessed January 11, 2024, https://bit.ly/47DVyNq.
8 U.S. Department of Health and Human Services, Office of Inspector General, "Criteria for implementing section 1128(b)(7) exclusion authority," April 18, 2016, https://bit.ly/3k1yErW.
9 U.S. Department of Health and Human Services, Office of Inspector General, *General Compliance Program Guidance*, November 2023, https://bit.ly/3FREWGe.