ChristianaCare Settlement Reveals FCA Pitfalls For Hospitals

By **Danielle Vrabie, David Fischer and Kayla Malone** (February 14, 2024)

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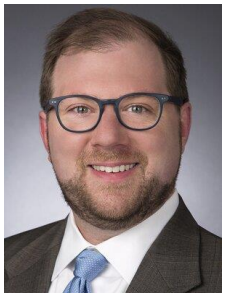

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Delaware-based ChristianaCare Health System[1] **recently agreed** to pay $47.1 million to resolve a lawsuit filed by the system's former chief compliance officer, Ronald Sherman.

Among other things, the complaint alleged that the system's arrangements with various private physician groups resulted in federal False Claims Act and Delaware False Claims and Reporting Act liability.[2]

Specifically, Sherman alleged that ChristianaCare violated the federal and state False Claims Acts by providing in-kind services to physician groups that were captured in the bundled billing codes submitted to federal health care programs by the groups themselves.

Following the resolution of this case, hospitals are encouraged to revisit their arrangements with private physician groups to ensure that proper safeguards are in place to mitigate FCA risk.

The ChristianaCare Lawsuit

Sherman's 2017 complaint alleged that ChristianaCare provided prohibited remuneration to Neonatology Associates, a private physician group with an exclusive contract to manage all care in Christiana Hospital's neonatal intensive care unit.

Under its contract with ChristianaCare, Neonatology Associates billed 24-hour global/bundled CPT codes for all care provided in the unit. However, ChristianaCare employees — including hospitalists, residents, physician assistants and nurse practitioners — worked in the unit alongside physicians from Neonatology Associates and were also providing care to those same patients.

As a result, Neonatology Associates billed globally for work that they themselves did not perform and that was instead performed by ChristianaCare employees.

Sherman alleged that these in-kind services constituted improper remuneration that was intended to induce the physicians to make referrals to ChristianaCare.

Although the complaint focused primarily on the neonatal intensive care unit arrangement, Sherman alleged that ChristianaCare had similar arrangements with other physicians groups involving neurosurgical, cardiovascular surgery, ear/nose/throat and urologic surgery practices.

The defendants denied the allegations and argued that Sherman failed to (1) establish the exchange of prohibited remuneration under the Anti-Kickback Statute, or the creation of a financial relationship under the Stark Law; (2) present evidence of referrals for Designated

Health Services as required under the Stark Law; (3) develop any evidence that the alleged remuneration was intended to induce or reward referrals; or (4) establish the required elements of falsity or materiality under the FCA.

Before the court ruled on the defendants' motion for summary judgment, the parties reached an agreement on settlement. ChristianaCare did not admit liability as part of the settlement.

Key Takeaways

While this is the first FCA settlement based on a hospital allegedly providing private physicians with free services in the form of hospital-employed clinicians, it may not be the last.

As the government and the relators bar ramp up scrutiny of compensation arrangements between hospitals and private physician groups that have been contracted to manage and provide care for certain units within the hospital, there are several key takeaways from the ChristianaCare settlement.

Hospital service agreements must be carefully structured and monitored to ensure compliance.

Hospitals often engage private physician groups to provide professional services to their patients. However, when these arrangements involve close collaboration between the private group and hospital employees, and also allow for separate billing by the group, both hospitals and physician groups need to pay close attention to the agreement and its execution.

Global billing or collaborative care arrangements are not per se violations of the Anti-Kickback Statute. However, there is greater fraud and abuse risk in these types of arrangements unless there is active, ongoing monitoring for compliance.

As part of their risk assessment process, hospitals should periodically review their arrangements with private physician groups, and vice versa, particularly those involving collaboration between hospital and private clinicians.

In these types of arrangements, it is advisable to conduct medical record reviews and speak with clinicians on the ground to ensure that hospital personnel are not providing services for which private physicians may be reimbursed, whether intentionally or unintentionally, and to confirm that the contract terms are being implemented in accordance with the contract.

Hospitals may also want audit rights to ensure that they have the ability to monitor billing compliance by private physicians on a regular basis.

Disclosures under corporate integrity agreements may not protect providers from FCA litigation.

The complaint included additional allegations based on ChristianaCare's preexisting corporate integrity agreement with the Office of Inspector General. ChristianaCare voluntarily entered into the corporate integrity agreement as part of its settlement of another prior unrelated FCA matter.

The agreement required ChristianaCare to make annual reports to the OIG between 2010

and 2015, and while it had complied with this requirement — and Sherman himself had submitted disclosure logs to the OIG — Sherman alleges that it failed to adequately report the arrangements it had with Neonatology Associates or any other private physician groups or return any alleged overpayments.

In response, ChristianaCare argued that Sherman himself was responsible for reporting any violations of the Anti-Kickback Statue or Stark Law to the OIG, and he did not do so, instead certifying compliance with the corporate integrity agreement.

ChristianaCare also noted that Sherman was required to submit disclosure logs to the OIG, which contained all internal reports and related investigations. According to ChristianaCare, the OIG therefore had notice and ample opportunity to investigate the arrangements in this case and did not do so.[3]

The inclusion of these allegations is both a reminder and a warning that disclosure to the OIG by an organization pursuant to a corporate integrity agreement does not necessarily protect providers from future FCA claims or liability.

Therefore, to the extent that issues are uncovered, organizations are encouraged to take more proactive steps to address these matters from a reporting perspective rather than assuming mere inclusion of the disclosure is sufficient to insulate it from FCA liability — or at least the risk of an FCA suit.

It should also be noted that in some cases, the violation of the corporate integrity agreement alone can also form the basis of an FCA claim.

Ensure that compliance officers are granted appropriate authority to investigate, report and help the organization take corrective action.

The relator in the ChristianaCare case was the system's former chief compliance officer, a role that is specifically tasked with uncovering and correcting compliance related issues. In this role, Sherman led ChristianaCare's internal investigation of the arrangements with Neonatology Associates and other groups.

The complaint alleges that Sherman reported the issues related to these physician arrangements multiple times, but that ChristianaCare did not effectively address or remediate them, instead cutting Sherman out of the process. ChristianaCare denied these allegations and claimed that Sherman was granted the necessary authority in full compliance with the agreement.

Providers must respect the independence of the compliance officer and ensure that compliance investigations and reports are taken seriously.

Compliance issues should be addressed proactively to ensure corrective action as appropriate, and work plans should be developed to ensure ongoing auditing and monitoring.

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[1] Other Defendants include ChristianaCare Health Services, Inc., Christiana Hospital, and Wilmington Hospital. The article refers to all entities as ChristianaCare consistent with Defendants' briefing.

[2] District of Delaware | ChristianaCare Pays $42.5 Million To Resolve Health Care Fraud Allegations | United States Department of Justice.

[3] See Defs. Opening Br. (Jan. 9, 2019) p. 8.