COSMOS
Navigate the Compliance Universe

Report on Medicare Compliance Volume 33, Number 1. January 08, 2024
ChristianaCare Settles FCA Case Over APPs for $47M; Former CCO Alleged He Was 'Shut Down'

By Nina Youngstrom

When Ronald Sherman was the chief compliance officer at ChristianaCare Health Services in Delaware, he became aware that the services of its employed advanced practice providers (APPs) were allegedly being provided free to certain nonemployed physicians who billed for them under global neonatal and surgery codes. After the compliance officer brought this to the attention of top executives, they developed rules "designed to immediately put an end to any potential violations within the entire surgery department," according to Sherman's 2017 whistleblower complaint.[1] But as far as he could tell, nothing changed, and Sherman would later say in a deposition that he was "marginalized." His complaint alleged that ChristianaCare provided the free or below-cost services of APPs to induce physician referrals in violation of the Anti-Kickback Statute (AKS) and Stark Law and that led to the submission of false claims.

Now ChristianaCare has agreed to pay a total of $47.1 million in separate false claims settlements with the U.S. Department of Justice (DOJ)[2] and Delaware Attorney General (AG).[3] The settlements were announced by the AG and the law firm representing the whistleblower, but not DOJ. No corporate integrity agreement (CIA) is required as part of the settlement.

"Any hospital in the United States that is engaging in this behavior should strongly consider putting an immediate stop to it," said attorney Dan Miller, with Walden, Macht & Haran LLP, the whistleblower's law firm.

ChristianaCare denies the allegations, which were fully investigated when they arose, said Shane Hoffman, director of communications. "We retained experts and outside counsel to work with us and review the matter. We determined that we were in compliance with all laws and regulations pertaining to the use of advanced practice clinicians to coordinate and provide continuity of care," he told *RMC*. Hoffman added that "ChristianaCare has consistently disputed the claim that the compliance officer was marginalized or the investigation shut down."

When some of the alleged violations transpired, Christiana Care was under a five-year CIA as part of an unrelated 2010 Stark-based False Claims Act (FCA) settlement.[4]

The use of hospital-employed APPs may be dicey if it comes off as a benefit to independent physicians, but it has its place, said attorney Holley Thames Lutz, with Dentons US LLP in Washington, D.C. Team-based care is a fact of life and has CMS's seal of approval, she said, and ChristianaCare's settlement seems to acknowledge this reality. It states that "when patients are hospitalized after a surgical procedure, surgical providers are sometimes permitted to bill for a series of services, commonly referred to as a global surgical package, that encompasses services provided directly by the surgical provider as well as additional services provided by ancillary support providers at the hospital." The government appears to be saying, "There are times where collaborative team-based care can involve more than just the surgeon and the surgeon can still get the global surgical fee," Lutz said. "It's a good thing if that's what they really mean. They're almost nodding that the glass is half full."

But the plot thickens when free APP services are allegedly provided as kickbacks. According to the complaint,

ChristianaCare—including Christiana Hospital and Wilmington Hospital—allegedly devised a scheme to "funnel" referrals from several private physician groups: neonatology, neurosurgery, cardiovascular surgery, urology and ear, nose and throat.

For example, Neonatology Associates had an exclusive contract to provide services to Christiana Hospital's neonatal intensive care unit (NICU) from 2010 to 2014. Neonatal and pediatric critical care codes cover all care provided over 24 hours and only one physician is allowed to bill for that period, the complaint states.

In late 2010, physician Laura Lawler, the assistant director of pediatrics, told a ChristianaCare compliance auditor that "she was distressed over the fact that Christiana employees were doing most of the work in the NICU, and that Christiana was refraining from billing for that work so that Neonatology Associates could bill the bundled 24 hour codes," according to the complaint.

CEO Suggested a Meeting

The compliance auditor, Rhonda Mullins, did a chart audit and told Sherman "that doctors at Neonatology Associates were not performing most of the services they were billing for; rather, the services were being provided by Christiana employees," the complaint alleged.

In response to the audit, the whistleblower did a compliance investigation and allegedly found that Neonatology Associates doctors "were so commonly 'unavailable' that hospital employees simply substituted for them in providing the required medical management and treatment of infants," the complaint alleged.

The situation was described in a memo written by Lawler and sent to Sherman and then-CEO Robert Laskowski. The CEO called Sherman to talk about the memo and asked him to set up a meeting with executives to decide next steps. Laskowski allegedly said to him, "Ron, if there was ever a whistleblower case, this is it."

At the request of the CEO, Sherman, Mullins and others met with Neonatology Associates to discuss the Stark and AKS implications of the arrangement and Lawler's memo. They agreed to hire a neonatology coding expert to review a sample of NICU charts and give her opinion on the arrangement between the hospital and neonatology group. The coding expert concluded the arrangement posed considerable risk of an enforcement action, according to the complaint. Neonatology Associates allegedly rejected the report because the coding expert wasn't a physician, and a neonatologist who was experienced in the NICU but not coding or auditing conducted another review. He focused on quality of care and found no serious problems with the arrangement, according to the complaint.

As word of the neonatology investigation spread, Sherman and Mullins were contacted by other practitioners with similar arrangements. Mullins reviewed a sample of charts and allegedly found that, before and after nonemployed physicians performed neurosurgeries and cardiovascular surgeries at ChristianaCare, its employees provided pre- and post-op care.

Mullins shared her findings with Sherman, who held a meeting with executives to discuss the billing of global surgery codes by outside surgery groups who allegedly didn't provide the services. They developed six rules for the surgery department to end potential violations. Two of them: "Christiana employed NPs or PAs may perform surgical follow up services and/or write daily progress notes for private patients but their work or documentation may not substitute for the work or documentation of a private attending physicians or a PA employed by an attending," and, "Private surgeons must dictate at least one comprehensive post-operative note to satisfy Medicare global surgical payment requirements."

But the words on the page allegedly never came alive, according to the complaint. As far as the whistleblower knows, "none of the policies were effectively implemented."

Report: Sherman Testified He Was 'Marginalized'

In the meantime, the CEO had retired and a new CEO, Janice Nevins, then the chief medical officer, was chosen by the board. After she took the reins, Sherman was terminated. The reasons he was separated "were totally unrelated to the allegations raised in the complaint," Hoffman said.

A report on ChristianaCare's compliance program was prepared for the whistleblower's law firm by former federal prosecutor Virginia Evans. She said that "the structure" of the compliance program "met most industry standards in that it was designed to result in: 1) reporting of compliance concerns, 2) investigation of compliance concerns, and 3) resolutions of compliance concerns through corrective actions." But the same couldn't be said for implementation, particularly the standard for resolving compliance concerns, Evans wrote. "My review of the materials revealed a lack of support for the Compliance Department's efforts in general and for Mr. Sherman's efforts in particular. This lack of support fell far below hospital industry standards."

Evans noted that Sherman testified in his deposition he was kept "'out of the loop'... with respect to the NICU arrangements." He also claimed he was "marginalized" after presenting an audit report on the free services provided to neonatologists and the "NICU free services investigation was 'shut down' without his consent" even though Sherman was obliged to investigate compliance issues under the CIA, Evans wrote in the report, which was an exhibit in the FCA case.

"Isolating the Compliance Officer or Department from decisions relating to compliance concerns is, in my experience, an effective way to prevent the department from doing its job," Evans wrote. "This strategy is typical of organizations wanting business to continue as usual even when they risk violating laws and regulations. This is not consistent with industry standards."

ChristianaCare had its own report by an expert, Kevin O'Brien, executive director of Berkeley Research Group, that was also an exhibit in the case. He looked at Sherman's authority as compliance officer and confirmed the compliance officer reports directly to the CEO and board's audit committee. The CIA requires the compliance officer to be part of senior management and report directly to the board on compliance issues. "It is important to note that Mr. Sherman himself has certified that [ChristianaCare] was in compliance with all aspects of the CIA," O'Brien wrote. He added that five reviews by the CIA's independent review organization, which included the Stark Law and AKS, "had no significant findings."

Evans acknowledged that the NICU and global surgical allegations were investigated "at some length," O'Brien said. But Evans contended in her report that the free services continued anyway.

Again, a point of disagreement. O'Brien noted the APPs, including nurse practitioners and physician assistants assigned to the NICU, were employed by ChristianaCare "generally to provide services that typically would be considered routine services and therefore part of the hospital's room and board charge submitted to payers including government programs. The cost associated with these individuals from 2007 through 2017 were considered facility costs and therefore do not represent 'free' professional services," O'Brien noted.

To Be or Not to Be: Free APP Services

Lutz noted that a premise of the complaint is that the global surgical package (GSP) requires the surgeon to provide all GSP services. She takes issue with that. "There are strong arguments, supported by CMS contractor RAND, upon which CMS relies in defining and refining the GSP ... that the GSP is more of a prohibition against unbundling," Lutz said. In other words, the surgeon is expected to perform a pre-op history and physical the day of surgery, the surgery and post-op and pain management services that are clinically required to be provided by

the surgeon. When providing the services within the GSP period (e.g., 10 or 90 days), the physician isn't permitted to bill for them separately, Lutz said. For example, Medicare shouldn't be billed separately for an office visit to remove the patient's sutures.

Is telling surgeons they may not bill for services they provided within the GSP the same thing as saying only the surgeon can provide all components of the GSP? Arguably that's not the case, Lutz said. The *Medicare Claims Processing Manual* (Chapter 10, Sec. 40) lists the components of the GSP. One of them is "Postsurgical Pain Management—By the surgeon" and another is "Complications Following Surgery—All additional medical or surgical services required of the surgeon..." If all the components of the GSP must be performed by the surgeon, Lutz wonders why CMS would single these out.

"My argument is it's permissible for a hospital to have an APP support a service line because it promotes clinical practice reflective of the benefits of collaborative team-based care, provided the support is not offered for impermissible reasons," Lutz said. For example, the APP may need to adjust a patient's medication post-op because of an allergic reaction when the surgeon is already engaged in another 12-hour surgery.

Is There a 'Patient-Centric, Non-Referral Rationale?'

If there's a "patient-centric, non-referral rationale" for employing APPs, it's a legitimate relationship, Lutz said. Benefits include quality of care, better patient outcomes and satisfaction, more timely and appropriate discharge and enhanced bed capacity.

"If the physicians keep doing what they clinically should do for patient care, there should not be an issue and the world is an easier place," Lutz said. "But if physicians don't maintain that level of service for patients, relying too heavily on APPs who may fear providing care above their scope of practice—and if that's the intent of a hospital in developing collaborative care programs—it's an issue. The challenge is in proving it's only for the hospital's benefit and not the physician's benefit."

And that gets back to the kickback allegations but also the subtext of the ChristianaCare settlement. The government contends that ChristianaCare submitted false claims by providing the services of their employed nurse practitioners, physician assistants and hospitalists free or below market value to nonemployed physicians in the neonatology, cardiovascular, urology, neurosciences and ear nose and throat departments. When the ancillary support services were intended to induce physician referrals to ChristianaCare, it allegedly violated the AKS. Because the claims were for designated health services and the arrangement didn't satisfy a Stark Law exception, they violated the Stark Law. For both these reasons, the government alleged ChristianaCare submitted false claims—from April 1, 2011, to Sept. 30, 2013, for the neonatology department and from April 1, 2011, to April 14, 2017, for the other departments.

But the settlement also acknowledged that "When patients are admitted to the NICU, the neonatologists managing their care are permitted to bill global procedure codes that encompass services provided directly by the neonatologist as well as additional services provided by ancillary support providers at the NICU. Similarly, when patients are hospitalized after a surgical procedure, surgical providers are sometimes permitted to bill for a series of services, commonly referred to as a global surgical package, that encompasses services provided directly by the surgical provider as well as additional services provided by ancillary support providers at the hospital."

ChristianaCare didn't admit liability in the settlement.

Contact Lutz at holley.lutz@dentons.com and Miller at dmiller@wmhlaw.com.

1 Complaint, United States of America and the State of Delaware ex rel. Ronald Sherman v. Christiana Care Health

Services, Inc., Christiana Care Health System, Christiana Hospital, and Wilmington Hospital, No. 1:17-cv-00419-RGA (D. Del 2017), https://bit.ly/48JLljp.
2 Federal Settlement Agreement, United States of America v. Christiana Care Health Services, Inc., https://bit.ly/3S4fZ1m.
3 State Settlement Agreement, State of Delaware v. Christiana Care Health Services, Inc., https://bit.ly/3TMk7Ek.
4 Settlement agreement, United States v. Christiana Care Health System, No. 05-244 (D. Del 2010), https://bit.ly/48pXyKb.