Report on
MEDICARE COMPLIANCE

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Weekly News and Compliance Strategies on Federal Regulations, Enforcement Actions and Audits

Contents

A Compliance Officer Is the Whistleblower in Sutter Health Case; Settlement Is $30.5M

The former compliance officer of Sutter Medical Center in Sacramento, California, was the catalyst of Sutter Health's $30.5 million settlement with the Department of Justice (DOJ) for allegedly overpaying Sacramento Cardiovascular Surgeons Medical Group (Sac Cardio) for physician assistants and medical director agreements in violation of the Stark Law. Although the compliance officer suspended the payments more than once with the support of Sutter Health executives, they resumed, according to allegations in the False Claims Act[1] (FCA) complaint.

DOJ announced the settlement Nov. 15.

Laurie Hanvey, the compliance officer turned whistleblower, filed the FCA lawsuit against Sutter Health in 2014, two years after joining the integrated delivery system. In a twist, Sutter Health is only released in the settlement from common law theories of unjust enrichment and payment by mistake.

Sutter Health is a nonprofit with 24 hospitals, 5,000 physicians and 48,000 employees. Sac Cardio includes three cardiovascular surgeons: Michael Ingram, Robert Kincade and James Longoria.

According to the settlement, Sutter Medical Center in Sacramento paid Sac Cardio compensation for three medical director agreements and one lease for the services of physician assistants (PAs) employed by Sac Cardio. "These arrangements qualified as

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Health System Pays $6.4M to Settle Case On Pre-Surgery H&Ps; The CoP Is Not Billable

In a vivid reminder that preoperative assessments aren't separately billable, Memorial Hermann Health System in Houston agreed to pay $6.4 million to settle a civil monetary penalty case about claims that included codes for the history and physical (H&P) and modifier 25. The settlement with the HHS Office of Inspector General (OIG) was signed around the same time that CMS finalized regulations that allow hospitals and ambulatory surgery centers (ASCs) to use an abbreviated version of the H&P before outpatient procedures.[1]

According to the settlement, OIG alleged that from April 1, 2011, to May 31, 2017, Memorial Hermann Health System submitted claims to Medicare, Medicaid and TRICARE that automatically appended a 99201 or G0463 facility CPT code to preoperative assessments performed by nurses in a hospital setting and/or automatically appended modifier 25 to some evaluation and management (E/M) services billed on the same day as surgeries. Memorial Hermann Health System reported the problems to OIG and was accepted into its Self-Disclosure Protocol in September 2018. The health system didn't admit liability in the settlement.

Hospitals may make the mistake of treating H&Ps/preoperative assessments as if they were a separately billable, medically necessary service instead of a Medicare condition of participation, says Marion Salwin, director of physician and regulatory

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compliance at Trinity Health in Livonia, Michigan. Preoperative assessments also may be confused with surgical consults.

"This is an area where everyone thinks there's a financial opportunity. In actuality, it's not an opportunity," she says. The H&Ps have to be baked into the medical staff bylaws if hospitals want to stay in Medicare's good graces.

When patients are referred to the hospital for surgery with anesthesia, they must be cleared beforehand, which includes an H&P/preoperative assessment. It's a high-level clearance for surgery that's often managed by a nurse practitioner or physician assistant at the hospital, who orders blood work, a chest X-ray and other diagnostic tests. The H&P is not the same as a presurgical consult, which is separately payable, Salwin says. Patients with comorbidities will be evaluated before surgery for medical conditions that could put them in danger or affect the outcome of the procedure. Suppose a patient with chronic obstructive pulmonary disease is referred by a primary care physician to a pulmonologist for a surgical consult. "The consult is at the request of a physician, whereas the H&P is at the request of the hospital to meet the conditions of participation," Salwin says. The pulmonologist will bill the payer for the surgical consult.

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CMS Lets Hospitals Slim Down Outpatient H&Ps

Another telling difference between surgical consults and H&Ps: Surgical consults have a chief complaint, and "the chief complaint and medical necessity go hand in hand," she says. There's no chief complaint bringing people to the hospital for preoperative clearance; the H&P is simply a requirement for continued participation in Medicare. "Typically, medical decisions are not being made to treat a specific condition that is being managed by another provider," Salwin says.

According to the conditions of participation, hospitals are required to state in their medical bylaws that H&Ps must be completed 30 days before outpatient surgery or a procedure requiring anesthesia and updated within 24 hours of admission. "Some hospitals require the surgeon to provide the H&P. Other hospitals will have a department that is designated as a pre-op clearance department so that the H&P is on the chart within the 30-day time period before surgery," Salwin says.

Although hospitals can't bill for H&Ps/preoperative assessments, they now can slim them down. In the Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction,[2] which was published in the Sept. 30 *Federal Register*, CMS gave hospitals and ASCs the option to compress their H&Ps/preoperative assessments for outpatient surgeries.

"We are allowing hospitals the flexibility to establish a medical staff policy describing the circumstances under which such hospitals can utilize a pre-surgery/pre-procedure assessment for an outpatient, instead of a comprehensive medical history and physical examination," the regulation stated. "In order to exercise this option, a hospital must document the assessment in a patient's medical record. The hospital's policy must consider patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and the level of anesthesia required for the surgery or procedure; nationally recognized guidelines and standards of practice for assessment of specific types of patients prior to specific outpatient surgeries and procedures; and applicable state and local health and safety laws."

The final regulation gives ASCs a similar option, although there was a slight language change in the final regulation, with CMS stating that "the ASC policy must be based on any applicable nationally recognized standards of practice and guidelines, and any applicable State and local health and safety laws."

The new regulation means that not every chart has to have a comprehensive H&P. "It's up to you whether you do a less full version," Salwin explains. CMS says it's trying to strike a balance between provider burden and patient safety. "It leaves the responsibility to

determine the need for this preoperative H&P to the joint responsibility of the facility and the surgeon," she notes.

Memorial Hermann didn't respond to *RMC*'s request for comment on the settlement.

Contact Salwin at marion.salwin@trinity-health.org. ✧

Endnotes

1. Nina Youngstrom, "CMS to Create Burden Reduction Office, Finalized Efficiency Rule," *Report on Medicare Compliance* 28, no. 34 (September 30, 2019), http://bit.ly/2njP4mL.
2. Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care, 84 Fed. Reg. 51,732 (Sept. 30, 2019), http://bit.ly/2NMWEQZ.

Hospital Settles ADA Case With DOJ Over Auxiliary Aids and Services

Three of the hospitals and 31 other entities in Beaumont Health in Michigan are now required to have an employee on hand 24/7 to help patients who are deaf or hard of hearing with auxiliary aids and services, including qualified interpreters, under a voluntary resolution agreement[1] with the U.S. Attorney's Office for the Eastern District of Michigan. It's one of numerous compliance reforms in the agreement, which stems from patient complaints that one of the facilities, William Beaumont Hospital, allegedly violated the Americans with Disabilities Act[2] (ADA), the U.S. attorney's office said Nov. 13.

Although multiple patients who are deaf or hard of hearing repeatedly asked for sign language interpreters for complex medical appointments and procedures, William Beaumont Hospital allegedly didn't provide them. The patients, who use American Sign Language, allegedly had to rely on their relatives as interpreters or used video remote interpreting (VRI) services that had "poor connectivity" or were hard to see because of problems with the patient's mobility or vision. As a result of the hospital's alleged failure to provide sign language interpreters, "deaf individuals were denied the benefit of effective communication with hospital staff, the opportunity to effectively participate in medical treatment decisions, and the full benefit of health care services provided by the hospital," the U.S. attorney's office said.

Beaumont Health denied wrongdoing and didn't admit liability in the settlement.

The ADA prohibits discrimination based on disability, and Title III specifically states that "No individual shall be discriminated against on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person who owns, leases (or leases to), or operates a place of public accommodation."[3] The term "public accommodation" includes hospitals, pharmacies, physician offices, lawyer's offices and government offices. The definition of "discrimination" includes "failure to take steps necessary to ensure that no individual with a disability is excluded, denied service, or otherwise treated differently because of the absence of auxiliary aids and services, unless such steps would fundamentally alter the nature of the good, service, facility, privilege, advantage or accommodation being offered or would result in an undue burden."[4]

If "auxiliary aids and services" sounds familiar, it's because that same language appears in regulations implementing Sec. 1557 of the Affordable Care Act,[5] which prohibits discrimination on the basis of race, color, national origin, sex, age or disability. Sec. 1557 magnifies the compliance risk for hospitals trying to meet the needs of patients who are deaf or hard of hearing, says attorney Drew Stevens, with Arnall Golden Gregory in Atlanta. It requires hospitals and other providers to give "primary consideration" to patients who request in-person interpreters instead of VRI services. In other words, their wishes must be honored unless a health system can provide an equally effective alternative or if the patients' preferences present an undue administrative or financial burden, although "it's not at all clear when it's an undue burden," Stevens says. HHS in the June 14 *Federal Register* proposed a regulation that would scale back Sec. 1557,[6] but it didn't revise the section on auxiliary aids and services, although the final version could venture into that territory.[7] The HHS Office for Civil Rights (OCR) enforces Sec. 1557.

'There Are More Requirements Than in the Regulations'

Hospitals don't want to let patients down and/or invite enforcement actions that come with corrective action plans from the Department of Justice or OCR, Stevens says. They tend to be far more onerous than complying with the ADA Title III and Sec. 1557 regulations. For example, in the William Beaumont Hospital system settlement, "there are so many more requirements than in the regulations," he says. "It's important to see how burdensome they can be." He recommends health systems review the settlement and others like it to see where they fall short.

The settlement requires Beaumont Health to have a program to provide "appropriate" auxiliary aids and services to deaf and hard-of-hearing patients and companions at three hospitals and 31 affiliated entities,

including free onsite interpreters or VRI. The health system will develop policies and provide training to that effect and make it clear a supervisor's approval isn't necessary. Which auxiliary aids and services are necessary must be decided when the appointment is scheduled for patients Beaumont knows are deaf or hard or hearing or when the patient arrives, whichever is earlier. Beaumont is also required to keep a log of patient requests for auxiliary aids and services and use its grievance resolution process to investigate disputes about effective communication.

Beaumont Has to Report on Compliance

The settlement describes the circumstances when it may be necessary to provide patients with a qualified interpreter:

- "Discussing a patient's symptoms and medical condition, medications and medical history;
- Explaining medical conditions, treatment options, tests, medications, surgery and other procedures;
- Providing a diagnosis and recommendation for treatment;
- Communicating with a patient during treatment, testing procedures and during a physician's rounds;
- Obtaining informed consent for treatment;
- Providing instructions for medications, pre- and post-treatment activities and follow-up treatments;
- Providing mental health services, including group or individual counseling for patients and family members;
- Providing information about blood or organ donations;
- Discussing powers of attorney, living wills and/or complex billing and insurance matters; and
- During educational interventions, such as birthing or new parent classes, nutrition and weight management programs, and CPR and first-aid training."

When VRI services take the place of onsite interpreters, Beaumont is required to make sure they're "appropriate" based on the patient's age, vision, mobility, past experience with VRI and other factors. The settlement detailed the technical requirements for VRI services (e.g., they must be "real-time, full-motion video and audio over a dedicated high-speed, wide bandwidth video connection or wireless connection that delivers high-quality video images…").

There are also training requirements for Beaumont ADA personnel and training requirements for all Beaumont employees on hearing impairment, the identification of the communication needs of people who are deaf or hard of hearing, the auxiliary aids and services policy, the use of qualified interpreters and related matters. Training must be documented in an electronic log. Physicians who are affiliated with Beaumont must be notified about its policy on communicating with deaf and hard-of-hearing patients and asked to review their ADA obligations, as well as Beaumont's policy on providing auxiliary aids.

Beaumont must report on its compliance with the settlement requirements to the U.S. attorney's office, and let it know if anyone complains or files a lawsuit alleging the health system failed to provide auxiliary aids and services to people who are deaf or hard of hearing.

'The Challenge Is When to Provide an Interpreter'

Hospitals and other providers have been struggling with the Sec. 1557 "primary consideration" requirement, Stevens says. Interpreters are pricey, and sometimes patients don't show up for appointments. "What health systems do is evaluate the cost of providing in-person interpreters and try to take a reasonable approach," he says. Some rely on alternative systems, such as VRI, if they're as effective. "The problem with that is if you provide VRI and it's choppy or there are other problems, it's not as effective as an in-person interpreter."

Stevens suggests gathering stakeholders, including people responsible for ADA and Sec. 1557 compliance, patient advocates, the representative from your interpretation services company and in-house counsel, to come up with a plan for auxiliary aides and services that everyone can agree on, "that's compliant and serves the patient well and minimizes legal risk and that the system can stand behind. Otherwise it's an ad hoc determination, and that can give rise to issues, complaints and discrimination."

In a statement on the settlement, Beaumont Health said, "We are committed to providing equal access to health care services for all patients and families, including those who are deaf or have hearing impairments. We fully cooperated with the government during its investigation and are unaware of any findings of violations of the law by a Beaumont entity. To best serve our patients and families, Beaumont has already taken steps to enhance its policies and procedures for providing appropriate accommodations and entered into an agreement with the government that reinforces our commitment to compliance with the law."

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Endnotes

1. "Voluntary Resolution Agreement Under the Americans with Disabilities Act between the United States of America and William Beaumont Hospital," November 13, 2019, http://bit.ly/2qcMMHe.
2. 42 U.S.C. § 12101, et seq.
3. 42 U.S.C. § 12182.
4. 42 U.S.C. § 12182.
5. 42 U.S.C. § 18001 et seq.
6. Nondiscrimination in Health and Health Education Programs or Activities, 84 Fed. Reg. 27,846 (June 13, 2019), http://bit.ly/2CKqkIs.
7. Nina Youngstrom, "In Proposed 1557 Rule, HHS Drops LEP Taglines And Rolls Back Sex Discrimination Protection," *Report on Medicare Compliance* 28, no. 20 (June 3, 2019), http://bit.ly/352y6cu.

Hospital Escaped Document Overload in 'Collaborative' FCA Resolution

Although this is counterintuitive, it's in the best interest of health care organizations to give the government a helping hand during False Claims Act[1] (FCA) investigations—and vice versa. That's the message from a prosecutor and an attorney who were on opposite sides of a Stark-related FCA case that was settled as efficiently as these things can be. The U.S. attorney's office tabled huge document production demands while the two sides hashed over allegations that compensation was not fair market value or commercially reasonable. With its limited resources, the Department of Justice (DOJ) also doesn't want to drown in documents, but it has to have faith in the credibility of the organization it's investigating.

"You should be trying to build trust with the government so communication can flow more freely," said Matthew Krueger, the U.S. Attorney for the Eastern District of Wisconsin. It depends on the circumstances, but he would rather have a phone call right away, "a really friendly phone call, not one that is rattling sabers and saying how outrageous the [Department of Justice] overreach is," he said Nov. 5 at the Health Care Compliance Association's Healthcare Enforcement Compliance Conference in Washington, D.C.

The opposing counsel, David Glaser, said the settlement wasn't a small sum, but there were various points when the U.S. attorney could have demanded documents and he held off, keeping costs and aggravation down on both sides of the table. "Much of the efficiency is in how many documents we had to gather and produce," explained Glaser, with Fredrikson & Byron in Minneapolis, at the conference. "There were times when they said, 'Hang on to the documents, but if you can explain to us how you did this, and put them someplace safe, and if we get convinced by talking to various people and reviewing a subset of [documents], we won't review all of them." That's significant, because producing documents is a major expense in three ways: retrieving, scanning and reviewing them, Glaser noted. This can run into the hundreds of thousands of dollars or more, depending on the magnitude of the case.

The FCA complaint got rolling with a whistleblower, who alleged that a hospital in Krueger's district was billing Medicare for services that weren't performed or weren't medically necessary. At the beginning, "It had nothing to do with Stark." An assistant U.S. attorney at the time, Krueger began the investigation the usual way, issuing civil investigative demands (CIDs), interviewing witnesses and reviewing medical records with outside experts. As evidence came in, however, the case took a turn toward suspected Stark violations. "We found certain documents that made us concerned about the way doctors were compensated," Krueger said.

Because DOJ has to move fast in whistleblower cases—it has 60 days to intervene in a false claims case, although usually DOJ gets numerous extensions from the court—Krueger said "good things came out of the need to move efficiently. We engaged in a more collaborative way with David and his firm, and moved right to the heart of key interviews and reached a settlement that was fair and that was the product of cooperative communication," he said. "It's a good way to do business."

U.S. Attorney: Government Has Four Interests

Krueger said the government has four interests:

- Protecting patients from harm and protecting public safety.
- Thoroughness: There's always a concern that the government has missed witnesses or documents that it doesn't know to ask for. It's helpful for health care organizations to narrow the universe, he said. "You can cut through costs if you can help government by saying, 'We have a document here and here. We don't have them there; they were archived 20 years ago.'"
- Efficiency: The government doesn't have unlimited resources, so it has a stake in resolving cases efficiently. For example, Krueger said organizations are welcome to request the narrowing of subpoenas. "Many times, we issue subpoenas that ask for everything under the sun," he said. "We want to make sure they are preserving data, but we can't process all of it. When [organizations] see how broad it is, they probably will call. The assistant U.S. attorney is probably expecting it. At least with

subpoenas, this is your opportunity to ask the [assistant U.S. attorney] to narrow it and share with them where the most pertinent information is. Is there a summary you are willing to put together to answer their questions most quickly?"

- Fairness: "We are really trying to do justice. We want to be mindful of the burdens our investigations place on regulated parties," Kreuger said. If health care organizations have suggestions for conveying information in a less onerous way, "we are all ears for conducting the investigation fairly," he said. "Stark puts an interesting overlay on that insofar as the damages that can come." Every claim for a designated health service that was related to the Stark financial relationship must be reimbursed, and when the FCA is added to the mix, there's potentially treble damages per claim. "The amount of damages can get enormous very quickly, so we need to define the universe quickly," Krueger noted.

'Don't Be Jerky or Blustery'

Glaser said he didn't agree with all of the government's positions, but it's always wise to cooperate "until the other side is being jerky," which was never the case during the resolution of the Stark case. "Start out being open and friendly, and you can always get harsher if necessary," he advised. "It wasn't like every time they said, 'Can you do this,' we said yes. Sometimes you couldn't because gathering stuff would be really expensive or it wasn't available." So he would ask what the government was looking for and say, "Let's see if I can find a way to get it for you."

And people should always keep their word. If you promise a document to the U.S. attorney's office, produce it on time or ask for an extension, Glaser said. Having a bad attitude could cause trouble in the relationship. "Don't be jerky or blustery," Krueger advised. "You will find lawyers who hold things close to the chest. The worst thing to do to erode trust is to promise something and [not] deliver."

If organizations mistakenly give the U.S. attorney's office bad information, "alert government counsel right away to minimize the hit to trust that it can take," Krueger said. Revisions are permitted under the Federal Rules of Civil Procedure.[2]

Another thing to keep in mind is "constituencies," Krueger said. "Let's say you're interfacing with a line assistant U.S. attorney and you don't like how it's going. What should you do? It's probably like escalating up the chain in any organization," he said. "There are costs," including potential harm to the relationship with the person you've been dealing with. "You want to do it advisedly." It's your right to go over the assistant U.S. attorney's head, and "I am always willing to meet with defense counsel, but I always have the [assistant U.S. attorney] with me and have them briefed."

There's an Upside to Sharing Expert Testimony

He also prefers when organizations share information about their expert witnesses, because "it allows government lawyers to assess the litigation risk." In the Stark case, Krueger hoped to push it through without experts, but it wasn't possible because the case turned partly on fair market value. However, Glaser said, "We gave oral summaries of what our experts would say," which is called a proffer. "We each were able to talk about strengths and weaknesses in the other's experts, and often that's what brings you to settlement."

Glaser thinks organizations should consider contacting former employees to inform them of the investigation and explain they may be contacted by the government. The communication should note that the employee doesn't have to talk to FBI and other government agents, but also explain that they are free to talk if they wish, and if they choose to talk, the company will provide a lawyer. "I don't love it, but that doesn't violate any rule," Krueger responded. However, there will be trouble if he finds out the employees, as witnesses to potential wrongdoing, were influenced by counsel. "You have to weigh the pros and cons. Why hire counsel?"

Glaser had an answer: "It's very traumatic for an FBI agent to come to your door. People are scared, and that's why we hire counsel." Krueger's rebuttal: It's also stressful and expensive if people don't show up for interviews voluntarily and he has to issue a subpoena. When people are cooperative in CID depositions, "it helps build trust."

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Endnotes

1. 31 U.S.C. §§ 3729-3733.
2. Fed. R. Civ. P., http://bit.ly/31npNpH.

CCO Is Whistleblower in Sutter Case

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compensation arrangements under the Stark Law and did not satisfy the requirements of any applicable statutory or regulatory exception to the Stark Law," DOJ alleged. The reasons: the compensation was above fair market value for the services provided by Sac Cardio; "the aggregate services contracted for exceeded those that were reasonable and necessary for the legitimate business purposes of the arrangements;" and the Sac Cardio physicians referred designated health services to Sutter Medical Center Sacramento, which billed Medicare for them from Sept. 1, 2012, through Sept. 30, 2014, DOJ alleged.

In a separate settlement with DOJ, Sac Cardio agreed to pay $506,000 to resolve allegations related

to its Medicare billing for services provided at Sutter Medical Center by the leased physician assistants from May 1, 2011, through Sept. 30, 2014.

"It is rare, but not unheard of, for someone in the compliance department to be a whistleblower," says attorney Bob Wade, with Barnes & Thornburg in South Bend, Indiana. "Compliance officers typically try to resolve issues internally, including reporting the issues up the chain and ultimately to the board. However, if the issue cannot be resolved, maybe the only alternative the compliance officer has is to report the issue to the government. I typically would not advise a compliance officer to be a whistleblower. However, depending upon the facts and the attempts to correct the issue, a compliance officer may have no choice but to blow the whistle."

Neither provider admits liability. Sutter Health also separately agreed to pay $15 million in connection with a voluntary self-disclosure. In a statement, Sutter Health said its "settlement of claims related to the matter United States ex rel. Hanvey v. Sutter Health, et al. reflects an agreement with the plaintiff and the Department of Justice and includes no fraud liability. The settlement resolves certain claims not pending in the Hanvey matter and returns alleged overpayments Sutter Health received from the Centers for Medicare & Medicaid Services. Sutter has taken active steps to improve its efforts to track all arrangement. We've implemented a rigorous centralized review and approval process, added additional legal and compliance staff, implemented advanced tracking software and employed further training to assure compliance with all relevant regulations." An attorney for Sac Cardio didn't respond to a request for comment.

There Was Stacking of Physician Agreements

The complaint described the details of the deals between Sac Cardio and Sutter Health. Sac Cardio leased four of its employed physician assistants (PAs), who have training in cardiovascular surgery, to the hospital, according to an exhibit to the complaint. The PA agreement required Sutter Health to pay Sac Cardio at the rate of $170,000 per full-time equivalent per year, and stipulated that their services couldn't be charged to patients or payers. But the surgeons allegedly billed third-party payers for some of the PAs' services anyway and kept the money.

"The cardiovascular surgeons who have zero money in it are then billing for what the mid-levels do as part of the professional services," says Marlan Wilbanks, one of the attorneys for the whistleblower. "What a windfall—you don't have to pay for them and you get to bill for them."

Sutter also paid Sac Cardio handsomely for medical director agreements and on-call coverage, a practice called stacking. The three surgeons were paid a total of $318,264 annually starting in 2006 for medical directorships, the complaint alleged. For example, Ingram was medical director of the cardiac intensive care unit and assistant medical director of the Sutter Heart Institute, and was paid $330 an hour for up to 120 hours per quarter.

Starting in July 2008, Sutter Health entered into call coverage agreements with Sac Cardio that generated up to $912,500 annually to ensure cardiovascular availability 24/7 in the emergency room. The rate that Sutter paid per shift for call coverage to Sac Cardio jumped more than 200% in 2010 and exceeded fair market value, the complaint alleged. Between the three agreements, Sutter Health paid $1.91 million a year to Sac Cardio. That was separate from their reimbursement for patient services, the complaint alleged.

CMS Transmittals and Federal Register Regulations, Nov. 8-14

Transmittals

Pub. 100-04, Medicare Claims Processing Manual

- Home Health (HH) Patient-Driven Groupings Model (PDGM) - Revised and Additional Manual Instructions, Trans. 4452 (Nov. 8, 2019)
- Home Health Prospective Payment System (HH PPS) Rate Update for Calendar Year (CY) 2020, Trans. 4453 (Nov. 8, 2019)

Pub. 100-20, One-Time Notification

- Positron Emission Tomography (PET) Scan - Allow Tracer Codes Q9982 and Q9983 in the Fiscal Intermediary Shared System (FISS), Trans. 2387 (Nov. 8, 2019)

Pub. 100-08, Medicare Program Integrity Manual

- Updates to the Medical Review Instructions Related to Skilled Nursing Facilities (SNF), Trans. 924 (Nov. 15, 2019)

Federal Register

Final Regulations

- Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements, 84 Fed. Reg. 60648 (Nov. 8, 2019)
- Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements, 84 Fed. Reg. 60478 (Nov. 8, 2019)
- Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Revisions of Organ Procurement Organizations Conditions of Coverage; Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Changes to Grandfathered Children's Hospitals-Within-Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, 84 Fed. Reg. 61142 (Nov. 12, 2019)

Compliance Pushback Went Awry

Questions about the payments to Sac Cardio under the PA agreement were first raised by the accounts payable department because there allegedly was no documentation supporting some of the payments. The director of Sutter Health's cardiovascular service line asked for revised PA timesheets, which were then reviewed by the compliance officer, Laurie Hanvey. She concluded the timesheets allegedly had false information and placed a hold on payments under the PA agreement, starting in January 2014. Hanvey questioned why some payments were reported since they should be included in the global surgery fee. Despite her concerns, Sutter Health resumed the monthly $56,666 payments to Sac Cardio in April 2014, the complaint alleged.

The compliance officer continued to investigate Sac Cardio's practices and found it allegedly was billing for the PAs' services "in breach" of the agreement with Sutter Health, which put a new hold on payments on July 28, 2014. Sac Cardio was being provided free employees and billing Medicare "for the physician assistants' services and retaining the payments," the complaint alleged. "This illegal benefit to [Sac Cardio] allowed them to profit from these services, which were not connected to personally performed physician services."

The compliance officer also looked at timesheets for medical director payments and allegedly found duplicative supervision of ICU staff. After discussions with her superiors at Sutter Health, Hanvey on June 19, 2014, put a hold on payments to Sac Cardio payments for medical director agreements pending further investigation, the complaint alleged.

This didn't go over well with Sac Cardio. Five weeks later, one of the surgeons, James Longoria, allegedly called Sutter Health's then-CEO, Patrick Fry, and left a message with his assistant. Longoria allegedly "threatened to shut down the operating rooms if the payment stop was not lifted," the complaint said. Sutter Health allegedly relented that day, reissuing the $56,666 payment for the PAs.

Hanvey resigned from Sutter Health in December 2014, one of her attorneys says.

Contact Wilbanks at mbw@wilbanksgouinlock.com. ✧

Endnotes

1. 31 U.S.C. §§ 3729-3733.

NEWS BRIEFS

◆ **North Carolina physician Damian Brezinski and his medical group, Wilmington Health, agreed to pay $244,000 to settle false claims allegations in connection with cardiac stent procedures**, the U.S. Attorney's Office for the Eastern District of North Carolina said Nov. 12. The investigation of Brezinski got underway after a self-disclosure from New Hanover Regional Medical Center in Wilmington, North Carolina. "The hospital reported that an internal audit uncovered potentially false claims for cardiac stenting procedures that Dr. Brezinski performed in that facility," the U.S. attorney's office said. An independent investigation by the government found that from 2010 to 2014, Brezinski put arterial stents in patients who allegedly didn't need them, according to their medical records. Then he and his medical group billed Medicare and TRICARE for the procedures. The U.S. attorney's office said that New Hanover Regional Medical Center separately agreed to repay $900,000 in facility fees it received for the stent insertions. There were no admissions of liability. Visit http://bit.ly/2NGN2Hx.

◆ **About two weeks after Sanford Health, Sanford Medical Center and Sanford Clinic agreed to pay $20.25 million to settle false claims allegations in connection with a former employed neurosurgeon**, Wilson Asfora, his spinal surgeries, and his physician-owned distributorship (POD),[1] the Department of Justice (DOJ) said Nov. 14 that it filed a False Claims Act[2] complaint against Asfora and his POD, Medical Designs LLC.[3] DOJ alleges that Asfora, Medical Designs and another company he and others created, Sicage LLC, "engaged in multiple kickback schemes designed to pay Asfora hundreds of thousands of dollars in exchange for Asfora using spinal devices distributed by Medical Designs and Sicage in his spine surgeries. Despite receiving numerous warnings that he was performing medically unnecessary procedures with the devices in which he had a financial interest, Asfora allegedly continued to perform such procedures while personally profiting from his use of devices sold by Medical Designs and Sicage."

Endnotes

1. Nina Youngstrom, "Sanford Health Settles FCA Case for $20M Over Spine Surgery; CCO Allegedly Was Warned," *Report on Medicare Compliance* 28 no. 39 (November 4, 2019), http://bit.ly/33S2HJK.
2. 31 U.S.C. §§ 3729-3733.
3. DOJ, "United States Files False Claims Act Complaint against South Dakota Neurosurgeon and Physician-Owned Distributorships," news release, November 14, 2019, http://bit.ly/351nMla.