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Contents

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Managing Editor
Nina Youngstrom
nina.youngstrom@hcca-info.org

Senior Copy Editor
Bill Anholzer
bill.anholzer@hcca-info.org

Academic Medical Center Settles Case Over Excluded Person Who Was Both Employee, Vendor

Thomas Jefferson University Hospitals Inc., an academic medical center in Philadelphia, Pennsylvania, has entered into a settlement with the HHS Office of Inspector General (OIG) in a case that underscores the risks of contracting with or employing someone who is excluded from federal health care programs—in this instance, the same person. Although the settlement amount is small—$19,958—the case is a reminder of the risks that hospitals and other health care organizations face if their exclusion screening doesn't encompass vendors and their employees, experts say. Sometimes people fall through the cracks anyway, which is why vendors are often asked to accept responsibility in their contracts for penalties stemming from excluded employees.

"With vendors, you need to arm yourself in two ways: check them for exclusions every month and include in your contracts a clause that requires them to check their employees for exclusions and notify you as soon as they know if they have an excluded person employed," said Kim Danehower, corporate compliance officer at Baptist Memorial Health Care Corp. in Nashville, Tennessee. She added that contracts with vendors should include indemnification clauses, which shift liability to the vendor for penalties the government imposes on providers in connection with the services provided by the vendor's excluded employee. Not all vendors are champing at the bit to agree to indemnification, however, so sometimes there are hard choices to make.

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CMS Vaccine Mandate Is Universal With Supreme Court Ruling; Surveys Are Provider Specific

The Supreme Court has cleared the way for CMS to enforce its COVID-19 vaccine mandate nationally at hospitals and other facilities regulated by the Medicare conditions of participation, with state surveyors using guidance that has been at their disposal since Dec. 28. In a Jan. 13 decision, the high court ruled that HHS Secretary Xavier Becerra "did not exceed his statutory authority in requiring that, in order to remain eligible for Medicare and Medicaid dollars, the facilities covered by the interim rule must ensure that their employees be vaccinated against COVID–19."[1]

Although the effective date of CMS's Omnibus COVID-19 Health Care Staff Vaccination regulation[2] has been delayed a bit by a legal standoff with 25 states, facilities now must ensure their employees and others have the first dose of the vaccine by Jan. 27 and the second dose by Feb. 28, unless they have a pending or approved medical or religious exemption or medically necessary delay in the vaccination.[3] State surveyors are standing by with facility-specific guidance to evaluate compliance with the mandate.

"It's in effect for the time being," said Richelle Marting, an attorney in Olathe, Kansas. The decision lifts the preliminary injunctions that have been holding up the vaccine mandate in states that sued CMS. Marting expects providers in those states to

continued

have a difficult time rolling out the vaccine requirement by the first deadline and could face enforcement actions. But there's talk that CMS may update guidance and give facilities in the states where the injunction was lifted by the Supreme Court decision more time to comply.

The question before the Supreme Court wasn't whether the vaccine mandate was legal, said attorney Sandra DiVarco, with McDermott Will & Emery in Chicago. The question was whether the injunction should be stayed, and that question is decided based on whether the "underlying case has a likelihood of succeeding on the merits," she explained. "That means the mandate is now enforceable in the entire country." But the Supreme Court decision may not be the last word. "States could continue to challenge the mandate," Marting said. In fact, it's likely the 25 states will return to court to try to stop the vaccine mandate based on the merits of the case, DiVarco said. "This back and forth continues to have health care facilities and their employees on edge with uncertainty, particularly in areas with low vaccination rates," Marting remarked.

CMS rolled out the vaccine mandate in November, with two phases: By Dec. 6, providers were required to have a plan for vaccinating staff, providing medical or religious exemptions and accommodations, and tracking and documenting vaccinations. Employees and other people (e.g., licensed practitioners, students, trainees, contracted staff and others "who provide care, treatment or other services at the facility") must have the one-dose vaccine or the first shot of the two-dose vaccine by that date or have requested an exemption. Everyone was required to be fully vaccinated by Jan. 4 unless an exemption had been granted. The dates have changed, but the substance of the regulation, with its copious documentation requirements, remains the same.

The regulation was challenged in separate lawsuits. One lawsuit led by Missouri on behalf of 10 states was filed in the U.S. District Court for the Eastern District of Missouri, which granted a preliminary injunction Nov. 29.[4] Then 15 more states led by Louisiana on Dec. 30 got a preliminary injunction from the U.S. District Court for the Western District of Louisiana, which stayed the vaccine mandate for the whole country (except the 10 states that had already gotten relief).[5]

CMS appealed to the Supreme Court, asking it to stay the preliminary injunctions. Meanwhile, CMS announced it would enforce the vaccine regulation in the 25 states that had not resisted the mandate.

Court: 'Vaccination Requirements are a Common Feature'

In its decision, the Supreme Court noted that HHS "routinely imposes conditions of participation that relate to the qualifications and duties of healthcare workers themselves." For example, employees must be trained on infection control. "When asked at oral argument whether the Secretary could, using the very same statutory authorities at issue here, require hospital employees to wear gloves, sterilize instruments, wash their hands in a certain way and at certain intervals, and the like, Missouri answered yes: '[T]he Secretary certainly has authority to implement all kinds of infection control measures at these facilities.' Tr. of Oral Arg. 57–58. Of course the vaccine mandate goes further than what the Secretary has done in the past to implement infection control. But he has never had to address an infection problem of this scale and scope before. In any event, there can be no doubt that addressing infection problems in Medicare and Medicaid facilities is what he does. And his response is not a surprising one. Vaccination requirements are a common feature of the provision of healthcare in America: Healthcare workers around the country are ordinarily required to be vaccinated for diseases such as hepatitis B, influenza, and measles, mumps, and rubella."

The Supreme Court's decision wasn't a surprise, DiVarco noted. "This is the outcome most people who

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have been watching the cases anticipated." What will be interesting to watch next is whether CMS pushes the compliance dates out further because hospitals and other facilities that may have slowed their efforts at compliance awaiting a decision only have two weeks from the date of the court decision to comply. "Many of their providers may have slow-walked their compliance and now in theory need to be fully compliant with phase one and have 100% of covered providers have a first shot in two weeks," DiVarco said. "In certain parts of the country that's not the case." The other intriguing aspect is what enforcement will look like, she said. CMS issued guidance for state surveyors on enforcing the vaccine mandate on Dec. 28 in the other 25 states, and "facilities are already concerned about enforcement of the phase 1 requirements, which hasn't happened as of yet."

CMS Survey Memo: Full Compliance in 90 Days

Hospitals and other facilities will now face the prospect of surveyors assessing their compliance with the vaccine mandate in their conditions-of-participation surveys. In the Dec. 28 memo from the Center for Clinical Standards and Quality to surveyors, CMS conveys that facilities risk their Medicare participation unless they fully comply with the mandate.[6] "Facility staff vaccination rates under 100% constitute noncompliance under the rule," CMS states. "Within 90 days and thereafter following issuance of this memorandum, facilities failing to maintain compliance with the 100% standard may be subject to enforcement action." CMS also released separate guidance for each type of facility subject to the vaccine mandate (e.g., hospitals, nursing homes, ambulatory surgery centers). In the survey guidance for hospitals, for example, CMS states that: "Compliance will be assessed through observation, interview, and record review as part of the survey process. … Surveyors will ask hospitals to provide vaccination policies and procedures. At a minimum, the policy and procedures must provide: A process for ensuring all required staff have received, at a minimum, the first dose of a multi-dose COVID-19 vaccine, or a one-dose COVID-19 vaccine, before staff provide any care, treatment, or other services for the hospital and/or its patients."[7] The memo also stated that surveyors should "examine the documentation of each staff identified as unvaccinated due to medical contraindications."

Although the mandate is a fait accompli unless the 25 states that challenged it go back to court and win on the merits, that doesn't make staffing problems disappear in low-vaccination states and facilities, Marting said. In long-term care facilities in many midwestern states, for example, there's a staffing shortage exacerbated by vaccine resistance, she said. Sometimes they're forced to rely on staffing agencies that rotate staffers in and out, making it hard to track their vaccination status or exemptions and to evaluate whether exemptions were given in good faith, she noted. How carefully does the facility question religious exemptions before they're accepted or declined? "The survey guidance will not scrutinize religious exemption requests," Marting noted.

Contact Marting at rmarting@richellemarting.com and DiVarco at sdivarco@mwe.com. ✧

Endnotes

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2. Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555 (November 5, 2021), https://bit.ly/3mPyG9y.
3. "Current emergencies," Centers for Medicare & Medicaid Services, last modified January 12, 2022, https://go.cms.gov/2MVnAgi.
4. State of Missouri et al. v. Joseph R. Biden, Jr. et al., Case No. 4:21-cv-01329-MTS (E.D. Mo., November 29, 2021), https://bit.ly/3ddtrLa.
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White Bagging Is Used to Cut Specialty Drug Payments, Lawyers Say

Health plans are using so-called white-bagging policies to reduce payments to hospitals for specialty drugs, and in the process, there may be a delay in patient care, attorneys say. Hospitals reportedly find white bagging thrust on them by Medicare Advantage plans and commercial payers in the middle of a contract year through amendments or policies, which means they won't be paid for oncology and other high-cost specialty drugs they prepare for patients on-site. Some hospitals have resigned themselves to white bagging and are making up lost revenue in other parts of their payer contracts, while others try to scrap the policies in future contracts or fight back in arbitration

and court battles. They are getting some help from state lawmakers, and relief possibly could come from federal agencies that are poking around white bagging, according to attorneys.

"This is a cautionary tale in the importance of contract language," said attorney Jim Boswell, with King & Spalding. "Providers too often focus only on pricing and don't pay attention to amendments and the effect of policies and protocols and the ability to vary the contract through things that are called utilization management but are really substantial changes to the scope of the contract." Payers have set in motion white-bagging and other policies that affect reimbursement for imaging and surgery while contracts are already under way, Boswell said at a Dec. 9 webinar sponsored by his firm. "The imagination is limitless in terms of what these policies can be. I don't find that COVID has slowed down these policy rollouts."

White bagging was announced in 2020 and implemented across the country in phases, said attorney Zuzana Ikels, with King & Spalding. Some commercial payers require hospitals to buy specialty drugs from nonhospital suppliers on lists approved by the payers, Boswell said. Normally, hospitals have their own specialty pharmacies and prepare the drugs on-site. The main focus of white bagging is expensive drugs for treating some of the most serious diseases, such as cancer, multiple sclerosis and neurological illnesses, Ikels said. Hospitals are worried that shipments of drugs from outside pharmacies, which may be delayed, put patients at risk, the attorneys alleged.

'The One Thing You Don't Want to do Is Nothing'

For example, in a provider bulletin on specialty pharmacy requirements for outpatient hospitals, UnitedHealthcare states that outpatient hospitals "source the specialty and oncology supportive care drugs listed on UHCprovider.com through an indicated specialty pharmacy."[1] Cigna reiterated recently that it "will no longer reimburse facilities directly for the drugs included in the Specialty Medical Injectables with Reimbursement Restriction list, unless otherwise authorized by Cigna. Please note that facilities cannot bill patients with Cigna-administered coverage for the cost of these injectables when they are not obtained from a specialty pharmacy in the Cigna network."[2]

About six months ago, Boswell said there was a new round of white bagging around oncology support medication, such as Neulasta. "We are representing a client challenging those in particular because the drugs are administered relatively close in time to chemotherapy and having to go through another process and pay another co-pay and have it shipped to the hospital is bothering people," he explained. For example, a United bulletin states that "Starting with dates of service on June 7, 2021, outpatient hospitals must obtain certain oncology supportive care medications from the participating specialty pharmacies we indicate, except as otherwise authorized by us."[3]

Hospitals should push back on white bagging in some way, shape or form, whether they have conversations with payers, lay the groundwork to ban white bagging in subsequent contracts or go all the way with arbitration or a lawsuit, Boswell said. "The one thing you don't want to do is nothing," he said. "You don't want to let policies roll by without any kind of response. Inaction could be construed as acquiescence."

Boswell's sense is that payers are willing to let hospitals provide the specialty drugs themselves, notwithstanding the white-bagging policies. "White bagging looks like a way to get a price reduction, and many hospitals have negotiated a way to continue to provide drugs themselves because it's in the best interest of patients and promotes the most timely delivery of drugs without prior authorization delays," he said.

Watch Your Language

Since the advent of white bagging, hospitals have responded in different ways, depending on where they're located, the volume of patients from a particular plan and whether they're in a major metropolitan area vs. a remote location, Boswell said. Some hospitals forbid white bagging for clinical reasons, he said. "It's also found to interfere with patient safety standards at the hospital," Ikels said. For example, physicians may change the drug cocktail on the day of administration, which wouldn't be a problem if the drugs were prepared at the hospital's in-house pharmacy but could delay treatment if the new cocktail has to be shipped from an outside pharmacy, Boswell said.

"You have to throw out the drug, reschedule infusion, and the process continues with a new infusion date," said attorney Daron Tooch, with King & Spalding. "We have had patients who have suffered real damages. One patient lost the use of a hand during this process of delays on infusions."

Other hospitals allow white bagging. They have found patients are receiving treatment that corresponds to what the provider orders in a timely way. The hospitals agree to lower prices and fix the reduction at the next contract negotiation, or make up lost revenue through price concessions by payers in other areas of the contract.

The reason that hospitals may get stuck with white-bagging policies is that health plans present them in

Checklist: Anticipating the Implications of White-Bagging Policies

Here are things for hospitals to consider when they are faced with so-called white-bagging policies (see story, p. 3).[1] Some commercial payers may amend contracts to require hospitals to buy specialty drugs from nonhospital suppliers on lists approved by the payers, said attorney Jim Boswell, with King & Spalding. Normally, hospitals have their own specialty pharmacies and prepare the drugs on-site. This checklist was prepared by attorneys Zuzana Ikels and Jennifer Lewin, also with King & Spalding. Contact Boswell at jboswell@kslaw.com, Lewin at jlewin@kslaw.com and Ikels at zikels@kslaw.com.

White Bagging Checklist

1. Analyze the source of the problem. Review your managed care contract to determine which provisions are implicated.
   - ☐ Provisions agreeing to be bound by Protocols, Policies, and Manuals.
   - ☐ Allowing one-sided "notice" amendments.
   - ☐ Consider pre-authorization, pre-certification, and specialty pharmacy provisions, as well as reimbursement schedules.
2. Consider whether any discussion was had during contract and amendment negotiations about the meaning of terms like "Protocol," "Policy," and "Network."
3. Quantify the impact.
   - ☐ Determine if there has been a drop in volume based on running the "J Codes" attributable to the specialty drugs.
   - ☐ Maintain records of communications by patients informing nurses, case managers, or physicians that they were steered away from the hospital.
   - ☐ Keep track of denials or delays in scheduling infusions.
   - ☐ Speak with oncologists, pharmacists, and infusion managers about white bagging's potential negative impact on patient care.
4. Consider your options for challenging white bagging.
   - ☐ Send an objection letter to the payer.
   - ☐ Develop internal policies prohibiting white bagging.
   - ☐ File a request for an injunction in arbitration or court.
   - ☐ Comply with the policy and seek damages during arbitration.
   - ☐ Refuse to comply with the policy and seek damages in arbitration.

Endnotes

1. Nina Youngstrom, "White Bagging Is Used to Cut Specialty Drug Payments, Lawyers Say," *Report on Medicare Compliance* 31, no. 2 (January 17, 2022).

provider manuals, utilization management procedures or protocols—some version of that language—and that the white bagging is therefore a routine part of the contract that hospitals agreed to, Boswell said.

"To solve these problems, you have to think creatively about what this animal called white-bagging policy is. Ditto on imaging or ambulatory surgery center policies," he said. "It requires getting into the definitions and the words." Boswell argues there's a difference between a routine adjustment in a contract and a unilateral decision to only pay for a specialty drug when it's purchased from an external vendor. "That doesn't look like a utilization management policy," he said. It's a significant amendment. Hospitals should question whether their contracts allow a one-sided amendment like this. "What does your amendment provision say about how a plan can be amended? Does it say amendments must be through bilateral signed writing? Does it specify what's a good provision to include? Does it say new protocols and policies will become part of the contract unless objected to? Does it require notification that a new policy will be applied on a certain day, and you have to be notified?" Hospitals also have to look ahead. "It is not only a present business issue, but a future business issue," Boswell said.

For example, hospitals should consider writing into their next contract a requirement that health plans will notify them of changes by certified letter or overnight courier "as opposed to publishing in a 50-page provider bulletin or some online reference that can be changed anytime."

Hospitals aren't on their own. The Federal Trade Commission in the summer of 2020 began investigating the relationship between health plans and pharmacy benefit management companies "and associated cost savings for patients and the coordinated nature of how white-bagging policies are implemented," Ikels said. CMS has been looking at the issue in the context of Medicare Advantage plans. And there's been action at the state level, she said. For example, Louisiana banned white bagging in July 2021 legislation.[4] Other state laws in states like New Jersey and Georgia took an indirect route that essentially had the same effect, Ikels said. Similar legislation is pending in California and elsewhere.

Arbitration May Help Stop White Bagging

Hospitals also may challenge white bagging in arbitration with health plans, Tooch said. If hospitals take that route, they have to decide whether to challenge white bagging in isolation or bring in other health plan behavior. The upside of including all underpayments is it shows arbitrators that white bagging is just one way that health plans reduce payments under the contract, Tooch said. The downside is white bagging may get lost in the shuffle. "Also, many arbitrators want to get repeat business from hospitals and insurers, and there may be a tendency to split the baby."

Tooch added that a preliminary injunction is an effective strategy before arbitration. It prevents white bagging from taking effect. "You say to the arbitrator that you need to stop the program immediately vs. going through an arbitration hearing and asking for damages and declaratory relief, which says health plans cannot use the policy to change the terms of the contract and seek an injunction at the end of arbitration to say they won't do it in the future." But there's a high bar for a preliminary injunction, Tooch noted. "You must show irreparable harm," he explained. "It's not just contractual damages or money. The most obvious harm here is patient harm."

AHIP Cites Benefits of Specialty Pharmacies

In a statement, Kristine Grow, senior vice president of communications for AHIP, which represents insurers, said "everyone should be able to get the medications they need at a cost they can afford. But drug prices are out of control, and hardworking families feel the consequences every day. The problem is the price, and health insurance providers are working every day to lower drug prices for all Americans. To fight back against these out-of-control drug prices, health insurance providers have developed many innovative solutions to make prescription drugs more affordable, including leveraging lower-cost pharmacies – called specialty pharmacies – to safely distribute certain drugs."

Grow noted that lower-cost specialty pharmacies save money and help make insurance premiums more affordable. "Specialty pharmacies can deliver drugs directly to a physician's office or to a patient's home right before a patient's appointment. This means that patients can avoid inflated fees and other costs that hospitals and physicians charge to buy and store specialty medications themselves," her statement said. "For example, specialty pharmacies can protect patients from a hospital's markup for prescribed drugs, which on average run between 200-400% of the hospital's acquisition cost."

Grow's statement asserted that "specialty pharmacies also protect patient safety." They're required to satisfy "extra safety requirements for specialty drugs imposed by the Food and Drug Administration (FDA), and by drug manufacturers. They also must satisfy stringent state and federal requirements for the safe storage, handling, and dispensing of the drugs."

Contact Boswell at jboswell@kslaw.com, Ikels at zikels@kslaw.com and Tooch at dtooch@kslaw.com. ✧

Endnotes

1. UnitedHealthcare, "Specialty pharmacy requirements for outpatient hospitals," accessed January 13, 2022, https://bit.ly/3fkOyMt.
2. Cigna, "Medical coverage policy update – Nutritional Support effective February 15, 2021," accessed January 13, 2022.
3. UnitedHealthcare, "Oncology supportive care medication sourcing requirement," news release, March 2021, https://bit.ly/3nigRQb.
4. S.B. 191, 2021 Leg., Reg. Sess. (La. 2021), https://bit.ly/3GpJ1jP.

Exclusion Case Settled Over Vendor Employee

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According to the settlement with Thomas Jefferson University Hospitals, which was obtained through the Freedom of Information Act, OIG contends that Debra Stallings provided consulting services to Thomas Jefferson University Hospitals from Oct. 25, 2018, to March 17, 2019, under a contract with a vendor. From March 18, 2019, to May 17, 2019, Stallings was employed by the academic medical center "for the provision of items or services for which payment may be made under a Federal health care program," the settlement stated. Stallings didn't perform patient care services, according to a statement from Deana Gamble,

assistant vice president of national media strategy at Thomas Jefferson University and Jefferson Health.

When Thomas Jefferson University Hospitals learned she was excluded and told OIG in July 2020, it was accepted into the Self-Disclosure Protocol in October 2020. "The OIG contends that Respondent knew or should have known, prior to May 17, 2019, that Ms. Stallings was excluded from participation in all Federal health care programs and that no Federal health care program payments could be made for items or services furnished by Ms. Stallings," the settlement states. OIG contends the conduct subjects Thomas Jefferson University to civil monetary penalties. The academic medical center didn't admit liability in the settlement.

Gamble added in her statement that "upon learning that a vendor failed to perform contractually required exclusion screening activities for an individual it provided to TJUH [Thomas Jefferson University Hospital] to perform certain non-patient care services, who later failed to disclose her excluded person status when she accepted a permanent position with the hospital, TJUH immediately took steps to investigate, remediate, and voluntarily disclose the issue through the Office of Inspector General's ('OIG') Voluntary Disclosure Protocol Program. As a result of TJUH's transparency and commitment to cooperating with the OIG, the parties entered into a settlement agreement in which TJUH agreed, without admitting liability, to pay to OIG $19,958.56 to resolve this matter and avoid any further litigation."

OIG Guidance Refers to Contractual Relationships

According to the OIG's List of Excluded Individuals/Entities (LEIE), a person named Debra Stallings was thrown out of federal health care programs in 2012 for a program-related conviction (1128(a)(1)) for five years. Her expertise is durable medical equipment (DME). That type of conviction is a felony, triggering a mandatory exclusion, said Michael Rosen, co-founder of ProviderTrust in Nashville, Tennessee. A news release from the U.S. Attorney's Office for the Eastern District of Pennsylvania states that a woman named Debra Stallings was charged with health care fraud in 2009 in connection with a DME scheme.[1] Stallings was sentenced to two years of probation in 2011 in connection with a conviction for health care fraud and ordered to pay $7,000 in restitution, according to a court document.

Stallings' five-year exclusion would have ended before Thomas Jefferson University hired her. But the termination of an exclusion doesn't mean automatic reinstatement to Medicare, a fact that's often misunderstood, Rosen said. People and companies that have been excluded from federal health care programs must apply for reinstatement when the terms of their exclusion expire. They can't bill Medicare, and their services can't be billed directly or indirectly, until they are back in the government's good graces, he noted.

Health care organizations should keep in mind that in addition to their own employees, their vendors must be screened for exclusion, as well as the vendor's employees, Rosen said. "The firm itself may not be excluded, but a lot of people try to hide behind the corporate veil," Rosen said. "OIG made it clear excluded persons can't hide behind the company." That came through in OIG's 2013 *Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs*.[2] "If a health care provider arranges or contracts (by employment or otherwise) with a person that the provider knows or should know is excluded by OIG, the provider may be subject to CMP liability if the excluded person provides services payable, directly or indirectly, by a Federal health care program," the bulletin says. It also notes that "OIG recommends that to determine which persons should be screened against the LEIE, the provider review each job category or contractual relationship to determine whether the item or service being provided is directly or indirectly, in whole or in part, payable by a Federal health care program. If the answer is yes, then the best mechanism for limiting CMP liability is to screen all persons that perform under that contract or that are in that job category."

'It's Not Difficult if You Have Good Software'

Danehower said Baptist Memorial Health Care Corp. runs all its vendors through the LEIE—and it has 30,000 vendors. That may sound mind-blowing,

CMS Transmittals and *Federal Register* Regulations, Jan. 7-13, 2022

Federal Register

Final rule with comment period; correction

- Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Correction, 87 Fed. Reg. 2,058 (January 13, 2022).

Updates to and selection of certain codes

- Medicare Program; Updates to Lists Related to Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Conditions of Payment, 87 Fed. Reg. 2,051 (January 13, 2022).

Proposed rule

- Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. 1,842 (January 12, 2022).

but it's an automated process. "It's not difficult if you have good software," she said. It provides potential matches to follow up on. "The problem that keeps me up at night is people hiding in a corporate structure," Danehower said. "That's why the contract is so important." Some vendors balk at indemnification, and you have to decide if it's nonnegotiable, Danehower said. For example, if it's a small specialty group that provides services unavailable elsewhere, perhaps the hospital will take on the risk of an excluded employee popping up. Also, sometimes "peripheral" vendors (e.g., companies that wash the linens) may not take exclusion screening seriously, Danehower said. "You will hold them accountable, but they will gamble it will never happen."

Her health system requires vendors to take responsibility for screening their own employees. While hospitals have the tax identification number of the vendor, they lack access to the Social Security numbers of their employees. "It would take a lot of due diligence to find that," Danehower said.

Also, people have been known to disguise their identities. For example, someone who is excluded may cross state lines, change their name and get a job. "People can be extremely devious," Danehower noted. That's why vendor employees are better left in the hands of the vendors, with the hammer of indemnification. And physicians can be excluded for failure to repay student loans, and again, physicians and prospective employers may be unaware they can't bill Medicare for services provided by the physician when the exclusion is over. "You have to apply for reinstatement," she emphasized.

Gamble noted in her statement that "Jefferson continues to maintain the highest standards of integrity and is committed to identifying effective means through which to enhance its compliance controls and programming. TJUH took prompt and effective action to evaluate the exclusion screening matter identified through industry-accepted monitoring activities and candidly and completely disclosed identified issues to the OIG. TJUH will continue to devote resources and attention to its efforts to do the right thing in all aspects of its business and patient care operations and remains committed to maintaining an effective compliance program to support its important work."

Contact Gamble at deana.gamble@jefferson.edu, Danehower at kim.danehower@bmhcc.org and Rosen at mrosen@providertrust.com. ✧

Endnotes

1. U.S. Attorney's Office for the Eastern District of Pennsylvania, "Durable Medical Equipment Company, Six Others Charged in Medicare Fraud and Kickback Scheme," news release, Federal Bureau of Investigation, December 10, 2009, https://bit.ly/3tokGag.
2. HHS OIG, *Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs*, May 8, 2013, https://bit.ly/315u9DJ.

NEWS BRIEFS

◆ **UC San Diego Health, the academic health system of the University of California, San Diego (UCSD), paid $2.98 million to settle false claims allegations over ordering medically unnecessary genetic testing paid for by Medicare, the Department of Justice (DOJ) said Jan. 11.**[1] According to the settlement, the government alleged "it has certain civil claims against UCSD arising from UCSD's ordering and submitting referrals for medically unnecessary genetic testing performed by the genetic testing labs CQuentia Arkansas Labs, CQuentia NGS, and Total Diagnostic II ('the CQuentia labs'), during the period from December 2015 through October 2019, which the United States contends caused false claims to be presented by the CQuentia labs to Medicare for payment of medically unnecessary genetic tests." There is no admission of liability in the settlement. In a statement, UC San Diego Health said: "Working at the forefront of patient care sometimes involves the use of new technologies from emerging companies. When UC San Diego Health learned that the Department of Justice had concerns about one of our technology providers, we fully cooperated and promptly resolved the matter. The DOJ's settlement announcement alleges that our doctors ordered tests from a company that then allegedly made false claims about those orders. This settlement does not assign any liability to UC San Diego Health and provides a prompt resolution that allows us to continue our focus on providing outstanding care for patients."

◆ **A suburban Chicago nurse was indicted in connection with her removing morphine from bottles prescribed to two patients and replacing it with a different liquid, the U.S. Attorney's Office for the Northern District of Illinois said Jan. 13.**[2] Sarah Diamond allegedly knew the diluted substance would be given to the patients, according to a federal indictment. Diamond, of Woodstock, Illinois, was the assistant director of nursing at a Chicago-area medical rehabilitation center. "The indictment alleges that Diamond tampered with the liquid morphine in August 2021 with reckless disregard and extreme indifference for the risk that the patients would be placed in danger of bodily injury," the U.S. attorney's office said. She's charged with two counts of tampering with a consumer product.

Endnotes

1. U.S. Department of Justice, "UC San Diego Health Pays $2.98 Million to Resolve Allegations of Ordering Unnecessary Genetic Testing," news release, January 11, 2022, https://bit.ly/3njokhL.
2. U.S. Department of Justice, U.S. Attorney's Office for the Northern District of Illinois, "Suburban Chicago Nurse Charged With Tampering With Morphine Prescribed to Patients," news release, January 13, 2022, https://bit.ly/3ntS4c1.