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

Contents

Publisher's Note

RMC will not be published next week. The next issue will be dated June 19, 2023. Have a great week!

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Unanimous Supreme Court Decision Restores 'Common Sense' to Interpreting FCA, Lawyer Says

In a highly anticipated opinion, the Supreme Court on June 1 killed off the idea that defendants in False Claims Act (FCA) cases could argue that even though they may have believed they were violating a regulation, they didn't submit false claims "knowingly" as defined by the statute.[1]

The unanimous ruling, which was written by Justice Clarence Thomas, centers on whistleblower cases filed against Safeway and Supervalu pharmacies over their "usual and customary" charges for drugs on claims submitted to Medicare and Medicaid. "What matters for an FCA case is whether the defendant knew the claim was false," Thomas wrote in *United States Et Al. Ex Rel. Schutte Et Al. v. Supervalu Inc. Et Al.* "Thus, if respondents correctly interpreted the relevant phrase and believed their claims were false, then they could have known their claims were false."

The decision "is a fantastic win restoring common sense to interpreting the False Claims Act," said Colette Matzzie, an attorney with Philips & Cohen, which represents whistleblowers. "This preserves the understanding that a defendant who acts in accordance with its subjective good-faith belief that they are following the law will generally be protected from False Claims Act liability."

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M.D., Nurse Burnout/Shortage Takes Toll on Compliance; Rounding, Micro Learning May Help

At Cleveland Clinic in Ohio, the chair of the corporate compliance committee and three other members are physicians, so Chief Integrity Officer Donald Sinko has given a lot of thought to the ways that physician burnout and shortages filter down at health care organizations.

"They play an important role in the compliance program, but when's their ability to do administrative tasks and focus on the risk assessment? Who now has time to do that?" Sinko said. Similarly, with the nursing shortage, "Who is going to say you should spend X number of hours working on the compliance program instead of at the bedside?" There are ways to reduce the time commitment, such as physicians attending compliance committee meetings virtually, but there's "exposure" every time compliance activities move further down the priority list.

The compliance and other repercussions of physician and nurse shortages and burnout—which took a turn for the worse with the COVID-19 pandemic—have been playing out at hospitals and health systems. They're finding ways to support their clinicians and adapt compliance activities when necessary to a stressed workforce and cramped finances, but it's a challenge.

"There's burnout from having gone through the pandemic," said Catherine Martin, chief compliance officer at Luminis Health in Maryland. She sees "something very different" because of the stress levels and the hours people have put in these past few

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years. As Martin rolls out annual compliance training, she notices that "people are worn out." Complicating the goal of reinforcing a compliant corporate culture is the greater use of agency nurses and temp staff. Because they're not a permanent part of the organization and may not live in the community, "naturally there's a disconnect. There's that sense of not being fully invested in compliance because 'I won't be here that long.'"

That raises the stakes for keeping compliance front and center. For example, Martin and her team have increased their rounding, visiting every department at Luminis hospitals, introducing themselves and handing out educational materials. They include a postcard series on various issues, such as ethical decision-making and snooping (see box, p. 3).

Rounding hit a snag for a while. "People weren't as comfortable doing rounds and we had a lot of restrictions about who could be where and masking and remote work," Martin said. "Now we are back onsite and masks are your own decision, so things are shifting back" and people are making more of a connection. She works full-time, while the rest of her team works two days remotely (with one full-time remote employee who lives out of state).

Luminis also updated its compliance training "so it's more along the lines of microlearning," Martin said. "It still has content but it's not death by Powerpoint." The training is more engaging and interactive and hits on high points rather than "making someone an expert on HIPAA and the fraud and abuse laws," she said. "They don't need that. They need just enough to identify if there's a concern." Martin wants employees to be "mindful of compliance" without viewing it as a burden or perceiving it as a threat to them "because there's already that burnout and resources are scarce in hospitals." She also added a compliance section to the health system's internal publication, Spark. The compliance section has short pieces designed to get people thinking about topics like evaluation and management changes, giving gifts during the holiday season, the good-faith estimate and Emergency Medical Treatment and Labor Act (see box, p. 5).

Adding Trauma Nurses and Other Ideas

Shelly Denham, senior vice president of compliance, risk and audit at UofL Health in Kentucky, said it has been concerned for a long time about burnout-driven departures from the organization and other ripple effects of physician stress. "We worry about the diminished quality of care and the increase in medical errors." She also mentioned the risk of medical malpractice claims and delays in providers completing and signing their notes. "You could have some claim delays associated with that," even with electronic medical records. There are myriad tasks to complete, such as looking at lab results, entering orders, closing out notes, signing notes and responding to phone calls.

"Before COVID, it was a monumental task. COVID has added to physician and nurse burnout," Denham said. "We are still dealing with the fallout from that as many organizations are." There's the toll it takes on them personally and the toll it takes on the organization. For example, patient satisfaction scores may drop. "If the provider is not completely engaged or they're not returning phone calls or the patient feels they're not getting information and time from providers, the scores suffer as a consequence," she noted.

To address burnout and well-being, UofL Health has multiple efforts underway at different hospitals across its large system. "We are early in the process," Denham noted. Here are some examples:

- The emergency department at one hospital has a "Zen den," which is "somewhere a physician can go to have a safe space, close the door, listen to music, read and take time out with no one interrupting them," she said.
- UofL is expanding the role of trauma social workers who work at its level one trauma center in downtown Louisville. They have always been available to support the families of patients who come in for traumatic events, such as the April mass shooting at the Old National Bank in Louisville, but the trauma social workers are also trained to support staff.
- Peace Hospital, a behavioral health hospital, developed an emotional support line and grief support group for employees and started the Peace Podcast, which encourages people to talk

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Examples of Compliance and Privacy Postcards

Here are examples of compliance postcards that Luminis Health in Maryland distributes to employees (see story, p. 1), said Catherine Martin, chief compliance officer. Contact her at cathy.martin@luminishealth.org.

Luminis Health Compliance and Privacy Postcard Series

Luminis Health

Shining a Light On Compliance

Together we can uphold our values and maintain a culture of compliance and integrity.

Report confidentially and anonymously.
1-800-XXX-XXXX
Call 24 hours a day, 7 days a week.

Compliance and Privacy Office
Scan this QR code with your smartphone camera to directly access our website for online reporting and more information.
Visit **luminis.health/cc**

Speak up and report any suspicious, illegal, or unethical behavior.

Retaliation is prohibited against those who report compliance concerns in good faith.

Examples of Things to Report

Compliance
- Falsifying any Coding, Billing, or Patient Information
- Billing for Services, Prescriptions, Supplies, or Equipment not Needed or Supplied
- Soliciting or Accepting Gifts from Outside Sources
- Violating Conflict of Interest Standards
- Failing to Follow Regulatory Standards, Policies, or Code of Conduct

Privacy Office
- Unauthorized Access of Patient Records
- Unsecured Records Containing Patient Health Information
- Improper Disposal of Patient Records
- Lost or Stolen Devices
- Disclosing and/or Unauthorized Release of Patient Information without Authorization
- Identified Patient Information in Wrong Patient Record

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Compliance and Privacy Office
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Visit **luminis.health/cc**

10 steps to ethical decision making.

We encounter tough decisions in our daily work. Behaving ethically means doing the right thing. Although our ethical standards are outlined within the Code of Conduct and policies, this "Ethical Path" has been designed to assist you in handling difficult decisions. Ask yourself the questions below before making a decision. Seek advice from your supervisor, Human Resources or Corporate Compliance if you are uncomfortable or need guidance making an ethical decision.

1. Do I need to make a decision? Would it be ethical to not make a decision or to not take action?
2. Have I gathered all the facts, identified the relevant people and resources related to this decision?
3. Do I have enough information to understand the range of options available?
4. Are the options I am considering legal? Do they comply with the LH Code of Conduct, policies and procedures?
5. Which option best supports LH's culture and aligns with the Core Values of Respect, Inclusion, Service and Excellence?
6. Which option best respects the rights of those affected and treats all stakeholders justly, equitably, and with dignity and respect?
7. Have I considered the impact? Which option does the most good, the least harm, and serves the whole community?
8. Does the decision have a reputational risk? Could I defend my decision if it was made public?
9. How can I implement my decision with attention to the concerns of all stakeholders?
10. What is the learning opportunity from this that should be shared from this decision?

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Call 24 hours a day, 7 days a week.

Compliance and Privacy Office
Scan this QR code with your smartphone camera to directly access our website for online reporting and more information.
Visit **luminis.health/cc**

No Snooping!

Electronic access to protected health information is a privilege.

Access to patients' protected health information (PHI) for any reason other than a job-related duty or as permitted by the HIPAA Privacy Rule can be a violation of patient privacy.

It is against Luminis Health policy to access your own, your family or your friends' medical records. It is also against policy to access your co-workers or any other medical record(s) without a work-related reason to do so.

Before you access a patient's record, ask yourself, "Am I performing a work-related duty?"

To access medical records – the "right way" you may choose any one of the following:
- MyChart patient portal to access your medical records;
- Ask family members to provide you with proxy access to their MyChart account; or
- Request medical records from Health Information Management.

If you suspect that someone has improperly accessed medical records – report the incident immediately to the privacy office.

Hotline: 1-800-XXX-XXXX
By phone: XXX-XXX-XXXX
By email: privacy@luminishealth.org

about their feelings, Denham said. The podcast is available on Apple and other platforms.

- UofL has a staff resilience advisory board. "The program was created to help empower health care workers by fostering collaborative and innovative ways to ensure emotional and physical support is available and easily accessible," she said. The goals are creating a culture of well-being and promoting workplace efficiency and personal resilience. "I am one of the advisory board members and my role is to assist in the development of system initiatives and workforce and culture support," Denham said.
- One of its downtown hospitals piloted relaxation rooms. Unlike employee break rooms, the relaxation rooms are private spaces where staff can go to "get a breather," Denham said. "It's not always easy for someone to leave the floor" but this gives them an outlet when they need a minute by themselves.

UofL is doing a gap analysis to identify what resources are available for providers at each location. The ultimate goal is to ensure consistency across hospitals, Denham said. The UofL employee who spearheaded the initiative mentioned the Healthcare Professional Well-being Academic Consortium for academically affiliated health systems, which has resources on its web site at https://healthcarepwac.org.

The End of the Waivers Has a Kind of Shock Value

Compliance also is being affected by the pandemic in terms of new risk areas and the end of the waivers. For one thing, the addition of telehealth codes and the different ways of interacting with patients opens up new avenues of risk, Martin said. At the height of the pandemic, providers didn't necessarily have time to put protections in place and ensure visits weren't always coded at the highest level. "I tell people we were not supposed to get everything right, but you now know what you're supposed to be doing," she said. "If you're not taking corrective actions and putting processes in place, you're increasing exposure and liability." The HHS Office of Inspector General has invested a lot of energy in telehealth oversight and produced a telehealth integrity toolkit.[1] "The government only has so many resources and if they put their resources into something," people should pay attention, Martin said.

Luminis completed a CMS waiver audit to identify whether a waiver was used and the person who championed its use. Then a lot of communication began about the May 11 end of the waivers. Compliance sent out reminders and talked about the waivers in leadership and compliance committee meetings. The message was clear: the government gave providers 60 days' notice and if they didn't revert to pre-public health emergency regulations—with the exception of telehealth flexibilities that have been extended—they would be vulnerable. "We were very focused on that, and it was a big piece of work we were doing," Martin said. But "we weren't heavy into use of the waivers."

Patient Care About 'More Than the Medical Procedure'

It irks Sinko when he reads about layoffs in the health care industry caused by operating losses and higher supply costs because the press releases say that employees providing direct patient care were not affected. "That means you're laying off administrative people and a lot of them are doing compliance activities and reassigning those activities to people who are already really busy," he said. If compliance isn't part of their usual workload and they're not evaluated on their performance of compliance tasks, those responsibilities may fall to the bottom of their to-do list, Sinko said. But even if people performing compliance activities aren't laid off, he doesn't consider compliance unrelated to patient care.

There's a slide he includes in his presentations that states "caring for patient data is caring for the patient." As Sinko explained, "Talk to any patient whose data got lost, stolen or misused and they don't feel like they were properly cared for." Similarly, patients aren't happy when they receive an incorrect hospital bill. "That's why people have to view patient care as more than the medical procedure."

Contact Martin at cathy.martin@luminishealth.org, Sinko at sinkod@ccf.org and Denham at shelly.denham@uoflhealth.org. ✧

Endnotes

1. Ann Maxwell, Deputy Inspector General for Evaluation and Inspections, *Toolkit: Analyzing Telehealth Claims to Assess Program Integrity Risks*, U.S. Department of Health & Human Services, Office of Inspector General, April 2023, OEI-02-20-00723, https://bit.ly/423Pxa2.

After Self-Disclosing During Investigation, Provider Settles FCA Case

In a settlement that hinged partly on a self-disclosure in the middle of a whistleblower-fueled investigation, Massachusetts Eye and Ear Infirmary, Massachusetts Eye and Ear Associates Inc. and the Foundation of the Massachusetts Eye and Ear Infirmary Inc. have agreed to pay $5.7 million to settle false claims allegations that compensation for 44 physicians violated the Stark Law, the U.S. Attorney's Office for the District of Massachusetts said May 24.[1]

Massachusetts Eye and Ear Infirmary (MEEI) is a teaching hospital and Massachusetts Eye and Ear Associates is a physician group mostly comprised of ophthalmologists and otolaryngologists who perform medical services at MEEI's clinical locations. The foundation is the parent group of MEEI, Massachusetts Eye and Ear Associates and other entities. On April 1, 2018, the defendants were bought by Partners HealthCare System, which changed its name to Mass General Brigham on Nov. 27, 2019.

Example of a Short Compliance Article in Luminis Health Newsletter

Here's a short article about the Emergency Medical Treatment and Labor Act that appeared in the compliance section of Luminis Health's internal publication, Spark. It's an example of the short pieces that are designed to get people thinking about compliance issues, said Catherine Martin, chief compliance officer (see story, p. 1). Contact her at cathy.martin@luminishealth.org.

Compliance Matters

CMS Issues Helpful EMTALA Training Materials

The Centers for Medicare & Medicaid Services (CMS) recently released new Emergency Medical Treatment and Labor Act (EMTALA) training materials, consisting of a guidance tip sheet detailing patient rights and an EMTALA training video.

As you may already know, EMTALA guarantees access to emergency medical services for individuals who present to a hospital emergency department regardless of an individual's ability to pay. Under EMTALA law, our responsibilities include providing all patients with a medical screening examination (MSE), stabilizing any patient with an emergency medical condition (EMC), and transferring/admitting patients as appropriate.

Here are some helpful highlights to keep in mind:

All individuals must be screened

All individuals who present to our hospital emergency department must be screened by a Qualified Medical Personnel to determine the presence or absence of an EMC.

Stabilizing treatment must be provided

We must ensure the patient is provided with stabilizing treatment prior to transferring them to another facility or being discharged.

No delay in examination and treatment

We should not delay in providing an appropriate MSE for any reason, including inquiring about individual's method of payment or insurance status.

Four requirements for appropriate transfer

Prior to transferring a patient to another facility, we must ensure the following four requirements have been met:

1. We have minimized the medical risks and stabilized the patient.
2. We have sent all available medical records related to the EMC to the receiving medical facility.
3. The receiving medical facility has available space, qualified personnel to provide treatment, and agrees to accept the transfer.
4. The patient is being transferred using appropriate personnel and transportation.

For additional information regarding the EMTALA, please contact the Corporate Compliance department at Compliance@luminishealth.org or visit https://www.cms.gov/regulations-and-guidance/legislation/emtala.

About six months after the acquisition, otolaryngologist Allan Goldstein filed a whistleblower lawsuit against his former employer, Massachusetts Eye and Ear Associates, as well as MEEI and the foundation. Goldstein, who died in February 2021, alleged the defendants violated the Stark Law and Anti-Kickback Statute (AKS). According to his complaint, they allegedly encouraged physicians to order outpatient services at MEEI outpatient departments by paying them bonuses from the facility fees. After Goldstein died, his estate continued the case on the government's behalf.

The whistleblower's complaint centered on the way that MEEI shared revenue with certain physicians who performed services at the hospital's outpatient departments/provider-based space.[2] Medicare pays physicians a lower professional fee for services performed in hospital outpatient departments (HOPDs), but it also pays the hospital a facility fee. "The receipt of facility fees gives MEEI a strong financial incentive to have [Massachusetts Eye and Ear Associates'] physicians practice in its hospital outpatient departments rather than in office-based locations," the complaint alleged.

Deals Were Terminated After Acquisition

During the government's investigation of the whistleblower complaint, "the Defendants self-reported 7 compensation models involving 44 physicians that may have implicated the Stark Law," the settlement stated.[3] The arrangements were executed before the Mass General Brigham acquisition. One arrangement ended before the acquisition and Mass General Brigham voluntarily killed the six other arrangements on Oct. 1, 2019.

The case "is reflective of the government emphasizing cooperation generally," said attorney John Lawrence, with K&L Gates in Research Triangle Park, North Carolina. The settlement specifically notes that the government "recognizes and credits the Defendants for disclosure, cooperation, and remediation of the Covered Conduct

under the Department of Justice's guidelines for False Claims Act cases embodied in the Justice Manual, §4-4.112." Lawrence said there's been debate in the industry about whether self-disclosure and cooperation yield returns, "but here is an example of tangible returns for disclosure even if it was in the middle of an investigation." Of the settlement amount, $3.56 million is restitution.

As the settlement explains, MEEI had various compensation arrangements with 240 physicians employed by Massachusetts Eye and Ear Associates that were investigated by the government. MEEI has various HOPDs in Massachusetts and some of them transferred a percentage of their operating margins—30% to 50%—to Massachusetts Eye and Ear Associates at the end of every fiscal year. "MEEI calculated the operating margin by subtracting the HOPD's expenses from its fiscal year revenue, such that the operating margin included revenue from designated health services," the settlement states. Massachusetts Eye and Ear Associates then included these funds in the overall revenue "allocated to otolaryngologists and/or ophthalmologists affiliated with the HOPD location," against which Massachusetts Eye and Ear Associates subtracted employment expenses.

As part of their aggregate compensation, physicians were paid any surplus as a bonus. In most cases, Massachusetts Eye and Ear Associates allocated the funds to every physician based on personally performed services or time-based units for hours worked, although in one instance, the funds were allocated in equal shares, according to the settlement. The defendants contend that the physician compensation was consistent with fair market value.

The government alleged that MEEI's incentive payments to Massachusetts Eye and Ear Associates, which were paid to its employed physicians from Oct. 1, 2008, to Oct. 1, 2019, created a financial relationship between MEEI and the physicians. Because the physicians referred Medicare patients to MEEI for outpatient hospital services that were billed to Medicare, and they didn't satisfy any Stark exceptions, the government alleged claims stemming from the services violated the False Claims Act.

The defendants accepted responsibility for certain facts in the settlement. Other than the covered conduct, MEEI denied the allegations. Mass General Brigham declined to comment.

Self-Disclosure Is a 'Complex Calculus'

DOJ sweetened the pot of voluntary self-disclosures in its January "corporate enforcement policy."[4] It gives tangible rewards to companies when they come forward and reveal their involvement in possible criminal misconduct. Although the corporate enforcement policy comes from the criminal division, "the criminal side informs the civil side," Lawrence noted.

When criminal prosecution is warranted even with self-disclosure, DOJ will recommend at sentencing a 50% to 75% reduction of the fine range from the U.S. Sentencing Guidelines, except in cases of criminal recidivists. Companies also are required to cooperate with DOJ, remediate the wrongdoing and forfeit ill-gotten gains.

Whether or not organizations should self-disclose when they find out they're under investigation depends on several factors, Lawrence said. Often the main consideration is whether the allegations at issue have merit, as determined by an internal investigation. "The significance of the issues and any potential exposure also represent significant points of consideration," Lawrence said. Another factor can be whether the particular U.S. attorney's office is inclined to give cooperation credit. "It can be a complex calculus," he noted. If an organization goes the self-disclosure route and presents its findings to the government, and the internal investigation is perceived as credible and comprehensive, it often will help the organization because it saves the government time and resources, Lawrence explained. "A disclosure can send a clear message to the government that the company is committed to compliance and doesn't represent a compliance risk moving forward," he added.

Linda Severin, an attorney for the whistleblower, said, "We're happy when companies cooperate and disclose compliance issues they discover while the government is investigating one of our *qui tam* cases. At the end of the day, that cooperation may reduce the amount of money that the government—and our client—recovers, but it's a win-win-win. With cooperation and disclosure, a case can be resolved sooner. And the company pays less money while sending a strong message that it's committed to compliance."

DOJ recently said the self-disclosure policy is having an impact. In a May 24 speech at a white-collar crime conference sponsored by the New York City Bar Association, Assistant Attorney General Kenneth Polite Jr. said the "department has already seen a shift in the number of corporate disclosures," according to an article in the Wall Street Journal.[5]

Contact Lawrence at john.lawrence@klgates.com and Severin at linda@whistleblowerllc.com. ✧

Endnotes

1. U.S. Department of Justice, U.S. Attorney's Office for the District of Massachusetts, "Massachusetts Eye and Ear Agrees to Pay Over $5.7 Million to Resolve False Claims Act Allegations," news release, May 24, 2023, https://bit.ly/43i1vOr.
2. Complaint, U.S. v. Massachusetts Eye and Ear, https://bit.ly/43C0797.
3. Settlement agreement, U.S. v. Massachusetts Eye and Ear, May 2023, https://bit.ly/3WHTjVg.
4. Nina Youngstrom, "In New Policy, DOJ Spells Out Rewards for Self-Disclosure, Reinforces Compliance Programs," *Report on Medicare Compliance* 32, no. 3 (January 23, 2023), https://bit.ly/3ZyvI9Z.
5. Mengqi Sun and Dylan Tokar, "DOJ Says More Companies Are Voluntarily Disclosing Possible Wrongdoing," *Wall Street Journal*, May 24, 2023.

Supreme Court Rules on Scienter Under FCA

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FCA liability only attaches to knowing violations, which are defined as actual knowledge the claims are false, deliberate indifference to the truth or falsity of the claims and recklessness, Matzzie said. The Supreme Court ruled if the pharmacies believed they were breaking the law, that's sufficient to say they knowingly presented false claims, she explained. Providers won't escape liability because of ambiguity in Medicare and Medicaid regulations they themselves understood.

"It's not enough to defeat scienter to show that somebody could come up with a reasonable interpretation that permitted the claim," said attorney Matthew Krueger, with Foley & Lardner LLP. "What matters is what the entity submitting the claim actually believes is the legal requirement." But the court's emphasis on what a party subjectively believes may still give providers the opportunity to protect themselves, Krueger said. He encourages them to contemporaneously document their understanding of the legal standard because "if it turned out to be wrong but they have evidence that they believed what they were doing was reasonable, it could help show they didn't knowingly submit false claims."

According to the decision, petitioners (who are the whistleblowers) filed separate FCA lawsuits against SuperValu and Safeway (the respondents), which operate hundreds of drug stores nationwide. Medicare and Medicaid limit reimbursement for drugs to the usual and customary charges or prices. Pharmacies are required to disclose their usual and customary charges to Medicare and Medicaid, but the whistleblowers alleged they reported higher prices than they charged to the public.

The FCA lawsuits alleged that Walmart in 2006 started offering customers a 30-day supply of many drugs for $4, according to the decision. "To compete with Walmart, SuperValu and Safeway adopted price-match programs in which their pharmacies would match a competitor's lower price at a customer's request. SuperValu's pharmacies would then automatically apply that price to future refills of the drug for those customers." The discount programs were popular; "petitioners have presented evidence that the discounted prices comprised a majority of sales for many drugs to customers who paid in cash (and not through insurance) for at least some years during the programs' operation."

Petitioners alleged that the discounted prices were the true "usual and customary" prices but that Safeway and SuperValu reported their higher, nondiscounted process for reimbursement, according to the decision. "To be sure, the phrase 'usual and customary' on its face appears somewhat open to interpretation. But petitioners contend that respondents were informed that their lower, discounted prices were their 'usual and customary' prices, believed their discounted prices were their 'usual and customary' prices, and tried to hide their discounted prices from regulators and contractors," the decision stated. "Petitioners have presented evidence that they claim supports that theory. For example, both SuperValu and Safeway received a notice in 2006 from a pharmacy benefit manager stating that the phrase 'usual and customary' refers to discounted prices; Safeway apparently received the same message from state Medicaid agencies."

Lower Courts Had a Different Take on 'Knowingly'

When the FCA cases against SuperValu and Safeway began their legal journey, the district court agreed that their discounted prices were their usual and customary and by not reporting them, the pharmacies submitted false claims. But the district court granted them summary judgment and dismissed the cases on the grounds that they couldn't have acted knowingly. The U.S. Court of Appeals for the Seventh Circuit affirmed the lower court's rulings,

CMS Transmittals and *Federal Register* Regulations, May 19-June 1

Transmittals

Pub. 100-04, Medicare Claims Processing

- July 2023 Quarterly Update to Healthcare Common Procedure Coding System (HCPCS) Codes Used for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Enforcement, Trans. 12,062 (May 26, 2023)
- July 2023 Update of the Ambulatory Surgical Center [ASC] Payment System, Trans. 12,060 (May 25, 2023)
- July 2023 Integrated Outpatient Code Editor (I/OCE) Specifications Version 24.2, Trans. 12,059 (May 25, 2023)
- Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens and New Updates for 2023, Trans. 12,045 (May 16, 2023)

Pub. 100-20, One-Time Notification

- Allowing Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order, Trans. 11,935 (March 30, 2023, recommunicated June 1, 2023)

Pub. 100-02, Medicare Benefit Policy

- Educational Instructions for the Implementation of the Medicare Payment Provisions for Dental Services as Finalized in the Calendar Year (CY) 2023 Physician Fee Schedule (PFS) Final Rule, Trans. 12,047 (May 18, 2023)

Pub. 100-08, Medicare Program Integrity

- Update to Chapter 3 of Publication (Pub.) 100-08 (Program Integrity Manual (PIM)) for the Voluntary Prior Authorization (PA) Process for Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) Accessories, Trans. 12,056 (May 25, 2023)

Federal Register

Proposed rule

- Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program, 88 Fed. Reg. 34,238 (May 26, 2023)

Final rule; correction

- Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Correction, 88 Fed. Reg. 34,779 (May 31, 2023)

relying on the Supreme Court decision in *Safeco Ins. Co. of America v. Burr*, which interpreted the term "willfully" in the Fair Credit Reporting Act (FCRA). "Under the Seventh Circuit's approach, a claim would have to be objectively unreasonable, as a legal matter, before a defendant could be held liable for 'knowingly' submitting a false claim, no matter what the defendant thought," Justice Thomas explained. "Specifically, the court reasoned that the phrase could have been understood as referring to respondents' retail prices, not their discounted prices—even if the phrase, correctly understood, referred to their discounted prices. It thus did not matter whether respondents thought that their discounted prices were actually their 'usual and customary' prices. What mattered, instead, was that someone else, standing in respondents' shoes, may have reasonably thought that the retail prices were what counted."

The Seventh Circuit's ruling was then appealed to the Supreme Court, which agreed to answer this question: "If respondents' claims were false and they actually thought that their claims were false—because they believed that their reported prices were not actually their 'usual and customary' prices—then would they have 'knowingly' submitted a false claim within the FCA's meaning?"

The answer is yes. "Based on the FCA's statutory text and its common-law roots, the answer to the question presented is straightforward: The FCA's scienter element refers to respondents' knowledge and subjective beliefs—not to what an objectively reasonable person may have known or believed. And, even though the phrase 'usual and customary' may be ambiguous on its face, such facial ambiguity alone is not sufficient to preclude a finding that respondents knew their claims were false," Justice Thomas wrote.

'It's Really an Important Touchstone'

The Supreme Court sent the cases back to the district court for trial and they will proceed separately on the merits, said Jacklyn DeMar, director of legal education at Taxpayers Against Fraud. Matzzie noted the respective juries could still decide the pharmacies did not act knowingly in submitting false claims.

"It's a big win for not weakening the False Claims Act," DeMar said. "Some members of the defense bar painted this as a big boon for relators, but it's not. It takes us back to the text of the law."

Krueger added that the Supreme Court has limited a way for defendants to defeat FCA cases early, such as with a motion to dismiss. "If the court had affirmed the Seventh Circuit, it would have left open an important and attractive way to defend FCA suits on a motion to dismiss by showing the defendant could not have acted knowingly because the legal standard at issue was ambiguous."

This decision will have the same kind of seismic impact on scienter that the Supreme Court's ruling in the Escobar case had on materiality, Krueger added, referring to *Universal Health Services v. United States ex rel. Escobar*. "It's really an important touchstone." The Escobar decision, also written by Justice Thomas, supported the theory of implied certification in an FCA lawsuit.

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Endnotes

1. United States Et Al. Ex Rel. Schutte Et Al. v. Supervalu Inc. Et Al., https://bit.ly/3ORW18D.

NEWS BRIEFS

◆ **In a settlement about the free or below-market services of mid-level practitioners, VHS of Michigan Inc., doing business as The Detroit Medical Center Inc. (DMC), Vanguard Health Systems Inc. and Tenet Healthcare Corp. have agreed to pay $29.744 million to settle false claims allegations** they paid kickbacks to referring physicians, the Department of Justice (DOJ) said May 31.[1] DMC runs hospitals in and around Detroit, including Sinai Grace Hospital and Harper University Hospital. Tenet bought Vanguard-owned hospitals and outpatient facilities, including DMC, in October 2013. The government alleged that from Jan. 1, 2014, through Dec. 31, 2017, Sinai Grace Hospital and Harper University Hospital provided the services of DMC-employed mid-levels to 13 physicians for free or below fair market value in violation of the Anti-Kickback Statute, DOJ said. "The government further alleged that the physicians were selected because of their large number of patient referrals to Sinai Grace Hospital and Harper University Hospital and that the purpose of these arrangements was to induce the physicians to refer additional Medicare patients to DMC facilities." The case was set in motion by a whistleblower.

◆ **In a new report, the HHS Office of Inspector General (OIG) said Medicare overpaid physicians more than $22.463 million during a two-year period for services provided to Part A skilled nursing facility or hospital inpatients by paying higher nonfacility rates.**[2] "Medicare did not always pay the proper rate for physician services coded with the nonfacility place-of-service code for a [nursing facility] or SNF without Part A coverage while enrollees were Part A inpatients of a SNF," the report stated. Among other things, OIG recommended CMS tell Medicare administrative contractors to reprocess physician claim lines for the audit period to recover the $22.463 million and CMS agreed.

Endnotes

1. U.S. Department of Justice, Office of Public Affairs, "Detroit Medical Center, Vanguard Health Systems, and Tenet Healthcare Corporation Agree to Pay Over $29 Million to Settle False Claims Act Allegations," news release, May 31, 2023, https://bit.ly/3IQTx6E.
2. Amy J. Frotnz, *Medicare Paid Millions More for Physician Services at Higher Nonfacility Rates Rather Than at Lower Facility Rates While Enrollees Were Inpatients of Facilities*, A-04-21-04084, U.S. Department of Health and Human Services, Office of Inspector General, May 2023, https://bit.ly/3oMoq5G.