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

Contents

Chief Compliance Officer Convicted in Fraud Scheme; Lawyer: Sometimes You Have to Say No

The conviction of a chief compliance officer in a $50 million Medicare scam is a cautionary tale about the potential for compliance professionals to be held responsible for corporate fraud like any senior executive. It's a variation on the accountability theme that hit home when the Department of Justice (DOJ) started requiring compliance officers to certify their organization's compliance program is functioning effectively as part of the resolution of certain criminal cases, experts say.[1]

Steven King of Miramar, Florida, chief compliance officer of A1C Holdings LLC, a Florida pharmacy holding company, was found guilty by a jury of conspiracy to commit health care fraud and wire fraud, DOJ said June 8.[2] The verdict came down about 10 months after James Letko, the CEO of A1C, pleaded guilty in the scheme, which included billing Medicare for refills of prescription drugs and diabetic testing supplies for dead beneficiaries.

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Health System Settles CMP Case Over Discounts, Copay Waivers for Employees, Family Members

Kaleida Health and Olean General Hospital in western New York state have agreed to pay $2.7 million in a settlement with the HHS Office of Inspector General (OIG) over discounts for employees and their families who were covered by federal health care programs. OIG alleged the perks—including copay waivers, discounts on services and free television—were remuneration that invited civil money penalties. The settlement stemmed from self-disclosures by Kaleida Health and Olean, an affiliated hospital.

"Any program that has the potential to provide benefits to federal health care program beneficiaries poses significant risk," said attorney Allison DeLaurentis, with Goodwin in Philadelphia. Whether a copay was waived or a room was upgraded to private, the government takes the position that the benefit "taints the entire claim," she said. "Even if the actual remuneration was fairly nominal, it could result in fairly large damages."

Although employee and family perks, discounts and copay waivers are off-limits in the federal health care realm, it's less clear with commercial insurance, but there's still risk, DeLaurentis said. Free valet parking and television are less likely to trouble private payers, but private-payer contracts may impose requirements on the collection of copays and deductibles and these payers may challenge routine copay waivers, she said.

If providers intend to offer some kind of benefit to employees or families, "they need to ensure tight controls and appropriate execution of the policy to ensure the payer is known, the benefit is compliant and only appropriate patients are eligible," DeLaurentis said.

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According to the settlement, which was obtained through the Freedom of Information Act, Kaleida Health self-disclosed to OIG in 2018 that its discount program for employees and their family members led to some federal health care beneficiaries receiving certain discounts. OIG alleged Kaleida Health paid some of these employees and their family members remuneration between Aug. 1, 2011, and July 31, 2018, in the form of:

"(1) discounts on inpatient, observation, and outpatient hospital services;

"(2) discounts on home care services and long-term care services;

"(3) complimentary local telephone service, television, valet parking, and cafeteria privileges;

"(4) upgrades from semi-private to private rooms with no additional charge;

"(5) reduced cost-sharing amounts for prescriptions filled at Kaleida Health pharmacies;

"(6) reductions in deductibles for subacute rehabilitation services; and

"(7) reductions or waivers of cost-sharing amounts for other services, including smoking cessation classes, in relation to services provided at 14 affiliates of Kaleida Health."

OIG contends the remuneration paid by Kaleida subjects the health system to civil monetary penalties.

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About a year after Kaleida was accepted into OIG's Self-Disclosure Protocol (SDP), Olean General Hospital self-disclosed to OIG its own set of discounts and was accepted into the SDP in November 2019. OIG alleged that from Oct. 1, 2012, to Sept. 24, 2019, Olean waived or reduced cost-sharing amounts to hospital employees and their family members who were federal health care program beneficiaries for:

"(1) inpatient services;

"(2) outpatient ancillary services;

"(3) same-day services;

"(4) rehabilitation services;

"(5) dialysis;

"(6) chemotherapy; and

"(7) radiation therapy."

Kaleida, which includes five hospitals and other entities, and Olean didn't admit liability in the settlement. Their attorney didn't respond to a request for comment.

OIG alleged Kaleida Health and Olean paid remuneration in violation of 42 U.S.C. § 1320a-7b(b)(2), which includes the Civil Monetary Penalty Law prohibiting beneficiary inducements. "Things like the complimentary telephone service, television, valet, cafeteria, upgrades, etc. may seem separate from the actual medical care being provided and therefore not related to fraud and abuse issues, but the theory is that these are all items of value being provided to patients, which have the potential to influence their decision-making and induce them to choose the provider providing remuneration," DeLaurentis noted.

With respect to the value of the $2.7 million settlement, she noted "the dollars probably add up across multiple facilities over seven years. And with the government's theory that an entire claim is tainted by unlawful remuneration, you can imagine there may have been some significant claims that could add up quickly."

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JZ Modifier Reporting Starts July 1; Vial-Size Pressure Eases a Bit

Although hospitals are required to start reporting the JZ modifier on Medicare claims July 1 when they don't discard drugs or biologicals from a single-use vial, the pressure to use the smallest vial available has lifted somewhat, a compliance officer says. CMS already requires hospitals to report JZ's counterpart, the JW modifier, when they waste drugs from single-use vials, which generates reimbursement. Now one modifier or the other must be on claims, according to a new Medicare transmittal (12,067).[1] But size apparently matters less.

"Effective July 1, 2023, providers and suppliers are required to report the JZ modifier on all claims that bill for drugs separately payable under Medicare Part B when there are no discarded amounts from single-dose containers or single-use packages," according to CMS, which is now using the terminology "single-dose container" or "single-use package" instead of "single use vials." Without one of the modifiers on claims, providers may be audited, the transmittal added.

After pushing hospitals for years to use the smallest-available vials to minimize reimbursable waste—and auditing hospitals on that score—CMS has reversed course. According to the 2023 Medicare Physician Fee Schedule (MPFS) rule, "With regard to what vial size should be used to calculate discarded amounts, discarded amounts should be calculated using the labeled amount of the product that is actually purchased to prepare the dose, not the labeled amount of the smallest vial size that could have been purchased. The guidance referenced in MLN Matters article SE1316 is no longer effective, as it has been superseded by MLN Matters article MM9603, which was issued on June 9, 2016, and effective January 1, 2017."[2]

The big difference is the regulatory equivalent of changing from a red to a yellow light: replacing "must" with "should." While MLN SE1316 stated that "The units billed must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient," MLN Matters MM9603, which now links to JZ and JW modifier guidelines in a local coverage article, states that "The units billed should where possible correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient, while minimizing any wastage."[3]

CMS alluded to this in the 2023 Outpatient Prospective Payment System rule, but it referred hospitals to the MPFS language, so the flexibility with vial size may have been overlooked, said Steve Gillis, director of compliance coding, billing and audit at Mass General Brigham in Boston. "It's a turnaround," he said. "I think CMS is basically saying people haven't been billing waste so maybe they're not paid for it, but also the manufacturers are getting off. They are saying, 'We want you to get paid for the waste' because it forces manufacturers to manufacture more appropriate vial sizes."

And that, in fact, was the catalyst for the JZ modifier, Gillis said. Although the JZ and JW modifiers are provider requirements, they are also vehicles "to hold pharmaceutical manufacturers accountable for developing, producing or distributing insufficient or inappropriate vial sizes," he explained earlier this year.

Their Eyes Are on the Prize of Vial Size

The 2021 Infrastructure Investment and Jobs Act requires manufacturers to return money to CMS for certain discarded amounts from single-dose containers or single-use package drugs. If more than 10% of the total amount spent on a drug is wasted—as revealed by JW and JZ modifier data—the manufacturer will have to give a rebate to Medicare, Gillis said. For example, if patients typically receive 75 mg out of a 100 mg vial, that 25 mg of waste, although it seems reasonable, could trigger Medicare receiving a rebate on that transaction, he said. Then manufacturers presumably would start making smaller vials.

Hospitals are now required to report one of the two modifiers on Medicare's claim form. "The JZ modifier is a HCPCS Level II modifier reported on a claim to attest that no amount of drug was discarded and eligible for payment," according to answers to FAQs on the CMS website.[4] Providers will report JZ when they used the entire single-dose vial for a particular patient. When it's 100 mg of a separately payable drug and they administer 100 mg, the claim line should include the billing code and the JZ modifier.

Compliance with JW Modifer Use is 'Low'

When providers waste part of the single-use vial of a separately payable drug (e.g., 5 mg of a 50 mg vial), 45 mg are billed on one line of the claim and 5 mg of waste are billed on another with the JW modifier. "Both line items would be processed for payment," the FAQs state. For example, if the physician orders 75 mg of a chemotherapy drug and it's administered from a 100 mg single-use vial, the hospital is allowed to bill Medicare for 25 mg. That requirement has been in effect since 2017, although CMS reports compliance has been "low."

Gillis said his health system will continue to encourage clinicians and pharmacists to use the most appropriate vial sizes, but if they use larger vial sizes, "hopefully you can explain why. If we use 75 mg out of a 200 mg bottle, we will bill 125 mg of waste." For example, pharmacists or clinicians may pull out the wrong size or the hospital unit may have run out of the smaller vial size. "We'll still try to be efficient, but CMS seems to be putting the burden on manufacturers to make the smaller vial sizes more readily available," he said.

An Avalere study of 44 drugs with waste over 10% estimates that the manufacturers of the 44 drugs "could be liable for $210 million in annual refunds. These findings are consistent with CMS's 10-year projections and mark growth in drug wastage from 2020."[5]

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Endnotes

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With Private Equity Growth, CCOs May Face New Pressures, Lawyers Say

Compliance officers may find the expectations of their private equity investors at odds at times with their roles and with the guidance for effective compliance programs from the Department of Justice (DOJ) and the New York State Office of Medicaid Inspector General (OMIG), a former federal prosecutor said.

"Under this particular model, it's even tougher to be effective as a compliance officer because there are a number of pressures being placed on the organization and on your role," said David R. Hoffman, a law professor at the Kline School of Law at Drexel University in Philadelphia, at the Health Care Compliance Association's Compliance Institute April 26.

For example, DOJ's Evaluation of Corporate Compliance Programs states that "The critical factors in evaluating any program are whether the program is adequately designed for maximum effectiveness in preventing and detecting wrongdoing by employees and whether corporate management is enforcing the program or is tacitly encouraging or permitting employees to engage in misconduct."[1]

Hoffman thinks that's a challenge for compliance programs with private equity involvement. "The enormous pressure placed on health care organizations to maximize reimbursement from health benefit payers can lead to noncompliant conduct at various levels within the health care provider," he said. "In turn, the effectiveness of the ethics and compliance program will be compromised."

'Private Equity Is So Invisible'

And OMIG, which requires providers to have compliance programs, says, among other things, they should be "designed to be compatible with the provider's characteristics."[2] Hoffman noted that "compliance programs are not one-size-fits-all. They have to be tailored to your entity's business needs and the characteristics associated with pressures imposed through private equity ownership pose a significant challenge."

Compliance officers should be thinking about the "special risks" of private equity because "the wave of private equity acquisitions is so large you will be working for these people or have relationships as a joint venture partner," former federal prosecutor Jim Sheehan, chief of the Charities Bureau in the New York State Office of the Attorney General, said at the conference. For example, what will be the impact on billing, coding and revenue cycle management (including charity care policies of nonprofits)? "The problem is private equity is so invisible" in terms of its mechanics, he said. It has been hard for enforcers and regulators to get their arms around it. But private equity firms and their portfolio companies are facing more False Claims Act (FCA) lawsuits, and Hoffman believes private equity investors in nursing homes will start to be held accountable through private lawsuits if they breach their fiduciary duty to residents.

Sheehan explained that private equity operates differently than "super conglomerates" buying small businesses. Private equity investors focus on the technology, management and capital needs of the organization, they're paid a 2% management fee on all the money under their control and take 20% of the gains realized, and have a five-to-seven-year exit strategy. "Historically, antitrust enforcement focused on very large organizations," he said, such as hospital mergers over a certain threshold, "so private equity firms identify businesses under the threshold." They purchase a number of smaller entities, and after capturing the market, private equity firms control the prices and the practices, Sheehan said. Private equity targets include physician practices, home stool testing, remote cardiac testing, orthopedic and sports medicine, pediatric behavioral health and urology practices.

'No Government Agency Oversees This Sector'

"How big is this? I can't tell," he said. "We have been looking for the past year. The only place that tells you some is Pitchbook," which reported an increase from 417 deals in January 2013 to 1,428 deals in January 2021. "But no government agency oversees this sector to say how big it is or what they're doing."

Meanwhile, private equity is attracting attention from Congress, regulators, enforcers and the media. A 2022 White House fact sheet that announced nursing

home reforms called out private equity.[3] "Private equity firms' investment in nursing homes has ballooned from $5 billion in 2000 to more than $100 billion in 2018, with about 5% of all nursing homes now owned by private equity firms," the fact sheet stated. "Recent research has found that resident outcomes are significantly worse at private equity-owned nursing homes."

In his role as chief of the Charities Bureau, Sheehan is looking into hospitals in the nonprofit world and their relationship to private equity. "We don't know yet what to do with it," he said. What are the positive things that private equity brings to the table? "There are some, but the attention level at this stage is how big is this. We don't have the metrics yet to do it and we are seeing complaints." Private equity's response so far is that the focus on it "is a red herring," Hoffman said. "What we hear is that private equity is moving on to home heath, revenue cycle management, physician practices, oncology practices and hospices."

Piercing the Corporate Veil

The conventional wisdom is that private equity investors are insulated if their portfolio companies (e.g., providers) are hit with FCA lawsuits. "One thing you will hear is you can't pierce the veil from the health care company to the private equity firm," Sheehan said. But it has been accomplished in several cases.

For example, a private equity firm and two former executives of South Bay Mental Health Center Inc. in Massachusetts in 2021 agreed to pay $25 million for allegedly causing the submission of false claims to Medicaid in connection with services provided to patients by clinicians who were unlicensed and unsupervised.[4] There were allegedly staffing and supervision deficiencies at all 17 South Bay clinics, according to the Office of the Massachusetts Attorney General's (AG) FCA complaint.

South Bay was founded in 1986 by Dr. Peter Scanlon, who was CEO until April 2012. At that point, he sold it to Community Intervention Services (C.I.S.) and served as its chief clinical officer until December 2014, the complaint said. A majority interest of C.I.S. was owned by H.I.G. Growth Partners LLC and H.I.G. Capital LLC, a private equity firm. Kevin Sheehan was CEO of C.I.S. from April 2012 through November 2016.

The case was set in motion by whistleblower Christine Martino-Fleming, a licensed mental health counselor formerly employed by South Bay and C.I.S. She filed the FCA lawsuit in 2015 against South Bay and the private equity defendants under the federal FCA and Massachusetts FCA. Although DOJ declined to intervene, three years later, the state AG filed a complaint in intervention. In 2018, South Bay and C.I.S. settled the case for $4 million. In 2019, the AG and the whistleblower filed an amended complaint, and H.I.G. settled for $19.95 million and Scanlon and Kevin Sheehan for $5.05 million.

The message of the Massachusetts case is that even if the private equity firm doesn't create the noncompliant conduct, "if presented with recommendations to fix it, you better do it," Hoffman said.

In another recent settlement, Diabetic Care Rx LLC or Patient Care America (PCA), PCA's CEO Patrick Smith, PCA's former vice president of operations Matthew Smith and private equity firm Riordan, Lewis & Haden Inc. agreed to settle false claims allegations they were involved in a kickback scheme to generate referrals for prescriptions of pain and scar creams and vitamins that were paid by TRICARE.[5] These and other settlements "stand for the proposition that private equity investors and portfolio health care companies can be held liable under the False Claims Act and there is significant risk," Hoffman said.

Lawyer: Pushing Back Based on Fiduciary Duty

Hoffman also is troubled by the shift to a private equity and private capital model of nursing home ownership. "I begin with the belief that nursing-home owners owe a fiduciary duty to people entrusted to care for them," he said. There's a special responsibility nursing homes have because their charges are the frail and vulnerable elderly. That view has been endorsed by several courts, Hoffman said.

For example, the administrator of the estate of a deceased man, Gary Stetts, who had been a resident at a nursing home, Manor Care of Williamsport PA (North) in Pennsylvania, sued the nursing home and its corporate owners, alleging both that employees were negligent and that "policies and procedures of the Corporate Defendants resulted in understaffing and generally unsafe practices at the Facility," according to a court decision. Hoffman said it's significant because the judge ruled that corporate defendants have a fiduciary duty to nursing home residents. "They can be held liable for personal injury claims if they were aiding and abetting a breach of fiduciary duty, which should scare them." (Parts of the Manor Care case were dismissed on summary judgment, however.)

"I want to empower compliance officers to push back and say 'we are a health care organization. We have compliance pressures. If we violate our obligations, our fiduciary duty to our patients, then we are exposing not only those of us in our roles, not only management, but corporate ownership, to a potential claim of breach of fiduciary duty and health care fraud,'" Hoffman said. Because the nursing home world is highly regulated, compliance officers should be looking at the results of prior surveys, plans of correction and compliance hotline

calls, and how they were escalated to the compliance committee and board, he said. "What are we doing on behalf of our patients and residents in our role as compliance officer?"

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5. U.S. Department of Justice, Office of Public Affairs, "Compounding Pharmacy, Two of Its Executives, and Private Equity Firm Agree to Pay $21.36 Million to Resolve False Claims Act Allegations," news release, September 18, 2019, https://bit.ly/3LsMxxl.

Compliance Officer Convicted in Fraud Case

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King faces a maximum of 20 years in prison when he's sentenced Sept. 14. Letko's plea calls for up to 10 years and he will forfeit $21.7 million. Three other co-defendants have pleaded guilty.

"This disposition illustrates the compliance officer was every bit as culpable and attractive to the government as the CEO," said former federal prosecutor Robert

CMS Transmittals and *Federal Register* Regulations, June 2-June 15

Transmittals

Pub. 100-04, Medicare Claims Processing

- October 2023 (2024 File) Update of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), Trans. 12,084 (June 15, 2023)
- Internet Only Manual Update, Pub. 100-04, Chapter 11 (Processing Hospice Claims), Sections 20.1.1 - 20.1.5, 30.2.1, 30.3, 130.1 and 130.2, Trans. 12,083 (June 15, 2023)
- New Waived Tests, Trans. 12,089 (June 15, 2023)
- October 2023 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files, Trans. 12,088 (June 15, 2023)
- Fiscal Year (FY) 2024 Annual Update to the Medicare Code Editor (MCE) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) and Procedure Coding System (ICD-10-PCS), Trans. 12,087 (June 15, 2023)
- Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 29.3, Effective October 1, 2023, Trans. 12,081 (June 15, 2023)
- July 2023 Update of the Hospital Outpatient Prospective Payment System (OPPS), Trans. 12,077 (June 13, 2023)
- July 2023 Update of the Ambulatory Surgical Center [ASC] Payment System, Trans. 12,076 (June 13, 2023)
- Internet Only Manual Update to Publication 100-04, Chapters 9 and 18 to Clarify Vaccine Payment Instructions for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs), Trans. 12,070 (June 7, 2023)
- Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - July 2023 Update, Trans. 12,072 (June 7, 2023)
- July Quarterly Update for 2023 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule, Trans. 12,068 (June 2, 2023)
- New Claims Modifier Requirement for Drugs and Biologicals from a Single-Dose Container or Single-Use Package, Trans. 12,067 (June 2, 2023)

Pub. 100-20, One-Time Notification

- Allowing Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order, Trans. 12,091 (June 15, 2023)
- Prior Authorization (PA) Changes to Implement the Inpatient Rehabilitation Facility (IRF) Review Choice Demonstration (RCD), Trans. 12,080 (June 15, 2023)
- Addition of New Data Elements to the National Claims History (NCH) Claims Data Output, Trans. 12,071 (June 6, 2023)

Pub. 100-21, Provider Documentation Manual

- Fiscal Year (FY) 2024 and After Payments to Hospice Agencies That Do Not Submit Required Quality Data - This CR Rescinds and Fully Replaces CR 9460, Trans. 12,090 (June 15, 2023)
- Prior Authorization (PA) Changes to Implement the Inpatient Rehabilitation Facility (IRF) Review Choice Demonstration (RCD), Trans. 12,080 (June 15, 2023)

Pub. 100-16, Medicare Managed Care Manual

- Update to Section 50 on Renewal Options and Crosswalks, Trans. 127 (June 2, 2023)

Federal Register

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. 37,174 (June 7, 2023)

Final rule

- Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID) To Provide COVID-19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID-19 Testing Requirements, 88 Fed. Reg. 36,485 (June 5, 2023)

Final action

- Medicare Program; Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate Patient Percentage, 88 Fed. Reg. 37,772 (June 8, 2023)

Trusiak, an attorney in Buffalo, New York. "With empowerment from the Department of Justice that comes with the compliance officer certification comes" the same treatment in civil and criminal cases as the CEO or CFO.

The case also is a reminder for compliance officers that if "their company's risk profile is more aggressive than you're comfortable with, it may be a good idea to find another place to work," said attorney Anthony Burba, with Barnes & Thornburg LLP in Chicago. "They're not likely to take your compliance advice as seriously as they need to."

But the ultimate responsibility for ensuring your organization prevents and detects noncompliance rests with management and the board, said attorney Gabriel Imperato, with Nelson Mullins in Fort Lauderdale, Florida. "To prevent being sucked into something they can be held accountable for, compliance officers should stick to the tasks under the compliance program." In the cases he's seen where compliance officers were indicted for participating in a fraud scheme, "they in effect stopped being a compliance officer."

According to the 2019 indictment[3]—which named King, Letko and three others—or to Letko's plea agreement,[4] Letko incorporated A1C Holdings in 2013 to operate as a parent company for All American Medical Pharmacy (AAMP) in Michigan and other retail pharmacies. "As CEO of these entities, Letko oversaw and engaged in an ongoing conspiracy and participated in it with other members of the executive leadership of AAMP and A1C Holdings LLC, including Chief Compliance Officer Steven King," to enrich themselves by submitting false claims to Medicare for prescription drugs and diabetic testing supplies that were medically unnecessary or ineligible for reimbursement, the plea agreement states.

Pretending to Be Retail Pharmacies

On behalf of A1C, King, Letko and others entered into pharmacy provider agreements with CVS Caremark, Express Scripts and other pharmacy benefit managers (PBMs), the indictment alleged. They hid Letko's ownership in A1C's pharmacies by "installing nominee owners to deceive PBMs into paying for prescriptions and agreeing to contracts with the individual A1C pharmacies they would have otherwise denied" if they had known Letko owned or controlled them. The reason isn't explained, and the name "James Letko" doesn't show up on the List of Excluded Individuals and Entities.

The indictment also alleged that between 2013 and 2018, King, Letko and the others:

- Misrepresented on their PBM applications that the A1C pharmacies were retail pharmacies when they were mail-order pharmacies. The reason for the deception: PBMs wouldn't have entered into mail-order contracts with the A1C pharmacies.
- Submitted false claims using the national provider identifiers (NPIs) of physicians without their consent to determine patient eligibility for pricey medications and diabetic testing supplies.
- Billed for refills of medically unnecessary drugs and diabetic testing supplies "that were shipped without patient consent, including but not limited to dead beneficiaries."
- Didn't collect copays to induce Medicare beneficiaries to accept refills.
- Redirected prescriptions, without patient consent, through A1C pharmacies after the PBMs canceled their contracts.

'Sometimes You Have to Say Hell No'

This is a case of "fact frauds" as opposed to regulatory frauds, Trusiak said. "If a defendant engages in conduct that might be permissible, then that drives a more lenient disposition."

Fact frauds also don't lend themselves to the compliance officer saying "yes, but," Trusiak explained. "Whatever the revenue idea is, you try to massage the thing and make it work from a compliance perspective, but sometimes you have to say hell no, and this case is a stark reminder." It's one thing when there's room to maneuver with a regulation—"you choose X and the government says Y and you have something to talk about in terms of whether you have criminal intent, but [sending prescriptions to] dead people is always Exhibit A when it comes to the government and once you have one fact-based fraud, any argument the defense posits after that has less credibility," he said. "It's important to recognize that cases are won and lost not on a jury's understanding of Stark or the Anti-Kickback Statute, but on the backs of badges of fraud."

Imperato said if compliance officers worry about being pulled into an activity where there might be culpability, they should document the chain of events: "We had a report of noncompliant activity, conducted an internal investigation and submitted our findings to management. We don't know whether management followed up with remediation." That way, "there could be no question in hindsight of whether you were involved in suspicious activity."

But if compliance professionals witness fraud and they're brushed off by senior leaders, they may have to blow the whistle to state or federal regulators, said Burba, a former federal prosecutor. Otherwise, they may wind up in the same boat as the defendant in the A1C case. As DOJ noted in its press release, "As chief compliance officer, King was in a unique position to prevent and

report the fraudulent scheme, but he used his position to defraud Medicare instead."

Burba suggests compliance professionals keep contemporaneous records showing they advised leaders and/or board members that their conduct was likely problematic. "Ideally you demonstrate you raised it to appropriate levels within the company and that you separated yourself from the conspiracy once those steps weren't effective," he said. "You don't necessarily need to show you reported that conduct to the government, but that would be another step that insulates you from prosecution."

Compliance officers also shouldn't "delude themselves" into thinking they're a mid-level person people who won't be caught in the net when DOJ comes after "the big fish. You're on a level with the CEO so act accordingly," Trusiak said.

This is consistent with DOJ's "very public" push for effective compliance programs, Burba said. "They're really loading up their self-disclosure program, and creating incentives for individuals and companies to cooperate," he said. "If you are a compliance officer who is viewed as culpable, especially in the criminal conspiracy but even in the False Claims Act context, you are likely to be targeted."

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Endnotes

1. Nina Youngstrom, "DOJ Certification Raises CCO 'Risk Profile'; Consider 'Your Own Due Diligence Checklist'," *Report on Medicare Compliance* 31, no. 26 (July 25, 2022), https://bit.ly/3T0Khj8.
2. U.S. Department of Justice, Office of Public Affairs, "Chief Compliance Officer Convicted of $50M Medicare Fraud Scheme," news release, June 8, 2023, https://bit.ly/43FKnTb.
3. Indictment, United States v. Letko, No. 2:19-cr-20652-DML-DRG (E.D. Mich. 2019), https://bit.ly/3NeeWYW.
4. Plea agreement, United States v. Letko, No. 2:19-cr-20652-DML-DRG (E.D. Mich. 2022), https://bit.ly/3Pc1uHB.

NEWS BRIEFS

◆ **The Promoting Access to Treatments and Increasing Extremely Needed Transparency (Patient) Act (H.R. 3561), which advanced out of the House Energy and Commerce Committee May 24 on a bipartisan vote of 49-0, includes some provisions with big implications for hospitals if it becomes law.** For example, the bill requires all provider-based departments to submit attestations to CMS that they comply with provider-based requirements at 42 C.F.R. § 413.65 by Jan. 1, 2026, said Martie Ross, a consulting principal with PYA, and Kathy Reep, a senior manager with PYA, at a June 14 webinar sponsored by the firm. Another provision requires a separate national provider identifier for every hospital outpatient department to bill government payers. Those are just two of the bill's provisions affecting hospitals and other industry players.

◆ **The HHS Office of Inspector General (OIG) has updated its work plan**.[1] Among the new items is a national audit of Medicare Advantage (Part C) high-risk diagnosis codes. "For these audits, we will focus on enrollees who received diagnoses that are at high risk for being miscoded and resulted in increased risk-adjusted payments from CMS to MA organizations," OIG said.

◆ **Fayetteville, North Carolina cardiologist Hari Saini and his practice, Carolina Heart and Leg Center P.A., have agreed to pay $5 million to the federal government and state of North Carolina to settle false claims allegations**, the U.S. Attorney's Office for the Eastern District of North Carolina said June 13.[2] The settlement was set in motion by a whistleblower, who alleged that Saini and his cardiology practice performed unnecessary atherectomy procedures to remove minor plaque blockage in leg arteries. They deny the allegations.

◆ **Yakima Valley Memorial Hospital in Yakima, Washington, agreed to pay $240,000 to resolve a HIPAA investigation by the HHS Office for Civil Rights (OCR)**.[3] OCR investigated allegations that several hospital security guards snooped in the medical records of 419 people. The hospital also agreed to a corrective action plan. It's required to do a risk analysis, develop and implement a risk management plan, disseminate policies and procedures, do training and take other steps. Yakima didn't admit liability in the settlement.

Endnotes

1. U.S. Department of Health and Human Services, "Recently Added Work Plan Items," last accessed June 16, 2023, https://bit.ly/2AxFtyP.
2. U.S. Department of Justice, U.S. Attorney's Office for the Eastern District of North Carolina, "Fayetteville Cardiologist Agrees to Pay Over $5 Million to Resolve Allegedly False Medicare and Medicaid Claims," news release, June 13, 2023, https://bit.ly/441bfN9
3. U.S. Department of Health and Human Services, "Yakima Valley Memorial Hospital Resolution Agreement and Corrective Action Plan," resolution agreement, June 15, 2023, https://bit.ly/3PhrHVb