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Outlook 2025: Look for MA Cases Based on Claim Denials; Incoming DOJ May Tweak Guidance

By Nina Youngstrom

Although there's consensus that Medicare Advantage (MA) plans will continue to be a top enforcement target this year, they may face new kinds of false claims allegations for denying payment and cherry-picking patients, according to a former U.S. Department of Justice (DOJ) prosecutor. That would take False Claims Act (FCA) cases beyond risk adjustment and strike at the heart of MA practices that draw complaints from providers and patients.

It's one of the changes on the horizon in what's expected to be another year of aggressive enforcement, with FCA cases on kickbacks, upcoding and MA, among other things, and with creative theories of liability in opioid enforcement and perhaps cyberfraud. If a new indictment of a hospital in connection with surgeries is any indication, less conventional cases could be looming. A federal jury on Jan. 8 indicted Chesapeake Regional Medical Center in Virginia for allegedly billing federal health care programs for unnecessary surgeries performed by one surgeon, Javaid Perwaiz. The hospital granted Perwaiz privileges even though it knew his privileges "had been terminated at another hospital for performing unnecessary surgeries and that he was convicted of two federal felonies in 1996," the U.S. Attorney's Office for the Eastern District of Virginia alleges.[1]

In the MA realm, the most significant change for 2025 will be shifting from risk adjustment and hierarchical condition category (HCC) coding enforcement to other alleged wrongdoing, said Kirk Ogrosky, former deputy chief of DOJ's fraud section. "DOJ prosecutes hundreds of providers every year for submitting unnecessary claims. The turn of the coin is when DOJ starts prosecuting insurers for wrongfully denying necessary claims."

Risk adjustment issues have already led to a series of MA plan settlements, including a biggie with Independent Health Association and its affiliate, Independent Health Corporation, which agreed to pay up to $98 million to settle false claims allegations that they submitted invalid diagnosis codes for MA enrollees to increase their Medicare reimbursement, DOJ said Dec. 20.[2] The case was set in motion by a whistleblower.

But Ogrosky thinks the tide will turn to false claims allegations for delaying and denying care and other potential offenses. "The risk adjustment issues will normalize in the markets and plans will learn to adhere, but health insurers that own and operate commercial plans, MA plans and Medicaid plans, as well as Medicare administrative contractors for traditional Medicare, will face federal investigations of how they operate, process claims, set gating requirements, manage appeals and how their actuaries address attrition and adherence to medically necessary protocols," he predicted.

Grassley Back on Top of Judiciary Committee

Whatever the target, experts doubt that the change in administration will blunt investigations and prosecutions. "We will continue to see robust enforcement under a new DOJ even if its main priority will be in other areas, such as violent crime, immigration and drug trafficking," said attorney Matt Krueger, with Foley & Lardner LLP. Bipartisan support for health care fraud enforcement and its high return on investment will keep investigations rolling. "One thing that could hurt the federal enforcement effort is if the new administration cuts OIG and DOJ

budgets, but health care enforcement is largely immune because a portion of the funding comes from the Health Care Fraud and Abuse Control Program," said Ogrosky, with Goodwin Procter LLP.

Also, whistleblowers drive a lot of enforcement, and their champion, Sen. Charles Grassley (R-Iowa)—an architect of the 1986 FCA whistleblower provisions—is the new chair of the Judiciary Committee. "It's an important position for the incoming administration," said Greg Demske, former chief counsel to the HHS Inspector General. Project 2025, which is considered Trump's blueprint for overhauling the government, has a favorable reference to the FCA "in terms of holding people accountable," said Demske, with Goodwin Procter LLP.

How investigators and prosecutors go about their work may shape-shift. Trump 2.0 may reverse the Biden administration's reversal of certain Trump 1.0 policies. For example, the incoming administration could revive a version of the 2018 Brand memo, which prohibited the use of subregulatory guidance to prove violations in affirmative civil enforcement cases (e.g., FCA lawsuits), unless it was rooted in laws or regulations. Attorney General Merrick Garland rescinded the Brand memo in 2021, calling it "overly restrictive," although he reiterated that guidance doesn't have the force of law, and "enforcement actions must be based on the failure to comply with a binding obligation, such as one imposed by the Constitution, a statute, a legislative rule, or a contract."[3]

It would just be a matter of emphasis, said Brenna Jenny, former CMS chief legal officer. "In the last [Trump] administration, they made clear that it's inappropriate to use a violation of a guidance document as a per se violation of law. That's true as a matter of foundational case law and the Administrative Procedure Act," said Jenny, with Sidley Austin LLP. "That doesn't need to be implemented by anyone but how strongly DOJ and HHS adhere to it can vary across administrations." Not using guidance alone as a predicate for an FCA violation will be more openly embraced in the new administration, she predicts. On a related note, because of the U.S. Supreme Court decision in *Loper Bright Enterprises et al. v. Raimondo, Secretary of Commerce, et al.*, more defendants will argue in FCA lawsuits that the regulations they allegedly violated are invalid because they're inconsistent with the statute, she said.

The abundance of enforcement and compliance guidance released by the Biden administration may be revisited this year, Krueger said. Among other things, DOJ's Criminal Division has put out guidance on voluntary disclosure and cooperation credit. "We could expect a more pragmatic approach to what counts as cooperation credit," he said. For example, the Obama administration introduced the individual accountability policy (also known as the Yates memo), offering organizations cooperation credit for naming culpable individuals in a corporate fraud case. "It was modified by the Trump administration to allow a more flexible approach to assessing cooperation," Krueger said. The Biden administration has hewed more closely to the original Yates memo. "We may see the pendulum swing back again," Krueger said. He hopes DOJ under Trump 2.0 will spell out the rewards for cooperation credit on the civil side (e.g., FCA cases) the way it does on the criminal side.

Krueger also expects Trump's DOJ to tweak the *Evaluation of Corporate Compliance Programs* where it's perceived to have gone too far. "The changes may be more around the margins" because both Trump administrations "see value in providing guidance to the regulated community." For example, DOJ may revisit the section on "compensation structures and consequences management," which says, among other things, that "prosecutors may consider whether provisions for recoupment or reduction of compensation due to compliance violations or misconduct are maintained and enforced in accordance with company policy and applicable laws."

More Creative Theories in FCA Cases

There are signs that fraud enforcement will go in more creative directions, said attorney Colette Matzzie, with

Phillips & Cohen LLP. For example, DOJ announced Dec. 13 that McKinsey & Company Inc., a global management consulting firm, agreed to pay $650 million to end a criminal and civil investigation into its consulting work with opioid manufacturer Purdue Pharma L.P. It's the first time a management consulting firm was held criminally responsible for advice resulting in a client committing crimes, DOJ said.[4] The settlement centered on McKinsey's advice to Purdue about the sales and marketing of OxyContin and included FCA allegations. An article in Bloomberg Law highlighted a prosecutor on the case, Assistant U.S. Attorney Randy Ramseyer from the U.S. Attorney's Office for the Western District of Virginia, for unique approaches to fighting the opioid scourge.[5] His office also is pursuing "Facebook parent Meta Platforms over opioid-related claims."

But a shadow has been cast over the future of whistleblowers in a federal court decision that's the talk of the FCA town. Judge Kathryn Kimball Mizelle of the U.S. District Court for the Middle District of Florida ruled Sept. 30 that whistleblowers violate the Appointments Clause of the Constitution, which vests executive power in the president and, by extension, the executive branch.[6] The judge threw out an FCA lawsuit filed by whistleblower Clarissa Zafirov against Florida Medical Associates LLC and other defendants over alleged unsupported diagnosis codes submitted to Medicare Advantage plans. The judge noted that "no one—not the President, not a department head, and not a court of law—appointed Zafirov to the office of relator. Instead, relying on an idiosyncratic provision of the False Claims Act, Zafirov appointed herself. This she may not do."

That decision is now being challenged in the U.S. Court of Appeals for the 11th Circuit. "What matters is if [Judge Mizelle] is affirmed or overturned and the scope of the decision in the 11th Circuit," Matzzie said. "If they affirm her, there would be a circuit split and the Supreme Court likely would then take the case because it's so important," Matzzie said. Every other federal court, including four other circuits—the Fifth, Sixth, Ninth and 10th—have rejected challenges under Article II, including the Appointments Clause, and supported the authority of whistleblowers to act on behalf of DOJ, she said.

If the legal reasoning of Judge Mizelle prevails, however, it would crush the power of whistleblowers to fight fraud without DOJ intervention, although whistleblower cases could continue with DOJ intervention. The impact of the Florida decision is already being felt. "It's an argument being added to every motion at every stage," said attorney Bill Mathias, with Bass, Berry & Simms PLC.

HIPAA Settlements Keep Coming for Now

Meanwhile, more FCA action is under way in the states, Jenny said. "We are seeing relators and the relators' bar pursue more actions in state court. Almost all states have their own False Claims Acts." She noted it's often harder for defendants to win a motion to dismiss in state court than federal court.

States also are a hotbed of privacy activity. "We will continue to deal with a state law patchwork," said attorney Iliana Peters, with Polsinelli. "Working with that will continue to be quite difficult especially when you have fairly aggressive states and states that aren't as aggressive but in different ways." For example, Florida prohibits offshoring of data, which means licensed health care providers can't use electronic health record or other vendors outside the United States. Other states may go that route, but for now it's limited to Florida.

Nationally, Peters expects the HHS Office for Civil Rights' (OCR) twin enforcement initiatives—on right of access and ransomware—to continue. On Jan. 7 and 8, OCR announced three separate settlements for alleged HIPAA violations. In one case, USR Holdings LLC agreed to pay $337,750 over unauthorized access to a database with electronic protected health information.[7] But enforcement may slow down the first year of the new administration while OCR awaits the appointment of a new director. That doesn't happen fast for "the last-staffed divisions that get political appointments," Peters said.

Will Enforcers Try to Tie HIPAA to the FCA?

Another open question is whether DOJ continues its Civil Cyber-Fraud Initiative, which wields the FCA against government contractors that allegedly violated the cybersecurity terms of their contracts. For example, DOJ said in May that Insight Global LLC, a staffing company, agreed to pay $2.7 million to settle false claims allegations in connection with its alleged failure "to implement adequate cybersecurity measures to protect health information obtained during COVID-19 contact tracing" under a contract with the Pennsylvania Department of Health. If DOJ sticks with the cyber-fraud initiative, "what I'm particularly watching to see is whether whistleblowers and DOJ pursue aggressive theories to try to tie the FCA to HIPAA's security requirements," Krueger said.

Kickbacks are anticipated to be a hotspot. "They will continue to be a mainstay" of fraud enforcement, Matzzie said. For example, expect Anti-Kickback Statute cases against independent contractor relationships when the compensation varies based on the volume or value of referrals, Jenny said. "Although not necessarily unlawful, such arrangements aren't covered by the personal services safe harbor."

Contact Matzzie at cmatzzie@phillipsandcohen.com, Jenny at bjenny@sidley.com, Krueger at mkrueger@foley.com, Ogrosky at kogrosky@goodwinlaw.com, Mathias at bill.mathias@bassberry.com, Demske at gdemske@goodwinlaw.com and Peters at ipeters@polsinelli.com.

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