Report on
MEDICARE COMPLIANCE

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

Contents

Hospital Settles FCA Case Filed by CO Over Modifiers; Make Sure People 'Feel Heard'

John Peter Smith (JPS) Hospital in Fort Worth, Texas, agreed to pay $3.3 million to settle false claims allegations in a case with a hot risk area, a compliance officer-turned-whistleblower and a self-disclosure. Erma Lee, the former director of compliance, alleged the hospital improperly billed for three modifiers and didn't return the overpayments even after she alerted executives, according to her 2018 False Claims Act (FCA) complaint.[1] During the subsequent Department of Justice investigation, the hospital voluntarily repaid its Medicare administrative contractor $438,673, according to the settlement, which was announced by the U.S. Attorney's Office for the Northern District of Texas Aug. 27.[2]

The government alleged JPS submitted Medicare claims with "inappropriate or otherwise unjustified" modifiers 25, 59 and XU from 2008 through 2016, the settlement states. The U.S. attorney's office declined to intervene in the lawsuit, and the hospital corrected the modifier problem after the whistleblower separated from the hospital, said its attorney, Jason Mehta.

Modifiers allow providers to bypass National Correct Coding Initiative billing edits that otherwise prevent improper payments for evaluation and management (E/M) services and procedures when they're not separately payable. They've been under the microscope of Medicare watchdogs for years, with the HHS Office of Inspector General (OIG) finding high error rates for certain modifiers. In April, OIG added an audit to the Work Plan of modifier 25 on dermatologists' claims for E/M services, while CMS produces comparative billing reports on modifier 25.[3]

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CMS Voids Mid-Build Audit Findings; New Audit Will Use Broader Construction Interpretation

CMS on Sept. 10 withdrew its determination that 202 provider-based departments (PBDs) flunked audits of the mid-build exception, which allows certain PBDs established after Nov. 2, 2015, to bill the outpatient prospective payment system (OPPS).

It's back to the drawing board for the mid-build audits, but PBDs don't have to write checks for the time being. "Providers that received failing audit determinations are no longer required to report or return overpayments based on those determinations," CMS said in a new document.[1] They will receive a letter rescinding the previous determination, and then CMS will review the 202 PBDs that failed the audits "for compliance with statutory requirements and for accuracy and completeness. An updated audit determination letter will be issued following the review of each provider's audit. A new overpayment return deadline for self-identified overpayments will be included in that letter should the provider receive a failing audit determination."

PBDs will have a chance to give CMS "all relevant evidence to support their mid-build exception requests," the document states. "CMS will consider any

continued

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additional documentation providers choose to submit to support their eligibility for the mid-build exception."

The decision is good news for hospitals and the attorneys who had argued that the CMS audit of the mid-build exception had strayed too far from the statute that authorized it and that the overpayment demand letters were too vague.

"It is gratifying that CMS listened to legitimate concerns from denied applicants as to how to have a fair and transparent process," said attorney Andrew Ruskin, with K&L Gates in Washington, D.C. "Many in the provider community are surely looking forward to constructive conversations regarding the statute and Congress's overarching intent in the days and weeks to come."

But the rescission may not be permanent, said attorney Larry Vernaglia, with Foley & Lardner LLP in Boston. "CMS is reviewing the audits and some applications may be denied again, though the promise of a broadened view of at least the 'construction contract' is very much welcomed. So providers should stay tuned for the next round of audit findings."

A lot of money is at stake. When Congress shut new PBDs out of the OPPS in Sec. 603 of the 2015 Bipartisan Budget Act, their Medicare reimbursement dropped to 40% of the OPPS rate under the Medicare physician fee schedule. But the following year, the 21st Century Cures Act included a mid-build exception for PBDs that were in the works on Nov. 2, 2015, when Congress flipped the switch. To qualify for the mid-build exception, hospitals were required to: (1) file an attestation with CMS that the department was, in fact, provider-based; (2) add the PBD to its 855A enrollment form; and (3) have proof of a signed contract with an unrelated party for the construction of the PBD before Nov. 2, 2015.

The 21st Century Cures Act also directed CMS to audit compliance with these requirements and prohibited appeals of audit findings. In 2018, CMS audited 334 clinics belonging to hospitals that requested the mid-build exception, and in January 2021, it announced that 202 PBDs didn't qualify for the mid-build exception and probably received overpayments if they have been billing the OPPS, according to CMS's fact sheet.[2] Hospitals were given 240 days to address overpayments, although the fact sheet said they may be eligible for an extended repayment schedule and to keep an eye out for audit determination letters.

In July, PBDs that flunked the audit were informed they had 60 days to return the money under the Medicare 60-day overpayment refund rule, with the January letter serving as credible information of the overpayment, Vernaglia and Ruskin said. The rule requires providers to refund overpayments 60 days after they are identified and quantified. PBDs are expected to return 60% of the outpatient reimbursement they generated—the difference between full OPPS payments (claims submitted with the PO modifier) and nonexcepted reimbursement (claims submitted with the PN modifier).

Attorneys: Audit Went Beyond Statute

But this was not a run-of-the-mill audit, the attorneys said. For one thing, Cahaba Government Benefit Administrators LLC, the Medicare administrative contractor (MAC) that reviewed mid-build compliance for CMS, failed many of the PBDs because their construction contract was with the landlord, not a construction company, Vernaglia and Ruskin said. Here's where they see a problem: The 21st Century Cures Act requires hospitals to have a binding written agreement with an outside party for a PBD structure, but hospitals don't necessarily have contracts with construction companies. They often lease space and ask the landlord to build it out. If Congress had meant to be more restrictive, it would have said so in the statute, and if CMS wanted to be more restrictive, it should have issued regulations spelling out what construction contracts would fly under the mid-build exception, according to Ruskin and Vernaglia.

"There's nothing pursuant to notice-and-comment rulemaking and program instructions on this point," Ruskin said. In their eyes, CMS was ignoring its own Office

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of General Counsel (OGC) advisory opinion,[3] which was issued Dec. 3, 2020, in the wake of the Supreme Court's decision in *Azar v. Allina Health Services, et al.*[4] The Supreme Court ruled that CMS is required to use the rulemaking process, with its notice-and-comment period, to make "substantive" changes to policies that affect payment.

In its advisory opinion, OGC said it "interprets the phrase 'substantive legal standard' in Section 1871(a)(2) to mean any issuance that: 1) defines, in part or in whole, or otherwise announces binding parameters governing, 2) any legal right or obligation relating to the scope of Medicare benefits, payment by Medicare for services, or eligibility of individuals, entities, or organizations to furnish or receive Medicare services or benefits, and 3) sets forth a requirement not otherwise mandated by statute."

The implication, Ruskin said, is "if you impose a standard not squarely in the statute itself, then you need to go through rulemaking, which didn't happen here. CMS *cannot* interpret without rulemaking. If the statute is not clear, then they have to interpret it as expansively as the words will allow, or they violate *Allina* and the advisory opinion."

Many of the hospitals were told they failed the audit because their construction was arranged through their landlord, who contracted with a construction company, not directly between the hospital and the construction company, Vernaglia said. "To me, that is a substantive rule that materially changes the statute, and without any rulemaking under the Administrative Procedure Act," Vernaglia said. "I don't think Congress meant because there are no appeal rights, CMS and its contractors can change the underlying law, at least not without rulemaking, which is what they did with the landlord rule," Ruskin added.

CMS: Lease Could Satisfy Mid-Build Exception

In the new announcement, CMS seems to speak to that. "All documentation submitted by providers, both before and after issuance of the audit determination letters issued in January 2021, will be considered during this review. These reviews will utilize a broadened interpretation of what constitutes a valid construction contract required to qualify for the mid-build exception. As an example, there now may be scenarios in which a lease agreement executed by the provider could satisfy this exception."

Vernaglia said his clients are obviously happy about the development. "It is gratifying that CMS addressed the industry concerns and took this action. It was a good example of government hearing from stakeholders and being willing to change direction," he said. Several members of Congress were also engaged in this issue, including Congressman Bill Keating from Massachusetts, he said.

He noted the letters request the submission of supplemental information in 30 days of the date of the letter, which probably will be received on Sept. 10th. "Previously reviewed material probably doesn't need to be resubmitted, but there is no harm in sending a complete package," Vernaglia said. "I strongly urge providers to carefully review all potentially relevant information and bring it to the attention of the auditors. Note that some providers did not receive notices of denials in January. I wonder if these providers have bad addresses in the system or, perhaps, emails went to mailboxes of former employees. If you are in a hospital that had a denial and you did not get a rescission letter today, I recommend reaching out to the MAC and the auditor, Myers and Stauffer LC."

One question not directly addressed is whether hospitals should return to billing as an excepted department. "I think most hospitals will do so, and anticipate that further instructions from CMS on that point will be forthcoming," Vernaglia said.

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Endnotes

1. CMS, "Mid-Build Exception Audit Rescission Announcement," September 10, 2021, https://go.cms.gov/3BYBTbp.
2. CMS, "Medicare Mid-Build Off-Campus Outpatient Departments Exception Audit Results," fact sheet, January 19, 2021, https://go.cms.gov/2KvikCx.
3. HHS, Office of the General Counsel, "Advisory Opinion 20-05 on Implementing *Allina*," December 3, 2020, https://bit.ly/2X2Zx7G.
4. Azar v. Allina Health Services, No. 17–1484, slip. op. (S. Ct. 2019), https://bit.ly/3ns0hhN.

AG Yanks Brand Memo; DOJ 'May Rely on Relevant Guidance Documents'

In a new memo, Attorney General Merrick Garland gave prosecutors at the Department of Justice (DOJ) the green light to incorporate subregulatory guidance, such as Medicare manuals, into their enforcement actions, reversing a position taken by the Trump administration.[1] But Garland 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."

Garland rescinded the 2018 Brand memo[2] on affirmative civil enforcement (ACE) actions, such as False Claims Act (FCA) lawsuits, and a related 2017 memo from former Attorney General Jeff Sessions, calling them "overly restrictive."[3] The *Justice Manual* also will be updated accordingly.

The Brand memo, written by then-Associate Attorney General Rachel Brand, stated that "the Department should not treat a party's noncompliance

with an agency guidance document as presumptively or conclusively establishing that the party violated the applicable statute or regulation." The scope of the Brand memo in health care was pretty broad. While all laws and regulations are always fair game for FCA cases because they have the force of law, the preambles to regulations, Medicare manuals and almost all guidance from the HHS Office of Inspector General (OIG) were out of bounds in the wake of the Brand memo.

But things will be different now. Garland explained that DOJ attorneys "may rely on relevant guidance documents in any appropriate and lawful circumstances, including when a guidance document may be entitled to deference or otherwise carry persuasive weight with respect to the meaning of the applicable legal requirements."

Reversing the Brand memo may make life more challenging for health care organizations in civil and perhaps criminal cases. "To the extent that defense counsel could push prosecutors away from basing cases on subregulatory guidance, the Garland memo may embolden prosecutors to push back," said Matthew Krueger, former U.S. attorney for the Eastern District of Wisconsin. But he thinks it's more consequential that Garland ordered the revision of sections 1-19.000 and 1-20.100 to 1-20.205 of the *Justice Manual*,[4] which address both civil and criminal enforcement. "People should keep an eye on the upcoming revisions to the *Justice Manual*," Krueger said. "That will become the new, authoritative guidance for prosecutors."

DOJ in July also published an interim final rule with a request for comments on its policies and procedures for the use of guidance documents.[5]

Settlement Negotiations Will Be Affected Most

Former federal prosecutor Pamela Johnston said the retraction of the Brand memo will be felt most in settlement negotiations, when DOJ "has maximum discretion." It's less significant from a purely legal perspective, she said.

"In the last couple of years, we got used to the fact that we didn't need to worry too much about guidance memos and policy pieces and all this administrative gloss that's out there. There's a lot of it in the health care world," said Johnston, with Foley & Lardner in Los Angeles. "You looked at the regulations and the statute and made a decision about what your client's exposure was. Now it becomes a lot more convoluted, and convoluted usually means it will be harder to explain simply to a court in a motion, which therefore increases a client's exposure to increased litigation costs in the coming litigation."

In practice, a prosecutor might point to a statute or regulation as the authority for a false claims lawsuit, but rely on the Medicare manual for interpretation, Krueger said. For example, the "reasonable and necessary" language in Section 1862(a)(1)(A) of the Social Security Act, which is the medical-necessity requirement for Medicare coverage, states that "no payment may be made under part A or part B for any expenses incurred for items or services…not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[6] That's rather broad, and prosecutors may point to specific medical-necessity language from a Medicare manual, local coverage determination or other subregulatory guidance for the service at issue in an FCA case to support their case, said Krueger, with Foley & Lardner.

The Brand memo made room for the continued use of guidance to demonstrate "scienter," or the defendant's knowledge of wrongdoing. "That is a constant," Johnston noted. For example, a defendant's awareness of a manual provision and other subregulatory guidance can prove a defendant was aware of the associated Medicare law or regulation at the heart of the FCA case.

It remains to be seen what the revisions to the *Justice Manual* will look like, but for now, it says that prosecutors can't use guidance for enforcement unless they use it in specified ways, Krueger said. For example, Section 1.20-204 of the *Justice Manual* allows prosecutors to use guidance that's incorporated into contracts like provider agreements. When providers enroll in Medicare, they promise in writing to comply with applicable laws and regulations, including Medicare policy manuals. That turns the participation agreement into a contract between CMS and providers, and Medicare guidance conceivably is part of the contractual relationship.

The message for compliance professionals in the Garland memo is to keep tabs on DOJ policy statements, such as advisory opinions, in addition to the usual slew of regulations and CMS and OIG subregulatory guidance, Johnston said. "Now all the subregulatory guidance matters more."

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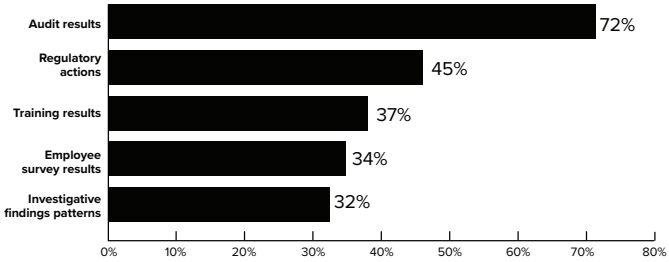
Endnotes

1. Merrick Garland, "Issuance and Use of Guidance Documents by the Department of Justice," memorandum, July 1, 2021, https://bit.ly/3ttxUR2.
2. Rachel Brand, "Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases," memorandum, January 25, 2018, https://bit.ly/3l6BGuH.
3. Jeff Sessions, "Prohibition on Improper Guidance Documents," memorandum, November 16, 2017, https://bit.ly/38QWG4s.
4. U.S. Dep't of Justice, *Justice Manual*, Limitation on Issuance of Guidance Documents, §§ 1-19.000, 1-20.100–1-20.205 (2018), https://bit.ly/3l9F6hr.
5. Processes and Procedures for Issuance and Use of Guidance Documents, 86 Fed. Reg. 37,674 (July 16, 2021), https://bit.ly/3tvo15g.
6. 42 U.S.C. § 1395y.

Chief Compliance Officer 2021 Survey: Compliance Imperatives

Here are some of the findings from the KPMG *2021 Chief Compliance Officer Survey*,[1] which represents responses from 249 chief compliance officers from large global organizations across various industries, including health care, life sciences, banking, capital markets and insurance, industrial manufacturing, consumer markets and retail, technology, media and telecommunications, and energy. Request the survey at https://bit.ly/3tsoNA9.

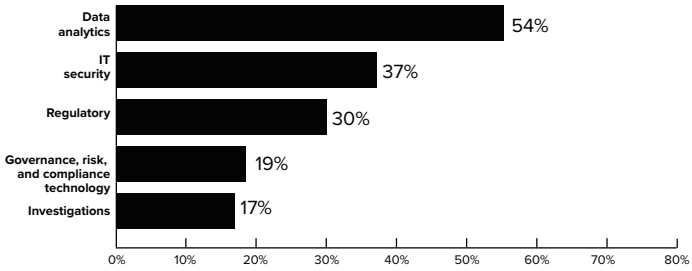
Top metrics used to assess the effectiveness of the compliance program



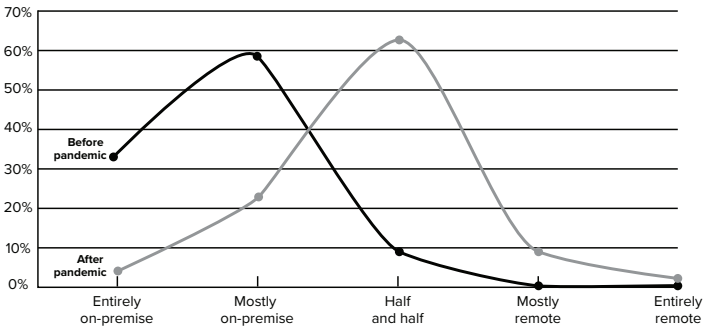
Plans to enhance compliance with data analytics is particularly important in light of the fact that respondents appear to be primarily leveraging reactive metrics, including internal and external audit reports and regulatory actions/inquiries, as a measure of the effectiveness of their compliance departments. When asked to identify the top three metrics that they were using to evaluate the effectiveness of their compliance programs, 72 percent of respondents identified internal and external audit results and 45 percent of respondents identified regulatory actions and inquiries as their primary metrics for evaluation. Comparatively, respondents were much less likely to be leveraging more predictive metrics as top indicators of their compliance department effectiveness. Only 32 percent of respondents are using pattern analysis related to their investigations as a top indicator of compliance, and only 19 percent of respondents identified root cause trends as top metrics for evaluation of compliance effectiveness.

Compliance departments have opportunities to shift their focus from reactive to predictive measures of compliance effectiveness, which will allow them to be more proactive in identifying and mitigating areas of risk and reduce the possibility of costly remediation efforts when compliance issues do arise. In essence, predictive analytics will help compliance to analyze and address issues before they become customer complaints or audit findings. Over the next few years, we expect to see an increased focus on accessing and leveraging appropriate structured and unstructured data, linking operational and behavioral metrics to compliance root cause analytics and actions.

Top areas to enhance compliance with subject matter expertise



Location of compliance department personnel



Skills

With an enhanced focus on automation and technology, including the integration of data analytics and predictive monitoring into various compliance department activities, chief compliance officers (CCOs) recognize that not only do they need to maintain traditional compliance skills and expertise, but they must also supplement their skill sets with subject matter expertise in these new areas. Fifty-four percent of CCOs identified data analytics as an area in which they need to enhance the existing compliance team with subject matter expertise. With a similar focus on refining activities around industry-specific regulations, consumer protection, and cyber/information protection, CCOs also will look to bring in individuals with expertise in IT security (37 percent of respondents) and regulatory experience (30 percent of respondents). CCOs will look to leverage increases to the overall compliance budgets in the next several years to address these current skills gaps.

Source: KPMG 2021 CCO Survey

Endnotes

1. "KPMG 2021 Chief Compliance Officer Survey," KPMG, accessed September 9, 2021, https://bit.ly/3tsoNA9.

CMS Transmittals and *Federal Register* Regulations, Aug. 27-Sept. 9, 2021

Transmittals

Pub. 100-04, Medicare Claims Processing

- Claims Processing Instructions for National Coverage Determination 20.33 - Transcatheter Edge-to-Edge Repair [TEER] for Mitral Valve Regurgitation, Trans. 10985 (Sept. 8, 2021)
- 2022 Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments, Trans. 10971 (Sept. 8, 2021)
- Influenza Vaccine Payment Allowances - Annual Update for 2021-2022 Season, Trans. 10983 (Sept. 8, 2021)
- Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October 2021 Update, Trans. 10969 (Sept. 8, 2021)
- Annual Clotting Factor Furnishing Fee Update 2022, Trans. 10973 (Sept. 8, 2021)
- January 2022 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder, Trans. 10972 (Sept. 8, 2021)

Pub. 100-08, Medicare Program Integrity

- Updates to Chapters 1, 3, 4, 5, 8 and 9 of Publication (Pub.) 100-08, Trans. 10984 (Sept. 9, 2021)
- Changes of Information Involving Certified Providers and Certified Suppliers, Trans. 10975 (Sept. 8, 2021)

Pub. 100-03, Medicare National Coverage Determinations

- Claims Processing Instructions for National Coverage Determination 20.33 - Transcatheter Edge-to-Edge Repair [TEER] for Mitral Valve Regurgitation, Trans. 10985 (Sept. 8, 2021)
- National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds, Trans. 10981 (Sept. 8, 2021)

Pub. 100-19, Demonstrations

- Kidney Care Choices (KCC) Kidney Care First (KCF) - Payment Mechanism (PM) and Benefit Enhancements (BEs) - Implementation, Trans. 10993 (Sept. 2, 2021)

Federal Register

Notice

- Medicare Program; National Expansion Implementation for All Remaining States and Territories of the Prior Authorization Model for Repetitive, Scheduled Non-Emergent Ambulance Transports, 86 Fed. Reg. 48149 (Aug. 27, 2021)

Continuation of effectiveness and extension of timeline for publication of the final rule

- Medicare and Medicaid Programs; Adjustment of Civil Monetary Penalties for Inflation; Continuation of Effectiveness and Extension of Timeline for Publication of the Final Rule, 86 Fed. Reg. 50263 (Sept. 8, 2021)

Hospital Settles Modifier FCA Case

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The JPS case is also the latest FCA lawsuit with a compliance professional as the whistleblower. It raises questions about the implications of the person who is responsible for helping identify problems internally filing a whistleblower complaint when they're rebuffed.

"I've known people who have gone down that road," said Kelly Sauders, a partner in Deloitte Risk & Financial Advisory. One compliance officer spent two years calling attention to problems at their organization, but leadership and counsel didn't seem sufficiently responsive. As the compliance officer's anxiety and depression mounted, along with worry about personal liability, the compliance officer eventually filed the whistleblower lawsuit, which settled, Sauders said. "It takes a toll on someone to do that. This person had to step away from the industry and do something different." In another case, the compliance officer didn't try to resolve problems internally, Sauders said. "There are different stories and different circumstances."

From her work on false claims cases, Sauders has learned the value of paying close attention to people's behavior in interviews and to their history. There are warning signs in the number of times they've complained about the same problem, and leaders are cavalier at their own risk, she said. "Sometimes it's obvious when people are nervous and the way they say certain things," Sauders explained. It's a red flag if the employee expressed concern about an issue several times and retained documentation "and they feel like they have done what they can and start to believe they have personal risk," she said. "Leaders should quickly determine who they can talk to, make sure the person feels fully heard and, within reason, knows that leadership is taking steps to address the concern." Even though compliance officers and senior leaders are often unable to share details of an investigation, they can follow up with the person raising the concern to check in and reassure that actions are being taken. "Organizations that help people be heard and try to share what they can help mitigate their risk," Sauders said.

JPS Whistleblower: Environment 'Grew More Hostile'

Lee, the whistleblower in the JPS case, joined the hospital in 1996 as an executive assistant, and from 2004 through late 2017, when she said she was terminated, Lee was director of compliance and privacy officer, according to the complaint.[4] Around 2015, she and her team began auditing modifiers 25, 59 and XU. Medicare doesn't pay physicians or other providers for E/M services (e.g., 99213-99215) performed on the same patient on the same day as a procedure unless the E/M services are significant and separately identifiable. If they are, providers append modifier 25 and are reimbursed for the E/M code. Modifier 59 "is used to identify procedures/services, other than E/M services, that are not normally reported together, but are appropriate under the circumstances," CMS said.[5] There are four more specific versions (XU, XE, XS and XP), but providers can default to 59, although CMS urges providers to use the "X" modifiers whenever possible.

The JPS compliance team audited a random sample of 450 accounts with modifier 25 and allegedly found a 95% error rate. An audit of 300 records with modifier 59 and 200 with modifier XU found a 70% error rate. The whistleblower "brought her team's findings and concerns to the attention of JPS Health's executive management. Defendant knew that refunds were owed to the United States," the complaint alleged. "JPS Health ignored the problem and failed to repay the amounts owed."

An exhibit to the FCA complaint includes the compliance team's audit findings. For example, for modifier 25, the report states that "Modifier 25 is appended inappropriately to E/M services when bundled service was charged incorrectly." Another exhibit includes the corrective action plan. For example, the health information management department "should review Modifier 25 usage weekly and report results in the quarterly Compliance Committee Coding Audit Review monitor" and "Patient Financial Services should review overpayments for potential repayment to appropriate payers and resubmission of claims if appropriate."

But the whistleblower alleged that six months after sharing the audit results, JPS didn't "adequately implement" the corrective action plans systemwide or repay overpayments. Throughout 2016 and 2017, the whistleblower followed up on the modifier audits, growing more concerned that JPS hadn't repaid the money, the complaint alleged. She said her "work environment grew more and more hostile" and eventually she was terminated because "of her efforts to do the right thing," the complaint alleged.

The JPS attorney said the hospital's "compliance program operated as it should have," and a follow-up audit of the modifiers "reflected the problem had been corrected." During the government's investigation, JPS also voluntarily refunded the $438,673 "related to the potential misuse of modifiers," said Mehta, with Bradley in Tampa

Mehta noted that JPS is "a hospital of last resort, with primarily a Medicaid population." After a very thorough internal investigation, "I can tell you with confidence there was no suggestion anyone at JPS orchestrated or acted intentionally to bill improperly." He said JPS settled Lee's retaliation lawsuit against the hospital.

Some Providers Steer Clear of Modifier 25

Many providers are afraid of using modifier 25, said Valerie Rock, a principal with PYA in Atlanta, Georgia. Long-running external audits have had a chilling effect on billing for E/M services with modifier 25 for some providers. But modifiers don't always lead to overpayments, Rock said. In fact, physicians may be underpaid when they provide E/M services in connection with procedures, such as infusions (e.g., chemotherapy), "if they don't bill it out of fear." But if patients require evaluation of their cancer diagnoses or other diagnoses managed by the physician, it may be appropriate to bill an E/M (e.g., 99213) separately from the chemo, which would warrant the use of a modifier, Rock said.

That won't fly, she cautions, if the medication or diagnosis hasn't changed. "If everything is stable, it will be considered bundled," she noted. However, if there was medical necessity for the review of the conditions assessed, the E/M should be supported and should be appealed if denied, Rock said. The use of modifier 25 in this context was persuasive to an administrative law judge in a recent decision in favor of an oncology center's appeal of its Medicare claim denials.[6] The decision reinforced the fact that providers may bill for chemo administration and E/M services provided to patients on the same day, as long as certain criteria are met.

Rock said the best practice is to bill the E/M service with any minor procedure when documentation supports one of the following: "(1) The visit was planned for review of the condition(s) per standard of care; (2) new or worsening problems are present and are addressed with a change in treatment, diagnostic tests ordered, or referral to specialist based on evaluation; and (3) counseling, coordination of care, and/or other services which qualify for the accounting of time which are unrelated to the procedure performed on the same date, with the documentation of the total time spent performing the qualified services."

'Don't Knock the CIA'

When compliance officers turn into whistleblowers, sometimes it's a reflection of an organization's culture, although that's not always the case, said Andrei Costantino, vice president of integrity and compliance at Trinity Health in Michigan. "Culture starts with leadership, and it's tough if you're reporting concerns to them and they're not addressed," he said. "If leadership embraces compliance, it's evident in the way they respond to issues and seek the compliance team's advice." For example, compliance has a seat at the table at Trinity. When a big project comes up, operational departments want to pick the brains of the compliance team. "A lot of folks reach out to us. That's how we know compliance is valued," Costantino said. "It doesn't happen overnight. There has to be confidence in the compliance team."

Signs of a "bad culture" include a lack of separation between the legal and compliance departments,

Constantino said. "I work closely with legal because they're an integral part of the process. However, you need to balance legal and compliance obligations to ensure regulatory requirements are met," he said. Trinity's chief compliance officer reports directly to the CEO with a dotted line to the audit committee of the board.

Costantino said compliance officers shouldn't be turned off if they're recruited by an organization under a corporate integrity agreement (CIA). "Don't knock the CIA," he said. "It might be a good place to go because it can mean leadership has recognized the importance of compliance, and they are likely to dedicate more resources to the function."

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Endnotes

1. Department of Justice, "Hospital to Pay More Than $3 Million to Settle Whistleblower Suit," news release, August 27, 2021, https://bit.ly/3twJgUC.
2. United States ex rel. Lee v. Tarrant County Hospital District d/h/a JPS Health Network, Civil Action No. A: 18-CV-0376-LY (W.D. Tex.), settlement agreement, August 17, 2021, https://bit.ly/2X57pG2.
3. HHS Office of Inspector General, "Dermatologist Claims for Evaluation and Management Services on the Same Day as Minor Surgical Procedures," Work Plan, August 2021, https://bit.ly/3yYMYaC.
4. United States ex rel. Lee v. Tarrant County Hospital District d/h/a JPS Health Network, Case No. 4:19-CV-00412-P (N.D. Texas, September 21, 2020).
5. CMS, "Proper Use of Modifiers 59 & –X{EPSU}," MLN Fact Sheet, MLN1783722, March 2021, https://go.cms.gov/3ySlJOU.
6. Nina Youngstrom, "Provider Wins $2M Appeal at ALJ Over Modifier 25, Random Sample," *Report on Medicare Compliance* 30, no. 11 (March 22, 2011), https://bit.ly/3tr9tDZ.

NEWS BRIEFS

◆ **Saint Francis Medical Center in Missouri agreed to pay $1.625 million in a civil settlement of allegations it violated the Controlled Substances Act, the U.S. Attorney's Office for the Eastern District of Missouri said Sept. 1.**[1] According to the U.S. attorney's office, Saint Francis employed Farmington physician Brett Dickinson, who allegedly "wrote prescriptions for controlled substances without legitimate medical purposes and outside the usual course of professional practice." The hospital, through Dickinson's actions, "issued invalid prescriptions for opioids such as morphine, hydromorphone, and oxycodone," the U.S. attorney's office alleged. "Dickinson prescribed these opioids to patients simultaneously with muscle relaxers and benzodiazepines." These drugs enhance "the addictive, euphoric effects of opioids and, as a result, are commonly sought-after in combination with opioids by individuals with substance abuse disorders and individuals who seek to use opioids recreationally." Dickinson allegedly prescribed them "while ignoring warning signs of drug diversion or misuse, including aberrant urine drug test results and patients' previous hospital treatment for medical problems related to drug misuse." The hospital cooperated with the government's investigation.

◆ **CMS is recouping the 2019 payments it made to hospitals under the site-neutrality payment policy for off-campus outpatient clinic visits at provider-based departments, according to the *MLN Connects* posted Sept. 9.**[2] CMS will begin reprocessing claims Nov. 1 after its position on site neutrality was upheld by the U.S. Court of Appeals for the D.C. Circuit in July 2020. CMS implemented the site-neutrality policy in the 2019 outpatient prospective payment system regulation, but when it was overturned by a federal district court, CMS refunded the payments to hospitals. Now that CMS has won its appeal, it's taking back the money.

◆ **The Biden-Harris administration said July 9 it will "require COVID-19 vaccination of staff within all Medicare and Medicaid-certified facilities to protect both them and patients from the virus and its more contagious Delta variant."**[3] An emergency regulation that mandates vaccines for nursing home workers will be expanded to hospitals and other facilities as a condition of participation.

◆ **The FBI is warning organizations that Hive ransomware, which uses mechanisms such as phishing emails with malicious attachments and remote desktop protocol to access and move through victim networks, exfiltrate and encrypt files, is on the rise**. This ransomware variant creates significant challenges for defense and mitigation, according to the FBI. Hive ransomware seeks processes related to backups, anti-virus/anti-spyware and file copying and terminates them to facilitate file encryption. The encrypted files commonly end with a ".hive" extension. After compromising a victim network, exfiltrating data and encrypting files, the actors leave a ransom note in each affected directory within a victim's system, which provides instructions on how to purchase the decryption software. The ransom note also threatens to leak exfiltrated victim data on the Tor site "HiveLeaks." The note contains a "sales department" link, accessible through a Tor browser, that enables victims to contact the actors through a live chat. Some victims reported receiving phone calls from Hive actors requesting payment for their files, the FBI said. The initial deadline for payment ranges between two and six days, but the FBI reported that actors have prolonged the deadline in response to contact by the victim company.[4]

Endnotes

1. Department of Justice, U.S. Attorney's Office for the Eastern District of Missouri, "Southeast Missouri healthcare system agrees to pay $1,624,957.67 to resolve allegations that physician wrote invalid prescriptions," news release, September 1, 2021, https://bit.ly/38Zj0Zj.
2. CMS, "Outpatient Clinic Visit Services at Excepted Off-Campus Provider-Based Departments: Payment Update," *MLN Connects*, September 9, 2021, https://go.cms.gov/3zTOhc2.
3. CMS, "Biden-Harris Administration to Expand Vaccination Requirements for Health Care Settings," news release, September 9, 2021, https://go.cms.gov/3CbVViX.
4. "FBI alerts organizations to new ransomware threat," American Hospital Association, August 25, 2021, https://bit.ly/3DE6ahb.