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

Contents

Penn State Health Settles Case About Two Hospitals Billing Same-Day Infusions, E/Ms

Penn State Health (PSH) has agreed to pay $1.252 million to settle allegations that two of its hospitals submitted claims for evaluation and management (E/M) services and infusion services on the same date of service in violation of Medicare rules, the U.S. Attorney's Office for the Middle District of Pennsylvania said March 7.[1] The settlement stemmed from PSH's self-disclosure.

The government alleged that Milton S. Hershey Medical Center billed Medicare Part B for E/M services that weren't supported by medical records on the same day as infusion between January 2015 and March 2019, according to the settlement.[2] The same thing happened with St. Joseph Medical Center between July 2015 and June 30, 2018.

"This issue was about technical, not clinical, billing for evaluation and management (E&M) services rendered on the same day as infusion services at Penn State Health Milton S. Hershey Medical Center and at St. Joseph Medical Center in Reading," PSH said in a statement. "It did not involve the quality of clinical care. The technical component of a service (or bill) covers the fees for the room, equipment, supplies and non-physician work. The services at issue were medically necessary and were correctly furnished to patients. Once the billing error was identified, we immediately took measures to correct our billing. We self-reported the error to the United States Attorney's Office, fully cooperated with the government during its review and repaid the amounts to Medicare and other federal health care payers,

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In Updated DOJ Compliance Guidance, Compensation Is a Lever; One-Word Change 'Slapped Me in the Face'

The change of one word in the Department of Justice's (DOJ) new version of the *Evaluation of Corporate Compliance Programs* is a potential bombshell in the eyes of Kim Danehower, corporate compliance officer at Baptist Memorial Health Care Corp. in Nashville, Tennessee.[1] Although there are also significant additions about "compensation structures" and messaging platforms in the document, which was revised in early March, she took note of DOJ's language switcheroo in the section on whether a compliance program is well-designed.

The 2020 version stated 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 pressuring employees to engage in misconduct."

The updated version replaces "pressuring" with "permitting" and in the process holds managers and supervisors accountable for misconduct that happens on their watch. "That one slapped me in the face," Danehower said. She thinks this single word will reshape training and prompt adjustment in policies at the health system, including its disciplinary policies. "Compliance officers need to stop and take note."

continued

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DOJ's *Evaluation of Corporate Compliance Programs* is guidance for white-collar fraud prosecutors who assess the effectiveness of compliance programs when deciding whether to file charges against a corporation and what the charges should be. The document, first published in 2017 and updated initially in 2020, also is used by compliance officers to benchmark their organization's compliance program. It modifies the Principles of Federal Prosecution of Business Organizations in the *Justice Manual*.

In this update, DOJ for the first time said prosecutors may consider whether organizations use compensation to encourage compliance or punish noncompliance, including "recoupment or reduction of compensation due to compliance violations." Prosecutors also are instructed to review "a corporation's policies and procedures governing the use of personal devices, communications platforms, and messaging applications, including ephemeral messaging applications."

The landmark changes on compensation and messaging platforms fulfill a pledge Deputy Attorney General (DAG) Lisa Monaco made in a September 2022 memo to link them to cooperation credit in criminal cases, said Matthew Krueger, former U.S. Attorney for the Eastern District of Wisconsin.[2] "Both of these things are now squarely called out as areas to inquire about in effectiveness reviews but they're relatively new areas."

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Hitting people in their wallets for noncompliance is another expression of DOJ's recommitment to holding allegedly culpable individuals accountable in corporate criminal cases, said attorney John Lawrence, with K&L Gates in Research Triangle Park, North Carolina. "On the criminal side often this type of guidance informs the civil side, particularly in health care," he noted. "DOJ has clearly put out that this is an expectation." Before organizations use compensation as a corporate-culture lever, however, they should consider the potential for lawsuits and other unintended consequences, the attorneys said.

DOJ also is attempting to keep up with changing technologies, Lawrence explained. The updated guidance reflects DOJ's realization that it's "having challenges accessing communications that might be key to investigations because they're happening outside email," he said. "It's a critical preservation piece."

Compensation Structures 'Can Deter Risky Behavior'

According to the revised guidance, DOJ draws a straight line between compensation schemes and compliance culture. "Compensation structures that clearly and effectively impose financial penalties for misconduct can deter risky behavior and foster a culture of compliance. At the same time, providing positive incentives, such as promotions, rewards, and bonuses for improving and developing a compliance program or demonstrating ethical leadership, can drive compliance," DOJ stated. "Prosecutors should examine whether a company has made working on compliance a means of career advancement, offered opportunities for managers and employees to serve as a compliance 'champion', or made compliance a significant metric for management bonuses." Prosecutors are instructed to consider five factors when assessing whether compensation and consequence management indicate a positive compliance culture.

In tandem with the updated *Evaluation of Corporate Compliance Programs*, Monaco announced in a March 2 speech the first pilot program on compensation incentives and clawbacks.[3] It has two parts: (1) every corporate resolution with the DOJ criminal division will require the corporation to have "compliance-promoting criteria within its compensation and bonus system" and (2) the criminal division will reduce fines on corporations in a criminal resolution if they try to claw back compensation from culpable executives and employees. The corporation is then allowed to keep the money it clawed back.

Krueger noted the update is "high-level guidance" and doesn't dictate specific ways for companies to claw back compensation. "It's uncharted territory for DOJ," he added. In fact, "one would question whether DOJ has the experience to do this." In deference to that experience

gap, DOJ has left companies space to experiment with ways to slap hands for noncompliance, said Krueger, with Foley & Lardner LLP in Milwaukee, Wisconsin.

He cautions organizations to tread carefully with compensation consequences for misconduct. "Clawing back executive compensation is a big deal," Krueger said. "People need to go slowly here and work with an executive compensation expert before they add clawback provisions in their agreements."

In fact, Lawrence suggested a leadership sit-down that includes compliance, legal, human resources and other stakeholders to consider the feasibility of clawbacks for noncompliance. Would they violate laws or regulations? What's the risk of inviting litigation with the managers and supervisors who would be penalized? "All of that has to be weighed against the likelihood of enforcement actions," Lawrence said.

Wading Into 'Ephemeral' Messaging Apps

As expected, the *Evaluation of Corporate Compliance Programs* addresses messaging apps. "In evaluating a corporation's policies and mechanisms for identifying, reporting, investigating, and remediating potential misconduct and violations of law, prosecutors should consider a corporation's policies and procedures governing the use of personal devices, communications platforms, and messaging applications, including ephemeral messaging applications. Policies governing such applications should be tailored to the corporation's risk profile and specific business needs and ensure that, as appropriate and to the greatest extent possible, business-related electronic data and communications are accessible and amenable to preservation by the company," DOJ said in its update. "Prosecutors should consider how the policies and procedures have been communicated to employees, and whether the corporation has enforced the policies and procedures on a regular and consistent basis in practice."

This is a sea change. "DOJ is saying loud and clear it's not going to accept at face value that a company can't account for these types of messages," such as texts and WhatsApp, Krueger said. Organizations that allow people to bring their own devices to work now are staring at a compliance and IT problem, he noted. Do they have a way to preserve business-related communications on devices that don't go through company servers? "This creates pressure on people to review policies on how employees communicate," Krueger noted. Even with policies requiring employees to communicate on certain channels, employees may text on others. Unless organizations audit and monitor this area and discipline employees accordingly, they risk DOJ consequences in the event of an investigation, he said.

Baptist Memorial Health Care Corp. is analyzing the clawback provisions and working toward formalizing compliance metrics as part of its executive metrics, Danehower said. "We try to bake compliance into everything we do." But she was a little stunned at the details of the updated DOJ document. "They have put a lot of specific information in it they didn't have before."

Contact Krueger at mkrueger@foley.com, Lawrence at john.lawrence@klgates.com, and Danehower at kim.danehower@bmhcc.org. ✧

Endnotes

1. U.S. Department of Justice, Criminal Division, *Evaluation of Corporate Compliance Programs*, updated March 2023, https://bit.ly/2Z2Dp8R.
2. U.S. Department of Justice, Office of Deputy Attorney General Lisa O. Monaco, "Further Revisions to Corporate Criminal Enforcement Policies Following Discussions with Corporate Crime Advisory Group," memorandum, September 15, 2022, https://bit.ly/3BqcDfk.
3. Lisa O. Monaco, "Deputy Attorney General Lisa Monaco Delivers Remarks at American Bar Association National Institute on White Collar Crime," speech, Miami, Florida, March 2, 2023, http://bit.ly/3ZFDCie.

Hunting and Dining: Kickbacks to Physicians Led to $43M Verdict in FCA Trial

At the heart of the False Claims Act (FCA) trial of Cameron-Ehlen Group Inc., doing business as Precision Lens (PL), and its owner Paul Ehlen were tales of the pheasant hunting trips, swanky dinners and other goodies they bestowed on ophthalmologic surgeons. After six weeks, the government persuaded the jury that the treats were kickbacks to induce the ophthalmologic surgeons to order intraocular lenses (IOLs) distributed by the defendants, the U.S. Attorney's Office for the District of Minnesota said Feb. 28.[1]

The jury concluded PL and Ehlen submitted $43 million in false claims to Medicare because the IOLs, which are used in cataract surgery, were tainted by the kickbacks. The gut punch doesn't stop there: PL and Ehlen are facing penalties of $400 million to $800 million, highlighting the reason why many health care defendants settle cases, said attorney Allison DeLaurentis, with Goodwin in Philadelphia.

"The fact that it went to trial is one of the most interesting things about this case," she noted. "When parties settle False Claims Act cases, they negotiate the single damages and a multiplier. Because they went to trial, the government will pursue treble damages and statutory penalties."

The jury determined the kickbacks to physicians caused the submission of 64,575 false claims to Medicare from 2006 to 2015. When all is said and done, that amount

will jump to more than $120 million because of treble damages and per-claim penalties ranging from $5,500 to $11,000, depending on the year the conduct occurred and the claims were submitted, DeLaurentis said.

The case was set in motion in 2015 by a whistleblower, Kipp Fesenmaier, who worked for Sightpath Medical Inc., PL's corporate partner, according to the complaint in intervention filed by the Department of Justice (DOJ).[2] The complaint alleged a scheme to pay kickbacks, primarily to ophthalmologists, to induce them to use products supplied by PL and Sightpath Medical. To hide their behavior, PL and Ehlen used a "slush fund" in part to pay for "lavish hunting and fishing trips with physicians."

PL, which is headquartered in Bloomington, Minnesota, distributes intraocular lenses, viscoelastics and other products related to ophthalmic surgeries, and Ehlen is its majority owner. PL sells them to places that perform the surgeries, including outpatient hospital clinics, ambulatory surgery centers and physician clinics, according to the complaint. Sightpath sells everything a practice needs to do cataract and refractive surgeries "on a mobile basis," including a surgical technician and supplies.

Because PL sold IOLs and other products for Abbott Medical Optics (AMO) and Bausch and Lomb (B&L), it had an incentive to influence physicians to buy those products, the complaint alleged. And they wanted to sell enough to keep the manufacturers happy, so they'd continue to do business with PL. Sightpath also bought its AMO and B&L equipment through PL.

Adventures for Free or Less Than Fair Market Value

As a distributor, not a manufacturer, PL had other ways to compete in the market, such as building good relationships with customers. They knew ophthalmologists doing the eye surgeries "are quite influential in determining which products to use," the complaint stated. To persuade ophthalmologists to buy the products they distributed, PL and Ehlen "took physicians on lavish trips in order to persuade them to work with PL and Sightpath, and also facilitated trips that were used to induce doctors to use products distributed by PL and Sightpath," the complaint said. In some cases, the trips were free and in others, physicians didn't pay fair-market value. A similar thing happened with PL providing frequent flyer miles to physicians to induce them to work with PL and Sightpath. PL also provided "expensive meals and entertainment," the complaint said.

DOJ described how ophthalmologists enjoyed outdoor adventures courtesy of PL and Ehlen. He belonged to Stock Farm Club, an exclusive private club in Montana. It offers upscale hunting, fishing and golfing, as well as gourmet meals and luxury accommodations. Ehlen also was a member of Sutton Bay in South Dakota, another exclusive club that offers an invitation-only hunting, fishing, golf and dining experience. The list goes on, with Ehlen's family owning Big Narrows Resort in Lake of the Woods, Ontario, Ehlen having an ownership interest in White Lake, South Dakota, and Ehlen owning a piece of private planes.

Ehlen and PL took several physicians to Stock Farm Club, Sutton Bay, Big Narrows Resort and White Lake from 2004 to 2014, often transporting them on Ehlen's private planes. Many times, the physicians paid nothing or a nominal amount of money for the trips. To finance them, PL used a slush fund, the complaint alleged. For example, Ehlen regularly took groups of physician customers pheasant hunting in White Lake, usually flying them on a private plane.

PL Allegedly Signed AdvaMed Code

PL and Ehlen allegedly were aware it was improper to provide remuneration to physicians in the form of trips and other incentives. "Defendants knew that compliance with the AKS [i.e., Anti-Kickback Statute] was a condition of payment and a material requirement for receiving Medicare and Medicaid reimbursement," the complaint alleged. "In 2004, Ehlen stated that the AKS prohibited PL from providing inducements to ophthalmologists."

Meanwhile, the Advanced Medical Technology Association (AdvaMed), an industry trade group, in 2009 published an updated *Code of Ethics on Interactions with Health Care Professionals*. Among other things, the AdvaMed code states that "a Company should not provide or pay for any entertainment or recreational event or activity for any non-employee Health Care Professional. Such activities include, for example, theater, sporting events, golf, skiing, hunting, sporting equipment, and leisure or vacation trips." In the wake of the update, AMO required PL to sign agreements to comply with the code, the complaint alleged. "PL did so, and required many of its owners and employees to individually sign documents indicating that they would comply with the AdvaMed code," according to the complaint. PL also independently held meetings about the AdvaMed code and agreed to restrict marketing. For example, PL said it would cancel hunting and fishing trips and golf/sport tickets. "PL discussed at a 2011 executive meeting that if PL paid certain fees on behalf of PL customers, it could create a problem under AdvaMed and the AKS," the complaint alleged. But the timing indicates the trips and other goodies allegedly continued after these dates, according to the complaint.

Some of the other defendants in the case didn't get off easy. Sightpath Medical and TLC Vision Corporation (collectively Sightpath) and their former

CEO, James Tiffany, agreed to pay $12 million to settle false claims allegations in connection with the case.[3] And physician Jitendra Swarup paid $2.9 million to settle claims he accepted kickbacks.

DeLaurentis noted there are legitimate reasons for health care professionals to have peer-to-peer discussions about products and medical advances in settings sponsored by pharmaceutical and medical device manufacturers, as long as the intent behind the interactions is not to induce purchases, and the nature of the interactions is consistent with the HHS Office of Inspector General's 2020 Special Fraud Alert on speaker programs and industry guidance.[4] The fraud alert warned that speaker programs pose a risk under the AKS, depending on the facts and circumstances and the intent of the parties, and listed suspect characteristics of speaker programs.

DeLaurentis explained they can be "an appropriate activity as long as you're going about it in the right way." The most salient question is "the rationale behind it," she said. Is there a new product, indication or development and you need to engage experts in the field? Who is speaking and attending and why? "If your intent is appropriate and you are complying with the fundamental principles articulated in the special fraud alert, they are an appropriate activity," she said.

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Endnotes

1. U.S. Department of Justice, U.S. Attorney's Office for the District of Minnesota, "Federal Jury Finds Precision Lens and Owner Paul Ehlen Liable for Paying Kickbacks in Violation of the False Claims Act," news release, February 28, 2023, http://bit.ly/3ZTjAAl.
2. Complaint in intervention, United States v. Cameron-Ehlen Group, Inc., Civil No. 13-CV-3003 PAM/FLN (D. Minn. 2018), http://bit.ly/3JtPXQW.
3. U.S. Department of Justice, U.S. Attorney's Office for the District of Minnesota, "United States Recovers More Than $12 Million In False Claims Act Settlements For Alleged Kickback Scheme," news release, August 21, 2017, http://bit.ly/3Jqlpzh.
4. U.S. Department of Health & Human Services, Office of Inspector General, "Special Fraud Alert: Speaker Programs," November 16, 2020, https://go.usa.gov/x7m3B.

Compliance Tensions Emerge With Data Retention, Privacy Requirements

Organizations are taking a closer look at their data retention policies and how those policies intersect with requirements for data privacy and minimization as regulators in the United States and abroad focus more on the sometimes-conflicting compliance expectations, two consultants said.

"Privacy is driving this whole idea of data minimization, and it's driving organizations to create data retention policies," said Mark Diamond, president and CEO for strategic information governance consulting firm Contoural. "We're seeing a lot of organizations struggling with this issue—quite frankly, trying to do the right thing but making some mistakes," Diamond said at a Feb. 1 webinar sponsored by the Society for Corporate Compliance and Ethics.[1]

Still, Kerry Childe, senior consultant for Contoural, noted that U.S. data protection laws also contain data minimization requirements, even though "these things have not been enforced a lot. Still, we're starting to see regulators pay more attention to this, and as a result, we're starting to see companies pay more attention."

Some of the impetus is coming from Europe, where the enforcement of data minimization is driving new looks at existing processes, Diamond said. In Europe, under the General Data Protection Regulation (GDPR), companies have reported that terminated employees were making broad data requests either for discovery purposes (which are of limited use in Europe) or because of the cost of searching and producing the information, he said.

In one case, Diamond explained, their client heard from its outside counsel that terminated employees were doing this to extract more in settlements. He worried this will happen over here (e.g., in California). "Companies that don't have control over their personal information or over retained personal information put themselves at risk," Diamond said.

Eight Steps to Creating a Policy

Creating a personal information data retention policy to meet privacy requirements is more difficult than it sounds, with companies stuck in a cycle of trying to reconcile conflicting requirements, Diamond said. "Organizations don't understand how to deal with the conflict, and it's not just regulatory conflict, but it's also business value."

Business records generally must be kept for some period of time, which is defined by the law and by a company's records retention schedule, Childe said. In many cases, the company's business need for information is longer than the legally mandated retention period, she said. "In other words, the business utility of that information lasts longer than the legal utility."

Most organizations already have a records retention policy and schedule dictating how long they must keep information, Childe said. However, organizations need a data retention policy specifically for personal information, she said. Personal information goes through the information lifecycle like other information, but "many privacy laws require that personal information, unlike other information, be kept 'no longer than necessary' and be able to be deleted on demand by the data subject," Childe explained.

To keep business records and information for as long as the business utility exists, but to only keep personal information "no longer than necessary" and be able to delete it on demand, organizations should use their existing records retention schedule, she said. "Just as you work through the business and legal need for other records, do the same for your records containing personal information."

"We don't care what you call it," Childe said. "You can call it a records retention schedule, you can call it a data retention policy. The issue is making sure that you're clearly documenting what you have, how long you're keeping it, and then in some cases also why" you're keeping the data.

Diamond added: "We don't like separate policies because that doesn't reduce conflict. If we know there's inherent conflict, you use the policy to make some decisions and document those decisions on how you manage that conflict." Similarly, he said, having privacy or record retention in different business silos actually raises the risk for noncompliance.

Eight Steps for a Combination Policy

Diamond and Child listed eight steps for organizations to follow to create a combination records-enabled data retention policy and privacy-enabled records retention schedule:

1. Include an inventory of all information types
2. Apply legal and regulatory retention requirements
3. Determine the business value of records
4. Address records containing personal information
5. Include disposition requirements
6. Identify legitimate business need for the retention period
7. Consider the need for legal holds
8. Obtain consensus with the business

As part of this process, organizations must understand what personal information they are holding, Diamond said. "Once we understand the personal information, we have to figure out how we are going to manage and be able to dispose of that information."

If the personal information carries a legitimate business use that holds value longer than the retention period of the personal information, then organizations must identify that use and consider whether the longer retention is reasonable and in line with the purpose for which the information was collected, he said. Organizations also must document the legitimate need for the retention, Diamond said. "Many times, business units will say, 'I need to save everything forever,'" Diamond said. "Um, no. Let's identify what the real business value is."

The privacy-enabled records retention schedule must list the records that contain personal information, and identify a legitimate business need for their retention, Childe said. "We're very clearly seeing that it's becoming more important that you document why you're taking these steps," she explained. "And so including those statements in your policy [and] including those statements in your retention schedule is becoming more important. You don't have to be perfect, but you do need to recognize where the questions are coming from and how to appropriately respond to them."

Diamond said organizations that employ "a reasonable process" for records retention and personal information should be compliant across all jurisdictions. "We're making the argument today that general business justification is going to apply to just about all the privacy laws. As long as you have a reasonable process, we think you're going to be compliant across the board."

Retained personal information that doesn't have a record-keeping requirement will carry a larger burden for having a business justification for the retention, Diamond said. That being said, "do not let perfect be the enemy of good," he explained.

Organizations also need to demonstrate compliance with the regulations, Diamond said. Regulators measure compliance by looking at what an organization said it would do in its policies and schedules, how that organization accomplished what it said it would do using its tools, processes and file plans, and how the organization checked whether it accomplished what it said it would do, via its training, surveillance, metrics tracking, reporting, audits and updates, he said. Many organizations get stuck at that first step—policies and schedules, Diamond said.

Common Mistakes That Organizations Make

There are several mistakes that organizations commonly make when they're trying to adopt their privacy policies and record retention policies, Diamond said.

The first is aggressive deletion, he said. "We understand the frustration of employees retaining too much in email, some of which contains personal information. And they save it forever, and it grows and grows," Diamond said. "But here's the problem: when you do aggressive deletion—when you say, 'We're going to delete all the email after 60 or 90 days, or we're going to find files with personal information and just delete it'—your behavior drives a counter behavior. And that counter behavior is something called underground archiving." The risk is driving files "into places that are less secure, more open to breach, and quite frankly, more difficult to find and delete," Diamond said.

Another common mistake organizations make is to overlook different types of media, Diamond said. "We need to look across all the different media," he said, including email, instant messages and text messages, wikis, social media, files, images and various databases. ✧

Endnotes

1. Mark Diamond and Kerry Childe, "Creating a Data Retention Policy to Meet Privacy Requirements," webinar, February 1, 2023, https://bit.ly/3X8RJdH.

Penn State Health Settles Case

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so the matter is now settled. We have taken steps to prevent this from happening in the future."

PSH declined to elaborate, and the settlement is vague. Although the press release doesn't use the phrase "False Claims Act," the settlement "releases PSH from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act." Of the settlement amount, $835,108 is restitution. The fact there's a multiplier indicates it's not a straight repayment, although PSH apparently got credit for its self-disclosure.

The settlement seems to implicate the use of modifier 25 in a hospital setting. Medicare doesn't pay physicians or other providers for E/M services performed on the same patient on the same day as a procedure unless the E/M services are significant and separately identifiable. When the E/M services are significant and separately identifiable, providers append modifier 25 and receive additional reimbursement. Misunderstanding and/or misuse of the modifier has made it a longstanding billing compliance risk.

"It's still a major risk," said Steve Gillis, director of compliance coding, billing and audit at Mass General Brigham in Boston. "There's grayness when you should bill an E/M with a procedure and when you shouldn't." Compliance depends on the services performed and their documentation.

CMS has instructed hospitals to bill Medicare for technical E/M services based on their own E/M criteria and to use the G0463 code, Gillis said. The code replaces the three levels of E/M service for low, medium and high levels of care in the hospital. "Now it's basically whether you're justified in billing a significant and separately identifiable E/M service," he explained. Most procedures like infusion include an element of the E/M, such as nurses taking vital signs, Gillis said. But if the nurse or physician is educating patients about the drug they're receiving and its side effects, that may be significant and separately identifiable. "If you look at patients coming in every month or two and you're providing the same education and billing separate E/Ms, that's where the medical necessity of that separately identifiable E/M component is questionable," he said.

There's some CMS guidance in the Medicare Claims Processing Manual about modifier 25 and drug administration. As one Medicare administrative contractor summarized on its website, "It may be appropriate to append modifier 25 to an E/M service when a separately identifiable, medically necessary service has been provided in addition to a procedure provided on the same date. The physician/NPP's documentation must indicate that on the day a procedure (identified by a CPT code) was performed, the patient's condition required a significant, separately identifiable E/M service. Typically, an 'interval history' with pertinent, focused exam is already a portion of the pre-service work of performing any procedure and not separately billable. In contrast, a separately billable E/M service does not relate directly to the actual performance of the procedure."[3]

The MAC noted that it's inappropriate to add modifier 25 to an E/M for use of a room, technician time, nursing care, assessment, monitoring or for routine "interval history" of "is everything OK" since the previous visit/treatment when there isn't another, more significant service. Suppose the patient arrives for chemotherapy. "The nurse completes an assessment including vital signs, confirms there are no new or interval issues; starts the treatment and continues to periodically monitor the patient during the treatment. A separately identifiable E/M service has not been provided and should not be billed with modifier 25," the MAC stated.

CMS Transmittals and *Federal Register* Regulations, March 3-March 9

Transmittals

Pub. 100-03, Medicare National Coverage Determinations

- Technical Revisions Only to the National Coverage Determination (NCD) Manual, Trans. 11,892 (March 9, 2023)

Pub. 100-08, Medicare Program Integrity

- Second Policy Change Request (CR) Regarding Implementation of the Provider Enrollment, Chain and Ownership System (PECOS) 2.0, Trans. 11,891 (March 9, 2023)

Pub. 100-20, One-Time Notification

- Upload of Notice Program Reimbursement (NPR) Letters, Interim Rate Reviews, and Tentative Settlement Documentation into the System for Tracking Audit and Reimbursement (STAR), Trans. 11,899 (March 9, 2023)

Guidance May Not Always Serve You in Real World

Richelle Marting, an attorney and certified coder in Olathe, Kansas, cautions providers against relying on Medicare manual provisions and coding guidance that indicate a different diagnosis is not necessarily required to bill an E/M and other procedure or service on the same date. Although the guidance states the E/M diagnosis may be the same as the procedure/service (e.g., infusion), "in reality, I find during audits or investigations involving modifier 25 that it's difficult to support separate E/Ms for the same diagnosis and providers often haven't documented well how the E/M is significant and separately identifiable enough to warrant separate payment," Marting said.

To get a better handle on E/M services that are appropriate to report separate from an infusion on the same day, she recommends reviewing American Medical Association Resource Utilization Committee meeting minutes "to understand all the steps and services that went into the valuation of an infusion code." They shed light on what's included in various infusion services (e.g., clinical staff time to prep the patient). "I use that resource a lot," Marting said. "I need to have a sense of what code is going into the payment and the value of that code before determining whether an evaluation and management service performed the same day is significant and separately identifiable."

Modifier 25 audits are not uncommon. UNC Health in North Carolina recently had the pleasure of a Targeted Probe and Educate (TPE) review of several hospitals that billed for E/M services on the same date of services as hyperbaric oxygen therapy (HBOT), which itself is a target of Medicare auditors, said Patrick Kennedy, executive system director of hospital compliance. "The only thing we could deduce" was that Palmetto, the MAC running TPE, was focused on wound care provided at the hospital outpatient departments also providing HBOT, he said. In light of the TPE, he and his team examined the wound care providers' documentation, including the history and physical and patient assessment, to determine whether the patients had a condition that was separate and distinct from the condition that led to the HBOT. "It wasn't an issue," Kennedy said. "We had a legitimate separate service." But the experience was a reminder for providers not to use modifier 25 cavalierly.

"If you're simply charging E/Ms and infusion automatically and applying modifier 25, you could run into some issues," Kennedy noted.

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Endnotes

1. U.S. Department of Justice, U.S. Attorney's Office for the Middle District of Pennsylvania, "Penn State Health Agrees To Pay $1,252,662.28 To Settle A Voluntary Disclosure Related To Milton S. Hershey Medical Center (HMC) And St. Joseph Medical Center (SJMC)," news release, March 7, 2023, http://bit.ly/3Lteze3.
2. Settlement agreement, United States v. Penn State Health, March 7, 2023, http://bit.ly/3Ld06mi.
3. Noridian Healthcare Solutions, "E/M Services and Drug Administration Billing," last updated March 3, 2020, http://bit.ly/41XWWZx.

NEWS BRIEFS

◆ **The HHS Office of Inspector General (OIG) said March 10 that the flexibility it provided in connection with the COVID-19 pandemic will expire at the end of the day May 11, when the public health emergency (PHE) is over.**[1] OIG described the enforcement discretion it has exercised over the past three years. For one thing, OIG told physicians and other practitioners they wouldn't face administrative sanctions for waiving patient copays for telehealth services. OIG also said it "would exercise its enforcement discretion not to impose certain administrative sanctions for certain remuneration related to COVID-19." And over the course of the PHE, it has answered questions from the industry about "how OIG views certain arrangements that were directly connected to the public health emergency and implicated OIG's administrative enforcement authorities, including the Federal anti-kickback statute and Beneficiary Inducements CMP." That will change May 11. "As stated in the FAQs, the informal, nonbinding feedback provided "applies only to arrangements in existence solely during the time period subject to the COVID-19 Declaration."

◆ **Lakeland Regional Medical Center (LRMC) in Lakeland, Florida, has agreed to pay $4 million to settle allegations it donated money to a local unit of government to improperly fund the state's share of Medicaid payments to the medical center, the Department of Justice (DOJ) said March 3.**[2] This is the latest in a series of settlements focusing on rules governing "bona fide" provider-related donations to the state or a local unit of government. In a nutshell, a bona fide donation doesn't have a direct or indirect relationship to the Medicaid payments received by the provider. If they aren't bona fide, the payments may set off a chain reaction that ends in extra Medicaid payments to the provider. In this case, DOJ alleged that LMRC made non-bona fide donations between October 2014 and September 2015 to Polk County, Florida, by paying some of the county's financial obligations to other health care providers. "These donations were designed to increase Medicaid payments received by LRMC, by freeing up funds for the County to make payments to the State as the state share of Medicaid payments to LRMC," DOJ alleged. The federal government matched the state share before it was returned to LRMC in the form of Medicaid payments.

Endnotes

1. U.S. Department of Health & Human Services, Office of Inspector General, "OIG's COVID-19 Public Health Emergency Flexibilities End on May 11, 2023 Upon Expiration of the COVID-19 Public Health Emergency Declaration," last accessed March 10, 2023, http://bit.ly/3JsuaZO.
2. U.S. Department of Justice, Office of Public Affairs, "Florida's Lakeland Regional Medical Center Agrees to Pay $4 Million to Settle Common Law Allegations for Impermissible Medicaid Donations," news release, March 3, 2023, http://bit.ly/3JuTQF5.