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

Contents

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At CMS's Behest, Hospitals Self-Audit Unreported Device Credits; Deadline Is Close

Some hospitals are facing a late August deadline to pay Medicare back for unreported cardiac device credits in the wake of a national HHS Office of Inspector General (OIG) audit that found significant noncompliance.[1] CMS has sent some hospitals letters instructing them to self-audit claims for procedures with replaced cardiac devices where manufacturers had given them credits and, where appropriate, return overpayments to Medicare. One caveat: before, during or after OIG's audit, hospitals may have refunded overpayments, a compliance officer said. They should check where they stand before a duplicative self-audit, although hospitals may find some unreported device credits are always lurking.

Meanwhile, hospitals should be poised for more self-audit requests after OIG audits, said Steve Gillis, director of compliance coding, billing and audit at Mass General Brigham in Boston. "This is a theme we have been seeing with CMS." It happened, for example, when Medicare administrative contractors (MACs) demanded overpayments caused by noncompliance with the post-acute care

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Credible Information Is Heart of 60-Day Rule; OIG: Self-Disclosure Pauses the Clock

When a hospital realized it had been billing for annual wellness visits without documentation of opioid and substance use screening,[1] it wasn't a heavy lift to calculate how much to repay Medicare in time to meet the deadline of the 60-day overpayment refund rule. The trail of breadcrumbs was followed to the effective date of the requirement and the hospital's failure to communicate it to physicians and nonphysician practitioners and/or build prompts in electronic medical records to capture documentation. "Sometimes the 60-day rule is easy," the compliance officer said. But often that's not the case, as the hospital is finding with clinical validation of diagnoses that drive MS-DRGs. "Where it is harder is those areas that are grey and not so straightforward." The compliance, health information management and legal departments are digging into diagnosis upcoding that could have caused higher-paying MS-DRGs. It's expected to take six months, and when the picture comes into focus, the 60-day countdown will begin, according to the compliance officer, who prefers not to be identified.

That captures one of the perennial challenges of compliance with the Medicare 60-day rule, which requires providers to return overpayments 60 days after identifying and quantifying them. The 2016 regulation[2] interpreting the 60-day rule, which was created by the Affordable Care Act, requires providers to use reasonable diligence to identify overpayments by doing proactive compliance activities to monitor for overpayments and investigating potential overpayments in a timely manner. CMS defined "timely" as within six months of receiving "credible information" about an overpayment. Providers must look back six years when they find errors themselves or get credible information of overpayments.

continued

"Understanding how to define credible information is the key to understanding this entire rule," said attorney Andrew Ruskin, with K&L Gates in Washington, D.C. Credible information "is the doctrine of whether you have the reasonable belief you might have an overpayment." That and other aspects of the 60-day rule, including when to start the clock, should be set forth in a policy, experts say. They also recommend a defined method for investigating credible information.

The stakes are high. Refunding overpayments under the 60-day rule is a litmus test of an effective compliance program. It's also a feature of the HHS Office of Inspector General's (OIG) provider compliance audits and a tripwire for False Claims Act violations if providers knowingly hang onto Medicare money they're not entitled to.

"We talk about this pretty frequently when we get in situations of 'do we have an overpayment or potentially an overpayment?'" said Patrick Kennedy, executive director of hospital compliance at UNC Health in North Carolina. "We immediately say, 'At what point on the spectrum are we at?' If it's a single account based on a patient complaint, for example, and through that review we have identified we were overpaid, that's pretty easy, and we will refund quickly and hit the 60-day mark easily." But life gets messier if, for example, an audit from UNC's work plan yields a high error rate based on a random sample of 30 claims. "These situations are not as clear cut because there are different aspects of the audit results and any subsequent audits we need to consider," Kennedy said. At this point, the work begins on quantifying the overpayment and perhaps extrapolating it because the total overpayment amount is still an unknown. "We can't refund the overpayment until we know how much it is. In other words, until we've identified it," he noted.

The 60-day rule has been useful because it helps compliance professionals light a fire under operations people who sometimes drag their feet, Kennedy said. "We're in a better position because of it. We are on the clock here. We have to make a repayment." He doesn't think there are major challenges understanding or complying with the 60-day rule. "Six months to investigate could be a crunch if there is a really big issue, but generally speaking, we have not had a challenge getting it done in six months."

OIG: Self-Disclosure Temporarily Stops the Clock

In CMS's eyes, anything from the government could qualify as credible information of an overpayment, including Medicare cost report adjustments, Targeted Probe and Educate reviews, OIG reports and the Program for Evaluating Payment Patterns Electronic Report (PEPPER).

Findings from internal audits also could be credible information. Presumably that's more than a single improper claim, Ruskin said. If you learn "a nucleus of facts" that gives you a reasonable belief that a pattern of error is emerging, a claims review should follow, he said. Were specific procedures or clinicians involved? Did the billing error only affect certain patients? Did the error correlate to a timeframe when a specific person (e.g., coder, clinician) was employed? "You get to the point where you have a command of the facts and can define your universe and do a random sample review because the universe is properly defined," Ruskin said. Then take your findings and ask more questions, he suggested.

"If you have an overpayment policy that says we only extrapolate if the error rate is 5% or 10% and it's an overly large universe, you may have too much noise and fall below the error rate when it may be a systemic problem and you won't catch it because the net was cast too wide," he explained. That's why he thinks the definition of credible information is at the heart of the 60-day rule.

When providers are unable to nail down a particularly complex matter in time, there's another way to minimize their exposure under the 60-day rule. "The HHS Office of Inspector General's Self-Disclosure Protocol is a good option, because the 60-day reporting obligation is suspended as long as the submission is timely made," said Susan Gillin, chief of the OIG's Administrative and Civil Remedies Branch. "Providers should be mindful that OIG

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does require that submitters calculate a damages figure within 90 days of submitting a disclosure, however."

Lab Error Repayment Was Laborious

The process of identifying overpayments is painstaking for various reasons. For example, one critical access hospital discovered it had overpayments in connection with its lab, which was billing Medicare for tests performed on lab specimens the same way it billed for tests administered directly on patients who walked through the door, said Traci Waugh, a senior manager at PYA. Sorting this out was time consuming because every lab account was registered the same way, and the hospital had to review years of data manually to separate the specimen from the in-person claims, she said. The hospital easily blew through 60 days quantifying the overpayment. "It was quite an experience trying to do the right thing. It was a long, laborious process," Waugh said. Ultimately, the hospital repaid the money, with the Medicare administrative contractor reprocessing the lab claims.

Sometimes hospitals are focused on the big picture and let small-dollar claims slide by even when they shouldn't, Waugh said. The business office may be in such a hurry to bring the money in that "they don't have time to sit back and say, 'I have been getting the same denial over and over.'"

When to start the clock is still murky, said Margaret Hambleton, president of Hambleton Compliance LLC and former chief compliance officer at Dignity Health in California. "The frustrating part about the 60-day rule is you are never going to get a one-size-fits-all," she said. "Every time you're refunding money, you're making a determination about whether you have to go further, and it's a completely different analysis based on timing and process and whether it's a one-off or systemic."

60-Day Process, Policy Is Necessary

Compliance with the 60-day rule requires a solid investigation process, which gets a leg up from a recall analysis tool or failure mode and effects analysis tool (a process for identifying failures in a system by breaking down the component parts and analyzing cause and effect), Kennedy said. "These types of tools help bake in what the process should be on the backside when you come out and identify the overpayment and issue," he explained. "Then you can hardwire the process."

Hospitals and other providers also should have a policy on overpayments. Although "it's an art as opposed to a science," the policy can include "guideposts" on what will be considered "systemic" for purposes of extrapolating the overpayment up to six years and define credible information "even if it's not perfect," Ruskin said.

UNC's overpayment policy is part of its billing and reimbursement policy, Kennedy said. "We have 10 standards in the compliance billing and reimbursement policy," and one standard explicitly includes refunding identified overpayments and credit balances in a timely manner, he explained.

Overpayments may fall through the cracks without tracking and coordination among departments, Hambleton said. But who's monitoring overpayment identification and watching the clock? Credible information about a potential error may come in through the health information department, internal audit, patient quality, investigations or the revenue cycle without a word to compliance, she said. As a result, there may be no tracking "to ensure a timely overpayment return and additional evaluation."

Because it can take years to sort out complicated issues, hospitals may not be able to refund overpayments within the six months plus the 60 days, Ruskin said. "It can take forever to do the review even if you are working the file on a routine basis," he noted. "If you are trying to prove you have been acting in good faith, creating a written record of the reasonableness of the time period for completing the steps is very important." Coupled with the overpayment policy, documentation will "vitiate" a prosecutor or whistleblower's attempt to prove you were reckless in not returning the money by the deadline, Ruskin said.

Contact Waugh at twaugh@pyapc.com, Ruskin at andrew.ruskin@klgates.com, Kennedy at patrick.kennedy@unchealth.unc.edu, Hambleton at margaret@hambletoncompliance.com and Gillin through OIG spokesperson Morsal Mohamad at morsal.mohamadakbar@oig.hhs.gov ✧

Endnotes

1. CMS, "Review of Opioid Use during the Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV)," *MLN Matters*, SE18004, August 28, 2018, https://go.cms.gov/3xcbjso.
2. Medicare Program; Reporting and Returning of Overpayments, 81 Fed. Reg. 7,654 (December 2, 2016), https://bit.ly/2UTAGT2.

CMS Transmittals and *Federal Register* Regulations, July 23-29, 2021

Transmittals

Pub. 100-20, One-Time Notification

- Viable Information Processing Systems (ViPS) Medicare Systems (VMS) Changes to Accommodate National Provider Identifier Associations, Trans. 10899 (July 27, 2021)

Federal Register

Proposed Rule

- Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements, 86 Fed. Reg. 39,104 (July 23, 2021)

Interview Tips: Asking Questions Effectively

Here's an excerpt from the interview tips in the Hazelden Betty Ford Foundation's Investigation Toolkit (see story, p. 5).[1] Contact Jackie Stemwedel, director of compliance, at jstemwedel@hazeldenbettyford.org.

- Silence is golden. Many people cannot stand silence and will fill up the void with talk, often saying something they had no intention of revealing. The average person expects no more than seven seconds of silence during a conversation. If you do not say anything after the interviewee answers a question, the interviewee will frequently give you more information than they intended to give you.
- Ask questions in chronological or systematic order, not randomly. Make your questions straightforward. If the questioning is confusing, you will lose the interviewee's train of thought and risk missing information. Avoid questions that are cute or tricky because you will lose the interviewee's trust.
- Ask one question at a time and get specifics. Do not move too quickly from one point to the next. Be methodical about pinning down all the surrounding details and asking follow-up questions. Be sure to ask whom? what? when? where? how many? and how often? Details that may appear insignificant at first glance often lead to discovery of highly significant evidence.
- If you ask a question that causes obvious high stress, you should consider noting that issue and change the topic. Continue with less stressful items to get all the information you need first, then return to the high-stress item and pursue it to its end.
- Explore the attitudes of the interviewee, looking for bias. Think about what the interviewee is saying—or not saying.
- Consider the manner, or demeanor, of the interviewee. How does the interviewee react? Are they straightforward or evasive? Cooperative or defensive? Confident or nervous? Does the interviewee tend to exaggerate for the sake of emphasis? Are they offering excuses and justifications when asked for facts?
- Be alert for answers that may suggest facts or issues you did not anticipate. Do not be so tied to your list of prepared questions that you fail to pursue other potentially significant points that come out during the interview.
- Do not settle for answers phrased in vague language or broad generalizations. For example, if an interviewee tells you that an employee "never gets to work on time," ask further questions to understand what they mean. How often? How late? Can they describe any specific instances? Are there any documents recording this information?
- Probe the issues using open-ended, nonleading questions. A leading question is one that suggests the answer that you want the interviewee to give. A blatant example would be: "You never sexually harassed the complainant, did you?" Answers tend to be more revealing and reliable when they originate with the interviewee:

  Leading: "Did you see Sam grope Jean behind the beverage machine?"
  Open-ended: "Have you seen or heard any conduct in the workplace that you think may be sexually intimidating or embarrassing?"
  Leading: "Wasn't Terry standing right beside them?"
  Open-ended: "Was anyone else present at the time of the incident?"
  Leading: "Did Sam tell you to forget you saw anything?"
  Open-ended: "What, if anything, did Sam say to you?"
- Avoid asking pointed and "why" questions until the end or until you think you may have exhausted the interviewee's initial recollection. When you sense that you may have as much information on a given point as you are likely to get from the interviewee, switch from open-ended questions to specific questions. As a general rule, everyone has more information than an interviewer obtains the first time through, so refresh the interviewee's recollection with specifics.

  Pointed: "Oh, come on now, you don't expect me to believe that!"
  Specific: "Do you know of anyone who can confirm what you have told me?"
- Probe the key factual issues more than once in different ways; people often remember things in waves, and this approach may bring out additional details.
- Press your interviewee to give general ranges when they are uncertain.

  Example: You may ask: "How many people were there at the meeting?" If the individual responds, "I don't know." Frame the next question with a range, such as, "Was it more than two, less than five?" Alternatively, "Was it less than 50?"

  If the interviewee is giving a physical description of someone, you may ask: "How tall was the man?" If the individual responds, "I don't know," reframe the question to something relatable, such as, "Was he as tall as I am?"
- If a person does not remember, try to help by asking questions that help recreate the situation.

  Example: If it is alleged that one employee falsified his vacation records to have more days off, you need to know who is involved in the process and how the process works. You might begin by asking the interviewee to describe the vacation approval process. If the answer is vague or inaccurate, you might break the process into parts and ask specific questions about each part. For example:

  > How many vacation days are you entitled to per year? When are vacation requests submitted? How are they submitted? Whom are they submitted to? Who approves a request? How do you amend a request?
- Explore answers that seems odd, unlikely or conflict with each other. If an interviewee tells you something you find hard to believe, follow up with probing questions. If information the interviewee is providing contradicts either something they said earlier or a piece of information gathered from another source, you should note the contradictions and then, at the appropriate point, ask the interviewee how these contradictory facts could be true. However, be careful not to call something a lie unless you have proof.
- Don't let the interviewee use legalistic words to answer your questions.
  Example: "Assault," "hostile work environment," or "embezzlement." The interviewee likely does not know the true meaning of the words. Your question should probe to describe the situation or action without the use of these words.
  Example: When asked whether or not the interviewee has witnessed any behavior that they believe to be unfair in their department and the interviewee responds as follows, "Oh yeah, all the time; it's really a hostile work environment," you might begin by asking the interviewee to describe the environment, drilling down further in each answer.
  Interviewer: "Can you tell me why you would describe your department in that manner?"
  Interviewee: "Because my boss is unethical."
  Interviewer: "Can you give me examples of situations where you disagree with the behaviors of your manager?"

Endnotes

1. Nina Youngstrom, "Investigation Toolkit Helps Keep Interviews Objective, Consistent," *Report on Medicare Compliance* 30, no. 28 (August 2, 2021)

Investigation Toolkit Helps Keep Interviews Objective, Consistent

With so much riding on effective compliance investigations, Hazelden Betty Ford Foundation uses mock investigations in its training. They include exercises that are analogous to board games in which interviewers sharpen their skills in an entertaining way by trying to solve the mystery of an alleged compliance or policy violation. Mock investigations are part of the investigation toolkit developed by Hazelden Betty Ford Foundation, which provides inpatient and outpatient addiction and mental health treatment, and there are ground rules now as well for virtual interviews because of the COVID-19 pandemic.

"It's helped us feel more confident in our interviewing skills," said Jackie Stemwedel, director of compliance, at the Health Care Compliance Association's Compliance Institute April 19.[1]

To practice interviewing skills, the investigation team, a multi-departmental group composed of compliance, privacy, human resources and legal, plays a game that's similar to the board game Clue. The goal is to gather facts and determine whether a company policy has been violated. Various investigators take on different roles (e.g., interviewer, interviewee, potential witnesses) and review fact sheets about the "allegations" based on their character. The interviewers use their skills to gather information, and the interviewees answer questions based on their character, and "little scenarios are interjected along the way," Stemwedel said. In the end, everyone comes together to share their conclusions. "It's a fun way to collaborate and figure out how people got through their investigations," she explained.

Toolkit Helps Standardize Investigations

Hazelden Betty Ford Foundation developed the toolkit, which contains templates and documents, to help guide investigations and ensure they're standardized and objective, Stemwedel said. "We have found it's easier when issues arise to have consistent templates." Sometimes the documents help you determine that an issue doesn't warrant a formal investigation, but at least there's a consistency to those conclusions. Because the compliance team is always learning lessons about what works and what doesn't, the toolkit is periodically updated.

The toolkit includes an investigation checklist, severity level guide, interview guide and template, evidence matrix, performance improvement plan, corrective action memo and final investigation report. Also in the toolkit are reference materials, including interview tips (see box, p. 4);[2] tips on interview note-taking; a retention policy; procedures (decisions the organization has made, for example, on whether other people can sit in on interviews); and the Upjohn warning, which informs employees that an attorney conducting the interview represents the organization, not the employees, which, by extension, means anything they say isn't confidential, and the organization is free to decide what to do with the information.

"These are all available at all times to our investigating team, but we may not need to use them in every investigation," Stemwedel said. For example, as a member of the compliance team, "I don't have a reason to use the performance improvement plan, but it's available to the human resources team."

Toolkit Was Adapted for Virtual Interviews

The toolkit was recently adapted for remote investigations, said Jacki Waltman, corporate privacy officer at Hazelden Betty Ford Foundation. They set ground rules for virtual interviews, which require technical expertise and document sharing. "You may want to think about drafting instructions and giving them to interviewees before logging in," she said. An organization's policies and procedures probably should incorporate virtual interviews.

Here are some ground rules:

- Choose a platform that's secure against hackers and video bombers. "Think about establishing a meeting password or using a waiting room functionality so you can ensure no one else is participating in the video call," Waltman said. Ideally, the interview takes place on a video call so the interviewer can observe facial expressions to help assess credibility and share documents. She recommends a backup plan in case you get disconnected.
- Remind interviewees not to take screenshots of documents or download them.
- Think about whether to record the interview. Some states allow people to record conversations without the consent of the person on the other end, but other states require both parties to agree to recording a conversation. It can get messy with a health system that has facilities in multiple states. "If you're in a one-party consent state and the person you're interviewing is in a two-party consent state, work with counsel to decide what's best for you," Waltman advised. And decide how you will manage disclosure: If you're recording, it's appropriate to let interviewees know. And will you allow them to record the interview at their request?
- Confirm that no one else is in earshot of the interviewee (e.g., family members). Speaking in private is necessary, same as in person, so

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Form for Confidential Interviews During Investigations

This form is part of the Investigation Toolkit used by Hazelden Betty Ford Foundation (see story, p. 5).[1] Contact Jackie Stemwedel at jstemwedel@hazeldenbettyford.org, Jacki Waltman at jwaltman@hazeldenbettyford.org and Melissa Edson at medson@hazeldenbettyford.org.

****CONFIDENTIAL - INTERVIEW NOTES****

Case No. ___

Attorney-Client Privileged: Yes ❑ No ❑

Interviewee Name:_____ **Date and Time:**_____

Interviewer Name:_____ **Notetaker Name:**_____

Introduction: Introduce yourself and provide an explanation of the goal for meeting with the individual (i.e., goal to gather information that person may have).

Example: Thank you for taking the time to meet with me today. My name is Jane Doe, compliance specialist, and this is John Doe, human resources business partner. We are gathering information related to a policy violation and believe you might have information that might be helpful. I will be asking the majority of the questions, and John will be taking notes. We have scheduled an hour for this meeting, but can schedule more time if needed. Do you have any questions before we begin?

Insert your introduction notes/comments here:
****Please utilize this document as a reference tool and consult with your organization for preferred statements to provide as part of your standard interview script and proper processes to follow within your organization.****

Confidentiality: You may want to consider describing to the interviewee your limits in keeping their information as confidential as possible. This may include an inability to promise complete anonymity due to needing to disclose information within the investigation team or to cooperate with other parties as required (e.g., regulators, government agencies).

Nonretaliation: You may want to outline your organization's nonretaliation policy.

Do you have any questions about confidentiality and nonretaliation?
Do you agree to keep this meeting confidential?
Do you have any other questions before we begin?

Confidentiality and Nonretaliation Notice Provided: Yes ❑ No ❑

Attorney-led Investigations: Do you need to provide the Upjohn Warning? If yes, please see Reference: Upjohn Warning for language.

Upjohn Warning Provided: Yes ❑ No ❑

Interview Questions: The questions following are recommended at the beginning and end of each interview; insert if applicable. Insert additional questions in the space provided. Use the Additional Notes section to note comments, observed behavior or additional questions.

Recommended Beginning Questions:
How long have you been employed by [name of your organization] and in what capacity?
How long have you worked with [complainant/implicated party/etc.] and in what capacity?
Are you aware of [describe alleged complaint or misconduct]?

Recommended Ending Questions:
Do you have any documents or emails related to this investigation?
Do you know of anyone else who may have information related to this investigation?
Is there anything else that I should know?

Insert questions here:

Question 1:
Response:

Question 2:
Response:

Interview Closing: At the end of each interview, thank the interviewee for their time, inform the interviewee of the potential need for follow-up, and remind the interviewee of confidentiality and nonretaliation expectations. If you asked for documentation, request that it be forwarded to you and provide a specific deadline. Provide your contact information, and encourage the interviewee to reach out if they think of any additional questions or feel they have further information they would like to discuss related to the interview.

Example: I don't have any other questions at this time; however, this investigation is ongoing, and I may need to contact you in the future to ask additional questions. Please reach out to me if you think of anything else that would be helpful or if you become aware of any new information. As discussed, please forward all information/emails related to this incident to me by the end of this week. I want to remind you to keep what was discussed during this meeting confidential and to report any retaliation, if it occurs. Thank you again for your time and cooperation. Feel free to reach out to me at any time with questions or concerns.

Additional Notes/Comments/Observations:

Endnotes

1. Nina Youngstrom, "Investigation Toolkit Helps Keep Interviews Objective, Consistent," *Report on Medicare Compliance* 30, no. 28 (August 2, 2021).

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the interviewee can feel comfortable answering questions candidly about sensitive issues.

- Ask interviewees for written confirmation that they understand the ground rules.

The toolkit also has tips on formulating questions for interviews. There are two ways to go about this: working from an informal outline versus using a script, said Melissa Edson, clinical compliance specialist. Scripts are more formal, with yes/no questions, said Edson, who prefers using an outline and eliciting answers after building a rapport. "You may not know the person, and building rapport is very helpful," she said. The toolkit also has a framework for interviews (see box, p. 6).[3] "We use the same introduction in all interviews and the same closing," and it reminds the interviewee of the nonretaliation policy, Edson said. "It's an opportunity for them to reach out to us."

Contact Stemwedel at jstemwedel@hazeldenbettyford.org, Waltman at jwaltman@hazeldenbettyford.org and Edson at medson@hazeldenbettyford.org. ✧

Endnotes

1. Jackie Stemwedel, Melissa Edson, and Jacki Waltman, "Internal Investigations: What's in Your Organization's Toolkit?" Compliance Institute, Health Care Compliance Association, April 19, 2021, https://bit.ly/3y5Qkc9.
2. Nina Youngstrom, "Interview Tips: Asking Questions Effectively," *Report on Medicare Compliance* 30, no. 28 (August 2, 2021).
3. Nina Youngstrom, "Form for Confidential Interviews During Investigations," *Report on Medicare Compliance* 30, no. 28 (August 2, 2021).

Deadline Looms for Device Credit Self-Audit

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transfer (PACT) payment policy after OIG audit found noncompliance related to the PACT policy and home health care.

With the unreported device credits, CMS said it believed it would take six months for hospitals to determine whether possible overpayments stemmed from unreported cardiac device credits because of their complexity, said attorney Jeff Thrope, with Foley & Lardner LLP, who has seen a copy of a letter. When the review is completed, "the letter indicated that facilities would have 60 days to refund any overpayments and provide a detailed explanation of the methodology used in their review," he said. "If a facility believes they need more time, they can express that to CMS," the letter stated. Hospitals that use statistical sampling and extrapolation to calculate their overpayments, for example, may require an extension, he said.

CMS requires hospitals to pass on to Medicare the credits they receive from manufacturers for recalled or malfunctioning medical devices or for medical devices implanted free as part of clinical trials. It's a big risk area because CMS uses device credits to reduce Medicare payments for inpatient and outpatient procedures performed to replace or fix devices, such as pacemakers and defibrillators. Explanted devices with a manufacturer credit of 50% or greater are reported on Medicare claim forms with value code FD (credit received from the manufacturer for a medical device) and, if applicable, condition code 53 (initial placement of a medical device provided as part of a clinical trial or free sample).

But hospitals often drop the ball. According to the report, OIG reviewed Medicare payments to 911 hospitals for claims that had a cardiac device replacement procedure with a date of service that matched to the device replacement procedure date on the credit listing. Its findings: "For 3,233 of the 6,558 Medicare claims that we reviewed, hospitals likely did not comply with Medicare requirements associated with reporting manufacturer credits for recalled or prematurely failed cardiac medical devices." About half the claims weren't billed with the condition and value codes, OIG said. As a result, the hospitals received $76 million for the procedures involving cardiac device implants instead of the $43 million they should have received. Presumably all of those hospitals have or will receive letters requiring them to self-audit and return identified overpayments, Thrope said.

'We Had Already Reprocessed All Claims'

Gillis said Mass General Brigham already had completed an internal self-assessment of medical device credit reporting when it found out one of its hospitals was part of OIG's national audit and OIG auditors came on-site. "We were already in the process and had refunded claims when they selected a sample," Gillis said. "We were able to show we had reprocessed them." A handful of the claims with unreported cardiac medical device credits hadn't been reprocessed, but "it was just a difference in timing, and they were quickly reprocessed," he said.

The water got muddied when Mass General Brigham was subsequently instructed in a letter from the MAC to self-audit another hospital in response to OIG's audit. "We had already reprocessed all claims," Gillis said. "We felt the MAC had not done its due diligence before sending the letter." To confirm the hospitals didn't overlook anything, they asked the device manufacturers to generate a report on device credits provided during a time period that hadn't been

covered by its most recent internal assessment, which would bring them current through December 2020.

Device credit reporting is a very fraught area of compliance, according to Dennis Beall, manager of medical device audit and compliance with SpendMend in Michigan, and Al Brander, chief sales officer with the company. There are a lot of moving parts at the hospital and device manufacturer, and the latter doesn't have skin in the game, they said.

"In the hospital world, this is what I would call an orphan program," Brander said. "It's very difficult to determine who owns this." Four circumstances could void the warranty: (1) the hospital fails to return it to the manufacturer; (2) there's an infection; (3) the hospital returns the device, but outside the 30 to 45 days after the procedure; and (4) the hospital removes one manufacturer's device and replaces it with another manufacturer's device.

'Connecting the Departments is the Struggle'

The hospital returns the explanted device to the device manufacturer with a note in the enterprise software explaining that the items have been returned. That way, the finance department is alerted that the items have been returned, and it can reconcile and match the credit with the return, Brander said. Unfortunately, credits may show up "without any insight" into what device they apply to. "Seven departments are involved in this," he said, including billing and compliance. "Most of the time, connecting the departments is the struggle. Unless the departments do their part, a gap will result."

It's not just that so many departments have to touch the devices; "It's a complex issue, because hospitals are 100% responsible for returning those devices, and manufacturers take no responsibility," Beall contended.

This isn't just a compliance issue, Brander noted. Hospitals only have to report credits of 50% or more, which means they keep the money when the credits are lower. It's a loss when hospitals don't return explanted devices consistent with manufacturer requirements, he said.

Gillis said Mass General Brigham gets quarterly reports from certain manufacturers that inform it of credits. "Based on the information, we reprocess the claims," he said. The real challenge is making sure the front end—the clinical department where the device is explanted—returns it to the manufacturer. "If they don't do that, it puts you in a bad spot very quickly. The manufacturer won't give you a credit," Gillis said. "We already paid full price and want to make sure we get a discount if it's under warranty. The manufacturers are generally pretty good if you send the device back to them." The next step is connecting with the billing office for guidance on reprocessing the claim.

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Endnotes

1. Amy J. Frontz, *Hospitals Did Not Comply With Medicare Requirements for Reporting Cardiac Device Credits*, A-01-18-00502, Department of Health & Human Services Office of Inspector General, November 2020, https://bit.ly/3BVRYPO.

NEWS BRIEFS

◆ **CMS has not fined any hospitals yet for noncompliance with price transparency requirements, a spokesperson tells *RMC***. "In April 2021, CMS began issuing warning letters to hospitals not in compliance with requirements of the Hospital Price Transparency final rule. Upon receipt of a warning letter for noncompliance, hospitals have 90 days to address the findings cited in the warning letter. CMS will rereview upon expiration of the 90-day window, or earlier if a hospital alerts CMS that the finding(s) of noncompliance has been addressed," the spokesperson said. "Should CMS conclude a hospital is noncompliant with one or more of the requirements to make public standard charges, CMS may take any of the following actions, which generally, but not necessarily, will occur in the following order: (1) Provide a written warning notice to the hospital of the specific violation(s); (2) Request a corrective action plan from the hospital if its noncompliance constitutes a material violation of one or more requirements; and (3) Impose a civil monetary penalty, not in excess of $300 per day, on the hospital and publicize the penalty on a CMS website if the hospital fails to respond to CMS's request to submit a corrective action plan or comply with the requirements of a corrective action plan." Meanwhile, in the proposed outpatient prospective payment system regulation announced July 19, CMS said it would increase the penalties for hospital noncompliance with the price transparency requirement.[1]

◆ **CMS's supplemental medical review contractor said July 26 it's auditing claims for carotid artery screening/testing with 2019 dates of service**.[2]

Endnotes

1. Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals To Make Standard Charges Public, 84 Fed. Reg. 65,524 (November 27, 2019), https://bit.ly/3rsTZhw.
2. "01-054 Carotid Artery Screening/Testing Notification of Medical Review," Noridian Healthcare Solutions, last updated July 26, 2021, https://bit.ly/3yjIThP.