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**Errors for Device Credits May Rise With New Code, Despite Simpler Billing Rules**

When it comes to reporting medical device credits, hospitals may fare better now that CMS has simplified Medicare billing regulations. But compliance is still a challenge, and things may take a turn for the worse with the debut of condition code 53 for devices provided at no cost for clinical trials or as free samples, one expert says.

Reporting of medical device credits is a prime audit target, with most Medicare compliance reviews by the HHS Office of Inspector General citing it as a source of over-payments. OIG auditors have repeatedly said they always include device-credit reporting “because they know they will find a bucket of money there,” Michael Calahan, vice president of hospital and physician compliance at HealthCare Consulting Solutions, said at a webinar sponsored by RACMonitor.com on Feb. 26. That’s the case even though CMS synchronized inpatient and outpatient device-credit calculations in 2014.

“Tracking the credits remains a mountain to climb for every hospital because they need to get department managers involved, but the back end is much easier now,” he said. “It’s great. It will allow some people to keep their hair and other people not to have their hair turn gray.” But that doesn’t solve the problem of identifying credits when they come in from manufacturers, often months after procedures to explant and replace medical devices.

And now there’s condition code 53, which will require hospitals to ramp up their oversight. In addition to monitoring devices that have a credit that’s 50% or greater.

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**Compliance Team Takes on Due Diligence For Merger, Aided by Electronic Access**

As it considered a merger with another health system, WellSpan Health in York, Pa., handed part of due diligence to the compliance department. Since compliance is accustomed to evaluating its own billing and documentation, why not do the same for a potential partner and save a bundle by keeping the work in-house?

WellSpan’s nurse auditors, coders, chargemaster analysts and compliance specialists dug in, says Wendy Trout, director of corporate compliance. With access to the electronic health records of the other health system, they did probe audits of multiple risk areas until satisfied its compliance program and billing and documentation were pretty robust. “Now that we have done it once, I would do it again in a heartbeat,” Trout says. But due diligence takes its toll, so she cautions that, if they undertake it, compliance departments should be prepared to spread their employees thin.

Given the pace of mergers, acquisitions and joint ventures, due diligence reviews are a popular topic at hospitals and health systems. “With successor liability that can attach, and ongoing compliance concerns, it’s important to get your arms around what business an entity is involved in and make sure it’s performing business activities in a compliant fashion,” says San Francisco attorney Judy Waltz, who is with Foley &
Lardner LLP. The due diligence is used to assess risk, Waltz says. “Sometimes the risk may be too great and the company [may nix the deal],” she says. “But more often than not, it goes to setting the purchase price or setting certain reserves in the event a claim is made against the company.” Her “dream list” for due diligence includes an analysis of claim denials and Medicare-Medicaid repayments because it quickly reveals whether a provider or supplier has something more troubling than occasional billing errors.

When WellSpan’s CFO asked Trout to assume partial due-diligence responsibility, she started by identifying the services the other health system provides. Then she assembled an internal team with relevant expertise and assigned them to review risk areas, including Kwashiorkor diagnoses; mechanical ventilation (96+ hours) claims; credits for replacing medical devices; place of service coding; incident-to billing; inpatient vs. outpatient kyphoplasty; the medical necessity of stents; and excessive payments (i.e., units of drug billing). They also looked more broadly at various compliance topics, such as inpatient rehab, the medical necessity of the health system’s inpatient admissions vs. observation services, inpatient coding, outpatient coding, claims integrity (e.g., modifiers) and requirements for provider-based status. The health system was also questioned about its compliance program and the extent of RAC activity.

Because Trout and her team are familiar with the rules and regulations for these services, due diligence didn’t feel like a stretch. The process was accelerated because the health system gave the WellSpan compliance reviewers electronic access to three years of medical records through a special HIPAA-compliant data repository designed for this purpose. “They populated the records into a queue and each person got a passcode,” she said. The electronic access allowed WellSpan to conduct most of the compliance due diligence without dispatching 10 people to the health system. If any documentation, such as an advance beneficiary notice, was missing, the health system tracked it down.

WellSpan also signed a confidentiality agreement and the entire pursuit was conducted under the protection of attorney-client privilege. Unless an attorney directs due diligence, everything is discoverable, she cautions.

Thirty records were audited from each risk area. Trout eyeballed them to make sure charts weren’t skewed toward one type of service. “You don’t want to get all colonoscopies on the outpatient side or all cardiac-related DRGs,” she says. “You make sure you have variety so you aren’t missing areas where there could be risk.” Trout says she’s happy with the results of the due diligence. The health system has a clinical documentation improvement program “and we could see some evidence of improvement,” she says.

Keep in mind, however, that due diligence may not be effective if the other entity isn’t receptive — for example, if it doesn’t grant timely access to records — or if your staff is overwhelmed with its own job duties. And it’s wise to stay within your area of expertise. WellSpan is looking at a venture with a behavioral health entity, but Trout says she isn’t familiar enough with regulations in that area to comfortably perform due diligence.

**Mini-Reviews Can Expose Weaknesses**

The compliance program and the culture are important aspects of a due diligence review, according to Janelle Wisssler and Chris Anusbizian, who are specialist leaders with Deloitte & Touche. Does the compliance officer report directly to the CEO and board? How many compliance employees are there? How is risk evaluated? Is there a written compliance plan? Is the compliance officer aware of coding and billing error rates and involved in the oversight of physician arrangements? When corrective action plans are implemented, does anyone follow up? Are repayments made?
Quick Responses Can Thwart Whistleblowers

Conversely, it’s comforting if the compliance officer addresses hotline calls quickly because whistleblowers could be lurking there, Anusbigian says. “If compliance officers can easily tell you what the risks are and what they have done about them, that gives you a good feeling,” she says.

Wissler also has had some coding surprises during due diligence. In one case, she reviewed 20 charts that all landed in the correct MS-DRGs, yet every one contained three to four errors. “Their data was worthless,” she says. “They had applied incorrect codes.” Although the hospital wasn’t overpaid on those DRGs, it had a larger problem with coding quality.

Increasingly, it comes up during due diligence that the entity up for sale or merger is under a corporate integrity agreement, Waltz says. Is that an asset or a liability? “You can look at it both ways,” she says. To OIG, a CIA may represent an assurance that your operations have been examined for compliance and that OIG itself is comfortable with them. “But if someone is looking at acquiring a company in the middle of a CIA or in year one, they are taking on a big load of work,” Waltz says. “It’s becoming a more common factor to evaluate during a due diligence.”

Waltz says there are certain “deal killers” that might emerge during due diligence. One example: when an organization doesn’t have a process to ensure it puts physician contracts in writing. Another example could be a supplier who seems baffled why Waltz asks whether it informed Medicare that one of its locations has a new address. “That supplier is facing potential retroactive enrollment revocation by not notifying CMS of address changes, so the acquiring company might conclude it would be facing too much risk,” she says.

Contact Trout at wtrout@wellspan.org, Waltz at jwaltz@foley.com, Wissler at jwissler@deloitte.com and Anusbigian at canusbigian@deloitte.com.

PEPPER Reports Coming to Home Health in July as Error Rates Rise

Amid pressure to ratchet down Medicare overpayments for home health services, home health agencies will soon be able to address their compliance issues using the Program for Evaluating Payment Patterns Electronic Report (PEPPER).

TMF Health Quality Institute, which generates PEPPERS for CMS, is planning the first release in July, says Project Director Kim Hrehor. TMF has been working with CMS home health subject matter experts to develop risk areas for the PEPPERS, which are free reports on billing rates in certain risk areas. PEPPERS are designed to help hospitals, hospices and other providers tailor their compliance monitoring to outliers unique to their facilities. They allow providers to compare their billing rates to those of their peers in the nation, in Medicare administrative contractor (MAC) jurisdictions and in states in the target areas. It’s a red flag when a provider’s billing in a target area is at or above the national 80th percentile, which means it bills a higher percentage for that target area than 80% of all providers nationally. That doesn’t necessarily mean there was an error, but it’s up to the providers to determine whether they have a compliance issue or some reasonable explanation.

A ‘Big New’ PEPPER Release

The home health PEPPERS “will be a big new release,” Hrehor says, because there are more than 12,000 home health agencies in the nation. Another reason is the intense focus on home health billing and documentation errors by Medicare watchdogs. The HHS Agency Financial Report says the fiscal year 2014 improper payment rate for home health claims jumped to 51.4% from 17.3% the year before. For the first time, a home health provider in February settled a false claims case over allegations it violated the Medicare face-to-face encounter requirement (RMC 2/16/15, p. 1).

“The continued increase in improper Medicare payments makes this new setting ripe for external focus and thus for these comparative reports,” she says. “Home health agencies would be wise to seek out their report once it is released to see how their claims data statistics compare, and consider whether they might be at higher risk for improper Medicare payments.”

Here are the six target areas that will be in the home health PEPPERS, Hrehor says:

1. **Outlier payments:** Medicare pays home health agencies extra for beneficiaries who incur unusually high costs. Outlier payments could be triggered when they provide too many therapy services during visits or too many visits overall, Hrehor says. In a 2009 report, for
example, OIG said that “Miami-Dade County accounted for 52 percent of the approximately $1 billion Medicare paid nationally in home health outlier payments, while only 2 percent of all Medicare beneficiaries receiving home health services resided there.” CMS has tried to get a handle on outlier abuse by capping the percent each agency can collect at 10% of its total home health payments, OIG said in a 2012 report.

(2) Average number of episodes per beneficiary: A home health episode is a 60-day span of care, and home health agencies submit a Medicare claim for each episode, Hrehor says. There is potential for abuse because there is no limit on the number of episodes that home health agencies can bill for or the length of time a patient can receive care, she says. Therefore, they have a financial incentive to continue to provide services, she says.

Monitoring Compliance With Billing Rules for Same-Day Surgery

This audit tool was developed by Trina Roberts, a senior medical review analyst at WellSpan Health in York, Pa. WellSpan uses it to review HCPCS, CPT and revenue codes and evaluate whether diagnosis codes support the medical necessity of the services. Contact Roberts at troberts3@wellspan.org.

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March 9, 2015 Report on Medicare Compliance

In fact, Medicare pays HHAs a higher rate for the third and subsequent 60-day episodes. “We want to look at the beneficiary level to see how long the HHA treats the beneficiary,” she says. “If an unusually high percentage of beneficiaries were there for four, five, or six episodes, why would that be?” While some beneficiaries may require longer care with an HHA, it might be questionable if most of an agency’s beneficiaries were in that category, Hrehor says. The PEPPER data will allow home health agencies to hold up a mirror to themselves.

(3) Average case mix: Hrehor says CMS suggested this risk area, which gets at the identification of beneficiaries with unusually high case mixes. “There’s a concern about potential overcoding with this risk area,” Hrehor says. In other words, HHAs perhaps exaggerate beneficiaries’ illnesses and/or their functional impairments on the Outcome and Assessment Information Set (OASIS), which home health agencies are required to submit to Medicare as a condition for payment.

(4) Episodes with five or six visits: HHAs receive the home health resource group (HHRG), which is the prospective payment, for beneficiaries who have at least five visits during the 60-day episode. Otherwise, Medicare pays HHAs a low utilization payment adjustment (LUPA), which is a per-visit payment and tends to be lower than the HHRG, Hrehor says. “We are looking at the percentage of episodes where home health agencies met the minimum amount of visits necessary to get the

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higher reimbursement” in the absence of medical necessity for the five or six visits, she says.

(5) Non-LUPA payments: In a reverse engineering of the above risk area, the PEPPER identifies HHAs that are outside the norm for payments that are not LUPAs. The national average of claims for LUPA payments is 8%, and HHAs that have very few or none might have a problem, Hrehor says. “It’s unrealistic for home health agencies to never have any LUPA payments,” she says.

(6) High therapy utilization episodes: HHAs generate higher reimbursement by providing more speech, physical or occupational therapy. “We are looking at the percentage of episodes that had 20 or more therapy visits,” Hrehor says. “The more therapy, the higher the HHRG payment,” she says. This has been a problem for skilled nursing facilities and is a risk area in the SNF PEPPERs (RMC 9/2/13, p. 1).

For more information, contact Hrehor at Kimberly. Hrehor@area-b.hcqis.org.

Device Credits Pose Big Risk
continued from p. 1

of the replacement cost, hospitals will have to monitor initially placed devices provided free by manufacturers, Calahan says.

Some patients need their medical devices replaced because they are recalled, malfunctioned or interacted badly with their body. When the warrantly still applies, the manufacturer will refund all or some of the cost of the replacement device, depending on its age. Hospitals are required to pass on credits to Medicare, which foots the bill for surgeries to implant replacement devices. Medicare uses credit information to reduce payments for inpatient and outpatient procedures performed to replace or fix devices, such as pacemakers and defibrillators. Whether the hospital will get a full or partial credit — and if so, how much — is decided by the manufacturer and perhaps negotiated with the hospital after the device is returned. Under the “prudent buyer” standard, OIG says hospitals owe Medicare the credits even if they don’t collect them from the manufacturer.

CMS changed some of the mechanisms of device credit reporting in 2014, and that affects how hospitals and ambulatory surgery centers (ASCs) will conduct internal audits and be held accountable by Medicare auditors, Calahan said. The pre-2014 methodology has ramifications for Medicare audits that include claims as far back as 2009, Calahan added.

For medical devices replaced during inpatient procedures, hospitals have to report credits only if they are worth 50% or more of the price the hospital paid for the device, which is represented by value code FD on the UB-04 claim form. Hospitals also put down the amount of the credit, which is used to reduce the MS-DRG payment for the corresponding procedure dollar-for-dollar, Calahan said. That’s what he calls a “one-level credit,” which is easier to report and monitor. They add condition codes 49 (outpatient) or 50 (inpatient) if the device is being replaced because of a recall. But hospitals no longer have to append modifiers –FB and –FC to claims for procedures to replace devices. The –FB modifier indicated the hospital got a 100% credit from the manufacturer, while the –FC modifier meant a credit of 50% to 99%. The distinction has not been necessary since 2014, according to Calahan, so the modifiers are extinct.

CMS made more dramatic changes to device-credit reporting requirements when procedures are performed in hospital outpatient departments and ASCs. The good news, Calahan said, is they conformed billing procedures to IPPS. “They rely on a value code to trip a reduction in the system,” he said. In the old days (2007 to 2013) there was two-level credit reporting, with hospitals and ASCs...
using –FB and –FC modifiers. They were “anchored” to the CPT and HCPCS code for the procedure, which triggered a preset APC reduction. “Logic says you would put the modifier on a pacemaker because that’s what got discounted to the MAC,” but that’s not how it worked, Calahan said. The pre-set APC discounts were based on the procedures themselves, not the device. As a result, sometimes the discounts exceeded the Medicare reimbursement for the procedure. For example, a manufacturer credit on a lead for an implantable cardiac defibrillator might be $3,900, but the APC device offset was $25,000, according to Calahan, so hospitals took a huge loss. He calls this the “OPPS epic fail.”

CMS fixed the epic fail in the 2014 OPPS regulation. Hospital outpatient departments and ASCs now report the value code FD and the amount of the credit for a dollar-for-dollar reduction to their payment. Also, he noted, CMS ended the reporting of free radiopharmaceutical agents used in nuclear medicine procedures with modifier –FB as if they were implanted devices.

Because audits are retrospective, however, they will include claims for replaced devices that may have failed to report device credits from 2013 and earlier, Calahan said. Some errors that auditors look for are whether:

- The amount of the outpatient device credit was declared on the claim;
- The modifier or value code was reported correctly and the condition code was reported at all (e.g., FB and FC modifiers can never be reported together);
- Adjusted claims still had some errors (e.g., missing modifiers); and
- Internal operational controls exist. Maybe different staff is entering the same procedure codes and device charges into the system at various points.

Suppose a hospital implanted an $8,500 device and then, when it malfunctioned, replaced it with a $12,500 device in 2010. The hospital received a credit memo from the manufacturer for $12,500, which should have been passed on to Medicare and reported with modifier –FB. If that didn’t happen, the hospital racked up an overpayment, Calahan said.

Even though the 2014 Medicare billing changes to device replacement are a relief, he said they won’t eliminate compliance risks. The same problems with identifying and reporting manufacturer credits persist. “They’re never reported to CMS because no one knows they should be reported,” he said. Credits on devices come back to the system months after the fact, on memos from manufacturers that just state, for example, $5,500 with no explanation. Since OIG and other auditors started to crack down on device credits, Calahan has urged hospitals to improve their policies and procedures for tracking and reporting them. “But it’s a challenge because it crosses so many service areas,” he said.

Hospitals should require device manufacturers to submit monthly or quarterly reports of all credits they issue, Calahan said. “Vendors send this information to OIG,” he noted, so hospitals will be outed in an audit. He also recommends “beta testing” five cases of manufacturer credits. “Hospitals have to follow a device through their own system,” he said. Involve every person and department that “touches the device in the lineage throughout your system,” he said. That includes the physician who orders the procedure; the surgeon who replaces the device; the pathology department, which is required by clinical protocols to identify and decontaminate the device; patient accounts, which flags it as a replacement device with a warranty; materials management, which buys the devices; and billing, which adds condition and value codes.

“The goal is to be able to identify any reportable device that has to be rebilled if it is 50% or greater,” Calahan said. He also suggested giving the people involved contact information for each other to improve communication, and to educate them on both the fundamentals of device-credit reporting and potential aberrations.

Device-credit reporting is about to get more precarious. CMS created a new condition code, 53, for claims for procedures for medical devices that are provided free by manufacturers in connection with a clinical trial or free sample (RMC 2/16/15, p. 8). It takes effect July 1.

Even though condition code 53 seems different on the surface because it refers to “initially placed” devices, not replacement devices, the underlying purpose and compliance risks are conceptually the same, Calahan says. Medicare will reduce reimbursement for these procedures since hospitals aren’t paying for the devices and condition code 53 errors will lead to overpayments.

CMS announced the new condition code, which was created by the National Uniform Billing Committee, in Change Request 8961 and MLN 8961. It applies to 100% device credits and must be reported on outpatient hospital claims, as indicated by value code FD, Calahan said.

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One potential glitch is how to apply the condition code when devices are implanted during outpatient procedures, but patients are admitted as inpatients because their clinical picture changes, Calahan said. CMS and MACs will have to answer this and other questions surrounding condition code 53 or hospitals will have problems using it. Another question is how hospitals will apply the condition code to claims dating to Jan. 1, 2014, which the change request alludes to, because they are outside the one-year timely filing deadline, Calahan said.

Meanwhile, he said, hospitals should get value statements from manufacturers for both initially placed and replacement devices because they will let hospitals enter on claim forms the exact value according to purchasing agreements, Calahan said. In the case of free samples, the value statement will show the cost of the device if the hospital had to buy it. It’s unclear, however, what amount MACs will use for free samples.

And, Calahan noted, hospitals that have effective policies and procedures for replacement-device credits will be able to piggyback condition code 53 on them. “People who come up short for clinical trials and free samples will be those who don’t have protocols in place for replacement devices,” he said. “Lots of hospitals are going by the seat of their pants and if they get audited, this will be a part of it. It could be a huge repayment if they have nothing in place and that’s what worries me.”

Contact Calahan at mcalahan@hcsglobal.net.

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**NEWS BRIEFS**

- The Eleventh Circuit Court of Appeals has ruled on the scope of the public disclosure bar of the False Claims Act, as amended in 2010 by the Affordable Care Act. The rulings came in an order dismissing with prejudice the case *Osheroff v. Humana* because the claim was based on information that had been “publicly disclosed.” The FCA prohibits actions that are based on information that has been publicly disclosed prior to the lawsuit. The court explained that under 31 U.S.C. §3730(e)(4), as amended, only information disclosed in federal court proceedings are considered public disclosures. Before the amendments, information disclosed in both state and federal proceedings was considered publicly disclosed. The court also for the first time interpreted the phrase “news media,” which is considered a public disclosure under the statute. It pointed to a Supreme Court declaration that the term has a “broad sweep” and noted lower court decisions finding publicly available websites and newspaper advertisements to be “news media.” For these reasons, it concluded that newspaper advertising and publicly available websites qualified as news media for purposes of the public disclosure provision. Visit http://tinyurl.com/pe2kvdd.

- A physician who co-chaired the Safe Practices Committee of the National Quality Forum in 2009 and 2010 agreed to pay $1 million to settle false claims allegations stemming from kickbacks, the Department of Justice said March 2. Patient safety consultant Charles Denham of Laguna Beach, Calif., runs a consulting company, Health Care Concepts Inc., and a research organization, Texas Medical Institute of Technology, both of which are parties to the settlement. While he co-chaired the Safe Practices Committee, Denham allegedly got monthly payments from CareFusion Corp., which makes ChloraPrep, a product to prevent surgical-site infections. Allegedly, the Justice Department said, “Denham solicited and received these payments in exchange for influencing the recommendations of the National Quality Forum and for recommending, promoting and/or arranging for the purchase of CareFusion’s product, ChloraPrep, in violation of the Federal Anti-Kickback Statute.” That resulted in the submission of false claims, the Justice Department alleged. Denham never revealed the Safe Practices Committee or anyone at the National Quality Forum that he took money from CareFusion. Visit http://tinyurl.com/pl4853k.

- A skilled nursing facility operator agreed to pay $3.5 million to resolve allegations of inflated Medicare claims for rehabilitation, the U.S. Attorney’s Office for the District of Massachusetts said on March 2. The Catholic Health Care System, also known as ArchCare, operates Terence Cardinal Cooke Health Care Center in New York City and Ferncliff Nursing Home in Rhinebeck, New York, and used to run Kateri Residence in New York City. ArchCare had an agreement for rehab with a subcontractor, Physical and Occupational Rehabilitation Therapy and Speech-Pathology Services, PLLC, an affiliate of RehabCare Group East, Inc. and Kindred Healthcare, Inc., the U.S. attorney’s office said. The settlement resolved allegations that the three ArchCare facilities submitted Medicare claims that involved inflated reimbursement based either on unreasonable or unnecessary rehab or false reports of therapy being provided. Visit http://tinyurl.com/1r7r8p3.
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