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Contents

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Hospital Settles CMP Case Over Billing a Drug as Waste and Again as Administered

Vassar Brothers Medical Center (VBMC) in Poughkeepsie, New York, agreed to pay $432,815 in a settlement with the HHS Office of Inspector General (OIG) over its billing for wasting a drug and administering it at the same time.

According to the settlement, which was obtained through the Freedom of Information Act, OIG alleged that VBMC submitted claims to Medicare, Medicaid, Medicare Advantage, Medicaid managed care plans and TRICARE for items or services that were fraudulent from Jan. 14, 2011, through Aug. 10, 2017. Specifically, the hospital "submitted duplicate claims for the antibiotic daptomycin, whereby leftover amounts of daptomycin, which had already been billed as waste for one patient, were administered to another patient and billed for again." OIG alleged this violated the Civil Monetary Penalties Law. The hospital self-disclosed in 2019 and was accepted into OIG's Self-Disclosure Protocol in February 2020. It didn't admit liability in the settlement.

The self-disclosure stemmed from an internal audit at VBMC "that was prompted by changes in how the JW modifier was billed to the Medicare administrative contractor," said Jana Kolarik, outside counsel for the hospital. The JW modifier is used to report to Medicare the amount of drugs or biologicals that are wasted, which is reimbursable. "In the audit, VBMC discovered there was a disconnect between how the pharmacy was supplying the drug, which was as a multi-use vial (MUV) and could be used over several patients, and how it was being billed. It was entered into the billing system as a single-use vial, which was billed for one patient as the administered dose with the remaining vial contents billed as the waste," said Kolarik, with Foley & Lardner LLP. "Upon discovering the disconnect, the billing was changed to reflect the use, i.e., as a MUV, so no waste would be billed."

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Bipartisan Bill to Amend FCA Tinkers With 'Materiality' in Wake of Supreme Court Case

A bill that amends the False Claims Act is seen as a way to right the False Claims Act (FCA) ship after it was knocked off course by a 2016 Supreme Court decision. It focuses on the relationship between the "materiality" of the noncompliance of a claim for payment and the government continuing to pay the claim. But some attorneys think the legislation is unnecessary and tips the scale too far toward whistleblowers.

The bipartisan False Claims Amendments Act of 2021 was sponsored by Republican Sen. Charles Grassley, the longtime champion of the FCA; Democrat Sen. Dick Durbin; and other senators.[1] It has been advanced by the Senate Judiciary Committee but so far has no companion in the House. A spokesperson for Grassley said the bill is awaiting action on the Senate floor, and "several House offices have expressed interest in teaming up with Senator Grassley on this issue and we are currently working with them."

The most significant change is a response to the U.S. Supreme Court's landmark decision in *Universal Health Services vs. United States ex rel. Escobar*, attorneys

continued

said.[2] The *Escobar* decision supported the theory of implied certification in an FCA lawsuit. Implied certification means the submission of a claim for payment carries with it the assurance that providers have complied with all conditions of payment, even if they haven't expressly certified compliance. The decision set forth two conditions under which the implied certification theory can be a basis for liability: (1) "The claim does not merely request payment, but also makes specific representations about the goods or services provided"; and (2) "The defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths."

Since the decision, some courts have applied *Escobar* in finding that if a federal agency, such as CMS, continued to pay a federal contractor (e.g., a hospital), even when the agency knows about noncompliance, the noncompliance under those circumstances was not material and can't be an FCA violation, said attorney Lori Rubin, with Foley & Lardner LLP.

"Many courts are relying on the government's decision to continue paying a claim as evidence that the violation was not material," according to Grassley's spokesperson, Megan Behrends. "However, courts are not putting that information into context and asking if other reasons could have existed for the continued payment in order to make a more informed decision on whether a violation was material to the government."

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New Qui Tam Filings Are 'At a 10-Year Low'

That has been a blow to whistleblower lawsuits, said Jeb White, president of Taxpayers Against Fraud Education Fund in Washington, D.C. "You don't have to look any further than Department of Justice statistics. New qui tam filings are at a 10-year low." Although the Department of Justice reported $5.6 billion in FCA settlements and judgments in fiscal year 2021, the most since 2014, with $5 billion coming from health care matters, White noted that "government filings went up but qui tam cases went down" and half of the FCA recoveries came from a single case (Perdue Pharma) that's now on appeal.[3]

The False Claims Amendments Act makes it easier for FCA cases to proceed even when CMS or other government agencies knew about the fraud and continued to pay the perpetrator anyway, attorneys said. The bill states that in "determining materiality, the decision of the Government to forego a refund or to pay a claim despite actual knowledge of fraud or falsity shall not be considered dispositive if other reasons exist for the decision of the Government with respect to such refund or payment."

Grassley's spokesperson said the bill "would simply require that courts take into account other reasons that the government could have had for paying a claim, thus resolving the issue." For example, a rural hospital could shut its doors if Medicare stopped paying claims, said White, a former whistleblower lawyer. Grassley's spokesperson noted there are multiple reasons why the government would not stop payment despite knowledge of fraud, such as fear of creating a drug scarcity. "Sen. Grassley's goal is to address misinterpretations in the courts around the *Escobar* opinion, which has led to defendants escaping liability by simply showing that the government was aware of the fraud and did not stop payment," Behrends said.

Even with valid reasons to continue to pay claims, White said "the way it is now, there is too much uncertainty under *Escobar* to even file those cases."

Attorneys: Bill Goes Too Far

But other lawyers say the *Escobar* decision already gave Grassley what he wanted, and the False Claims Amendments Act provision is unnecessary. "*Escobar* leaves open the possibility that an alleged misrepresentation could be material even if the government continues to pay," said attorney Matt Krueger, with Foley & Lardner LLP. "*Escobar* created a totality of circumstances test, where courts look at all facts relevant to the government's decision to pay." The False Claims Amendments Act goes too far and would

"tip the scales" by saying the government's payment is not dispositive (i.e., can't be considered conclusive in reaching a decision about materiality), Krueger said.

There are times when the agency at issue in an FCA lawsuit, such as CMS, is fully aware of the alleged fraud and pays anyway for various reasons, political or otherwise, but "that doesn't mean it's a good False Claims Act case," said attorney Pam Johnston, with Foley & Lardner LLP. "It has to be fraud. If the government already knows what's going on, how can it be fraud? The threat of litigation is onerous. This thing has a big wallop because of attorneys' fees and treble damages." The government can always recover overpayments without resorting to an FCA lawsuit, she noted.

Anyway, the materiality decision on payment is best left up to judges, case by case, Rubin said. "We're not saying the government's decision to pay should always be dispositive," she noted. "We just think the court should make the decision itself."

DOJ Would Have to Explain Dismissals to a Judge

The False Claims Amendments Act has other provisions. It would also require DOJ to go before a judge to explain why it's dismissing a whistleblower case and "identify a valid government purpose and a rational relation between dismissal and accomplishment of the purpose." DOJ has dismissed far more whistleblower cases since a 2018 memo from Michael Granston, now the deputy assistant attorney general of the commercial litigation branch.[4] When whistleblowers file FCA cases on behalf of the government, DOJ is required to investigate, and it may either intervene, which means it throws the government's investigative weight behind them; decline to intervene; or actively dismiss the cases, which prevents whistleblowers from pursuing the FCA lawsuit on their own. The Granston memo encouraged more dismissals, saying "the Department should consider moving to dismiss where a *qui tam* complaint is facially lacking in merit—either because relator's legal theory is inherently defective, or the relator's factual allegations are frivolous."

The bill doesn't define "valid government purpose," which is a little vague, Johnston said. Also, "what gets lost in the debate is the costs imposed on the health care system by the many qui tams that don't have merit," Krueger said. When DOJ doesn't intervene, whistleblowers often dismiss the cases without prejudice, Johnston said. When that happens, "there's no remedy for the defendant, no way to get attorneys' fees, even though they may have spent $1 million to produce documents and hire counsel. It feels really unfair."

The legislation also would extend to former employees the protection from retaliation enjoyed by current employees.

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Endnotes

1. False Claims Amendments Act, S. 2428, 117 Cong. (2021), https://bit.ly/36o1tfD.
2. Universal Health Services, Inc. v. United States et al. ex rel. Escobar et al., 842 F.3d 103 (2016), http://bit.ly/2rC1abg.
3. Department of Justice, "Justice Department's False Claims Act Settlements and Judgments Exceed $5.6 Billion in Fiscal Year 2021," news release, February 1, 2022, https://bit.ly/3L2iSKE.
4. Michael D. Granston, "Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)," memorandum, January 10, 2018, https://bit.ly/3LHaC2I.

Compliance Programs May Need 'Crisis Proofing,' Attorneys Say

When attorney Brian Burke helped a company with a recent investigation, he saw some of the ripple effects of remote working on a compliance program. Because the company had shifted to 100% teleworking when the COVID-19 pandemic hit, "we had to pivot to remote interviews." During an interview, Burke noticed the employee paused before answering questions. "We could hear whispering offscreen," he said.

Burke realized the employee's partner was in the room supplying answers. "She was sitting next to him off camera. It wasn't even hard to figure out two people were answering." The partner, who wasn't employed by the company, obviously shouldn't have been in the room. "If it was two years ago, this wouldn't have happened. This is now reality."

That was a vivid reminder of the risks of remote working. "Nothing is as good as being in the same room with the person," Burke said. But assuming some remote interviews are inevitable, "you have to do them as effectively as possible." He recommended preparing a protocol in advance "so you are drawing on a protocol rather than drawing up a protocol in the middle of a pandemic or other crisis."

Mitigating the risks of remote working is one of the ways that compliance officers should think about "crisis proofing" their compliance programs, according to Burke and attorney Cáitrín McKiernan, with Shearman & Sterling (see box, p. 5).[1] "The focus has been on health and safety rightfully, but pandemics, like any crisis, have an impact on corporate compliance programs as well," he noted. They're referring to crisis proofing

for micro-crises a company might encounter (e.g., employee protest, product recall, breach, bribery/fraud case, sexual harassment scandal), and macro-crises that affect an entire industry, geography or population (e.g., natural disaster, pandemic).

Remote working is one of the top five risks to emerge in the COVID-19 pandemic. The others are supply chain disruptions, reallocation of compliance funding, COVID-19 vaccine development/distribution and the great resignation, Burke and McKiernan said at a Feb. 15 webinar sponsored by the Society of Corporate Compliance and Ethics & Health Care Compliance Association.[2]

"It's hard to understate the significance of the impact of a remote workforce on compliance," Burke said. It's tantamount to removing the compliance posters overnight. Depending on the organization, compliance officers aren't walking the halls or available for a spontaneous conversation with an employee who has a question or concern. "There are fewer compliance touchpoints," he noted. Even though companies have sign-in sheets for remote training, it's hard to know whether employees are paying attention. During a crisis, companies should increase the "volume, frequency and cadence of training," he said. "I would rather risk training fatigue than misconduct or employees not knowing what to do." If companies are investigated, "it's a weak excuse to say we were concerned about training fatigue." At the same time, "compliance messaging should not be relaxed," Burke said. It "should be enhanced."

Company data also is more vulnerable because home Wi-Fi is not as secure as the workplace internet. "We recommend using VPN, anti-hacking and anti-cyber theft tech," he said. It also may be worth investing in printers and shredders for employees' homes so they don't use the corner store or throw sensitive documents in the garbage.

'Don't Lower Your Compliance Standards'

Another compliance risk during a crisis is supply chain disruption. "Businesses may conduct hasty, inadequate or even no due diligence when forced to pivot to new suppliers," Burke said. When dealing with vendors who are not the usual "trusted third parties," companies can mitigate the risk in the future by having backup, vetted third parties. "If one day you are faced with a supplier or agent being unavailable, you can pivot to a known entity, someone already familiar to you, and they are already vetted and on a backup list," Burke said. He also recommends diversifying so you're not overly reliant on one vendor for a service. "If you have to onboard a new, unvetted third party, you should still conduct due diligence. Don't lower your compliance standards," he said. Regulators after the fact will inquire whether you would have onboarded the vendor under normal circumstances.

The third risk is reallocation of compliance funding. Because compliance is often viewed as a cost center, its funding may be cut during a crisis. That's why Burke recommends reminding internal stakeholders about "the dangers of a compliance pause" and explaining that compliance is more of a "revenue protector" than a cost center. "If you think compliance is expensive, you should try noncompliance," he said. "Billions have been lost and spent recovering from a compliance crisis." Burke said he had a health care client that was the target of a criminal investigation. In addition to the cost of the investigation, the health care company paid a fine, "but what really impacted the CEO, CFO and the board was for the first reporting period after the investigation made it into the news, their sales were down 80%," Burke said. "Putting aside compliance headaches, because the public no longer trusted the company's product, physicians and hospitals were no longer comfortable putting it on the formulary and prescribing it as a result of a compliance investigation. If you're speaking to the business side of house, speak in their language. You are a revenue protection center."

Great Resignation vs. Corporate Culture

The fourth risk is COVID-19 vaccine development, distribution and funding. With enormous public and private investments in vaccines, "it's a perfect storm for corruption and bribery," McKiernan said. "Everyone in the world is looking for these vaccines." She recommended doing a risk assessment and having a protocol to ensure all employees, from the receptionist to the CEO, knows what to do when visited by regulators. Also, during a crisis, training should be frequent and creative. "There are fun ways to do it" (e.g., with TikTok).

The fifth risk is the great resignation. "The workforce is leaving in droves," McKiernan said. "There are risks associated with compliance because how do you maintain a culture of compliance if you don't have the same workforce year to year?" There are a lot of mitigation strategies. For example, "put compliance at the center of the onboarding process" so employees understand that "it's integrated into the company," and make compliance an element of performance reviews, McKiernan said.

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Endnotes

1. Nina Youngstrom, "Examples of Emerging Compliance Risks and Mitigation Strategies," *Report on Medicare Compliance* 31, no. 7 (February 21, 2022).
2. Brian Burke and Cáitrín McKiernan, "Crisis Proofing Your Compliance Program: Lessons Learned from COVID-19," webinar, Society of Corporate Compliance and Ethics & Health Care Compliance Association, February 15, 2022.

Examples of Emerging Compliance Risks and Mitigation Strategies

Mitigating the risks of remote working is one of the ways that compliance officers should think about "crisis proofing" their compliance programs in the wake of the COVID-19 pandemic, according to attorneys Brian Burke and Cáitrín McKiernan, with Shearman & Sterling (see story, p. 3).[1] "The focus has been on health and safety rightfully, but pandemics, like any crisis, have an impact on corporate compliance programs as well," Burke noted. They're referring to crisis proofing for micro-crises a company might encounter (e.g., employee protest, product recall, breach, bribery/fraud case, sexual harassment scandal), and macro-crises that affect an entire industry, geography or population (e.g., natural disasters, pandemic). Contact Burke at brian.burke@shearman.com and McKiernan at caitrin.mckiernan@shearman.com.

Specific Risks and Mitigation Strategies—Remote Workforce

Specific Risk	Mitigation Strategies
Increased use of personal devices and unauthorized messaging applications create the risk of data breaches and books and records issues	• Before crisis, develop and implement company guidelines with respect to the use of non-company devices and unauthorized messaging applications • Train, train, and train again on those guidelines • During crisis, amplify messaging and training regarding those guidelines

Work on insecure non-office Wi-Fi networks and at home create the risk of data breaches (including HIPAA violations) and hacking	• Before crisis:
	  • Require use of security tools to remotely access company data (e.g., virtual private network)
	  • Don't forget to implement simple security measures (e.g., require employee laptops to lock after certain period of idle time; require employees to shred confidential papers; watermark hard copy documents)
	• During crisis:
	  • Conduct spot checks of employee readiness
	  • Increase training and messaging surrounding data security

Fewer compliance touchpoints with employees	• Increase number of trainings and opportunities for informal compliance check-ins • Increase visibility and accessibility of compliance team • Boost messaging regarding whistleblower hotline

Witness interviews must be conducted remotely, challenging the integrity of compliance investigations	• Before crisis:
	  • Develop remote interview protocol, including how to preserve privilege and ensure confidentiality and how to address technical challenges
	• During crisis:
	  • Continue best practices for witness interviews (e.g., Upjohn warnings)
	  • Document rationale for any departures from traditional interview methods
	  • If interviews or other investigative steps need to be postponed due to extraordinary circumstances, consider interim compliance measures to address alleged misconduct

Evidence necessary for compliance investigations is often located remotely and therefore difficult to collect and preserve	• Before crisis: • Develop comprehensive remote evidence collection and preservation protocol, which designates responsibilities and outlines risk mitigation strategies related to document review by remote third parties

Specific Risks and Mitigation Strategies—Reallocation of Compliance Funding

Specific Risk	Mitigation Strategies

Scarce funds are reallocated from compliance—a cost center—to address urgent business needs	• Before crisis:
	  • Discuss the dangers of a "compliance pause"
	  • Educate internal clients on how compliance saves money in the long run
	• During crisis:
	  • Remember the importance of internal communications regarding the value of compliance
	  • If funds are reallocated, consider how to maximize existing funds (e.g., move resources away from audits of nonexistent travel and entertainment expenses to higher risk areas)

Endnotes

1. Nina Youngstrom, "Compliance Programs May Need 'Crisis Proofing,' Attorneys Say," *Report on Medicare Compliance* 31, no. 7 (February 21, 2022).

'Mini-Appeals' May Be Fruitful During Clinical Validation Reviews

Recovery audit contractors (RACs) are not permitted to perform clinical validation reviews anymore, but they're popular with Medicare Advantage (MA) and commercial payers, which may deny inpatient claims for acute respiratory failure, sepsis and other diagnoses that they say aren't supported in the medical records. But some payer arguments may not be grounded in clinical evidence or a contract provision or policy, and hospitals have a better shot at changing the payer's mind about the diagnosis at the time they respond to a documentation request than during a full-on appeal, an attorney said.

A "mini-appeal" is one strategy for dealing with the growth in clinical validation reviews, said Richelle Marting, an attorney and certified coder in Olathe, Kansas, at a Jan. 27 webinar sponsored by the Health Care Compliance Association.[1] In response to a payer's documentation request, hospitals would put a single page on top of the medical records that explains how the elements for the diagnosis were met. "It's a lot easier to stop the appeal on the front end than to appeal the adverse decision," she said.

For example, payers often target sepsis and other complications or comorbidities (CCs) or major CCs because they fatten MS-DRG reimbursement. When they request the medical records, Marting recommends hospitals also include a cover sheet that highlights how the Sepsis-3 diagnosis criteria were met, including information about the patient's Sequential Organ Failure Assessment (SOFA) score. "If the chart isn't strong with Sep-3 criteria, and if the payer requesting records has not formally adopted Sepsis-3 as the only diagnostic criteria they will accept for payment, I may lead with something like, 'The hospital has adopted criteria for Sep-1 or Sep-2.'" Unless the payer has formalized its use of Sepsis-3 in the contract or a provider manual, the hospital has a strong argument for the physician's diagnosis with other criteria.

Marting got the idea for mini-appeals when working with a hospital on a RAC's denial of neurostimulator implant procedures. The RAC had denied six cases at $20,000 per procedure. Even though the hospital had submitted the history and physical, progress notes, and discharge summary, the RAC had denied the claims because the hospital hadn't thought to include outpatient notes from several weeks before the procedures. The preadmission records contained the patient's psych evaluation, which was required by the local coverage determination (LCD) for the neurostimulator implant. The hospital now puts a page on top of its medical-records packet with a list of the documentation elements required in the LCD and the pages where they're located in the record, and highlights key coverage requirements in the records themselves.

Clinical Validation vs. DRG Validation

Mini-appeals may be helpful as the volume of clinical validations by MA plans and commercial payers grows, Marting said. Although clinical validation originated with RACs, they're no longer allowed to do them. According to the RAC statement of work: "Clinical validation is prohibited in all RAC reviews."[2]

It's ironic that CMS backed off clinical validations while private payers have embraced them, she said. "The only safeguards and parameters on how clinical validation reviews should work were within the RAC statement of work, and there is one *Coding Clinic* article that talks about them, but private payers have adopted this concept and run with it," Marting noted. "They have nothing in writing explaining what the procedural safeguards and guardrails are."

Clinical validations are different from DRG validation reviews, although payers may do both on the same claim. The purpose of DRG validation is to determine whether principal and secondary diagnoses and procedures that potentially affect the MS-DRG match the information in the patient's medical record, including the attending physician's description, by applying the *Official Guidelines for Coding and Reporting*. With clinical validations, payers often accept the condition was diagnosed and documented, but a reviewer, who should be a clinician (e.g., registered nurse under a physician's supervision), reviews the medical records for underlying clinical indicators (e.g., lab values) to determine whether the physician's diagnosis is supported.

Severe protein-calorie malnutrition is a diagnosis that's often targeted in clinical validation reviews, Marting said. Payers are focusing on documentation inconsistencies and lack of evidence of weight loss. Payers often use the GLIM criteria for the diagnosis of malnutrition, which has two parts: the etiology (e.g., cancer or gastrointestinal issues causing a lack of nutrition) and phenotypic (e.g., weight loss, reduced muscle mass). Typically, payers and hospitals agree on the etiology but not so much on the phenotypic.

CMS Transmittal, Feb. 11-17

Transmittal

Pub. 100-04, Medicare Claims Processing

- Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April 2022 Update, Trans. 11268 (February 17, 2022)

It's helpful in a mini-appeal or regular appeal to include an outpatient note from a month or two before admission that has the patient's weight and body mass index. "Dietician assessments can be really helpful here too," because they often contain more detail on signs of muscle wasting than may appear in physician records, she said. Beware of conflicting documentation; physicians' exam findings may say "well nourished" but weight and body mass index point to malnutrition.

Another clinical-validation target is acute respiratory failure. "This has become a focus of a lot of major payers during clinical validation," Marting said. Often the diagnosis is denied because arterial blood gas (ABG) measurements aren't in the medical records or the patient didn't require a BiPap (a type of ventilator) or other mechanical ventilation. While ABGs are ideal, articles by Dr. Richard Pinson, a physician educator, and others say ABGs are not required to establish an acute respiratory failure diagnosis. "For a patient to have acute respiratory failure, it must be symptomatic and meet diagnostic criteria based on arterial blood gas (ABG) or pulse oximetry readings (SpO2)," Pinson wrote on his website.[3] Marting recommended looking at whether the payer has a policy requiring ABGs for respiratory failure diagnosis and, if not, whether a claim was rejected based on an oxygen saturation measurement that's consistent with the medical record. "Don't assume it's accurate if the payer asserted the patient's oxygen saturation was 95%," she said. "I often find actual oxygen saturation measurements lower than what the payer cited. Trust but verify." Marting said she also has seen payers mischaracterize Pinson's articles discussing clinical diagnostic criteria for acute hypoxic respiratory failure.

Another target is hyponatremia. Patients suffer a drop in sodium levels, but many payers don't have a policy on what that means, Marting said. Payers may say a threshold of 135 meq/L per liter or 130 is required and that IV hydration is insufficient treatment to validate the diagnosis, but there's not a universally recognized, bright-line standard, she said. And "monitoring is an appropriate treatment" based on UpToDate, a clinical decision support and content tool often cited by payers, and *Official Guidelines for Coding and Reporting* standards for reporting additional diagnoses. "The interesting part of the UpToDate articles on hyponatremia that payers rely on is that the article itself began with a statement that hyponatremia is defined as sodium < 135, but then proceeds to identify a number of studies that define hyponatremia as sodium below anywhere from 130, 135, or up to 135 meq/L," she said.

Payers May Have Agreed to Pay for Records

There are other matters to address up front with MA plans and commercial payers to try to prevent a denial. The rules of the road are generally determined by the contract or policies and procedures, and hospitals should hold the payers to them, Marting said. For one thing, the contract outlines the number of days hospitals and other providers have to produce medical records, but she has found that audit companies hired by the payers will give a shorter deadline. "That may need to be escalated to the managed care contracting team."

And if payers are contractually required to pay for copies of medical records, send an invoice before you produce them. Also, nail down whether the payer's contract, policies or manuals even allow prepayment clinical or DRG validations.

Contact Marting at rmarting@richellemarting.com. ✧

Endnotes

1. Richelle Marting, "Clinical Validation Reviews: Trending Topics and Response Strategies," webinar, Health Care Compliance Association, January 27, 2022, https://bit.ly/3LHLF7j.
2. CMS, *Statement of Work (SOW) for the Part A/B Medicare Fee-for-Service Recovery Audit Contractor (RAC) – Region 1*, accessed February 17, 2022, https://go.cms.gov/34IfmVt.
3. "Acute Respiratory Failure - All There Is To Know," Pinson & Tang LLC, September 5, 2017, https://bit.ly/358sp1X.

Hospital Settles CMP Case Over Drug Billing

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Kolarik said OIG allowed VBMC to "delay consideration of the self-disclosure" because of the COVID-19 pandemic "until there was an ability to focus time on any additional questions. Once the green light was given, OIG asked a few questions, and we moved quickly to settlement discussions."

Wasted drugs refer to the medication left over in single-use vials after the prescribed amount is administered. Patients often get less than the amount in a single-use drug vial, and the rest should be thrown out according to guidance from the Centers for Disease Control and Prevention (CDC). Medicare pays for waste assuming there's documentation to support it. Waste is a compliance risk for various reasons (e.g., lack of documentation).

There are challenges with using a single-use vial for multiple patients. Medicare recognizes the CDC guidance,[1] but leaves wiggle room if providers are judicious in their use, said Steve Gillis, director of compliance coding, billing and audit at Mass General Brigham in Boston. CMS presumably is keeping dollars in mind, he said. If a vial has 100 mg and the patient only needs 20 mg, Medicare is paying for 80 mg of wasted drugs that aren't helping anybody. For example, at an infusion clinic where the same drug is used with patient after patient, it may be safe to draw from a

single-use vial, Gillis said. But that wouldn't be the case in the emergency room where too much time would elapse before a second patient is prescribed the same medication, he said. It's a problem in terms of the shelf life of a drug. For example, daptomycin is stable for 12 hours at room temperature and up to 48 hours if refrigerated.

But charging can get complicated and prone to error if hospitals try to use waste from a single-use vial for certain patients and bill waste for other patients, Gillis said. "Charging processes need to be understood by clinicians and pharmacy staff involved in preparing or administering drugs," he said. Hospitals want to avoid a charging decision to bill waste when the drug isn't being wasted because it's used for multiple patients. However, if hospitals choose clinically "to attempt to use single-use vials for multiple patients, trying to bill for waste when it sporadically occurs is even more difficult," Gillis said. "Identifying when a drug is no longer safe for use and deciding which patient the waste charge should be linked to would be very difficult to manage."

Billing for waste at the end of the day and charging the final patient for that waste also creates challenges in terms of documentation and billing. The infusion nurse may decide to hold onto the last 70 mg of a vial for an hour until it expires. Who was the last person the nurse administered the drug to? Was that patient's account charged? Or was the drug wasted after all? "It requires conversations between the clinical and finance people," Gillis said.

Administering multiple doses of a drug from a single-use vial is a "clinical decision as to whether you think it's safe," Gillis said. Mass General Brigham doesn't do it; the hospital's systems are set up to bill for waste.

Identifying drug waste billing in an organization has been easier since Medicare mandated the use of the JW modifier nationally. Hospitals must append modifier JW on the line item reporting the amount of the drug being wasted if they want reimbursement for it. That means the amount of the drug administered is on one line item of the claim, and the amount of the drug wasted is on a separate line item with the modifier.

Before the JW modifier, hospitals may not have realized when they billed for waste versus giving patients doses from the same single-use vial. Now they can run reports to see where they're billing for waste and audit documentation to determine whether it's compliant.

This only matters if Medicare pays separately for the drug. Separate payments apply to drugs with a status indicator of G or K, meaning they're separately payable. Drugs with other status indicators, including N, are irrelevant because they're bundled into the ambulatory payment classification. Gillis said daptomycin now has a status indicator of N.

Contact Gillis at sjgillis@partners.org. ✧

Endnotes

1. "Questions about Single-dose/Single-use Vials," Centers for Disease Control and Prevention, last reviewed June 20, 2019, https://bit.ly/3I3X6Ed.

NEWS BRIEFS

◆ **The Senate on Feb. 17 confirmed Christi Grimm as HHS Inspector General (IG), according to the Congressional Record**.[1] She is now Principal Deputy IG and will remain in that role until she is sworn in, according to OIG spokesperson Yvonne Gamble. "Grimm began leading OIG on January 1, 2020, serving as the Principal Deputy Inspector General, performing the duties of the Inspector General. In total, Ms. Grimm has more than two decades of leadership and expertise in health and human services programs, both at OIG and previously at CMS," Gamble said.

◆ **OIG has updated its Work Plan**.[2]

◆ **NCH Healthcare System (NCH), which runs two hospitals in Collier County, Florida, has agreed to pay $5.5 million to settle false claims allegations over "donations to local units of government to improperly fund the state's share of Medicaid payments to NCH," the Department of Justice (DOJ) said Feb. 14**.[3] According to the settlement, DOJ alleged that from Oct. 1, 2014, to Sept. 30, 2015, NCH made "non-bona fide donations" to Collier County and to the Collier County School Board by "(1) providing free nursing and athletic training services to the School Board; and (2) assuming certain of the County's financial obligations and paying them on the County's behalf. These non-bona fide donations freed up funds for the School Board and County to transfer to Florida's Medicaid program on NCH's behalf, and ultimately caused NCH to receive federal Medicaid funding to which it was not entitled."[4] NCH didn't admit liability in the settlement.

Endnotes

1. Cong. Rec. 168, no. 32, S798 (February 17, 2022), https://bit.ly/3uW5DFH.
2. "Recently Added," Work Plan, U.S. Department of Health & Human Services, Office of Inspector General, accessed February 18, 2022, https://bit.ly/2AxFtyP.
3. Department of Justice, "Florida's NCH Healthcare System Agrees to Pay $5.5 Million to Settle Common Law Allegations for Impermissible Medicaid Donations," news release, February 14, 2022, https://bit.ly/358SSMR.
4. NCH Healthcare System, settlement agreement, February 14, 2022, https://bit.ly/35a8u2Y.