Report on
MEDICARE COMPLIANCE

Volume 32, Number 4 • January 30, 2023

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

Contents



# All OIG Claim Denials From a Vent Audit Are Overturned; OIG National Audit Is Underway

Even as the HHS Office of Inspector General (OIG) has a national audit underway of compliance with Medicare requirements for noninvasive home ventilators (NHVs),[1] an administrative law judge (ALJ) has thrown out the last set of claim denials stemming from an OIG audit of NHV claims submitted by a durable medical equipment (DME) supplier, ending the saga of a $29.1 million overpayment finding.[2]

The surge in Medicare spending on NHVs triggered OIG's national audit, which focuses on medical necessity and compliance with payment and documentation requirements. But the fact that Sleep Management LLC, doing business as Viemed Healthcare Inc., overturned all the appealed denials for NHVs in the OIG audit raises questions about how medical necessity is judged, according to Viemed's attorneys, Stephen Bittinger and Josh Skora with K&L Gates. Bittinger said he's never had a case where all denials were overturned. "I have never had one and I have never heard of one because there are usually at least a few claims that must be conceded based on technical noncompliance." Because of the ALJ's findings, the DME Medicare administrative contractor (MAC) has returned the "previously remitted funds" to Viemed, according to a Jan. 23 announcement by the company.[3]

The divergence between the audit findings and the ultimate disposition in the appeals process underscores tensions over the way OIG and its independent medical reviewers apply some Medicare coverage criteria, Bittinger and Skora say. Some attorneys and providers contend that OIG or its independent medical reviewers sometimes misconstrue Medicare requirements and make other mistakes when reviewing claims.[4]

*continued on p. 6*

# Former OIG Chief Counsel: Noncompliance in Complex Environment at Times Is 'Inevitable'

Although health care organizations have shown "a major commitment to voluntary compliance efforts in trying to do the right thing in a complex regulatory environment," there's room for improvement, especially from leaders, according to the former chief counsel to the HHS Office of Inspector General (OIG).

"I'm not sure if they fully appreciate the importance of developing that culture and bringing compliance into the fabric of the organization and making sure the actions of the organization reflect that," said Gregory Demske, who left OIG in November after 30 years there, a decade as chief counsel and a stint as acting principal deputy inspector general. Compliance is about more than having the right compliance officer, policies and procedures, training and the rest of the compliance-program infrastructure, said Demske, now with Goodwin in Washington, D.C. "How do they create an atmosphere where people can bring forward suggestions and concerns and they are handled appropriately?" Similarly, is the organization conducting audits and correcting errors? That's the kind of evidence you'd expect with a "strong culture and commitment to compliance," he said in an interview with *RMC*.

Because OIG recognizes there will be noncompliance at organizations, it won't automatically result in a scarlet letter. "People make mistakes in a complex

*continued*

HCCA

**Managing Editor**
Nina Youngstrom
nina.youngstrom@hcca-info.org

**Copy Editor**
Jack Hittinger
jack.hittinger@hcca-info.org

regulatory environment and noncompliance of all types is inevitable,"Demske said. "Given the size and types of health care organizations and the complexity of delivering health care, I don't see it as a black and white world where either you're in total compliance and you're good or a problem happened and you're bad." OIG doesn't look at things in that binary way and he brings the same perspective in his job at the law firm. Now that he's in private practice, Demske said he hopes to apply the same principles he brought to the government: "to act with integrity" with the overarching goal of "helping health care entities that are benefiting the health and well-being of people."

While "a compliance-centric culture" is beneficial, it's not easy to achieve, said attorney Judith Waltz, with Foley & Lardner LLP in San Francisco. "Health care providers are very resource-stretched, working in a somewhat chaotic environment, and subject to public health emergency stresses and strains like everyone else," she noted. "It can be hard to find the time to reflect on how to assure that your compliance program is front of mind, still relevant, demonstrates its value, and that it is effective." The more tools provided by the government, including guidance on thorny but common billing issues, checklists, toolkits (e.g., *Measuring Compliance Program Effectiveness: A Resource Guide*), "the more likely it will be that providers can meet the strong-culture goal outlined by Demske," she said.[1]

**Report on Medicare Compliance** (ISSN: 1094-3307) is published 45 times a year by the Health Care Compliance Association, 6462 City West Parkway, Eden Prairie, MN 55344. 888.580.8373, hcca-info.org.



## 'Compliance Only Works Well If It's Not Siloed'

Demske said health care organizations have something to learn from OIG's use of data mining and the collaboration of its different components, including audit, evaluations, investigations and the chief counsel's office. "Compliance only works well if it's not siloed," Demske noted.

He mentioned the "incredible increase in the capabilities as far as data analytics and that has really helped OIG prioritize its work. There has also been increasing coordination and a unified approach to priority issues across the entire organization." This coordination has played out in OIG's work on opioids. OIG examined data on prescribers, pharmacies and beneficiaries to zero in on those doctors/prescribers and pharmacists/pharmacies with worrisome volume and patterns, Demske said. OIG investigators also work with the Drug Enforcement Administration and Department of Justice (DOJ) when opioid abuse affects Medicare and Medicaid populations. Although the opioid prescription rate in the Medicare population has dropped, OIG "continues to look at opioids in the global sense and is more focused on access to treatment."

OIG also has done a really good job of "bringing all disciplines together with respect to Medicare" in the nursing home arena, which is a "major priority" of Inspector General Christi Grimm, Demske said. Waltz added "it's another example of OIG's focus and success."

## 'Good Level of Cooperation' in Self-Disclosures

On the OIG's Self-Disclosure Protocol (SDP), Demske said submissions by health care organizations are "pretty good" in general. "There's a good level of cooperation." The SDP ground rules are clear and "I think it's been a successful process" for resolving violations. When health care organizations are reporting billing for services provided by an excluded employee, "that's pretty straightforward and pretty well laid out," he noted. With thornier cases involving more complex billing, the process will go faster if organizations do more thinking ahead of time "to figure out what happened and why and quantify that."

Waltz noted the SDP now has categories, and that the category for the types of situations described by Demske is called "Health Care Fraud." As described in the SDP, its purpose is "to facilitate the resolution of matters that, in the disclosing party's reasonable assessment, potentially violate Federal criminal, civil, or administrative laws for which CMPs [civil monetary penalties] are authorized."[2] Waltz explained that "the universe of these cases is smaller and of higher risk than many common compliance mistakes, and the SDP requires the provider to characterize its conduct as 'Health Care Fraud' with potential CMP liability."

She added that the SDP can be a good move, partly because it includes a pathway to a release of CMP liability if the provider discloses and cooperates. "Much of the drama of the case – including an internal investigation and a decision to disclose – typically occurs before the SDP is filed and OIG learns of the issue. Providers are grateful to have a way to address these situations and put them behind them."

### 'We Hired and Nurtured Really Good People'

Outside of self-disclosure, "sometimes people aren't as motivated to resolve the matter," Demske said. When a case advances to the corporate integrity agreement (CIA) phase, usually as part of a False Claims Act (FCA) settlement, he said negotiations would benefit from "focusing on how best to allocate the resources that are being devoted to real risk areas so it's not a waste of money to be doing audits that won't help inform the entity's compliance efforts." It's in everyone's interest to avoid arguing about the organization's liability because "we wouldn't be talking about the CIA if there weren't going to be an agreement that led to the resolution" of the FCA allegations. He said it's better for organizations in this boat to focus on resource allocation in the CIA than "arguing about the language" of the CIA provisions because "OIG won't want to change those provisions."

As far as the accomplishments of the chief counsel's office, Demske said it has grown "in size and scope" during his tenure and "we hired and nurtured really good people." He also said that "we increased our sophistication on a lot of fronts." For one thing, the chief counsel's office carved out an affirmative litigation branch to focus on CMP cases and exclusions. The office also became more focused on FCA cases, which DOJ takes the lead on. Using criteria published by the chief counsel's office in the Fraud Risk Indicator and risk spectrum, OIG has become more deliberative about how best to collaborate with DOJ in resolving civil cases with administrative penalties, he said.[3] Given the large volume of HHS-related FCA complaints, "we wanted to prioritize those where we could have the maximum impact," Demske said. That includes pursuing exclusion of the subject of DOJ's settlement and/or CMPs against people or entities that are not part of DOJ's settlement. The Fraud Risk Indicator is OIG's "assessment of future risk posed by persons who have allegedly engaged in civil healthcare fraud," according to its web site. The spectrum ranges from highest risk (exclusion from federal health care programs) to lower risk (self-disclosure). OIG updated its criteria for using its exclusion authority in 2016.[4] It routinely reports on where FCA cases land along the risk spectrum.[5]

Contact Demske at gdemske@goodwinlaw.com. ✧

**Endnotes**

1. Health Care Compliance Association, *Measuring Compliance Program Effectiveness: A Resource Guide*, March 27, 2017, https://oig.hhs.gov/documents/toolkits/928/HCCA-OIG-Resource-Guide.pdf.
2. U.S. Department of Health & Human Services, Office of Inspector General, *Updated: OIG's Health Care Fraud Self-Disclosure Protocol*, updated November 8, 2021, https://bit.ly/40ayDXa.
3. U.S. Department of Health & Human Services, Office of Inspector General, "Fraud Risk Indicator," accessed January 26, 2023, http://bit.ly/3XSmvIM.
4. U.S. Department of Health & Human Services, Office of Inspector General, "Criteria for implementing section 1128(b)(7) exclusion authority," April 18, 2016, https://bit.ly/3k1yErW.
5. U.S. Department of Health & Human Services, Office of Inspector General, "False Claims Act Settlements on the Risk Spectrum," accessed January 26, 2023, http://bit.ly/3JcM4jw.

## Improving Website Accessibility Helps Avert ADA Lawsuits: Attorney

Health care organizations, facing a rising tide of litigation from plaintiffs under the Americans with Disabilities Act (ADA) alleging that the organizations' websites aren't ADA-compliant, don't have a safe harbor from the Department of Justice (DOJ) to fall back on, an attorney said. But there are ways to ward off most lawsuits.

Court rulings have been mixed on whether an organization's website must be ADA-compliant, said James Fetter, an attorney with Nelson Mullins in Cleveland, at a Jan. 11 webinar sponsored by the Health Care Compliance Association.[1] However, that hasn't stopped plaintiffs from suing, he said, noting that anyone with a relevant disability who visits a health care organization's website could bring a claim.

"There are a lot of places out there looking for inaccessible websites," potentially to bring legal action against them, Fetter noted. Research has shown that since 2018, website and mobile app accessibility lawsuits have made up roughly one-fifth of all ADA Title III filings in federal court, which now consistently exceed 10,000 lawsuits annually, he said. It's unclear if mobile apps are covered, but plaintiffs are beginning to target them.

The ADA doesn't expressly apply to websites, so some courts—although not all—have required a nexus between web and physical access, Fetter said. In the context of health care, this could limit plaintiffs to those who actually could use your facility. Other cases might be dismissed. Other courts, particularly in the northeast, take the position that you don't need to have a physical facility to have a website ADA case, he said. "This could really come into play in terms of telehealth."

In contrast, in the U.S. Court of Appeals for the 11th circuit, which covers Florida, Georgia and Alabama, Fetter said "there are rumblings" that websites are not places of public accommodation for ADA purposes. In *Gil v. Winn-Dixie Stores, Inc.*, which was vacated for other reasons, the court noted that all public accommodations listed in the ADA are physical places.[2] This stance could reappear in future rulings, impacting Florida cases, he said.

DOJ hasn't issued regulations on what an ADA-covered entity must do for its website to be considered accessible, Fetter said. "Unfortunately, there is no safe harbor for organizations looking at web accessibility issues," he remarked. "There's no regulation that says, 'If you do this, this, and this, you're covered.'"

The Obama administration was planning on issuing regulations, but failed to do so, and the Trump administration didn't take them on, Fetter said. The Biden administration in March 2022 issued guidance on web accessibility and the ADA, but Fetter said the guidance "is not a regulation and is not really binding on anybody."[3]

## WCAG Standards Are Recommended

Still, some best practices exist that might help organizations "to hopefully avoid most litigation," Fetter said. Organizations can follow version 2.0 of the Web Content Accessibility Guidelines (WCAG) published by the Web Accessibility Initiative of the World Wide Web Consortium, the main international standards organization for the internet. "They're developed by a private foundation, so they're not regulations, but a lot of courts have looked at these standards and said, 'Okay, if you meet those, you're accessible.'"

Alternatively, organizations can use the standards outlined in the regulations for Section 508 of the Rehabilitation Act of 1973, which requires federal agencies to develop, procure, maintain and use information and communications technology that are accessible to people with disabilities, regardless of whether they work for the federal government. The WCAG standards may be easier to use and less cumbersome, Fetter said.

To ensure that people with disabilities can access a website, Fetter recommended that organizations structure their websites so users can navigate them with a keyboard, since some people can't use a mouse. He also stressed the importance of labeling graphics and images with alternative text, captioning and, where possible, providing audio describing videos. "That would mean, if you're showing something on a video, try to have an alternative link for audio description or an alternative track, or at the very least, have closed captioning on the video so a person who's hard of hearing can at least know what's being said," Fetter explained.

The organization's website developers should make certain they are familiar with the WCAG 2.0 standards. He noted that there are automated tools available to test accessibility, but added, "don't rely on those to the exclusion of a human being, because they're still not that great. Don't assume that if it says your website is accessible, you're good to go. Have a human being look at it—especially a human being with some expertise in this area."

The key, Fetter said, is to make accessibility part of the web development process, not an afterthought. "It's much more expensive to fix mistakes than to do it right the first time," he said. "It's also much more expensive to settle lawsuits than to just do it right the first time. Now, realistically, a lot of these website cases don't settle for that much—it might be 10 grand or 15 grand, something like that. Sometimes you get more than that. But you get hit multiple times. So rather than paying off plaintiffs' attorneys, just try your best to make sure the website's accessible."

## Physical Access, Communications Are Important

Website accessibility is a hot topic, but meaningful physical access to facilities and policies concerning patient communication continue to be critical to consider when developing a compliance plan, Fetter said.

DOJ has been active in ensuring physical access. For example, on Jan. 17, DOJ said two eye care practices – Barnet Dulaney Perkins Eye Centers (BDP) and American Vision Partners (AVP) – will pay $1 million in a proposed consent decree to resolve allegations the practices violated the ADA.[4] The lawsuit alleged that the two practices refused to operate on certain patients who needed assistance transferring from their wheelchairs for surgery and required other such patients to pay for third-party medical transport and transfer assistance. BDP operates eye care facilities throughout Arizona, and AVP partners with BDP and with other eye care providers in Arizona, New Mexico, Nevada and Texas.

Physical access is more than just wheelchair access, Fetter said. ADA standards also cover older facilities as long as accessibility fixes are "readily achievable," he added, and failure to remove barriers, when easy to do, is unlawful. Courts have required health care facilities to implement readily achievable accessibility fixes, such as repaving parking lots and adding wheelchair ramps, lowering toilets or urinals and rearranging or removing furniture as needed.

Health care organizations should ensure that new construction or alteration of buildings meets ADA requirements, and that patients who use wheelchairs are examined on accessible tables, not while in their wheelchairs, he said. In addition, if a patient brings a companion, the health care provider should always address the patient, rather than the companion, he said.

Organizations also should consider other physical access situations, Fetter said. "One of the major barriers for a blind person or a visually impaired person is a touchscreen kiosk or a touchscreen check-in, and these are all over the place now," he said. "So, it's very important to be thinking about how a patient checks in at your facility. If it's a touchscreen, it can still be perfectly fine, but you need to have access features on that device which allow a blind or visually impaired person to interact with it in another way." DOJ released a technical assistance publication in 2014 on effective communication.[5]

Covered entities must provide "auxiliary aids and services" when needed to communicate effectively with disabled people, which could include providing

a qualified reader or interpreter or information in alternative formats, and also may include staff trained to recognize unclear speech, he said. Communication with both patients and any companions must be effective, he said. Physician offices often use video remote interpreter services for patients who are hearing-impaired and who use American Sign Language, but an in-person interpreter may be needed for taking a medical history or for discussing a serious diagnosis and treatment options, Fetter said.

Contact Fetter at james.fetter@nelsonmullins.com. ✧

**Endnotes**

1. James Fetter, "ADA Compliance for Healthcare Facilities and Services," January 11, 2023, webinar, https://bit.ly/3R1AcTs.
2. Gil v. Winn-Dixie Stores, Inc., 993 F.3d 1266, 1277 (11th Cir. 2021).
3. U.S. Department of Justice, Civil Rights Division, "Guidance on Web Accessibility and the ADA," March 18, 2022, https://bit.ly/3J9wRzs.
4. U.S. Department of Justice, Office of Public Affairs, "Eye Surgery Practices Agree to Pay $1 Million and End Discriminatory Policies Towards People with Disabilities," news release, January 17, 2023, https://bit.ly/3koHR1G.
5. U.S. Department of Justice, "ADA Requirements-Effective Communication," January 2014, https://bit.ly/3Ws1Ee8.

## New Data on Compliance Budgets and Staffing

Here are some of the results from the new Healthcare Industry Compliance Staffing and Budget Benchmarking and Guidance Survey published by the Health Care Compliance Association.[1]

### SURVEY DATA

Most firms in the health care industry with revenues under $500 million have 1-5 employees in their compliance group. Compliance staff size ramps up dramatically above that revenue level; in fact, a majority of firms with revenues of $3 billion or more have more than 20 employees in compliance.

### BY REVENUE OF ORGANIZATION AS A WHOLE

| | EMPLOYEES IN COMPLIANCE GROUP | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1 | 2 to 5 | 6 to 10 | 11 to 15 | 16 to 20 | 21 to 50 | More than 50 |
| Less than $5 million | 39% | 30% | 12% | 8% | 2% | 3% | 5% |
| $5 million to less than $15 million | 26% | 47% | 15% | 4% | 3% | 3% | 1% |
| $15 million to less than $30 million | 25% | 47% | 15% | 5% | 3% | 3% | 1% |
| $30 million to less than $50 million | 32% | 38% | 17% | 5% | 1% | 3% | 4% |
| $50 million to less than $100 million | 18% | 46% | 18% | 8% | 5% | 2% | 3% |
| $100 million to less than $500 million | 14% | 50% | 17% | 11% | 4% | 4% | 0% |
| $500 million to less than $1 billion | 4% | 40% | 19% | 11% | 6% | 15% | 6% |
| $1 billion to less than $3 billion | 0% | 24% | 25% | 16% | 18% | 11% | 5% |
| $3 billion or more | 4% | 10% | 9% | 9% | 13% | 25% | 30% |

That general pattern is the same when we look at the number of compliance employees by the revenues for just those portions of the organization the compliance team serves. Specifically, majorities of organizations with compliance-reliant revenues under $500 million have compliance teams made up of 5 or fewer employees, while 56% of firms with $3 billion plus in revenues have teams of more than 20 employees.

### BY REVENUE OF PORTION OF ORGANIZATION COMPLIANCE GROUP SERVES

| | EMPLOYEES IN COMPLIANCE GROUP | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1 | 2 to 5 | 6 to 10 | 11 to 15 | 16 to 20 | 21 to 50 | More than 50 |
| Less than $5 million | 28% | 34% | 13% | 10% | 3% | 4% | 8% |
| $5 million to less than $15 million | 24% | 45% | 14% | 6% | 3% | 4% | 3% |
| $15 million to less than $30 million | 25% | 48% | 13% | 3% | 4% | 6% | 0% |
| $30 million to less than $50 million | 34% | 41% | 11% | 9% | 0% | 1% | 4% |
| $50 million to less than $100 million | 17% | 46% | 20% | 6% | 6% | 2% | 4% |
| $100 million to less than $500 million | 15% | 51% | 17% | 8% | 2% | 4% | 3% |
| $500 million to less than $1 billion | 4% | 38% | 22% | 11% | 5% | 16% | 4% |
| $1 billion to less than $3 billion | 1% | 20% | 25% | 15% | 20% | 12% | 7% |
| $3 billion or more | 0% | 4% | 11% | 12% | 17% | 28% | 28% |

In general, we see a big shift in the size of compliance teams once firms hit 5,000 employees overall. Below that level, most firms have 1-5 member compliance groups. For firms with 5,000-9,999 employees, most have 2-10 employee teams. Another shift occurs at 10,000 employees: from 10,000 to 29,999, most have teams of 6-20 employees, while for the most part, firms with 30,000 or more employees tend to have compliance groups of 20+ members. Note: nearly 6 in 10 firms with 100,000 or more employees overall have a compliance team with more than 50 members.

**BY EMPLOYEES IN ORGANIZATION AS A WHOLE**

| | EMPLOYEES IN COMPLIANCE GROUP | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1 | 2 to 5 | 6 to 10 | 11 to 15 | 16 to 20 | 21 to 50 | More than 50 |
| Less than 100 | 47% | 39% | 5% | 0% | 0% | 5% | 3% |
| 100-249 | 48% | 44% | 4% | 1% | 0% | 1% | 1% |
| 250-499 | 35% | 46% | 8% | 4% | 1% | 0% | 6% |
| 500-999 | 29% | 51% | 13% | 4% | 1% | 1% | 1% |
| 1,000-1,999 | 10% | 54% | 21% | 9% | 1% | 3% | 1% |
| 2,000-2,999 | 18% | 53% | 16% | 3% | 4% | 6% | 0% |
| 3,000-4,999 | 13% | 49% | 18% | 8% | 4% | 6% | 3% |
| 5,000-7,499 | 3% | 39% | 29% | 19% | 7% | 9% | 0% |
| 7,500-9,999 | 0% | 22% | 37% | 15% | 15% | 12% | 0% |
| 10,000-14,999 | 2% | 18% | 23% | 24% | 21% | 8% | 5% |
| 15,000-19,999 | 3% | 13% | 31% | 19% | 19% | 16% | 0% |
| 20,000-29,999 | 3% | 11% | 19% | 19% | 22% | 22% | 5% |
| 30,000-49,999 | 3% | 19% | 5% | 5% | 16% | 43% | 8% |
| 50,000-74,999 | 8% | 8% | 17% | 8% | 13% | 17% | 29% |
| 75,000-99,999 | 0% | 12% | 24% | 6% | 6% | 35% | 18% |
| 100,000 or more | 7% | 11% | 4% | 4% | 7% | 9% | 58% |

**Endnotes**

1. Health Care Compliance Association, *Healthcare Industry Compliance Staffing and Budget Benchmarking and Guidance Survey*, January 2023, https://bit.ly/3kFPm4t.

## All Denials in Vent Case Are Overturned

*continued from page 1*

For example, the independent medical reviewer based its denials partly on the premise that patients must fail a "lesser device" before they can have an NHV, Skora said. "This is clinically inappropriate and dangerous for patients," he contended. And "there is no requirement to fail a lesser device because there are patients on ventilation in the hospital and they need the home version upon discharge. For this patient population, failure of a lesser device would likely result in patient death prior to NHV therapy."

According to a Medicare national coverage determination, NHVs are covered for the treatment of neuromuscular diseases, thoracic restrictive diseases and chronic respiratory failure consequent to chronic obstructive pulmonary disease.[5] NHV claims are under OIG scrutiny because Medicare payments for them increased from $3.1 million to $268.8 million between 2009 and 2017. Viemed and two other DME suppliers accounted for most of that growth, OIG said in the audit report. An earlier OIG audit concluded that NHVs had features that "created an opportunity for abuse" because DME suppliers could bill Medicare for an NHV as if it were being used as a ventilator "when use of a lower cost respiratory assist device (RAD) or basic continuous positive airway pressure (CPAP) device was indicated by the beneficiary's medical condition."

### OIG: No 'Objective Evidence' for Qualifying Diagnosis

For the Viemed audit, OIG reviewed a random sample of 100 claim lines from 2016 and 2017, and Viemed provided OIG with supplier and medical records to support them. OIG turned over the records to an independent medical reviewer to determine whether they complied with Medicare requirements. OIG's findings: 98 claim lines worth $74,288 were out of compliance—an amount OIG extrapolated to $29.1 million—because the NHVs weren't medically necessary and in 28 cases continued use of the devices wasn't supported.

"For most claim lines, the physician's order listed a qualifying diagnosis, and frequently, the supporting medical records contained a statement from the

treating physician that the beneficiary had a qualifying diagnosis. However, the medical records did not contain objective evidence to support the diagnosis," the OIG report stated. "Generally, the medical records (1) did not support that the severity of the beneficiary's condition warranted an NHV, (2) contained no medical tests or functional measurements to support a qualifying diagnosis, (3) supported other nonqualifying diagnoses, (4) indicated that the NHV was prescribed while the beneficiary was in a hospital setting during an acute medical episode, or (5) did not rule out co-contributing factors."

In one example, independent medical reviewers concluded the physician order said the beneficiary was prescribed an NHV for COPD and chronic respiratory failure with hypercapnia. But the COPD was only mentioned in a list of historical diagnoses, and no objective evidence—such as arterial blood gas results or electrolyte panel results—was documented to validate the severity of the COPD or chronic respiratory failure with hypercapnia, OIG said. "The combination of morbid obesity and severe sleep apnea documented in the record and the very limited information about COPD made obesity hypoventilation syndrome the only conclusively documented condition that can cause chronic hypercapnia. Obesity hypoventilation syndrome is not a qualifying diagnosis for an NHV." In a written response to the draft audit findings, Skora said Viemed disagreed with them primarily because the claims were medically necessary and OIG and Maximus, the independent medical reviewer, "improperly applied clinical guidance and/or applied clinical guidance that is not required by CMS."

### Some Claims Were Outside Reopening Period

He contended that OIG can only rely on the NCD and general DME documentation policy articles because there's no local coverage determinations (LCDs) for ventilators that would apply to Viemed's claims. "The medical records and other documentation provided by Viemed demonstrate that each of 97 NHV claims, and 1 invasive ventilator claim, reviewed by OIG are for respiratory care provided to Medicare beneficiaries previously diagnosed with one of the three qualifying diagnoses. Therefore, each of the 98 claims meets the NCD standard, and the claims were fully justified and properly paid by Medicare," Skora wrote.

OIG and Maximus reviewers tried to apply the LCD for RAD to the Viemed claims in the audit, Skora wrote. But "the RAD LCD does not apply to claims for ventilators."

Maximus reviewers also denied many claims because the documentation showed that NHVs were prescribed during a hospitalization for an acute clinical episode. "In other words, Maximus reviewers allege in these cases that because the beneficiary did not require NHV therapy prior to the acute inpatient admission, the NHV therapy was not medically necessary," Skora wrote. But he said there's no Medicare requirement that NHVs have to be ordered outside the acute episode.

The points that Skora made in his letter to OIG didn't change its findings, so Viemed appealed. At the first level of appeal, MACs in three jurisdictions where appeals were filed sided with OIG on the substance of the claims, but unilaterally knocked down the overpayment amount to $13 million because claims above that amount were, by that time, outside the four-year reopening period, Bittinger and Skora said. "The MACs wholly adopted OIG findings without making any determinations of their own," Bittinger said. In response, Viemed appealed the reduced amount of $13 million.

Next stop on the appeal train was reconsideration before a qualified independent contractor (QIC). Because Maximus, the company that served as OIG's independent medical reviewer, also was the QIC, Bittinger and Skora contacted the HHS Office of General Counsel (OGC) and requested Maximus be disqualified from serving as the QIC for Viemed's appeal. OGS agreed and reassigned the case to another QIC, C2C Innovative Solutions, they said.

The basis for the appeal included the premise that OIG and the MACs denied the claims based on "application of the RAD LCD to NHVs or application of

## CMS Transmittals and *Federal Register* Regulations, January 20-January 26, 2023

### Transmittals

**Pub. 100-04, Medicare Claims Processing**

- January 2023 Update of the Hospital Outpatient Prospective Payment System (OPPS), Trans. 11,801 (January 20, 2023)
- Home Health Prospective Payment System (HH PPS) Rate Update for Calendar Year (CY) 2023, Trans. 11,802 (January 20, 2023)
- Correction to the Manual Instructions Update Established under Change Request 10,971 (Implementation of the Medicare Performance Adjustment (MPA) for the Maryland Total Cost of Care (MD TCOC) Model), Trans. 11,807 (January 26, 2023)

**Pub. 100-02, Medicare Benefit Policy**

- Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Medicare Benefit Policy Manual Chapter 13 Update, Trans. 11,803 (January 26, 2023)

### Pub. 100-08, Medicare Program Integrity

- Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100-08, Trans. 11,808 (January 24, 2023)

**Pub. 100-20, One-Time Notification**

- Update to Change Request (CR) 12636 Payment for Critical Access Hospitals (CAHs) Ancillary Services Submitted on 12X Type of Bill (TOB) Claim, Trans. 11,813 (January 26, 2023)

medical necessity standards not found in any Medicare guidance," Bittinger said.

### Lawyer: ALJ Said Claims Were Medically Necessary

The QIC agreed with Viemed on most of the claims, overturning all but 12 of the denials, Bittinger said. "We went from 98% to 12%" in terms of the error rate. But the QIC upheld OIG's use of sampling and extrapolation, leaving Viemed with a not insubstantial overpayment. Next Viemed appealed to the ALJ, who consolidated the cases, and the DME supplier won, Bittinger said. "The ALJ determined every single one of the claims met the NCD and were medically necessary."

In response to a request for comment from *RMC*, OIG said it has "no information to provide regarding this matter."

Bittinger believes Viemed prevailed partly because it did a good job with basic compliance protocols. "They understood the coverage requirements under the NCD very well," he said. "When a referral would come in from an ordering provider, they would also request a copy not just of the DME documentation but the note that would support the order." Viemed wanted to ensure it had back-up evidence, he explained. When it didn't, Viemed would return to the physicians and ask them to properly correct notes to match their orders. "They had back-up for durable medical equipment on every one of these claims to confirm NHVs were only provided to patients who truly needed them," Bittinger said.

Contact Bittinger at stphen.bittinger@klgates.com and Skora at joshua.skora@klgates.com. ✧

#### Endnotes

1. U.S. Department of Health & Human Services, Office of Inspector General, "Noninvasive Home Ventilators - Compliance With Medicare Requirements," accessed January 26, 2023, http://bit.ly/3wvolDv.
2. Amy J. Frontz, Sleep Management, LLC: Audit of Claims for Monthly Rental of Noninvasive Home Ventilators, A-04-18-04066, Office of Inspector General, U.S. Department of Health & Human Services, May 2021, https://bit.ly/3JqcXh6.
3. Viemed, "Viemed Wins Complete Overruling of Appealed OIG Claims Resolving Multiyear Process With HHS and CMS," news release, January 23, 2023, http://bit.ly/3XWNrqv.
4. Nina Youngstrom, "Provider Frustration Mounts That OIG's Independent Medical Reviewers Are 'Shielded,'" *Report on Medicare Compliance* 31, no. 10 (March 21, 2022), http://bit.ly/3ja79QZ.
5. Centers for Medicare & Medicaid Services, "Durable Medical Equipment (DME) Reference List," accessed January 27, 2023, https://go.cms.gov/3HzNBit.

## NEWS BRIEFS

◆ **CMS on Jan. 26 released guidance on rural emergency hospitals (REHs), a new provider type created by the 2021 Consolidated Appropriations Act.** The guidance from the director of CMS's Quality, Safety & Oversight Group comes in the form of a memo to state survey agency directors.[1] "CMS is providing guidance regarding the REH enrollment and conversion process for eligible facilities, Frequently Asked Questions (FAQs), and a newly developed State Operations Manual Appendix (Appendix O) with survey procedures and CoP regulatory text. The interpretive guidance for REHs is pending and will be provided in a future release," the memo stated.

◆ **CMS said its updated Medicare Outpatient Observation Notice (better known as the MOON) and Important Message from Medicare have been approved by the Office of Management and Budget**, according to a Jan. 26 MLN Connects.[2] "CMS added revised standardized nondiscrimination language required on our forms and notices; other information on the notices remains the same," the agency stated, adding that hospitals must be using the forms by April 27.

◆ **Utah plastic surgeon Michael Kirk Moore Jr., of Salt Lake County, his medical corporation and three co-defendants were charged with conspiracy to defraud the United States and other offenses** for allegedly issuing fake COVID-19 vaccine cards and giving saline shots to children who thought they were getting COVID-19 vaccines, the U.S. Attorney's Office for the District of Utah said Jan. 18.[3] "The defendants allegedly destroyed at least $28,028.50 worth of government-provided COVID-19 vaccines, and distributed at least 1,937 doses' worth of fraudulently completed vaccination record cards to others in exchange for either direct cash payments or required 'donations' to a specified charitable organization, without administering a COVID-19 vaccine to the card recipient," the U.S. attorney's office said. "As charged in court documents, defendants also administered saline shots to minors – at the request of their parents – so children would think they were receiving a COVID-19 vaccine."

#### Endnotes

1. Centers for Medicare & Medicaid Services, "Guidance for Rural Emergency Hospital Provisions, Conversion Process and Conditions of Participation," Center for Clinical Standards and Quality/Quality, Safety & Oversight Group, January 26, 2023, https://bit.ly/3RdiVGT.
2. Centers for Medicare & Medicaid Services, "Hospitals: Revised Beneficiary Notices Required April 27," MLN Connects, January 26, 2023, http://bit.ly/3DkT1Lt.
3. U.S. Department of Justice, U.S. Attorney's Office for the District of Utah, "Utah Doctor and Co-Defendants Charged for Running a COVID-19 Vaccine Scheme to Defraud the Government and CDC," news release, January 18, 2023, http://bit.ly/3wwuCiq.