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

Contents



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*Outlook 2023*

# Outlook 2023: Loss of COVID-19 Waivers Looms, But Providers May Gain With Rules on MA

Although betting on the end of the COVID-19 public health emergency (PHE) is starting to feel as safe as investing in cryptocurrency, it probably will expire in April or July and the waivers and flexibilities along with it. For hospitals and other providers, that means reverting to pre-PHE rules, which attorneys and compliance professionals see as high on the list of challenges in the coming year—along with related audits and enforcement actions. "By the spring of 2023, we will be looking at three years. That's a long time," said Patrick Kennedy, executive director of hospital compliance at UNC Health in North Carolina. "The more time that has passed, the further away we have gotten from the way we used to operate." Case in point: one of its hospitals relies on a waiver to treat inpatients on a unit that had previously been reserved for 25 observation beds. "It will have to go back to being an observation unit exclusively," Kennedy said, but the use of that unit for inpatients has "become ingrained" and "I think those changes may be hard conversations to have with operations and providers."

The end of the PHE may be the blunt force trauma of 2023, but there are many other events in the mix. Some of them stem from regulatory and legislative changes announced in December. They include proposed changes to the Medicare 60-day overpayment rule and Medicare Advantage, the extension of Medicare coverage for telehealth and Acute Hospital Care at Home and the introduction of coverage

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# Outlook 2023: With Enforcement Picking Up, Expect More Private Equity, MA, Telehealth Cases

It wasn't long ago that whistleblowers and their attorneys found the government "less than interested" in False Claims Act (FCA) cases against private equity and their portfolio companies, but times have changed, according to Jeb White, president of Taxpayers Against Fraud (TAF). The shift became apparent when Department of Justice (DOJ) lawyers started attending TAF conferences on private-equity whistleblower cases and presenting at private-equity industry conferences, warning firms against "stepping over the line," he said. It was a feedback loop, because more whistleblower attorneys are willing to file FCA complaints if they think DOJ will bite.

It's why private equity investors and their health care portfolio companies are expected to have a target on their back in 2023. That has the potential to affect players across the industry. "Every corner of the health care world has been infused with private-equity money," White said. What drives the cases: "Greed before patient need is often the mantra we hear from whistleblowers."

In addition to private equity, attorneys predict the enforcement action will be in the Medicare Advantage (MA) space, kickbacks, telehealth and antitrust, along with the usual grab bag of billing and coding violations. An active year of enforcement is expected

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after "a lot of deferred maintenance of compliance and enforcement during the pandemic," said attorney Larry Vernaglia, with Foley & Lardner LLP. "Buckle your seatbelts for 2023 and 2024."

In terms of private equity investors, "DOJ believes there is a prioritization of profits over patient care," said attorney Asher Funk, with Troutman Pepper in Chicago. Even President Joe Biden made a statement to the effect that quality of care is lower in nursing homes that are owned or backed by private equity in his 2022 State of the Union address. "I disagree and dispute that DOJ's sentiment about private equity is accurate, but acknowledge that's how the government views it." The involvement of private equity firms with their portfolio companies can vary, Funk said. Investors may provide funds, sit on the board and select managers of their portfolio companies and possibly have a more hands-on role. They could face FCA liability, depending on their level of oversight, but "simply having people on the board is probably not enough to cross the line," he explained. Dictating strategy and involvement in day-to-day operations is another story.

Private equity's profile is high partly because providers and payers are starting to pursue far more strategic partnerships with private equity as "traditional buy-sell mergers and acquisitions are receding," Funk said. For compliance officers, not that much should change if their organizations, or entities in which they jointly invest, provide medically necessary services, comply with payer requirements, code accurately and avoid tainted referrals, he noted. But be aware that at a high level "the government will take a jaundiced eye the minute they know private equity is involved because they have these biases."

This may take time to play out. FCA lawsuits "are like bourbon," White said. "They have to sit in a barrel for five or six years before they come out."

Enforcement actions against MA plans are playing out in real time and although most have taken on risk adjustment, there are newer variations. "I think we'll see more focus on vertical integration in some of the Medicare Advantage and other managed care plans," said whistleblower attorney Colette Matzzie, with Philips & Cohen. "Something we are looking for is the relationship between providers and MA plans and the extent to which data is provided to MA plans by providers and incentives to cheat to maximize reimbursement." She said this kind of thing was alleged in an Oct. 14 FCA complaint in intervention filed against Cigna Corp. by the U.S. attorneys' offices for the Southern District of New York and Middle District of Tennessee.[1] According to the complaint, Cigna allegedly submitted false diagnoses for certain chronic and serious medical conditions based entirely on in-home assessments performed by a vendor. The forms were usually completed by nurse practitioners during visits to patients' homes without performing or ordering any tests to diagnose the conditions or treating them, the complaint alleges. Cigna allegedly submitted the diagnoses to Medicare to leverage higher payments.

## The Supreme Court's 'Weird Fascination'

The enforcement landscape may be affected by cases pending before the Supreme Court on aspects of the FCA. "The Supreme Court has a weird fascination with the False Claims Act," White said. It has agreed to hear about a dozen FCA cases since 2000. "They answer one question and decide to answer a bunch of other questions that weren't asked," he remarked.

Matthew Krueger, former U.S. Attorney for the Eastern District of Wisconsin, has his eye on two cases. The first is United States ex rel. Polansky v. Executive Health Resources Inc., which focuses on whether DOJ is free to dismiss whistleblower cases at will or must have a good reason. Based on oral arguments in December, "the court is likely to agree the Department of Justice has broad authority to dismiss qui tam suits," said Krueger, with Foley & Lardner LLP. When DOJ dismisses cases, whistleblowers are unable to proceed on their own.

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In the second, potentially more explosive one, the Supreme Court is considering whether to hear a case about the ability of FCA defendants to argue they aren't liable for false claims if they come up with "an objectively reasonable interpretation of a rule they violated," Matzzie said. The case, United States ex rel. Tracy Schutte, et al., v. SuperValu Inc., et al., is assigned to a Jan. 6 conference at the court, so "we will know soon," she said. The government is asking the Supreme Court to throw out a circuit court ruling that providers can escape FCA liability even when they believe they were violating the rules, she explained. "It's a very significant case for law enforcement," Matzzie said. If the Supreme Court upholds the circuit court decision, "it won't end FCA practices, but it puts a thumb on the scale for defendants."

The ruling "could be as impactful as the Escobar case was on materiality," added Krueger, referring to the Supreme Court decision in Universal Health Services v. United States ex rel. Escobar. The Escobar decision supported the theory of implied certification in an FCA lawsuit.

Antitrust enforcement is a very active area for DOJ and health care is a target, said attorney Pam Johnston, with Foley & Lardner LLP. For example, "the competition case that went to trial regarding the poaching of employees was in the health care world," she noted. In October, VDA OC LLC, a Nevada health care staffing company, pleaded guilty to "entering into and engaging in a conspiracy with a competitor to allocate employee nurses and to fix the wages of those nurses," according to DOJ.[2]

And DOJ and the HHS Office of Inspector General (OIG) announced an antitrust enforcement partnership in December.[3] They signed a memo of understanding setting forth steps they will take "to better protect health care consumers and workers from collusion, ensure compliance with laws enforced by OIG and the Antitrust Division, and promote competitive health care markets."

Johnston describes this as "a sea change." OIG and Federal Bureau of Investigation (FBI) coordination on fraud cases goes way back, but joining forces on antitrust is an expansion for OIG. It means two things, she said. OIG will have less time for other priorities "but they think it's worth it," and they're worried enough about anticompetitive behavior "to devote resources and not just rely on the FBI," Johnston explained. She added that FTC just proposed a new rule that would ban health care and other companies from imposing noncompete clauses on their employees.

COVID-19 auditing and enforcement also will pick up. "We've already seen false claims investigations increase beyond people buying Lamborghinis with Paycheck Protection Program money," said attorney Tony Maida, with McDermott, Will & Emery in Washington, D.C. "There's so much money in COVID it will become a permanent facet of government enforcement efforts and relators probably will move into that area." But Johnston doubts COVID-19 fraud enforcement "will be all that important to the mainline health care world." Organizations that acted in good faith will only be in jeopardy if "they didn't do a good job on reporting" their use of money from the Provider Relief Fund, she predicted.

Attorneys also expect to see a steady drumbeat of FCA cases based on violations of the Anti-Kickback Statute. Things will heat up for speaker bureaus and key opinion leader programs, Vernaglia said. Biogen in September agreed to pay $900 million to settle false claims allegations it paid kickbacks to physicians to induce them to prescribe Biogen drugs in the form of speaker honoraria, speaker training fees or consultant programs.[4] "There are a lot of programs like that out there," Vernaglia said.

And there will be plenty of audits and enforcement of the "bread and butter issues around billing, coding and medical necessity at hospitals and health systems," Funk said. Judging by OIG's work plan, they include urine drug testing and modifiers, just to name-check two. Telehealth services also will be a target, including remote monitoring, Matzzie said. In late December, for example, BioTelemetry Inc. and its subsidiary CardioNet LLC agreed to pay $44 million to settle false claims allegations they billed Medicare and other government payers for heart monitoring tests that were performed in part outside the country and in many cases by unqualified technicians.[5] "This is kind of a weird year," Funk said. "Things are all over the map."

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## Endnotes

1. United States ex rel. Cutler v. Cigna Corp et. al., No. 3:21-cv-00748 (M.D. Tenn., 2022), https://bit.ly/3VRaAsW.
2. U.S. Department of Justice, Office of Public Affairs, "Health Care Company Pleads Guilty and is Sentenced for Conspiring to Suppress Wages of School Nurses," news release, October 27, 2022, https://bit.ly/3WMDgVm.
3. U.S. Department of Justice, Office of Public Affairs, "Justice Department's Antitrust Division and the Office of the Inspector General of the Department of Health and Human Services Announce Partnership to Protect Health Care Markets," news release, December 9, 2022, https://bit.ly/3ImAgL8.
4. U.S. Department of Justice, Office of Public Affairs, "Biogen Inc. Agrees to Pay $900 Million to Settle Allegations Related to Improper Physician Payments," news release, September 26, 2022, https://bit.ly/3CrVjZ3.
5. U.S. Department of Justice, Office of Public Affairs, "Cardiac Monitoring Companies to Pay More than $44.8 Million to Resolve False Claims Act Liability Relating to Services Performed by Offshore Technicians," news release, December 20, 2022, https://bit.ly/3GjKh97.

## Outlook 2023: End of PHE, Waivers Looms

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of Software as a Service. In the enforcement arena, private equity is on everyone's lips along with Medicare Advantage and the Anti-Kickback Statute, and there are new Department of Justice (DOJ) crossover operations—partnering with the HHS Office of Inspector General (OIG) on antitrust enforcement and deploying the civil rights division to pursue inaccessible health technology, including telehealth, with HHS (see enforcement story, p. 1).[1] "There is a hook potentially under the False Claims Act," said attorney Colette Matzzie, with Phillips & Cohen.

It's an interesting time to be a compliance officer, with more freedom personally to hire anywhere across the country because of remote technology and more leverage inside their organizations in light of DOJ's new compliance officer certifications, said Donnetta Horseman, chief compliance officer at Moffitt Cancer Center in Tampa, Florida. "Skilled and tenured compliance professionals" may have expanded opportunities because they can work remotely, she noted. "It's opening doors for compliance professionals and giving them more options to consider when contemplating a job change." At the same time, when resolving certain corporate criminal cases, DOJ has started requiring CEOs and chief compliance officers to sign certifications that their organization's compliance program is "reasonably designed and implemented to detect and prevent violations of the law" and functioning effectively. Compliance officers and CEOs face the threat of prosecution for making false statements if they drop the ball.

### Certification Raises Stakes for Evaluations

This can be positive for compliance officers. "If presented the right way, the information gives compliance officers additional leverage," Horseman said. Moffitt had a conversation about the DOJ certification with the board compliance committee, which led to the endorsement by board members of an external compliance effectiveness review after several years without one. The certification "is a good avenue for a compliance officer to reinforce the need for periodic evaluation of the program," especially if the organization is in the middle of a self-disclosure or possibly facing an enforcement action, she noted.

The certification is also why compliance officers should "go to the appropriate corporate official and ask whether the directors and officer's liability policy covers them, and if so, to what extent," said former prosecutor Robert Trusiak, an attorney in Buffalo, New York. He noted that compliance officers in New York state also will be held to higher standards this year now that its Medicaid compliance program requirements have been updated. The Office of Medicaid Inspector General finalized regulations that, among other things, require auditors to have Medicaid audit expertise.

### Surprise Package: A Change to 60-Day Rule

This year or next, regulatory changes will take effect with some potentially far-reaching consequences—if they're finalized. Medicare Advantage (MA) plans would have to make changes to policies if a regulation published in the Dec. 27 *Federal Register* is finalized, but whether things get better for providers on the ground remains to be seen.[2] The CMS rule puts teeth into the requirement that MA plans follow traditional Medicare's two-midnight rule, inpatient-only list and case-by-case exception, experts say. The rule proposes to codify regulatory language that would explicitly require MA plans to live by coverage criteria for inpatient admissions under Part A (42 C.F.R. § 412.3). According to the rule, "MA organizations may not limit coverage through the adoption of policies and procedures—whether those policies and procedures are called utilization management and prior authorization or the standards and criteria that the MA organization uses to assess and evaluate medical necessity—when those policies and procedures result in denials of coverage or payment where the Traditional Medicare program would cover and pay for the item or service furnished to the beneficiary." In another MA proposed rule published in the *Federal Register* on Dec. 13, CMS would require MA plans to respond much faster to prior authorization requests.

"I'm really interested to see how the MA plans will react in 2023 to this new proposed rule," said Ronald Hirsch, M.D., vice president of R1 RCM. "Since theoretically it's already in place, they should start honoring the inpatient-only list and two-midnight rule." If that's the case now, he wonders why CMS hasn't been enforcing it. The other possibility is MA plans will frantically deny claims because they know they'll lose money in 2024 when they're unquestionably bound by the two-midnight rule, Hirsch said. Whether it's enforced this year or next, at least hospitals get paid. More significantly, CMS is unambiguous in the proposed rule that MA plans must fix their approval process for skilled nursing facilities and inpatient rehabilitation facilities. "They are denying patients access to covered care," Hirsch noted.

In the same regulation, CMS surprised people when it proposed to refashion Medicare's 60-day overpayment rule. The 60-day rule—which came to life in the Affordable Care Act (ACA)—requires providers to report and return Part A and B overpayments within 60 days of identifying them. According to the 2016 regulation interpreting the 60-day rule, providers are obligated to use reasonable diligence to identify overpayments by doing proactive compliance activities to monitor for overpayments and investigating potential overpayments

in a timely manner. CMS defined timely as within six months of receiving "credible information" about an overpayment.

CMS envisions replacing "reasonable diligence" with language more consistent with the False Claims Act's knowledge standard, said attorney Andrew Ruskin, with K&L Gates. "Under the proposed rule, a provider or supplier has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment," according to CMS. The new definition shouldn't get anyone bent out of shape, Ruskin said. "They are taking away the obligation to do reasonable due diligence, but performing due diligence is a way to show you're not acting in reckless disregard of the truth," Ruskin explained. "It's probably close to the same thing." It looks like CMS is floating this change because there's nothing in the ACA about reasonable diligence. "The agency doesn't want to put itself out there as having exceeded its statutory authority," he said.

### Consider Compliance Risks of SaaS

Ruskin recommends providers comment on the proposal and ask whether they still have eight months to investigate and quantify (if warranted based on the investigation) an overpayment. "Even if CMS responds that there is no longer an eight-month safe harbor, providers can still take away from that response there isn't conclusive liability after the 60th day," Ruskin said. "Indeed, since many complex issues take longer than eight months to resolve, the reckless-disregard standard may be even better."

On the payment front, the new year brings Medicare payment for Software as a Service (SaaS). CMS served it up in the 2023 outpatient prospective payment system rule, and there are compliance implications although it's early days, Hirsch said. There are new technology add-on payments for SaaS, which is performed after patients already have a service (e.g., CT scans of their coronary arteries) when the physician orders additional software evaluation of the test (performed by an SaaS vendor), he said. If hospitals aren't already involved in SaaS, they should have a process to evaluate the services, Hirsch said. He recommends they determine what Medicare covers, how to protect the privacy of the data when it's transferred to vendors and when to get an advance beneficiary notice from patients. SaaS includes clinical decision software and computer-aided detection. There's also an SaaS component in the proposed Sec. 1557 anti-discrimination rule that may be finalized this year.

Compliance professionals also are focused on preparing providers for changes to evaluation and management (E/M) guidelines that took effect Jan. 1. Notably, physicians are permitted to select E/M levels of service provided in the hospital, including observation, initial and subsequent visits and consultations based on time or medical decision-making without factoring in the patient's history and exam. But CMS reminded providers in the 2023 Medicare Physician Fee Schedule (MPFS) of requirements in the hospital conditions of participation, and The Joint Commission (TJC) requires that the patient receive "a medical history and physical examination no more than 30 days prior to, or within 24 hours after, registration or inpatient admission, but prior to surgery or a procedure requiring anesthesia services," it explained in an email to Hirsch. As a result, specific elements of the history may still be required even if they're not considered for the visit code selection, he said. But billing and coding aren't in the TJC wheelhouse. As Amanda Buonocore, coding and reimbursement senior manager at Northwell Health in New York, explained, the MPFS "is really a methodology change on coding." Documenting the exam and history, however, is still important to support the medical necessity of the patient encounter and continuity of care.

### Audits: Getting to the Heart of the IRF Matter

Audit activity from MA plans seem to get under hospitals' skin lately more than traditional Medicare. "They kill us. The sheer volume," Kennedy said. On the fee-for-service side, Targeted Probe and Educate (TPE) audits have been consistent for about a year, but they still haven't returned to pre-pandemic levels, he said. TPE audits have included MS-DRG validation for psychoses, neuromuscular re-education, manual therapy and hyperbaric oxygen therapy. A hot audit topic generally for 2023 will be inpatient rehabilitation facilities (IRFs), said attorney Kyle Gotchy, with King & Spalding. OIG recently announced an IRF nationwide audit, although its focus is partly on determining whether there are areas where CMS could clarify payment criteria.[3]

"There's been a record wave of hospital compliance audits where they're nailing the hospitals for a mix of [noncompliance with] medical necessity and documentation requirements, but the error rates are really crazy," Gotchy said. He said auditors are supposed to defer to treating physicians, but that hasn't been the case. "It's not a good situation now. I'm happy to see OIG will be taking a look at this."

Internally, audits are increasingly risk-based because they spare hospitals and health systems the shot-in-the-dark approach that wastes time and resources. In the past, Moffitt Cancer Center hit entire departments with physician documentation and coding audits, "but now we use our data to pinpoint which physicians or codes might be at risk for [error]," Horseman said. "We are conducting more focused audits and reviews." This approach expanded the audit focus from physician coded-services to coder-coded services. "What was intended to be focused on physicians has opened a Pandora's box," Horseman noted. "It's a positive thing.

We are identifying and fixing issues that we may not have otherwise identified."

Attorneys have high hopes in 2023 and beyond for value-based enterprises (VBEs). "This is the year we will see increased willingness on the part of providers to embrace and adopt value-based enterprises," Gotchy said. Because the VBEs in the revised Stark rule and Anti-Kickback Statute safe harbors took effect Jan. 19, 2021, at the height of the pandemic, "people were exhausted and just trying to get by," he said.[4] "As a practical matter, the appetite to pick that up and run with that ball wasn't there." But looking ahead, providers are ready, and Gotchy predicts a "self-reinforcing domino effect."

A "value-based reimbursement structure" is where the marketplace is going and "the safe harbors and Stark exceptions are going to be more of what people need to rely on," said attorney Tony Maida, with McDermott, Will & Emery. "I also view them as hopefully a first iteration because there are things the safe harbors don't cover." For example, the safe harbor requires "some sort of risk sharing to protect monetary compensation between participants in VBEs, but you can't do risk sharing with fee-for-service patients," Maida said. "A lot of arrangements have this gap where parties want to be able to share financial resources, but you are not fully within a safe harbor. Parties are left with getting comfortable in a facts-and-circumstances analysis, but there are no advisory opinions or other guidance from OIG on how it thinks about the facts and circumstances in this situation," he said. Maybe over time providers will see advisory opinions or revisions to safe harbors because exceptions and safe harbors will become increasingly important as more patients move into a value-based plan, Maida explained.

## 2023 CAA Extends Telehealth Coverage

Medicare coverage of many telehealth services across the country and Acute Hospital Care at Home will continue through the end of 2024 thanks to the 2023 Consolidated Appropriations Act (known as the omnibus spending bill) signed into law by President Joe Biden Dec. 29. The telehealth services are the same that Congress already extended for 151 days past the end of the PHE, said Allison Kassir, senior government relations advisor with King & Spalding in Washington, D.C. (although Congress added a medical review of telehealth services). The law removes rural area requirements and expands originating sites, which means Medicare will continue to pay for certain covered telehealth services everywhere in the country and in patient homes. The law also rescued audio-only telehealth services, which CMS planned to stop covering until Congress stepped in. "This has been something everyone agrees on," Kassir said. It's part of unwinding the PHE where telehealth coverage in the law isn't so "tethered to a declaration of a PHE."

Some people were disappointed telehealth wasn't permanently added to Medicare, "but paying for things like that becomes difficult so a two-year extension makes a lot of sense," Kassir explained.

A note on reading the PHE tea leaves: Kassir said it looks like HHS may extend the PHE twice more, until July. She takes her cue from the Congressional Budget Office's work on Medicaid redeterminations. During the PHE, states were allowed to keep people continuously enrolled in Medicaid in exchange for a federal bonus, but with the PHE expected to end this year, states must disenroll and re-enroll them.

## New Appeal Process Should be Coming

As 2023 unfolds, the regulatory and judicial machinery will lurch back toward normal or a version of it, said attorney Daniel Hettich, with King & Spalding in Washington, D.C. "It will be a really interesting year." Emerging from the pandemic "will give us a glimpse or maybe a full picture of what the new normal will be. It will be a period of transition." Hettich already sees some of this playing out. For example, the Provider Reimbursement Review Board (PRRB) recently announced it will return to regular operations. "There will be a floodgate phenomenon of reimbursement hearings," he said. "The PRRB is a pipeline to federal courts," which themselves slowed down during the pandemic, and "when all that returns to normal, there will be a lot of new decisions affecting provider reimbursement and a lot of new litigation and, at the same time, CMS will likely start to pay more attention to routine but important issues" (e.g., finalizing the disproportionate share hospital Part C proposed rule, which has been pending for two years).

Hospitals should keep an eye out for directions on setting up a new appeal process for certain Medicare patients. In January 2022, the U.S. Court of Appeals for the Second Circuit said the constitutional rights of Medicare beneficiaries are violated when they can't appeal a hospital's decision to change their status from an inpatient to an outpatient receiving observation services. The court ordered CMS to allow an appeals process for denials of inpatient status under certain circumstances, but so far it hasn't materialized. "As I read it, it will only be patients who are initially admitted as inpatient and then change to outpatient/observation while hospitalized," Hirsch said. "That limits the universe of affected patients but also means hospitals must really hard-wire their processes to ensure patients are placed in the right status up front."

Meanwhile, the challenges with the No Surprises Act will continue. On Dec. 23, CMS announced it's increasing the 2023 fees for using the independent dispute resolution process from $50 to $350.[5] And lawsuits will continue, said former CMS chief legal officer Brenna Jenny. "Litigation related to the No Surprises Act has so far been against the federal government, but we'll see litigation by providers

against insurers over reimbursement that's unfairly low," said Jenny, with Sidley Austin LLP. On the bright side, HHS in December gave providers a break, indefinitely postponing an aspect of the good-faith estimate requirement of the No Surprises Act that was set to take effect Jan. 1. That means "convening" providers don't have to worry about incorporating the costs of associated services from co-providers in the cost estimates they give to uninsured and self-pay patients.

### Possible Revisions to Information Blocking Rule

On the health information privacy front, "it will be a significant year" as the HIPAA Privacy Rule proposed in January 2021 is probably finalized, said attorney Adam Greene, with Davis Wright Tremaine. He expects the

## CMS Transmittals and *Federal Register* Regulations, December 16, 2022-January 5, 2023

### Transmittals

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

- Home Health Prospective Payment System (HH PPS) Rate Update for Calendar Year (CY) 2023, Trans. 11,777 (Jan. 4, 2023)
- Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update, Trans. 11,768 (Dec. 30, 2022)
- Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) - April 2023, Trans. 11,770 (Dec. 30, 2022)
- National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) Tcell Therapy, Trans. 11,774 (Dec. 30, 2022)
- New Medicare Part B Immunosuppressant Drug Benefit (PBID) - Implementation, Trans. 11,764 (Dec. 22, 2022)
- Manual Update to Pub. 100-04, Chapter 20, Pre-Discharge Delivery of DMEPOS for Fitting and Training, Section 110.3, Trans. 11,760 (Dec. 21, 2022)
- Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 18 Section 170.1 and Chapter 32 Section 270.2 due to the National Coverage Determinations (NCDs) April 2023 Change Request (CR) 12960, Trans. 11,759 (Dec. 21, 2022)
- File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions, Trans. 11,758 (Dec. 21, 2022)
- January 2023 Update of the Ambulatory Surgical Center [ASC] Payment System, Trans. 11,762 (Dec. 21, 2022)

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

- Internet-Only Manual (IOM) Updates for Nurse Practitioners (NPs) and Clinical Nurse Specialists (CNSs), Trans. 11,771 (Dec. 30, 2022)

**Pub. 100-05, Medicare Secondary Payer**

- Electronic Correspondence Referral System (ECRS) Restoration of Patient Relationship Code 18, Update to Medicare Secondary Payer (MSP) Inquiry Transactions for Deceased Beneficiaries, and Clarification of Existing ECRS User Guide Policy Based on the Medicare Administrative Contractors Feedback, Trans. 11,754 (Dec. 21, 2022)

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

- Direct Mailing Notification to Hospice Providers Regarding the Value-Based Insurance Design (VBID) Model, Hospice Benefit Component, Participating Medicare Advantage Organizations, Trans. 11,776 (Jan. 5, 2023)
- Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter As Certain Colorectal Cancer Screening Tests, Trans. 11,772 (Dec. 29, 2022)
- Provider Education for Prior Authorization (PA) Process for Facet Joint Interventions in the Hospital Outpatient Department (OPD) Setting, Trans. 11,753 (Dec. 21, 2022)

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

- Internet-Only Manual (IOM) Updates for Nurse Practitioners (NPs) and Clinical Nurse Specialists (CNSs), Trans. 11,771 (Dec. 30, 2022)
- Manual Update Pub. 100-02 Medicare Benefit Policy, Chapter 15, Section 110.8 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Benefit Category Determinations, Trans. 11,769 (Dec. 30, 2022)
- Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2023, Trans. 11,767 (Dec. 23, 2022)
- New Medicare Part B Immunosuppressant Drug Benefit (PBID) – Implementation, Trans. 11,764 (Dec. 22, 2022)

**Pub. 100-01, Medicare General Information, Eligibility and Entitlement**

- New Medicare Part B Immunosuppressant Drug Benefit (PBID) - Implementation, Trans. 11,764 (Dec. 22, 2022)

### *Federal Register*

**Final rule**

- Basic Health Program; Federal Funding Methodology for Program Year 2023 and Changes to the Basic Health Program Payment Notice Process, 87 Fed. Reg. 77,722 (Dec. 20, 2022)

**Proposed rule**

- Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications, 87 Fed. Reg. 79,452 (Dec. 27, 2022)

**Final rule with comment period and final rule; correction**

- Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID-19; Correction, 88 Fed. Reg. 297 (Jan. 4, 2022)

**Final rule; correction**

- Medicare Program; Implementing Certain Provisions of the Consolidated Appropriations Act, 2021 and Other Revisions to Medicare Enrollment and Eligibility Rules; Correction, 87 Fed. Reg. 80,468 (Dec. 30, 2022)
- Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model; Correction, 87 Fed. Reg. 80,469 (Dec. 30, 2022)

final rule to look pretty much like the proposal, including the provision shortening the right of access to records from 30 to 15 days.

Greene also anticipates clarifications to the information blocking rule. HHS indicated on the regulatory agenda it may make some changes, which he said could involve adding or tweaking exceptions. Providers are still struggling to understand their compliance obligations, including the extent "they have to make all health information proactively available through the patient portal."

Also expect "fallout" this year from the Supreme Court's decision to reverse the constitutional right to abortion enshrined in Roe v. Wade, Greene said. The recent ruling in Dobbs v. Jackson Women's Health Organization raises questions about whether HIPAA needs revising to protect reproductive health information. HHS could "potentially limit the extent that reproductive heath information may be disclosed in response to law enforcement requests even where HIPAA may otherwise permit law enforcement disclosures," he said. The 1996 HIPAA statute "provides HHS with extremely broad authority to draft privacy standards and allows for pre-emption of state law."

Rising to the challenges of the new year requires bodies, and they may be in short supply. "Providers are continuously in a triage mode just trying to keep the place staffed from a clinical and billing standpoint and that personnel disruption creates havoc," Trusiak said. It's an invitation to compliance risk. But it's also driving innovation in education and communication. Because of the pandemic-related shortage of clinicians, Lifespan's compliance department is developing new ways to present its materials to employees this year, said Donna Schneider, vice president of corporate compliance and internal audit at the Rhode Island academic health system. "No matter what your risks are, if you're able to educate, that's half the battle," she noted. But clinicians typically don't sit at a computer for long stretches to do administrative tasks. Training must be short and sweet and grab people with graphics and stories, Schneider said. They may not remember policies, but they remember stories.

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### Endnotes

1. U.S. Department for Health & Human Services, Office for Civil Rights and U.S. Department of Justice, "Guidance on Nondiscrimination in Telehealth: Federal Protections to Ensure Accessibility to People with Disabilities and Limited English Proficient Persons," July 29, 2022, https://bit.ly/3IuMxxg.
2. Nina Youngstrom, "Proposed Rules: MA Plans Must Follow Two-Midnight Rule, IPO List and Expedite Prior Auth," *Report on Medicare Compliance* 31, no. 45 (December 19, 2022), https://bit.ly/3Ir9Jwb.
3. U.S. Department of Health & Human Services, Office of Inspector General, "Inpatient Rehabilitation Facility Nationwide Audit," accessed January 5, 2023, https://bit.ly/3GEDPuK.
4. Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,492 (Dec. 2, 2020), https://bit.ly/3g3eprL.
5. Centers for Medicare & Medicaid Services, "Amendment To The Calendar Year 2023 Fee Guidance For The Federal Independent Dispute Resolution Process Under The No Surprises Act: Change In Administrative Fee," guidance, December 23, 2022, https://bit.ly/3vFnTSJ.

## NEWS BRIEFS

◆ **In the Jan. 5 MLN Connects, CMS announced three new claim modifiers for home oxygen use** under national coverage determination 240.2 "to indicate the appropriate treatment regimen and presence of supporting documentation for each Medicare patient group."[1]

◆ **The HHS Office for Civil Rights (OCR) said Jan. 5 that Life Hope Labs, LLC in Sandy Springs, Georgia, has agreed to pay $16,500** to settle a potential violation of the HIPAA Privacy Rule's right of access provision.[2]

◆ **HHS and the departments of labor and treasury have released an initial report** on the independent dispute resolution process under the No Surprises Act.[3]

### Endnotes

1. Centers for Medicare & Medicaid Services, "Home Oxygen: 3 New Claims Modifiers," MLN Connects, January 5, 2023, https://bit.ly/3GpwFcs.
2. U.S. Department of Health & Human Services, "Life Hopes Resolution Agreement and Correction Action Plan," January 3, 2023, https://bit.ly/3WQMDUd.
3. U.S. Department of Health & Human Services, U.S. Department of Labor, U.S. Department of the Treasury, *Initial Report on the Independent Dispute Resolution (IDR) Process April 15 – September 30, 2022, December 29, 2022*, https://bit.ly/3QsFcQz.