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Outlook 2025: Disruption Is Expected, Along With More OIG Guidance, Payment Changes

By Nina Youngstrom

Potentially "drastic" changes coming under the second Trump administration are rattling Carolynn Jones, chief compliance and risk officer at Harris Health in Texas. With Medicare and Medicaid policies, immigration and reproductive rights on the table, Jones says the stakes are higher for compliance officers to be "strategic leaders for the organization on trying to be reasonable and measured in terms of how we are assessing potential policy changes because there's a lot of emotion around some of these topics."

Although that's the case to some extent every four years, "it feels a little different this time," Jones said. "I work for a safety net health care system and funding from state and federal programs is critical to providing patient care to those in need. There is a concern that the new administration may change or create policies that impact that funding. The challenge is that patients will continue to come to us for care and we will have to determine how to meet that need."

She echoed the words of other attorneys and compliance professionals, who foresee "uncertainty" and perhaps "chaos," particularly at federal agencies. Amid the unpredictability, don't expect audits and enforcement to ease up. "This is too lucrative an area for the government to ever walk away from," said attorney Judy Waltz, with Foley & Lardner LLP.

There are some things that hospitals and health systems probably can count on in the compliance and enforcement arena this year. The HHS Office of Inspector General (OIG) promised to release industry-specific compliance guidance for hospitals, and CMS said it would unveil a revised version of the Program for Evaluating Payment Patterns Electronic Report (PEPPER). Hospitals also should brace for more audits of compliance with national coverage determinations (NCDs) and local coverage determinations (LCDs). Medicare Advantage (MA) will be center stage in 2025 partly because of the incoming administration's apparent interest in its growth and pitched payment battles between plans and providers.

The enforcement picture will remain colorful (see story),[1] with experts expecting the usual flood of False Claims Act (FCA) lawsuits from whistleblowers and the U.S. Department of Justice (DOJ), perhaps with creative new theories of liability. Some uncertainty has been injected into non-intervened whistleblower cases, however, by a Florida federal court decision. Its fate in an appeals court and perhaps the U.S. Supreme Court could change the FCA landscape.

But it's the upheaval anticipated inside the federal government that dominates conversations. "The fact Trump wants disruptors has me very concerned," said attorney Sandy Teplitzky, with Baker, Donelson, Bearman, Caldwell & Berkowitz, PC. "I have been contacted by many career people in DOJ, HHS, CMS and OIG who for the first time are considering leaving the agencies. They're nervous and that makes me nervous."

'Every Day Will be a Surprise'

That would be unfortunate for providers, said attorney Kyle Gotchy, with King & Spalding. In "trying to read the

tea leaves about what will happen in the next 100 days," he has zeroed in on the ramifications of the Trump team's plans to convert civil service positions into essentially political appointees who can be fired at will. As a result, many experienced people may leave.

"I have a lot of concerns," Gotchy said. "The regulated community benefits from having dedicated career civil servants throughout HHS and other agencies." He relies on good working relationships with agency people who have been developing Medicare and other knowledge for years. "That makes my job for my clients so much easier when I have someone on the other end of the phone or across the table" who has deep technical regulatory expertise.

Waltz predicts "total chaos" for the first six months of the second Trump administration. "Every day will be a surprise and not all of them will be good surprises." But some forthcoming changes will benefit health care organizations through a possible reduced regulatory burden, she said. For example, Waltz predicts nursing home staff ratios "will be on the chopping block" and the administration may drop civil monetary penalties still pending against nursing homes for noncompliance with the COVID-19 vaccine mandate.

New NCD, LCD Invites Audits

In the auditing world, compliance with Medicare coverage policies is a probable target. For example, UNC Health in North Carolina is "acutely focused" on two new coverage policies, said Patrick Kennedy, executive director of hospital compliance. One is an LCD on skin substitutes for the treatment of diabetic skin ulcers and venous leg ulcers (dl39806) that goes live Feb. 12.[2] The other is an NCD on percutaneous transluminal angioplasty (20.7) that took effect in May 2024 and has already led to recoupment by the Medicare administrative contractor (MAC).[3]

The LCD and local coverage article on skin substitutes (dl59691), which supplement an NCD, have "stringent documentation requirements and billing changes," Kennedy said. UNC Health previously audited skin substitutes and now will train wound care centers at its hospitals to make sure they're up to speed. The LCD also has a new KX modifier requirement: "Use of the KX-modifier is added as an attestation of medical necessity for use over 4 applications." Kennedy sees ample room for errors that could lead to denials. "The LCD is 57 pages. The more extensive the requirements are, the more likely something will be missed, whether documentation, charging or billing," he noted.

Challenges have also surfaced with the angioplasty NCD, including compliance with the shared decision-making requirement. Before performing procedures in NCD 20.7, practitioners "must engage in a formal shared decision-making interaction with the beneficiary." Kennedy noted the number of procedures requiring shared decision making seems to be rising, but subtle differences in the NCDs may lead to noncompliance. For example, the non-implanting physician may do shared decision making for cardiac resynchronization therapy, but carotid stenting just refers to a "practitioner," which could be a nonphysician practitioner (NPP). "You need to look at the fine print in the coverage," Kennedy said. "You could have denials and audits if there's no shared decision-making." It happened to UNC Health earlier in 2024 when its MAC audited atrial appendage closure and "unfortunately, we had some shared decision-making encounters" performed by an NPP. "We had paybacks and made operational changes to ensure physicians are doing shared decision-making" when required, he said.

Kennedy is looking forward to OIG's publication this year of industry-specific compliance program guidance (ICPG) for hospitals, a modernization of its decades-old compliance guidance for different industry segments. OIG has already released an ICPG for skilled nursing facilities/nursing facilities and next up is one for MA plans. Kennedy finds the compliance program guidance helpful in emphasizing that compliance officers should be in the thick of things. "The OIG guidance reiterates the importance of engaging leaders and having compliance

officers in discussions of risks," he said. "We see things a certain way and it's always good to get the other side of the operational coin."

Also due in 2025 is the new version of PEPPER, a free comparative data tool that helps hospitals and other entities with compliance monitoring. "The temporary pause in distributing PEPPERs will continue through the Spring of 2025, as we continue working to update the program and reporting system," a CMS official said in an email to Ronald Hirsch, M.D., vice president of R1 RCM. He's hoping CMS will incorporate some of his suggestions (e.g., including the hip replacement with the knee replacement inpatient admission percentage).

And the new year brings a new appeals process for certain traditional Medicare patients whose inpatient status is changed to outpatient with observation services. Hospitals are required to give them the new Medicare Change of Status Notice starting Feb. 14. CMS on Dec. 27 released an MLN that explains the new requirements and links to the notice.[4] "CMS estimates that hospitals will need to provide this new form to a patient less than five times a year, but they still must develop policies and procedures to ensure it is delivered properly in those rare instances," Hirsch said. "More daunting for hospitals, though, may be the retrospective appeals where the hospital will be asked to search for medical records for hospital stays going back as far as 2009."

Tension With MA Plans Will Continue

The two-midnight rule will be the source of more denials on the MA side even though CMS reiterated in a 2024 MA regulation (CMS-4201-F) that MA plans are bound by the two-midnight rule and other "fully established" traditional Medicare policies. "We saw a lot of tension in 2024 between payers and providers and I don't see that alleviated in 2025," said Tiffany Ferguson, CEO of Phoenix Medical Management. Proposed changes in the 2026 version of the MA rule (CMS-4208-P) also may affect the denial and appeal merry-go-round. For one thing, CMS may require patient notification when MA plans refuse a hospital's request for inpatient admission but agree to observation if it means the patient pays more. "CMS called it out and said the hospital and payer are having these agreements and nowhere is the patient in the story," Ferguson said.

As the rule explains, "It is important to note that in many circumstances the MA organization does not inform the enrollee of the concurrent review determination and the enrollee is not afforded the opportunity to appeal the decision (or have an appeal submitted on their behalf) as required. The result of the concurrent review is the hospital may either continue to provide non-covered inpatient services or it may reclassify the enrollee's hospital status from inpatient to outpatient. Many times, the enrollee does not know a change in status has occurred until they are required to pay the outpatient deductible and applicable cost-sharing." For this and various reasons, CMS proposed a clarification that "a decision by an MA organization made pre-service, post-service, or concurrent with the enrollee's receipt of services in an inpatient or outpatient setting is an organization determination subject to the rules in part 422, subpart M which includes providing the enrollee (and the provider, as appropriate) with timely notice and applicable appeal rights."

Another provision, however, bars providers from appealing MA denials on behalf of patients when "there's no financial difference one way or another to the patient," Ferguson said. If CMS finalizes the provision, the appointment-of-representative track of appeals would be off the table if the patient has no money at stake. Between the two provisions, "there is this win and this loss," she noted.

More reviews of short hospital stays may be on the agenda this year. A recent OIG audit found that CMS could do much more to identify and prevent overpayments for short inpatient stays under the two-midnight rule and an OIG audit of hospital inpatient billing for sepsis is now underway.[5] Medically unnecessary inpatient admissions are a vehicle for false claims allegations, as Oroville Hospital's $10.25 million settlement in December shows.[6]

Payment Picture May Not Be Pretty

Hospitals will be hard hit in the coming years, as the administration slices discretionary spending, said attorney Andy Ruskin, with K&L Gates. For example, "site neutrality will be very big next year," he said. Although it's unclear how far Congress will take site-neutral payment policy—which means hospitals and independent physician's offices are paid the same for services —more of it will land. "Trump 1.0 created site-neutral payments for evaluation and management services in off-campus provider-based departments," and they may be extended to radiology, labs or drug infusions, Ruskin said.

Other significant Medicare reforms are anticipated as the government focuses on "efficiency" and spending cuts, said Martie Ross, a consulting principal with PYA. Consistent with reports that Mehmet Oz, the nominee for CMS administrator, favors MA plans over traditional Medicare, Ross envisions a shift in that direction. There's even been talk of autoenrollment in MA plans when people become Medicare eligible. But there are headwinds. "The public perception of MA plans has soured and particularly the high profitability of large insurance companies is concerning," Ross noted. That was underscored by support in some quarters for Luigi Mangione, the accused killer of UnitedHealthcare CEO Brian Thompson. Even so, Ross thinks there will be a push to expand MA using the "disproven theory that private insurance can do a better job than the federal government in managing the Medicare program."

Meanwhile, hospitals should brace for more of a shift to services at ambulatory surgery centers (ASCs), Hirsch said. "Hospitals may be challenged to ensure that patients having surgery in the hospital have clear, documented justification for that setting rather than an ASC." More commercial payers are adopting site-of-service policies and "hospitals may start seeing denials because the procedure was scheduled at the hospital when the patient was safe to have it at the ASC," Hirsch explained. He sees "a double-edged sword": at the same time, hospitals are pushing to end prior authorization for procedures like colonoscopies and cholecystectomies; payers won't pay for them if they're performed in the wrong setting. "It's something to watch for as we shift away from prior authorization," Hirsch noted.

Fate of New Security Rule Is Hazy

Covered entities also have a new proposed HIPAA Security Rule to contend with, although it's anyone's guess whether the second Trump administration finalizes it.

The HHS Office for Civil Rights (OCR) has proposed changes to help fend off cyberattacks. The proposed rule, which was published in the *Federal Register* Jan. 6, is the first overhaul since the original 2003 Security Rule and revisions in the 2013 HITECH Act.[7] Among other things, the rule would ditch the distinction between "addressable" and "required" specifications and mandate the use of encryption and multifactor authentication (MFA).

"It's a pretty burdensome proposed rule," said attorney Iliana Peters, with Polsinelli. She thinks the attempt to upgrade the rule could backfire. "I'm not convinced the Security Rule is outdated and a lot of changes they're proposing are quite prescriptive," said Peters, former acting OCR deputy director. "The idea has always been you have to do what's reasonable and appropriate as required," and that changes over time. For example, although the proposed rule requires MFA and encryption, the versions in use may soon be outdated, she said. In fact, the National Institute of Standards and Technology (NIST) in August released encryption tools designed to withstand an attack from a quantum computer.[8] "Researchers around the world are racing to build quantum computers that would operate in radically different ways from ordinary computers and could break the current encryption that provides security and privacy for just about everything we do online," NIST stated.

More Challenges to Come Under *Loper Bright*

The regulatory foundation may wobble because of the June 2024 U.S. Supreme Court decision in *Loper Bright Enterprises et al. v. Raimondo, Secretary of Commerce, et al.* The decision overturned Chevron deference, which required courts to defer to the regulatory agency's reasonable interpretation of an ambiguous statute. In *Loper Bright,* the Supreme Court put the ball in the court of the courts. It's up to them "whether an agency has acted within its statutory authority. Courts may not defer to an agency interpretation of the law simply because a statute is ambiguous." Only the "best" statutory interpretation is allowed, whether it comes from an agency or not.

Between *Loper Bright*, other recent Supreme Court decisions and Trump's plans, "you will now see more challenges to regulations when they're issued by HHS or CMS," said attorney Bill Mathias, with Bass, Berry & Sims PLC. Initially, he expects them to focus on "social issues"—including reproductive health care and gender identity (e.g., OCR's 2024 reproductive health care privacy rule)—"where a conservative judge might think the Biden administration overstepped and where you didn't have any legislation to prompt this." At the same time, "you may see more liberal organizations bringing suits in New York, California and Massachusetts to" try to get judges to overturn Trump initiatives, Mathias said.

The twist here is that *Loper Bright* "says the executive branch can't act unilaterally and the courts have to make these tough decisions and yet Trump is filled with big ideas," Ruskin said. Trump will use federal agencies to get what he wants even when Congress doesn't go along and that will land his administration on the wrong side of *Loper Bright*, Ruskin predicted. "An agency can put out any regulation it wants if it doesn't care if it gets sued," he noted. None of this will happen quickly. "I am still fighting cases where the policy was implemented by the first Trump administration."

Acute Hospital Care at Home Is at Risk

On the telehealth horizon, experts are cautiously optimistic about broader Medicare coverage of telehealth services because there's bipartisan support for it. So far, Congress on Dec. 21 passed only a three-month extension of telehealth flexibilities. The 2025 American Relief Act again removes geographic limitations on telehealth services, expands originating sites (e.g., to patient homes) and pays for audio-only telehealth and Acute Hospital Care at Home, among other things. But the uncertainty of what happens after March 31 is taking its toll. For example, providers' schedules were built years ago to accommodate both in-person and telehealth visits on the same day in a timely manner, and the fate of patients who rely on telehealth hangs in the balance, Kennedy noted. "I worry more about the Acute Hospital Care at Home program," he said. "Hospital systems like ours have stood up these sophisticated remote inpatient units and spent a ton of resources. It would be disheartening to see all that go away and these patients have to be admitted to brick-and-mortar hospitals."

Telehealth flexibility for controlled substance prescriptions is faring better for now. The Drug Enforcement Administration (DEA) is permitting physicians to remotely prescribe Schedule II-V controlled substances through 2025 without an in-person evaluation of the patient. On Dec. 31, DEA also submitted a more permanent proposed rule to the Office of Management and Budget on remote prescribing of Buprenorphine for treatment of opioid use disorder, Gotchy said. He encourages providers to make their views known to regulators about the value of telehealth prescribing of controlled substances before rules are carved in stone.

Health care organizations will continue their analysis and oversight of artificial intelligence (AI) this year. HHS announced in October it would release a strategic plan for AI this month, although all bets are off because of the administration change, Gotchy said. HHS plans to address "the potential roles AI may play across the industry's entire value chain and considering the role that the government may play in those domains," he said. Meanwhile,

the Food and Drug Administration on Jan. 6 released draft guidance for AI-enabled medical devices to ensure their safe use.[9]

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