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Another Extension of Telehealth Waivers Looks Promising; OCR May Update Security Rule

By Nina Youngstrom

Congress will probably authorize Medicare to keep telehealth coverage rolling next year and maybe forever along the lines of the COVID-19 flexibilities, according to Kim Brandt, former principal deputy administrator of CMS. That would mean continued payments for services delivered everywhere by audiovisual and audio-only technology, she said. They've already been kept alive through the end of this year by the 2023 Consolidated Appropriations Act (CAA). "We'll definitely see action in Congress on telehealth," said Brandt, who also was the Senate Finance Committee's general counsel for five years, at HCCA's Compliance Institute April 16. "The expectation is they will be extended again or be made permanent."

The CAA removed rural area requirements and expanded originating sites, which allows Medicare to pay for certain covered telehealth services everywhere in the country and in patient homes. The law also covers audio-only telehealth services, added physical, occupational and speech therapists as distant site practitioners, continued payments for telehealth services delivered by rural health clinics and federally qualified health centers and delayed the in-person visit requirement for telebehavioral health services, among other things. Congress also is expected to extend the Acute Hospital Care at Home program beyond 2024, said Brandt, a partner at Tarplin, Downs & Young LLC.

But time is of the essence for enacting telehealth and other health care legislation because several lawmakers who are knowledgeable in this area—including members of "the Doctors Caucus"—are leaving Congress, she said. "Most centrist moderates in the House are retiring. That's huge. There are new people behind them who don't understand" things like the sustainable growth rate and site neutrality. "It will be a real challenge," Brandt said. "The loss of these people leaves a huge knowledge gap." Because it will be harder to pass meaningful health legislation when they're gone, Brandt said there's a push to get as much accomplished while they're still here.

Separately, CMS in the 2024 Medicare Physician Fee Schedule (MPFS) rule added one service—social determinants of health risk assessments—to the permanent Medicare telehealth services list.[1] Another new service—health and well-being coaching services—was added on a temporary basis, and it's still covering other services on a temporary basis through 2024.

Hospitals in 2024 also got the green light to keep billing for outpatient physical, occupational and speech therapy, diabetes self-management training (DSMT) and medical nutrition therapy (MNT) delivered by telehealth to patients at home, the same way they did during the public health emergency and were allowed to do through 2023 because of an extended COVID-19 waiver, although patient homes won't have to be registered as provider-based departments anymore.

Brandt said other congressional priorities for 2024 include artificial intelligence legislation, site-neutral policies and prior authorization. Also in the spotlight: Medicare Advantage (MA). Brandt said the Medicare Payment Advisory Commission (MedPAC), which advises Congress, has had a series of sessions on MA and generally concluded that plans are overpaid. CMS is projected to spend $88 billion more on MA than on traditional

Medicare in 2024, something that's attracting "a lot of chatter in congressional circles," she said. "CMS is doubling down on how we can better align MA payments and be more accountable and transparent. It will have huge ramifications. It means more audits and oversight."

Chevron Deference Ruling Could Change Everything

The regulatory world should keep its eyes open for a looming U.S. Supreme Court decision on so-called Chevron deference, said Greg Demske, former chief counsel to the HHS Inspector General, at the Compliance Institute.

"Hundreds of cases have been decided by the federal courts based on this doctrine," said Demske, with Goodwin Procter LLP in Washington, D.C. According to the Chevron doctrine—which comes from a 1984 Supreme Court decision—when a statute is ambiguous, courts are required to defer to the regulatory agency's reasonable interpretation of the statute. Although Chevron deference has been the law of the land for decades, the Supreme Court agreed to hear two cases challenging it, and a ruling is expected by June.

"The majority of the Supreme Court doesn't seem to like Chevron," Demske said. If it's diluted or goes away, the heavily regulated world of health care may be in for a bumpy ride. "The impact of this could really affect the level of certainty one can get from the statute based on what the regulatory agency says."

On a different matter, a Supreme Court decision that came down last year killed off the idea that defendants in False Claims Act (FCA) cases could argue that even though they may have believed they were violating a regulation, they didn't submit false claims "knowingly" as defined by the statute. The unanimous ruling centered on whistleblower cases filed against Safeway and SuperValu pharmacies over their "usual and customary" charges for drugs on claims submitted to Medicare and Medicaid. "What matters for an FCA case is whether the defendant knew the claim was false," Justice Clarence Thomas wrote in *United States et al. ex rel. Schutte et al. v. SuperValu Inc. et al*. "Thus, if respondents correctly interpreted the relevant phrase and believed their claims were false, then they could have known their claims were false."

The bottom line of the decision from a compliance perspective is "you should be very thoughtful about what you're doing and make sure you have a reasonable basis for your decision," Demske said.

He also spoke about enforcement priorities. They include MA, Stark and kickbacks, nursing homes, and third-party actors—private equity firms, electronic health record vendors and coding consultants and billing specialists. Demske mentioned some of the major FCA settlements that have come down in recent months. For example, the U.S. Department of Justice (DOJ) in December 2023 announced the largest FCA settlement ever based on alleged Stark Law violations. Community Health Network (CHN) in Indiana agreed to pay $345 million to settle false claims allegations that it paid over-the-top salaries to hundreds of physicians and rewarded them for their referrals in violation of the Stark Law.[2]

More broadly, Demske said that "everybody is turning a critical eye to private equity because of the concern that" their drive to save money and increase profits is potentially harmful to patients.

The Federal Trade Commission (FTC), DOJ and HHS are conducting a public inquiry into "the role of private equity in health care and corporate profiteering," Brandt said.[3] The FTC will deploy the full scope of its authorities to protect the public from anticompetitive and unlawful tactics." She noted that 40% of emergency rooms are overseen by for-profit staffing companies owned by private equity.

Update to Security Rule Is on the Table

Meanwhile, the HHS Office for Civil Rights (OCR) is planning to review and possibly update the HIPAA Security

Rule, said OCR Director Melanie Fontes Rainer at the Compliance Institute. The rule took effect at a time (2005) when lost laptops and fax snafus were top security risks. Now OCR is more worried about the security of things like electronic protected health information and telehealth.

Rainer noted that "the elephant in the room for many of you" is the increase in the number of large breaches. Between 2022 and 2023, that number almost tripled, from 56 million people affected to 135 million; OCR expects it to double this year because of the Change Healthcare breach.[4]

Other OCR priorities in the HIPAA realm include finalizing its proposed changes to the Privacy Rule to support reproductive health care privacy.[5]

OCR also has a big to-do list unrelated to HIPAA. For example, "one area we do a lot of work on is language access," Rainer said. "It's really important in health care." HHS is trying to improve meaningful access to language assistance services for people with limited English proficiency, partly in response to President Joe Biden's Executive Order 13,985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.[6]

In the next few months, HHS agencies will put out new language access plans specific to their operations (e.g., CMS, National Institutes of Health). "You can use them to drive compliance," Rainer said.

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1 Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program, 88 Fed. Reg. 78,818 (Nov. 16, 2023), https://bit.ly/3UeZ8dp.
2 Nina Youngstrom, "In Biggest Stark-Based FCA Settlement Ever, Indiana Hospital Pays $345M, Has Unusual CIA," *Report on Medicare Compliance* 33, no. 1 (January 8, 2024), https://bit.ly/3Q4xdu7.
3 U.S. Department of Health and Human Services, "Issue Request for Public Input as Part of Inquiry into Impacts of Corporate Ownership Trend in Health Care," news release, March 5, 2024, https://bit.ly/49UqPNG.
4 Nina Youngstrom, "Data on Types of HIPAA Breaches," *Report on Medicare Compliance* 33, no. 15 (April 22, 2024).
5 Nina Youngstrom, "Proposed HIPAA Rule Would Protect Abortion PHI From Law Enforcement," *Report on Medicare Compliance* 32, no. 15 (April 17, 2023), https://bit.ly/3W3VHaL.
6 Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, Exec. Order No. 13,985, 86 Fed. Reg. 7,009 (Jan. 25, 2021), https://bit.ly/49NAR2h.