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Outlook 2022: New Year Brings Big Billing Changes, More Audits, Key Supreme Court Cases

By Nina Youngstrom

To some extent, compliance predictions for 2022 are like the coronavirus itself with its variants—things are fluid and everyone will know more when they're in the thick of it. That applies to the challenges of reverse-engineering waivers after the public health emergency (PHE) ends and complying with the No Surprises Act, which requires hospitals and other facilities to determine when patients are treated by out-of-network providers and how much to charge them. Other predictions for the new year come easier. Compliance professionals and attorneys foresee a surge of short-stay audits and Targeted Probe and Educate (TPE), confusion with the reversal of the elimination of the inpatient-only list and complications in implementing a new rule on split/shared billing, among other things. Enforcement is also undergoing a sort of metamorphosis with the Monaco memo, which raises the stakes for compliance and corporate governance.[1]

"It is a time of extreme flux," said attorney Daniel Hettich, with King & Spalding. And it's "a difficult time" with new regulatory requirements, an uptick in COVID-19 cases and staffing shortages. "It feels more of the same from a compliance standpoint, but another layer has been added on top of the complexity of things we already deal with," said Patrick Kennedy, executive director of hospital compliance at UNC Health in North Carolina. "You add surprise billing, you add appropriate use criteria—that takes a lot of resources and time from a compliance standpoint to make sure we are putting it in place correctly the first time."

This year, health care organizations should prepare to let go of COVID-19 waivers. "We have to start thinking about the post-PHE even if we don't know when it will end," said attorney Judy Waltz, with Foley & Lardner LLP. HHS may declare the PHE is over "before clinically we can say there is an end to the pandemic." That opens up waivers to audits under different standards and potentially False Claims Act (FCA) lawsuits. "People should be concerned," said attorney Andy Ruskin, with K&L Gates. "Do people even remember what they relied on?" The longer the PHE remains in effect, the harder it will be for a physician to tell patients, for example, they can no longer receive audio-only telehealth services. Ruskin also bets that many hospitals don't recall which provider-based clinics were only eligible because of a waiver and, when the PHE ends, won't be entitled to the higher outpatient payment. The pullback of the telehealth waivers will hit hardest, Waltz said. "Even though telehealth expanded incredibly during the PHE, CMS didn't make a lot of them permanent, so it will require people to figure out what they did to adapt during the PHE and unwind it," Waltz said. "If you think back to the chaotic first days of the PHE, hopefully people kept notes of what they did so they can change things back. It will be tough. It will be a little bit crazy."

Supreme Court May Forever Change Guidance

A sure thing in 2022 will be two Supreme Court decisions that could profoundly alter Medicare guidance for providers, Ruskin said. The two cases address Medicare 340B payment cuts and how CMS calculates disproportionate share hospital payments, and both question how much deference government agencies should enjoy in policymaking, he said. The Supreme Court already reined in CMS's subregulatory guidance (e.g., transmittals, Medicare manuals) in a 2019 decision, *Azar v. Allina Health Services,* which requires CMS to use

rulemaking, with its notice-and-comment period, for "substantive" changes to policies that affect payment and scope of benefits.[2] "Allina has ushered in a new era of less informal guidance," Ruskin said. In the two cases due this spring, "there possibly will be a frontal assault" on the doctrine of Chevron deference, which refers to the benefit of the doubt that courts give federal agencies when they interpret statutes through rulemaking and guidance. If the high court throws out the Chevron doctrine, there "could be a huge difference in the way the agency conducts business," he said. CMS would have to spend much more time justifying why its policies are "procedurally and substantively sound" and not arbitrary and capricious. What this may mean for providers: fewer, but better-reasoned and fairer transmittals, manual provisions and *MLN Matters*—and perhaps less regulatory change, Ruskin said. "The agency will do less and explain more as to everything it does."

Compliance officers will be rebuilding or reinforcing their programs this year, experts said. "Compliance has shifted in terms of core expectations in light of COVID, but it is no longer temporary," said attorney Jon Drimmer, with Paul Hastings in Washington, D.C. There was a little reprieve with COVID-19 affecting the operations of a compliance program (e.g., updating policies and training, risk assessments), "but you have to figure out how to do those tasks you might have been postponing because you figured the government will cut you slack. It's not there anymore. COVID is the new normal." Compliance officers may have more clout to get the job done. "I believe their place at the table has been enhanced over the past several years, especially recently," said attorney Gabriel Imperato, with Nelson Mullins Broad and Cassel. "I don't know what the measurement of that is exactly, but it stands to reason that as the risk increases, the effectiveness of an organization's compliance program becomes more essential to manage that risk," he said. "As more whistleblower cases impact health care organizations, your compliance program capability is front and center."

For some smaller organizations, 2022 will be a time to reboot their compliance programs, said Margaret Hambleton, president of Hambleton Compliance LLC. "They have sort of languished in many cases for the past year or so," she said. "They are trying to ramp all the systems back up to do monitoring, auditing, training and reporting." That will require leveraging expertise in their organizations, such as care coordination and coding, Hambleton said. And compliance officers have to tackle new challenges, including oversight of interoperability requirements and COVID-19 testing. Her advice: Make sure you're caring for your patients, yourself and your families. "Who knows what this year will look like."

Compliance updates will probably continue to be provided remotely or partly live with a virtual option, said Donald Sinko, chief integrity officer for the Cleveland Clinic. "In the past 18 months, everything has gone to Zoom and Teams meetings," he said. "In some ways, it has probably improved communication because you talk to more people." Cleveland Clinic's monthly updates now include significantly more people because they don't have to show up in person.