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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.

TPE Is Back 'the Way it Was'

Audits are expected to gain steam this year. One target: the two-midnight rule. "I feel like the boy who cried wolf talking about short-stay audits. We have been warning about it for months, and yet there hasn't been the tsunami of chart requests we expected," said Ronald Hirsch, M.D., vice president of R1 RCM. But in 2022, Livanta, the Beneficiary and Family Centered Care-Quality Improvement Organization that won the CMS contract to review short stays, should start auditing admissions, he said. On the Medicare Advantage and commercial plan side, hospitals will continue to face clinical validation of "the usual suspects": diagnoses for acute respiratory failure, malnutrition and acute kidney injury, Hirsch said.

Now that TPE is back after a long pandemic-induced break, hospitals are under the microscope for a variety of claim types. "We have seen a flurry from Palmetto," Kennedy said. Some of UNC's facilities are being audited for chemotherapy drugs, such as pembrolizumab and pegfilgrastim. Palmetto is also auditing cataract surgery, DRG

885 (psychoses), hyperbaric oxygen therapy, manual therapy and therapeutic exercise, among other things. "We have seen 259 audits in three months," Kennedy said. "It seems to be back to the way it was" pre-pandemic.

In terms of self-audits, in addition to the usual risk areas (e.g., two-midnight rule, condition code 44, modifier 59), Kennedy said this year UNC plans to review its compliance with CMS's Acute Hospital Care at Home program, which included an individual COVID-19 waiver of Medicare's 24/7 nursing care requirement.[3] For example, "we contracted to third parties to go into homes and provide some of the services," he explained. "What does that look like on the back end" (e.g., their billing and documentation)?

Hospitals also will face greater scrutiny this year of their compliance with price transparency requirements from CMS and state attorneys general, said attorney Ahsin Azim, with King & Spalding. Penalties rose Jan. 1 for noncompliance with CMS's mandate, which requires hospitals to reveal to the world five sets of charges for all items and services: gross charges, payer-specific negotiated charges, the discounted cash price, and the minimum and maximum payment amount they accept from payers for every item and service without identifying the payers. They also have to post a shoppable list of 300 payer-specific negotiated charges for common services in a consumer-friendly way.

"CMS has sent numerous warning letters to hospitals for noncompliance and been far more aggressive in its enforcement efforts than anticipated," Azim said. State attorneys general in New York, North Carolina and perhaps elsewhere are investigating hospitals for possible noncompliance with the price transparency rules, presumably to enforce state consumer protection laws, he noted.

Regulatory Changes Push Hospital Buttons

While they appreciate the benefits for patients, compliance officers and attorneys consider the No Surprises Act, which took effect Jan. 1, easier said than done.[4] "It's a nightmare," said Robert Bacon, vice president and billing compliance officer at Penn Medicine, an academic medical center in Philadelphia. "In general, it's a concept I endorse. It's when you try to apply it it's not so simple anymore." Kennedy doubts CMS and lawmakers grasp "all the downstream effects and what we have to put into place operationally to comply" with the No Surprises Act, which protects patients from large or unexpected bills from out-of-network providers for emergency and many nonemergency services provided at hospitals and other facilities and requires them to give patients good faith cost estimates of their services. Identifying out-of-network emergency services and providing accurate cost estimates with a $400 margin of error boggles the mind, the compliance officers say. The latter "could be a PR nightmare," Kennedy said. CMS in late December released answers to frequently asked questions on cost estimates, and other guidance has been coming out to help with No Surprises Act compliance.[5]

Another area of hand-wringing is the reversal of the elimination of the inpatient-only (IPO) list, which took effect Jan. 1, although financially it may bring relief. "The IPO list changes back and forth make it more confusing to figure out what status doctors use for what patients," Hirsch said. "Doctors just want to do surgery and provide safe, effective care for patients. The last thing they want to get involved with is patient status." For the sake of compliance and revenue, he recommends hospitals use Addendum B, the all-surgeries list in the outpatient prospective payment system rule, and their coding book to nail down what's truly on the IPO list, and not just Addendum E, the IPO list, which only has short code descriptors.

Split Billing: 'An Unbelievable Nightmare'

The IPO list and patient status (inpatient vs. outpatient/observation) also cause friction with Medicare Advantage plans and commercial insurers, and Hirsch predicts the tug-of-war will continue to worsen because of the payment differential between inpatient admissions and outpatient. "At some point, hospital finance people have

to realize their contracts need to address more than just a payment rate. There needs to be rules in place about who should be inpatient and who should be outpatient," he said. "No matter how good an inpatient rate finance negotiates, their rate is only valuable if hospital stays are paid at that rate."

Medicare's new rule on split/shared billing also is causing considerable angst. After withdrawing its manual guidance on split/shared billing because it was never rooted in notice-and-comment rulemaking, CMS formalized its policy in the 2022 Medicare Physician Fee Schedule rule.[6] With split/shared billing, Medicare pays 100% of the physician fee schedule for evaluation and management (E/M) services provided jointly by a physician and nonphysician practitioner (NPP) at an institution (e.g., hospital, skilled nursing facility).

According to the rule, "only the physician or NPP who performs the substantive portion of the split (or shared) visit would bill for the visit," and "substantive portion" is defined as more than half the time. That essentially creates a new requirement for all providers to document the duration of their services so that the correct billing practitioner can be identified. The practitioner (physician or NPP) who spends the most time with the patient or on patient-related tasks (e.g., documentation, reviewing lab results) bills for the services. For example, if the NPP spends 21 minutes with the patient and the physician spends 20 minutes with the patient, the visit must be billed under the NPP's national provider identifier (NPI), which pays 85% of the physician fee schedule.

CMS gave physicians and NPPs a year to absorb the new definition of substantive portion. In 2022, they have a choice to bill under the NPI of the physician or NPP who spends more than 50% of the time spent on the patient, or under the NPI of the physician or NPP who rendered one of the three components of an E/M service: history, exam or medical decision-making. Starting in 2023, time is the only option for deciding who provided the substantive portion of the services.

"They have truly created an unbelievable nightmare," Bacon said. "The concept of working with APPs [advanced practice providers] is efficiency. They spend more time by definition with the patient because you rely on them to do the history and exam, but in the outpatient setting, that doesn't determine the level of service. It's medical decision-making." Bacon added that time isn't documented in "a high percentage of outpatient notes," but now there must be two sets—one from the APP and the other from the physician—"and someone needs to determine which is primary." CMS is due to release FAQs on split/shared billing, which he hopes will shed some light on how to bridge the gap between the regulation and operations.

One of the most anticipated payment decisions for 2022 is whether Medicare will cover Aduhelm, the controversial Alzheimer's drug that won Food and Drug Administration approval but is not being prescribed at some hospitals because of concerns about its side effects and doubts about its effectiveness, Hirsch said. CMS is expected to release a proposed national coverage determination (NCD) in February that "will give people an idea of whether or not it's covered." Even if CMS gives Aduhelm a green light, Medicare administrative contractors may decide it's medically unnecessary and decline to pay the claim, Hirsch said. "The NCD should be carefully scrutinized to find inclusion and exclusion criteria, and these must be followed to the letter."

Payment for remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) also will be hot areas of reimbursement this year, followed inevitably by audits and enforcement, said attorney Brenna Jenny, with Sidley Austin LLP. Medicare started paying separately for remote physiologic monitoring in 2018 and has been incrementally increasing reimbursement since. On Jan. 1, five new codes took effect for RTM, which focuses on patient self-reported data (e.g., respiratory status). "The pandemic supercharged the interest in using these modalities," Jenny said. The "regulatory churn leads to an enforcement churn," compounded by CMS's lack of clarity on the billing rules. "This will percolate" to the unified program integrity contractors, which investigate fraud and abuse on CMS's behalf and refer possible cases to the Department of Justice and HHS Office of Inspector General, Jenny said.

More globally, Waltz predicts that CMS will continue to be more flexible with respect to health care delivery. That came through in its new "Guidance for Hospital Co-location with Other Hospitals or Healthcare Facilities,"[7] FAQs confirming CMS is not requiring clinical laboratory improvement amendment certificates for locations where patients perform self-testing and "more encouragement for telehealth."[8] This isn't all a reflection of COVID-19 battle fatigue, Waltz said. "CMS has been sensitive to problems of patient access for years, and this is a way of removing some barriers to care," she explained. "The themes are improved access and reduced cost."

There are burdens as well. Sinko said without relief, 2022 will be another year of providing evidence it has met compliance requirements to every Medicare Advantage plan, as required by CMS for First Tier, Downstream and Related Entities. "Every year we have to jump through these hoops," which he said provide "zero benefits to Medicare patients."

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