Report on Medicare Compliance
Volume 24, Number 1 • January 12, 2015

2015 Outlook

2015 Should Be an Action-Packed Year for Regulators, Hospital Compliance Officers

If the release of the final regulation on the Medicare-Medicaid 60-day overpayment refund mandate is a sign, then 2015 will have a lot of compliance and enforcement activity. The rule is in clearance, which means CMS apparently will publish it sometime soon, sources say. Hopefully that will clarify this Affordable Care Act provision, which requires providers to return overpayments within 60 days of identifying them. The regulation was proposed in 2012, and its ambiguity has troubled providers, who are at risk of false claims lawsuits if they drop the 60-day refund ball *(RMC 12/15/14, p. 1)*.

There is a lot more on the horizon for the coming year, according to compliance officers, attorneys and consultants interviewed by *RMC*. Medicare administrative contractors (MACs) will be free in April to review inpatient admissions under the two-midnight rule while denying, for the first time, physician fees for "related" procedures. Scrutiny of medically unnecessary services is expected to intensify, as will other types of audits. But the incumbent recovery audit contractors, who are back in business through December 2015, "will not conduct any inpatient hospital patient status reviews," a CMS spokesman tells *RMC*.

In other areas, ICD-10 implementation is seen as inevitable for Oct. 1, partly because hospitals have sunk so much money into it. And they are expected to disclose more potential Stark and anti-kickback violations to head off false claims lawsuits, and turn more attention to disaster preparedness and monitoring pay for performance.

These and other developments call for more attention from senior leaders and the board, partly because regulatory and enforcement trends are moving front and center. "Things are changing rapidly in health care, and one result is that your board and senior leadership need to be involved in more key areas than before," says Debi Weatherford, executive director of internal audit at Piedmont Healthcare in Atlanta. "The board is asking more questions of senior leadership."

Hospitals will be hit by the double whammy of risks from aggressive business strategies and losses due to audits, enforcement actions and regulatory changes, says former federal prosecutor Robert Trusiak, chief compliance officer and associate general counsel at Kaleida Health in Buffalo, N.Y. "The specter of shrinking hospital margins also means new areas of hospital business development and with new business models comes new risk," he says. For example, hospitals will continue to buy physician practices because they enhance profits, but the compensation that results can invite scrutiny under the Stark self-referral and anti-kickback laws.

Stark Looms Large for 2015

In fact, Stark looms large for 2015 because it can be a "gimme" for the government. A violation of the Stark law requires no proof of intent. The government just has to show that entities providing designated health services billed Medicare for services referred by physicians with whom they had a financial relationship and that no exception was met. Because of what's at stake — and in the wake of the Halifax Health $85 million Stark-based false claims settlement last year *(RMC 3/10/14, p. 1)* — "there will be more voluntary disclosures for Stark violations and anti-kickback violations," says attorney Gabriel Imperato, of Broad and Cassel in Fort Lauderdale, Fla. Hospitals are looking closely at physician arrangements and inundating the CMS self-referral disclosure protocol and other self-disclosure vehicles (e.g., the HHS Office of Inspector General, U.S. attorneys' offices) to resolve potential liability, he says. This year, Trusiak adds, "Stark must be the significant compliance focus due to the ease of civil prosecution through the False Claims Act." That includes an analysis of fair-market value and nonmonetary compensation and the evaluation of administrative positions to ensure physicians satisfy hourly requirements, Trusiak says.

Medicare and Medicaid audits will bring new challenges this year. For one thing, there will be the link between claim denials for inpatient admissions and corresponding claims for physician services. CMS in September announced its plans to deny physician claims for inpatient procedures "related to" hospital claims that are denied as medically unnecessary, according to Medicare Transmittal 540, which was later updated to 541 *(RMC*

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9/15/14, p. 3, 9/22/14, p. 8). That formally links, for the first time, facility and professional claim denials on the inpatient side. Hospitals presumably won't feel the effects until at least April 1, when MACs (and, next year, RACs) are unleashed to audit inpatient admissions under the two-midnight rule. But it's uncharted territory and has some compliance people nervous. "We are trying to do reviews to see where we stand in these areas, but we can only move so fast," says Catherine Hicks, director of compliance audit services at University of Colorado Health. She and Chief Compliance Officer Christine Newgren are trying to convey to surgeons that their payments are at risk — both for the surgery and follow-up visits — and have set up a system to feed them financial data on the losses they will suffer if admissions are denied. "Hospital money is one thing, but surgical money will be a shock to them," Newgren said.

Meanwhile, it's clear that physician orders will precipitate more denials this year and beyond. "A lot of claims we see don't have an official inpatient order," Hicks says. The orders may state "admit," but that's not good enough; physicians must specify "admit to inpatient," according to CMS. Novitas, the MAC, "says almost half the battle now is orders," she says. With electronic health records, "it seems very odd to have that much trouble getting valid orders."

Audit and enforcement attention will increasingly shift to the medical necessity of the services, experts say. "There is a lot of money in denials of the medical necessity of the procedures," says Ronald Hirsch, M.D., vice president of education and regulations at Accretive Physician Advisory Services. The writing is on the wall for certain procedures with high error rates, according to the Medicare Fee-For-Service 2014 Improper Payments Report *(RMC 12/22/14, p. 3)*. This includes spinal fusion except cervical, for which Medicare overpaid more than $200 million, mostly because of insufficient documentation and lack of medical necessity. The report also said Medicare improperly paid $345 million for joint replacement for the same reasons. MACs have their eye on medical necessity as well. For example, CGS on Jan. 5 posted results of a targeted review of urinary stent placements in Ohio. The MAC denied 87.8%, saying providers failed to adequately document medical necessity. But MACs may continue to focus on inpatient admissions in terms of their compliance with the two-midnight rule. Patients with chest pain, for example, apparently continue to be admitted, according to the report, which cited a whopping 99.8% error rate for lack of medical necessity.

UPICs to Replace ZPICs and MICs

More globally, CMS eventually will start replacing zone program integrity contractors (ZPICs) and Medicaid integrity contractors with a "unified program integrity" contractor *(RMC 4/7/14, p. 1)*, although a CMS spokesman says the contract hasn't been awarded yet. "CMS expects to implement the UPIC strategy beginning with initial contract awards in FY 2015 with additional transitions to occur in subsequent fiscal years," it said in its FY 2014 to 2018 Comprehensive Medicaid Integrity Plan. Shantanu Agrawal, M.D., director of the CMS Center for Program Integrity, envisions UPICs will recover a significant amount of improper payments, says Austin, Texas, attorney Brian Flood, who is with Husch Blackwell. In lockstep with UPICs, CMS is expanding the Health Fraud Prevention Partnership, which enables private payers to share claim data with the government on the assumption that providers that cheat Medicare or Medicaid do the same to nongovernment payers, Flood says.

Beyond traditional audits, compliance officers will be challenged in new ways. They will tackle nontraditional risk areas, such as disaster preparedness. "As we see all kinds of things happen with climate changes and increased crime in hospitals, disaster preparedness and business continuity become more of a front issue," Weatherford says.

EHRs and P4P Are Continuing Risk Areas

Similarly, compliance will be more involved in electronic health record systems and pay-for-performance programs, Flood says. They are interrelated, something that is often misunderstood, he says. "There is more to it than meaningful use money." Hospitals and physicians will lose much more reimbursement in 2015 and 2016 unless they comply with CMS requirements for meaningful use of interoperable electronic health records *(RMC 11/24/14, p. 1)*, the physician quality reporting system (PQRS), e-prescribing incentive program, value modifiers and value-based purchasing program. "If providers are not installing those systems and using them in a way the government wants and the government checks on them and they don't comply, they could have an aggregate gross loss of 6% to 10%," Flood says. It's also auditable every year, he notes.

The future also looks different for corporate integrity agreements (CIAs), which are compliance programs mandated by OIG in many fraud settlements. "There is a new model of CIA that is interesting and suggesting the OIG expects a significant risk evaluation," says Atlanta attorney Sara Kay Wheeler, who is with King & Spalding. It was used in the CIA that was part of the recent false claims settlement with Dignity Health, which agreed to pay $37 million to resolve allegations that 13 of its hospitals billed Medicare and TRICARE for inpatient admissions that should have been outpatient services. What's different about this CIA is the way the monitoring will adapt to respond to emerging risks, Wheeler says. "If you

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go back to older CIAs," she says, the audits are random. Dignity's CIA has a dynamic risk evaluation and claims testing requirement, allowing for targeted audits, training and policies that respond to potential risks identified by various sources, such as external audits and data mining.

It won't just be the government looking over the shoulders of compliance and internal audit. "I think there will be a lot more scrutiny from the board and senior leadership perspective," Weatherford says. As 2015 unfolds, she anticipates more review of policies with regulatory implications. *One example*: Form 990 for tax-exempt organizations, which is available to the public, and includes executive compensation for the top earners and first-class travel (schedule H).

In the HIPAA realm, 2015 probably will be the year that covered entities and business associates "embrace the fact that a thorough security rule risk assessment is maybe the most critical aspect to HIPAA compliance," says Philadelphia attorney Brad Rostolsky, who is with Reed Smith. The HHS Office for Civil Rights always asks for a copy of the risk assessment during an enforcement action, even if that didn't trigger it, he says. If a security risk assessment shows laptops aren't encrypted, for example, covered entities and BAs should have an answer for why not and what they will do about it, Rostolsky says. The new year also may have some surprises with the turnover in OCR leadership. The OCR chief, Leon Rodriguez, left, and was replaced by former Department of Justice attorney Jocelyn Samuels; there also are three new directors of OCR regional offices. "With the relatively significant amount of leadership change at OCR, the agency may feel the need to reinforce its authority," he says. It also would not surprise him if 2015 brought multiple announcements of business associate enforcement actions. "This is further buttressed by the announcement late in 2014 by a senior adviser for HIPAA compliance and enforcement at OCR that findings from the audit program, which is being re-launched in 2015, may play a role in the agency bringing enforcement actions," Rostolsky says *(RMC 10/13/14, p. 1)*.

Hospice Reform Is a Possibility

There may be radical new payment regulations this year. CMS is flirting with a new payment for short hospital stays, although it could create another set of headaches, Hirsch says. CMS also is "leaning toward" hospice reform, says Emily Evans, a partner in Obsidian Research Group in Nashville. Hospices incur more costs at the beginning and end of the episode of care, and CMS is considering paying them more at those junctures than in the middle, she says.

Medicare enrollment also will be a source of "increased enforcement," says Washington, D.C., attorney Don Romano, who is with Foley & Lardner LLP. "CMS has now merged conditions of payment into enrollment criteria," he says, and can revoke billing privileges if providers repeatedly submit noncompliant claims *(RMC 12/8/14, p. 1)*.

Circling back to the 60-day Medicare overpayment refund mandate, Wheeler predicts it will be one of the hottest issues this year and beyond, especially with the false claims lawsuit pending against Continuum Health Partners in New York City *(RMC 7/21/14, p. 1)*. Compliance officers will need to consider the theories advanced in this case when designing audits and anticipating potential obligations emerging from various audits, she says.

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