

MEDICARE COMPLIANCE

Outlook 2013

Compliance Faces Major Challenges as Risks Evolve, Health Systems Transform

Compliance officers will straddle two worlds in the coming year, as their health systems face the usual audits and enforcement actions while adapting to risks that emerge as the industry reinvents itself. Although most of their brainpower will be invested in the familiar and emerging risks of Medicare fee-for-service medicine and perhaps managed care, compliance officers will plant a second foot in the parallel universe of payment for outcomes and quality, which introduces payment arrangements that could run afoul of fraud and abuse and other laws.

"It's a new ballgame in terms of what you are worried about," says Becky Cornett, Ph.D., director of fiscal integrity at Wexner Medical Center at The Ohio State University. But the action will be just as intense as ever. "People think auditing is brutal now but it's just a fraction of what it will be in the future," says Roy Snell, president of the Health Care Compliance Association. *The reason:* "Health care enforcement remains a profit center," notes Nashville attorney Sheila Sawyer, with Waller Lansden.

Expect a year of high drama. The American Taxpayer Relief Act of 2012 was signed into law by President Obama on Jan. 3, and in addition to all of the fiscal-cliff provisions, it gives Medicare contractors more time — five years instead of three — to recover overpayments from providers, although these provisions don't appear to apply to recovery audit contractors (RACs).

In the coming year, two health systems — Tuomey Health Care System and Halifax Hospital Medical Center — will go on trial for allegedly submitting false Medicare claims; CMS will probably release two landmark compliance regulations, on Medicare repayments and compliance programs; and HHS's Office for Civil Rights will issue its long-overdue regulations implementing enormous changes in HIPAA/HITECH Act patient privacy and security provisions.

Transformation of the health care industry will continue, fueled partly by the release of final regulations on accountable care organizations and health insurance exchanges. "It will be the wild west of changing relationships, contractual arrangements and attempts to control the market in different ways by different entities," says

Kevin Cornish, national director of the healthcare dispute, compliance and investigation practice at Navigant Consulting. This will trigger greater federal scrutiny of financial relationships and potentially result in Stark and anti-kickback enforcement actions.

Auditors, Enforcers Are Driving Change

The way compliance officers, attorneys and consultants think about risks and compliance programs will start to evolve partly because they see significant changes on the horizon in the way auditors and enforcers approach their work, due in part to advances in data mining.

For example, OIG audits will link physician bills to inpatient bills, says Florie Munroe, chief compliance officer at Bronx Lebanon Hospital Health System in New York City. "OIG is doing data mining and looking more globally at Part A and B bills," she says. Audits will examine the entire episode of care, whether it's one day in a clinic or one week in a hospital. Suppose a patient was implanted with a medical device. "Everything that touched that episode of care will be subject to audit," Munroe says. "It's not just about billing for the medical device. It's an all-in approach." Are progress and visit notes thorough? Are lab and radiology orders in the medical record? Do results support the need for the order? "It is a different approach on the OIG's part and I think OIG inquiries will be riskier," she says. That's a departure from a narrow focus on billing as a discrete service, and the physician's role is a significant part of the equation.

Meanwhile, hospitals will ask physicians to step up and share the financial burdens of recoupments that are partly of their own making, says former federal prosecutor Robert Trusiak. "It is important to recognize that institutions on shrinking margins will not continue to sit back and accept all that financial risk created by their employed physicians," he says. Instead, he predicts they will require physicians to indemnify them against losses. "I am not suggesting this as a first step," says Trusiak, chief compliance officer and senior counsel for Kaleida Health in Buffalo, N.Y. But if physicians continue to admit patients to the incorrect setting or fail to reduce preventable readmissions despite education, "they should share in the financial exposure with hospitals," he says.

OIG has been questioning hospitals on sensitive subjects, including electronic health records (*RMC 12/3/12, p. 1*) and physician-owned distributorships (*RMC 10/29/12, p. 1*). That's all well and good, but Trusiak says that just because hospitals receive these surveys doesn't mean they must respond — as long as the letters don't come from the Office of Audit Services. But hospitals often give the OIG Office of Investigations whatever it wants because they fear retribution otherwise, he says. "The idea the government will [retaliate] if you don't respond is silly," he says. In fact, there is some risk in answering surveys because OIG requires providers to attest to the veracity of their responses. "If you make a material false statement, you create exposure for your facility and perhaps the individuals who responded," Trusiak says. "This is voluntary and you should make a judgment as to whether it is in your self-interest to respond." Either way, the surveys are valuable tools for internal compliance reviews.

No compliance officer, consultant or lawyer interviewed by *RMC* foresees an abatement in audits and enforcement. In fact, they predict raging storms ahead because the health reform law was funded partly on billions of additional dollars that the feds will recover from fraud, waste and abuse, Snell says. "We will just get crushed," he predicts. That should keep compliance officers busy although their jobs will have to evolve. "The need for compliance programs is as acute as ever because the risk of liability is as acute as ever," says Fort Lauderdale, Fla., attorney Gabe Imperato, with Broad and Cassel.

RACs and MACs will keep doing their thing, although more energy will shift to prepayment audits consistent with CMS's emphasis on preventing improper payments instead of paying and chasing after them later.

But that doesn't mean audits will be static. Lawyers and compliance officers see auditors going off in new directions and exposure looming in unexpected places. "Don't just look for the usual cast of characters," Trusiak advises.

Here are some audit and enforcement areas to watch out for in 2013:

◆ **Zone program integrity contractors (ZPICs) — CMS's fraud and abuse hunters — will start to pursue quick administrative actions against providers**, such as revocations of Medicare billing numbers, says San Francisco attorney Judy Waltz, with Foley & Lardner, LLP. "CMS has indicated it will want ZPICs to spend less time on cases that require medical-chart reviews and long-term audits and more time on quicker actions, like deactivating billing privileges," she says. This fits with CMS's emphasis on provider enrollment and revalidation as a program-integrity tool, Waltz

says. "It is evolving in tandem with the CMS Fraud Prevention System," which uses predictive modeling to identify improper payments in fee-for-service Medicare.

◆ **New frontiers of medical necessity and quality of care investigations will emerge.** "They are moving away from traditional technical violations — whether there is the right code or date or signature — and moving toward whether the service was appropriate to begin with and whether it was the appropriate quality," Cornish says. He predicts all sorts of targets, with medically unnecessary diagnostic tests (EKGs, MRIs, CT scans) high on the hit list. "We have seen enough instances that would suggest someone on the federal side is looking at patterns of diagnostics and questioning whether they are appropriate." It shouldn't come as a surprise that the feds will go gangbusters in the quality arena. Not only are they "chartered to protect patients and prosecute wrongdoers, but they are able to identify possible patient harm and address it, which is a feel-good thing for them, and monies can still be significant." Scrutiny of quality will intensify as payment is linked to value and outcomes, Sawyer notes. "The government is always looking for a nexus between financial considerations and patient harm," she says. "Cuts in reimbursement will bring pressure on providers to achieve certain financial goals and to the extent the government thinks that translates into reduced quality, that will be a problem."

◆ **Medicare as secondary payer (MSP) will have the added twist of medical malpractice**, Trusiak says. When patients register, hospitals must determine whether Medicare is their primary or secondary payer. If Medicare is secondary, hospitals must bill the other insurer first and get the denial before billing Medicare. "More importantly, where hospitals miss the boat is when they have tort matters," he says. When Medicare pays for goods and services stemming from treatment of an injury that results in a malpractice settlement with a hospital, Medicare expects to be repaid. If not, there is false claims liability arising from the failure to satisfy the MSP obligations. "Hospitals better make sure they address MSP actions and liquidate MSP obligations upon settlement, or face double damages under the MSP statute or treble damages under the False Claims Act," the former prosecutor says. Trusiak adds that MSP liability may extend to the failure of some self-insured hospitals to inform CMS about tort settlements. *One caveat:* In December, Congress, surprisingly, amended the MSP statute so hospitals should check this out; the bill (S. 1718/H.R. 1063) awaits the president's signature.

◆ **There will be a continuing focus on post-acute care**, such as nursing homes, skilled nursing facilities, home health and hospices. “We have seen a tremendous uptick in audits and investigations of post-acute care by ZPICs and Medicare RACs,” says Atlanta attorney Sara Kay Wheeler, with King & Spalding. Even Medicaid RACs in some states, such as Georgia, are reviewing claims for post-acute care.

◆ **Physical, occupational and speech therapy are risk areas to watch closely**, especially in post-acute care settings, although auditors may have to lay off a bit in light of the Oct. 30, 2012, settlement of a lawsuit against HHS in the U.S. District Court in Vermont, says Cleveland attorney Alan Schabes. The lawsuit, *Jimmo v. Sebelius*, was filed by the Center for Medicare Advocacy, says Schabes, who is with Benesch, Friedlander, Coplan & Aronoff. It challenged the application of Medicare’s coverage rules for outpatient therapy and skilled nursing services, which required proof that they improved patients’ functioning. According to the settlement with HHS, Medicare will expand payment to rehab and skilled nursing that maintain a patient’s ability to function. “ZPICs and the RACs are looking at therapy now at nursing homes and skilled nursing facilities, but they do not take *Jimmo* into account,” Schabes says. “I think it will have a profound change.”

◆ **Pressure will build regarding short hospital stays**, which are a fixture on the RAC and MAC prepayment and postpayment audit lists. Expect the tension over payment denials for the incorrect setting (inpatient vs. outpatient/observation) to come to a head. As early as this month, CMS will propose a rule on patient status and Parts A and B rebilling in hospitals (see story, p. 2). Meanwhile, the new year should bring a resolution to the American Hospital Association’s lawsuit against HHS over outpatient and observation payments that hospitals are denied after RACs determine admissions were medically unnecessary (RMC 11/12/12, p. 5). Raising the stakes in this arena is the first criminal case over Medicare claims for the incorrect setting, which led to the Department of Justice’s deferred prosecution agreement and civil settlement with WakeMed Health & Hospitals in Raleigh, N.C. (RMC 12/24/12, p. 1). “There will be some middle-ground solution,” Waltz predicts.

◆ **Services performed by nurse practitioners and physician assistants will be scrutinized by the feds.** “I think the feds will expend considerable effort on this,” Cornish says. “Mostly it gets down to incident to. It’s a messy area.”

◆ **Physician arrangements and compliance with the Stark and anti-kickback laws will remain a high priority for CMS and OIG.** The government will continue to investigate all types of Stark violations, especially when hospitals should have identified and self-report-

ed them, which implicates the False Claims Act, says attorney Bob Wade, with Krieg DeVault in Mishawaka, Ind. He predicts more activity around the CMS self-referral disclosure protocol for actual or potential Stark violations.

Congress Just Raised the Stakes

With these and many other potential errors to focus on, compliance is already challenging. And Congress just upped the ante by allowing certain Medicare auditors, such as MACs and ZPICs, to recover overpayments from providers going back five years instead of three. The recently enacted “fiscal-cliff” law limits the length of time a provider can qualify for waiver of recovery of an overpayment based on the “staleness” of the claim for which an overpayment has been determined, Waltz says. Section 1870 of the Social Security Act permits limited waivers of recovery when a provider was “without fault” in causing the overpayment, she says. Until now, recovery was capped at the third year after the year in which the provider was told the claim would be paid. “In essence, this extends the period in which a hospital will be considered liable for repayment of an erroneously paid claim, even if the hospital was without fault in causing the overpayment,” Waltz says. She doesn’t believe the change applies to RACs because they have a limited look-back period.

Speaking of overpayments, the final rule on the 60-day repayment obligation is one of two watershed regulations expected from CMS in 2013. The other requires providers and suppliers to implement compliance programs as a condition of Medicare and Medicaid enrollment.

Health Reform Changed the Rules

Both regulations stem from the Affordable Care Act, but the one causing the most anxiety requires providers to return Medicare and Medicaid overpayments within 60 days of identifying them. They fear the version in the proposed rule, which floats a 10-year look-lack period to calculate liability for a payment error and generally defines when CMS considered an overpayment “identified” (RMC 2/20/12, p. 1). “I think providers wanted more clarity, so it will be very interesting to see whether CMS takes into account the significant comments offered,” Wheeler says.

The regulation on the compliance program mandate will presumably be CMS’s blueprint for an effective compliance program. That may provide a challenge for sectors of the industry that have not formalized comprehensive compliance programs, or even for hospital systems that are picking up post-acute care entities that may lack formal compliance infrastructure, Wheeler says.

This year, two unrelated hospitals will battle it out with the Department of Justice in front of a jury, a rare event in False Claims Act cases. Both lawsuits allege that the hospitals' compensation arrangements with certain physicians violated the Stark law. Tuomey Healthcare System in Sumter, S.C., will go to trial for round two in February after the government's partial victory was thrown out by the U.S. Court of Appeals for the Fourth Circuit (*RMC 4/16/12, p. 1*). In the first trial, the jury found Tuomey liable for Stark violations but not false claims in connection with its payments to 19 part-time employed physicians. But the U.S. District Court judge who oversaw the trial set aside the false claims verdict, giving the government another shot, and granted the government's request to recover \$45 million from Tuomey in Medicare repayment stemming from the Stark noncompliance (*RMC 6/14/10, p. 1*). The appeals court, however, made it all go away, saying the hospital's 7th Amendment right to a jury trial was violated in certain post-trial rulings.

In Daytona Beach, Fla., Halifax Hospital Medical Center and its subsidiary, Halifax Staffing, are slated to go on trial in late 2013, with the U.S. Attorney's Office for the Southern District of Florida alleging they overpaid certain neurosurgeons and oncologists in violation of the Stark self-referral law (*RMC 11/19/12, p. 1*).

"We are seeing greater challenges to what might have been thought of previously as secure arrangements," says one attorney, who prefers not to be identified. "The legacy of Tuomey, Halifax and other cases challenging hospital-physician relationships is that it doesn't appear as if any arrangement is truly safe." Meanwhile, hospitals are spending a fortune on legal fees and consulting costs and are being damaged by negative publicity that almost always focuses only on one side of the story — the plaintiff's allegations, the attorney contends. "It's a quagmire" of expenses and challenges and many of the allegations are without true merit, he contends.

Attorney-Client Issues Will Be Center Stage

The new year will bring more attention to the parameters of attorney-client privilege and conflicts of interest, says Julie Chicoine, senior assistant general counsel for the Wexner Medical Center at The Ohio State University. "I am seeing more new evaluations of attorney-client privilege and internal investigations, partly in the wake of the Penn State scandal," which culminated in the child sex-abuse conviction of former football defensive coordinator Jerry Sandusky. The report on the scandal by former FBI Director Louis Freeh said that "internal and external counsel dropped the ball in terms of protecting the university and being true to the rules of professional responsibility," Chicoine says. "The lessons here are that personal relationships and professional relationships can undermine internal and external counsel's job in providing advice."

Attorney-client privilege also took center stage in a November federal court decision ordering Halifax Hospital to release documents to the Department of Justice and its whistleblower. Halifax Hospital had tried to shield compliance, audit and other documents from disclosure under attorney-client privilege, but the judge said, among other things, they aren't protected just because they were stamped accordingly or because the compliance department reports to legal (*RMC 11/19/12, p. 1*). "Going forward, compliance and legal professionals need to be mindful of professional boundaries and the need for objective, competent advice," Chicoine says, especially with the 2013 implementation of the Physician Payments Sunshine Act.

The Organization, Not the Exec, Is the Client

She urges internal counsel to remember that the organization is the client. "It's not the senior executives or rising medical/athletic/educational leadership," Chicoine says. "If you are aware an official has always had problems with audits and conflict of interest with their university obligations, but you don't want to rock the boat, you need to rethink what you are doing in your organizational role. It is a new era, and you can't be blind to matters that require a proper investigation."

With so much tumult in the industry, it's time for compliance officers to let go of old ways of thinking about their job and embrace a different, more comprehensive role, Cornett says. "I prefer big-picture thinking" instead of an obsession with every regulation, she says. Compliance officers have gotten bogged down by process and structure for its own sake, Cornett says. Their true goal is to support the organization's effort to deliver value and quality to patients and payers. "We can't just check the box and say we did that so everything is fine. That's not true because our business is different than making hammers," she says. "We have to look at bigger issues. That's what accountable care is about. We are raising the bar on health care."

For example, compliance officers can work with care management and physicians to reduce readmissions for heart failure, pneumonia and acute myocardial infarction because they are harmful to patients' quality of care as well as the hospital's bottom line (*RMC 10/22/12, p. 1*). Reducing readmissions shouldn't be thought of as a regulatory mandate, she says, and neither should core measures (e.g., pneumonia vaccine, preventing central-line infections). Fixating only on the indicators of the moment may not correlate to better outcomes for patients and for the organization, she says.

Part of this shift will require a different kind of program integrity, where payers are less invested in a fee-for-service system, Chicoine and Cornett say. Overpayments take on new meaning when payers are more focused on

episodes of care (i.e., bundled payments). One way to prepare for this is better integration of compliance, quality, utilization and risk management “so they are not seen as add-ons but as parts of a whole,” each bringing different skill sets to the table, Cornett says. Otherwise, they may be “separate power centers that withhold information.”

There’s no doubt that compliance officers should position themselves for a future that looks different. The dramatic market change underway will spur all kinds of compliance risks. “It has never been this turbulent,” says Austin attorney Brian Flood, former Texas Medicaid Inspector General. CMS 2012 regulations on ACOs and health care exchanges will accelerate the absorption of smaller providers into larger organizations, Flood says. Payers and providers are joining forces. For example, payers may buy health systems — or health systems, such as Piedmont Healthcare and WellStar Health System in the Atlanta area, are partnering to develop a health insurance plan.

As organizations struggle for control of the market, they will search for ways to push the envelope, Cornish

says. And that’s where the feds will come in and compliance should run interference. Regulators may question whether new payment arrangements or collaborative models comply with the Stark, anti-kickback or antitrust laws, he says. “The biggest law of unintended consequences is that no one knows what they are.”

And that worries Munroe from a compliance standpoint. Hospital consolidation sometimes results in smaller compliance departments, even though regulations, audits and enforcement are thriving. “If the volume of the work has not changed, getting rid of staff [will only compromise the quality of the work].”

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