Report on
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Outlook 2012: Compliance Officers Should Prepare for Long, Strange Trip in Year Ahead

A shift is taking place in the world of program integrity, compliance and enforcement that will be felt in 2012 and beyond. With so much on CMS's plate — continued implementation of the health reform law and expanded program integrity initiatives — providers will be expected to do more self-policing, such as reporting overpayments within 60 days as required by law, disclosing Stark violations and ensuring they have an effective compliance program as a condition of Medicare and Medicaid enrollment.

Medicare watchdogs and enforcers will be ready to pick up the slack, however, tipped off by the growing number of whistleblowers and armed with new laws that convert Stark violations and kickbacks into false claims.

The year ahead will be an interesting one for compliance officers, who face kaleidoscopic challenges. There's broad consensus that the enforcement and overpayment recovery juggernaut will continue. Even if the Supreme Court strikes down the individual mandate of the health reform law or the entire thing, "the program-integrity piece will end up coming back," according to Ed Gaines, chief compliance officer at Medical Management Professionals, Inc. in Greensboro, N.C. "Whether the presidency changes, whether Congress changes, we know the program as currently structured is not sustainable." That means the government is desperate for savings from fraud enforcement and overpayment recoupment, as well as demonstrations designed to reduce expenditures and improve quality (e.g., ACOs and bundled payments).

The next 12 months may mark the beginning of far more synthesis between Medicare and Medicaid. As of Jan. 1, RACs now pursue Medicare and Medicaid mistakes. The compliance-program and overpayment return mandates apply to both Medicare and Medicaid, and information-sharing between state Medicaid agencies and CMS is growing in the provider screening arena. And the perception of data analysis as the key to program integrity and enforcement treats Medicare and Medicaid as inextricably linked. All this argues for more comprehensive compliance programs to complement the fact that state and federal agencies collaborate to squeeze every purported overpayment out of providers — and put bad apples in jail.

"They are elevating the need for integrated compliance programs," says Brian Flood, a national managing director for KPMG and a former Texas Medicaid inspector general. The stakes are raised for compliance officers to be "strategic partners with CFO, CEO, COO-level decision making so someone is watching the liability and has more authority — not in a standalone way."

So what's on the agenda for the coming year? Compliance officers, lawyers and consultants tossed their predictions into the ring.

Audits will keep coming, fast and furious. They will take more of a toll on revenue, and that means fewer resources for compliance initiatives, says Wendy Trout, director of compliance and revenue management at WellSpan Health in York, Pa. With Medicare RACs, Medicare Advantage "RAC-like" auditors and Medicaid auditors recouping money, "we are in kind of a reactive mode instead of being proactive," she says. "The challenge is getting more resources," Trout adds, especially because Medicare Advantage and Medicaid auditors don't actually do the legwork. Medicare Advantage RAC-like auditors and Medicaid auditors send hospitals a list of claims and tell hospitals to review them, and if they don't, they lose the money. "At least with Medicare RACs, they review records and put the effort in."

Audits May Have an Upside

RACs and MACs will continue to move beyond the low-hanging fruit this year, Flood says, pounding away at short stays, the medical necessity of inpatient versus outpatient or observation services, cardiac care, oncology, infusion therapy, home health and durable medical equipment documentation for medical necessity.

One potential benefit to RACs is they are starting to level the playing field, Gaines says. "They are identifying noncompliant entities and applying a level of audit scrutiny that has not existed in the past 10 years," he says. It's been frustrating for compliant organizations, "because

we are competing against firms that will do things we will not do to gain revenue." Audits and enforcement benefit providers that play by the rules. Otherwise, hospitals that overcompensate physicians and ambulance companies that pay kickbacks for referrals have a leg up on their competitors and no incentive to change, and physicians who push the evaluation and management coding envelope will dismiss the compliance officer's concerns on the grounds that they are subject to interpretation.

For compliant organizations and compliance officers who run into these kinds of problems, the future may soon get brighter because their noncompliant counterparts face the dangers from running afoul of the 60-day overpayment refund requirement, and eventually must prove they have an effective compliance program as a condition of Medicare and Medicaid enrollment. And while there is still a lot of subjectivity in E/M coding, CMS and its MACs are becoming more specific in their documentation requirements for an array of compliance hot topics, including non-physician practitioners (e.g., physician assistants) versus clinical staff who don't independently report professional services, resident and teaching physicians versus medical students, and electronic signatures in EHRs versus date and time stamps that don't authenticate the medical records, Gaines says.

For hospitals that face Medicare compliance reviews by the HHS Office of Inspector General, 2012 may be an intense year. Boston attorney Larry Vernaglia, with Foley & Lardner LLP, says "it can be very distracting." OIG reviews multiple risk areas at the same time, a

Conflict-of-Interest Attestation

This attestation is part of the Medicare enrollment form (855), but it can be inserted into a hospital's conflict-of-interest disclosure form to require physicians, board members and certain employees to own up to any sanctions against them. It's a strategy used by Catholic Health Partners in CIncinnati. Contact Cheryl Rice, vice president and chief corporate responsibility officer, at clrice@health-partners.org.

SECTION 3: FINAL ADVERSE LEGAL ACTIONS/CONVICTIONS

This section captures information on final adverse legal actions, such as convictions, exclusions, revocations, and suspensions. All applicable final adverse legal actions must be reported, regardless of whether any records were expunged or any appeals are pending.

Convictions

1. The provider, supplier, or any owner of the provider or supplier was, within the last 10 years preceding enrollment or revalidation of enrollment, convicted of a Federal or State felony offense that CMS has determined to be detrimental to the best interests of the program and its beneficiaries. Offenses include: Felony crimes against persons and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pre-trial diversions; financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pre-trial diversions; any felony that placed the Medicare program or its beneficiaries at immediate risk (such as a malpractice suit that results in a conviction of criminal neglect or misconduct); and any felonies that would result in a mandatory exclusion under Section 1128(a) of the Act.
2. Any misdemeanor conviction, under Federal or State law, related to: (a) the delivery of an item or service under Medicare or a State health care program, or (b) the abuse or neglect of a patient in connection with the delivery of a health care item or service.
3. Any misdemeanor conviction, under Federal or State law, related to theft, fraud, embezzlement, breach of fiduciary duty, or other financial misconduct in connection with the delivery of a health care item or service.
4. Any felony or misdemeanor conviction, under Federal or State law, relating to the interference with or obstruction of any investigation into any criminal offense described in 42 C.F.R. Section 1001.101 or 1001.201.
5. Any felony or misdemeanor conviction, under Federal or State law, relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

Exclusions, Revocations or Suspensions

1. Any revocation or suspension of a license to provide health care by any State licensing authority. This includes the surrender of such a license while a formal disciplinary proceeding was pending before a State licensing authority.
2. Any revocation or suspension of accreditation.
3. Any suspension or exclusion from participation in, or any sanction imposed by, a Federal or State health care program, or any debarment from participation in any Federal Executive Branch procurement or non-procurement program.
4. Any current Medicare payment suspension under any Medicare billing number.
5. Any Medicare revocation of any Medicare billing number.

FINAL ADVERSE LEGAL HISTORY

1. Has your organization, under any current or former name or business identity, ever had a final adverse action listed on page 16 of this application imposed against it?

   ❑ YES–Continue Below ❑ NO–Skip to Section 4

2. If yes, report each final adverse action, when it occurred, the Federal or State agency or the court/administrative body that imposed the action, and the resolution, if any.

Attach a copy of the final adverse action documentation and resolution.

FINAL ADVERSE LEGAL ACTION	DATE	TAKEN BY	RESOLUTION

departure from the traditional reviews that focus on only one error type. Whether your hospital is picked this year will depend both on its claims history and OIG auditor judgment *(RMC 1/9/11, p. 1).*

In coming years, providers will be held more accountable for identifying and reporting their own mistakes. The health reform law requires providers to return and explain Medicare and Medicaid overpayments within 60 days of identifying them. Without CMS guidance, the ambiguity inherent in the deadline continues to trouble providers. For example, if Medicare overpays a hospital because of a decimal-point mistake — $3,000 instead of $300 — when does the clock start ticking? When the check is deposited in the bank? When an employee notices an overage? After the case is researched and the overpayment found? The answer is unclear, but that won't necessarily stem a tidal wave of enforcement, Flood says.

He contends the convergence of three statutes makes false claims cases for unreturned overpayments a "freebie": the defining of an "improper payment" in the 2002 Improper Payments Information Act; the Fraud Enforcement and Recovery Act's establishment of false claims act liability for failure to return overpayments; and the health reform law's 60-day return policy. "Those three things make it a real easy target [for DOJ]. They will get more money back and quicker, cause there is virtually no defense," Flood says. "A bell rings and 60 days later you have liability."

2012 Will Be Big Year for Medicaid

Providers should brace for a big year in the Medicaid arena. For starters, Section 6401 of the health reform law increased state Medicaid plans' screening and enrollment obligations, and things are starting to move along, says San Francisco attorney Judy Waltz, with Foley & Lardner LLP. In a Dec. 23 memo, CMS told states to submit a plan by April 1 for complying with the mandates, which were fleshed out in a Feb. 2, 2011, regulation. For example, Medicaid must screen providers according to their risk for waste, fraud and abuse (by provider category); impose a temporary moratorium on enrollment; and inform CMS and other states when providers have been terminated from Medicaid. CMS is giving Medicaid plans access to the Provider Enrollment Chain and Ownership System (PECOS), the online enrollment system.

"We are starting to see state Medicaid plans revalidate enrollment," says Cheryl Rice, vice president and chief corporate responsibility officer for Cincinnati-based Catholic Health Partners. Facilities in her system, which includes 32 hospitals as well as home health agencies, skilled nursing facilities and hospices, are receiving Medicaid revalidation forms with new questions. Like the revised Medicare 855 enrollment form, the Medicaid forms are nosy. "There are more pointed questions about ownership, the relationships between facilities and the parent company and leadership," as well as tax IDs, provider-based status and dates of purchase, she says. The Medicaid enrollment terminology is getting closer to Medicare's, but Rice says filling out state forms will not be a matter of copying information from the 855. With CMS requiring states to crack down on questionable provider activity through the enrollment process, Rice says this issue requires more attention. "It's something to add to your checklist," she says. It's not easy — state records may be outdated.

Rice also suggests catching up on state health regulations. The Medicare conditions of participation increasingly defers to state regulations *(RMC 10/24/11, p. 1)*,

CMS Transmittals and *Federal Register* Regulations
For the week of January 3-6

Transmittals ((R) indicates replaced transmittal)

Pub. 100-03, National Coverage Determinations
- Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (R), Trans. 140, CR 7431 (Jan. 6; impl. Aug. 8, 2011)

Pub. 100-04, Medicare Claims Processing
- Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (R), Trans. 2380CP, CR 7431 (Jan. 6, 2012, impl. Aug. 8, 2011)

Pub. 100-06, Medicare Financial Management
- Recovery Audit Program MAC-issued Demand Letters (R), Trans. 202, CR 7436 (Jan. 6; impl. Jan. 3, 2012)

Pub. 100-20, One-Time Notification
- Use of Revised Remittance Advice Remark Code N103 When Denying Services Furnished to Federally Incarcerated Beneficiaries, Trans. 1012, CR 7678 (Jan. 6; impl. July 2, 2012)
- Instructions to Teaching Hospitals for Reporting the Internal Revenue Service Refund of Medical Resident FICA Taxes (R), Trans. 1014, CR 7685 (Jan. 6; impl. Feb. 6, 2012)

Federal Register Regulations

Link to the rules at *www.federalregister.gov/articles/current*; in the menu on the right, find the date of publication and CMS.

Final Rules: Corrections

Payment Policies Under the Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012; Corrections, 77 Fed.Reg. 227 (Jan. 4, 2012)

Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Patient Notification Requirements in Provider Agreements; Corrections, 77 Fed. Reg. 217 (Jan. 4, 2012)

which sometimes conflict with Medicare (e.g., scope of practice or documentation requirements).

Medicaid recoupment will be a high priority given the growth in expenditures from just over $200 billion to an estimated $408 billion in 2010, a decade later, according to the Government Accountability Office. The dollars will grow as health reform expands Medicaid eligibility, but CMS and its outsourced auditors are expected to drive down the share of that money that comes from overpayments, which hit $21.9 billion in fiscal year 2011, according to CMS statistics cited in GAO testimony to Congress on Dec. 7.

Which Auditors Will Lead Medicaid Recoveries?

The question is, which auditors will do the bulk of Medicaid overpayment recovery? Will it be the Medicaid RACs, which should have been installed in every state by Jan. 1, or will it be the Medicaid integrity contractors (MICs), which were unleashed at the federal level five years ago?

The jury is still out on the MIC program's effectiveness — OIG will weigh in sometime, according to its work plans — but Medicaid RACs are expected to recover more money than MICs, says Atlanta attorney Sara Kay Wheeler, with King & Spalding. Partly it's because Medicaid RACs have two things that MICs lack: the contingency-fee motivator and better data. MICs have been hampered by flaws in the Medicaid Statistical Information System (MSIS), she says, while Medicaid RACs will get their data directly from the states.

Don't expect Medicaid RACs to be copycats of Medicare RACs, however, Wheeler says. "Medicare RACs have been largely implemented at the federal level, while states have the authority to implement the Medicaid RAC program" to their own liking, as long as they follow the relevant CMS dictates. Presumably the contractor will be more tuned in to a state's regulations, payment formulas and provider categories, she says. "You would think the reviews will be more tailored to each state's program," Wheeler says, although that won't help organizations operating across state lines.

Conflicts Will Take Center Stage

Compliance officers will have their fingers in more pies as time marches on, which may account for some of the stress running rampant in the profession, according to a new survey from the Health Care Compliance Assn. (see brief, p. 8). For example, a new era of conflict-of-interest scrutiny will soon begin thanks to the Physician Payment Sunshine Act, a provision of the health reform law. Starting March 31, 2013, pharmaceutical and device manufacturers and group purchasing organizations are required to disclose to CMS all manner of payments to physicians above $10, with the agency making it available to the public on a website by Sept. 30, 2013.

"There will be a lot of nervous physicians once the information is out there," says Rice. It forces physicians to be completely forthright to their hospitals and to their boards because anything they don't reveal on conflict-of-interest disclosure forms will be revealed for them by device and drug manufacturers. This includes payments for consulting, education and research. "It gives compliance officers the ability to say, 'here is what you told me on your disclosure form and here is what [vendors] say they pay you. Why is there a discrepancy?'" The government can see the same numbers, and anything that looks suspicious could morph into a kickback case.

A lot of false claims cases spring from insiders who know about behind-the-scenes deals, and the Physician Payment Sunshine Act may provide that same X-ray vision. In light of more scrutiny of physician payments and vendor relationships, health care organizations continue to refine their conflict-of-interest disclosure process to improve oversight of potential conflicts in physician relationships. Although the conflict-of-interest disclosure process evolves, it focuses on individuals (e.g., board members, committee members, physicians and staff) who are in a position to make decisions on behalf of the organization, such as buying, selling or acquiring services (e.g., nurses who make post-acute care referrals), Rice says. For example, Catholic Health Partners' conflict-of-interest process incorporates the Medicare sanctions attestation statements from the 855 and poses "other probing questions to support required disclosures," she says.

On the health fraud enforcement front, prepare to see the adrenaline-fueled "HEAT" investigations and prosecutions continue, with DOJ and HHS coordinating. Success breeds success, so the march of arrests, convictions and settlements will show no signs of abating, especially with whistleblowers to fuel them. Every year, the bar is raised higher with yet another groundbreaking false claims settlement, says John Kelly, former assistant chief for health care fraud in the DOJ criminal division.

The Department of Justice collected $3 billion from fraud cases in fiscal year 2011, and $2.4 billion came from false claims against federal health care programs.

Publicly traded health care companies face new perils from whistleblowers because of a provision in the Dodd-Frank financial reform law. Whistleblowers can report violations online to the SEC and collect a share of any consequent fines or penalties, says Kelly, with Bass, Berry & Sims in Washington, D.C.

OIG has been busy in the exclusion department, settling a steady drumbeat of civil monetary penalty cases

with hospitals and other entities that employed people excluded from Medicare. Seven CMP settlements were posted in December 2011 alone, and three of them were significant dollar amounts, including a $442,909 fine paid by New York City Health and Hospital Corp. to settle allegations it employed eight people who were excluded from federal health programs.

More false claims cases based solely on violations of the anti-kickback statute will be filed, predicts Philadelphia attorney Jeb White, former president of Taxpayers Against Fraud. "In the past, DOJ has been hesitant to get involved in pure kickback cases," White says. Prosecutors wanted to see other offenses — patient harm or Stark violations — on top of kickbacks before intervening. Now, they are interested even when a case involves kickbacks alone, because the health reform law made kickbacks a *per se* False Claims Act violation, says White, with Nolan & Auerbach. The same goes for the Stark law, which makes these cases easier to prove.

The coming years will also bring more prosecutions of executives and board members when their organizations commit fraud, with prosecutors using the "responsible corporate officers doctrine" to hold health care executives criminally responsible for corporate violations, among other tools *(RMC 10/10/11, p. 1)*. For example, in November, a former senior manager of Maxim Healthcare Services was sentenced to five months in prison after pleading guilty to one count of health care fraud, and former executives of Synthes Inc. were sentenced to prison for charges related to illegal clinical trials of medical devices. "There is no doubt that the federal government currently and in the future will hold individuals accountable for health care fraud," says Fort Lauderdale attorney Gabriel Imperato, with Broad and Cassel.

Transformation is a theme for this year. Organizations are entering into new arrangements, such as physician practice acquisitions, to position themselves for health reform-driven payment mechanisms (e.g., bundled payments, accountable care organizations) and value-based purchasing, which bends the reward curve toward outcomes instead of volume of services. Because there are payments between hospitals and referral sources, Stark and kickback violations are a looming risk, although OIG and CMS have softened the blow to ACOs with new waivers.

"It will be very tempting for organizations to sign ACO contracts and go about their business because it will be small dollars for many of them," Vernaglia says. "But three years down the road, people will forget about their obligations under these contracts and compliance officers can't afford to. There won't be enforcement this year, but the work done by compliance and legal now will pay dividends by not causing mischief." This also applies to payer-provider integration, because insurers are buying practices and hospitals. "The plans are starting to believe they will be the key to their own success," says Jeffrey Sinaiko, president of Sinaiko Consulting. "There could be Stark and anti-kickback issues with payments to providers."

There may be some disappointment as the newfangled arrangements unfold. Many hospitals are entering into hospital employment agreements that base compensation on work relative value units (RVUs), "which have nothing to do with value or quality," says Philadelphia attorney Alice Gosfield, with Alice G. Gosfield & Associates PC. "They purport to be about clinical integration and quality," but are still built on hospitals' attempts to control referrals and physicians' quests for financial security. And the current rash of compensation agreements for employed M.D.s is not sustainable when hospitals face payment reductions for readmissions, hospital-acquired conditions and value-based purchasing, she notes.

To move the health care system in a new direction, Gosfield says physicians must be paid for the quality and value of the services they deliver. Steps are being taken in that direction by the government and in the private sector. The health reform law mandated the implementation of a value-based purchasing modifier with Medicare physician fee schedule payments starting in 2014, she says. Physicians with higher scores on composite measures of quality will be paid more than physicians with lower scores. Medicare's bundled-payment pilot also rewards outcomes by putting hospitals, physicians or both, depending on the model, at risk for the care they provide.

Hospitals don't have to start from scratch when designing evidence-based payment rates and software to support a shift in the way physicians are paid, says Gosfield, who worked on the Prometheus payment model, which was developed with a grant from the Robert Wood Johnson Foundation. It starts with clinical practice guidelines and creates a budget for an episode of care that's allocated among all the providers (e.g., hospitals, physicians, rehab) who treat the patient for the episode condition. Prometheus now has 21 case rates covering medical and procedural conditions. "The design of these systems is not a walk in the park, but the implementation of these systems is not as complex as everyone makes it seem," she says.

EHRs Create New Compliance Risks

Another area of transformation is electronic health records. They are a *sine qua non* for the health care delivery revolution envisioned by health reform, but the road to EHR hell is paved with good intentions. "EHRs are beginning to create all kinds of compliance problems," says Mark Pastin, president of the Council of Ethical Organizations in Alexandria, Va. Unlike paper, you can't lock them

up anywhere. "There will be lot of discussion about privacy in medical records and I predict it will be substantive enough to slow down implementation of the EHRs."

Compliance officers continue to grapple with EHR risks, such as ensuring compliant, functional templates and avoiding inappropriate copy/paste. Compliance officers will need to partner with their practice physicians, IT people, clinic/billing staff and vendors "to develop systems where the creation of compliant documentation is transparent to the users," adds Nina Tarnuzzer, assistant dean, physician billing compliance, University of Florida College of Medicine in Gainesville, Fla. Also, she notes, "you have to hop over the electronic-record fence before you get to ICD-10." Given the October 2013 implementation date, "now is the time to have compliance staff and coders brushing up on anatomy and physiology, and attending train-the-trainer programs. Compliance should be at the table as your institution charts its way through this huge challenge," Tarnuzzer says.

The challenges will keep mounting — for government and providers — as the rest of the health reform law mandates take hold and CMS, OIG and DOJ keep the heat on providers. It's unclear how CMS will keep up because it is stretched to the limits, Flood says. "They must implement large pieces of the health reform law in 2013 to 2014, including mandatory compliance programs," Flood says.

CMS Has Its Hands Full

"You can't imagine they have the resources. They have new programs to pay under new payment models, or to chase," he says. "They run out of arms and legs and talent." He predicts CMS will continue the trend of hiring contractors instead, but federal procurement takes a long time. Meanwhile, implementing the key features of health care reform that are designed to control costs and recover overpayments — including payment-model, access to care and program-integrity requirements — requires access to meaningful data, Flood says. But there are serious flaws with its data mining, according to a June 2011 report from the Government Accountability Office (GAO-11-475).

CMS has two IT systems to integrate claims and identify fraud, waste and abuse: the integrated data repository (IDR) and One Program Integrity (One PI). While CMS has made progress with these systems, there are limits to how much they can accomplish. For example, IDR has most Medicare claims data, but lacks Medicaid data. Although CMS planned to have 639 program-integrity analysts using One PI by the end of 2010, "only 41 were actively using the portals and tools," GAO said.

CMS is under pressure to change all that. "There is testimony on the Hill surrounding this need for CMS and it has been recommended by CMS and OIG that they have this level of oversight," Flood says.

Not all compliance officers will have a productive year. Some will be thwarted by the people who hired them, and turn in frustration into whistleblowers, says White. "They are tasked with making sure their company follows the rules but sometimes they get pushback from their superiors, and when that happens they can use the False Claims Act to rectify the wrong."

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