

# MEDICARE COMPLIANCE

## 2011 Outlook

### Providers Will Find 2011 Is 'Big Year' for Regulations, Recoupment, Whistleblowers

In compliance and enforcement, 2011 will be the year that proves past is prologue.

"To predict the future, you have to look at the past," says former Department of Justice prosecutor John Kelly, now with Fulbright & Jaworski in Washington, D.C. The previous two years have brought a slew of new laws and regulations, including health reform, piles of money for program integrity and fraud enforcement, and growing urgency to cut government spending. "It forecasts a buildup to 2011, which I would imagine will be a big year in terms of regulations, prosecutions and recoupment," he says.

Welcome to 2011, the year that Medicare and Medicaid program-integrity contractors spread to every corner of the country, executives are held responsible for their organizations' folly, health reform hits home and enforcement agencies deploy their new weapons, according to predictions from various experts. As the year unfolds, the industry will move closer to mandatory compliance programs, ICD-10 diagnosis and procedure coding, and interoperable electronic health records. It will be a record year for recoveries from whistleblower-initiated false claims lawsuits, and more frustrated compliance officers will morph into whistleblowers, says Jeb White, former president of Taxpayers Against Fraud, a watchdog group in Washington, D.C. "There is a lot of pressure in this administration to get settlements. Fraud-fighting is the political gold ring."

2011 will be a turning point for compliance programs and Medicare and Medicaid exclusions in different and unexpected ways. The nexus between them will be whistleblowers, who will capitalize on providers' failures to identify and self-report overpayments — including overpayments stemming from excluded providers.

Sec. 6402 of the health reform law requires providers and suppliers to disclose and return Medicare and Medicaid overpayments within 60 days of identification, with an explanation of their cause. Providers may submit overpayments to HHS, the state, an intermediary, a carrier or a contractor.

"Sec. 6402 is huge," says New York state Medicaid Inspector General Jim Sheehan, a former longtime associate U.S. attorney. But complying with the repayment mandate is another story. The New York state Office of Medicaid Inspector General (OMIG) has a self-disclosure process for Medicaid errors, and "in our experience, [providers] can't quantify an overpayment within 60 days," he says.

#### Extensions May Be Inevitable

Suppose a home health agency (HHA) realizes that one of its home health nurses is billing for services provided to an inpatient. The HHA puts a stop to it, but must then determine whether the nurse has pulled this stunt with other patients. After reviewing the medical records, the HHA tries to interview the nurse, but he refuses to answer questions and quits. That sets back any attempt to quickly calculate the overpayments.

"We are working our way through this," Sheehan says. If providers send the state a letter explaining the progress and asking for two additional weeks or months, New York is inclined to grant it. And CMS might do the same, especially because it hasn't issued guidance to help providers navigate the process or ask for extensions in the event an overpayment opens a can of worms that proves far too complex to be quantified in 60 days.

The worst thing providers can do is stick their heads in the sand. "My expectation is we will see a fair amount of whistleblower activity. Providers will identify an overpayment and not report it," he says. "We are already hearing about it from relators and relators' counsel."

At the same time, activity on the exclusion front will intensify. "Organizations not checking the exclusion list are toast," Sheehan says. Any whistleblower or relators' counsel can run an organization's employee roster through the OIG exclusion database. If there are hits, and they are paired with the Sec. 6402 Medicare repayment obligation, "you got your whistleblower case," he says, because reimbursement stemming from excluded employees is an overpayment. "It's no longer just the government" enforcing the exclusion rules.

“Anyone can check” exclusion and debarment databases, he says.

OIG might soon shed more light on provider screening for Medicare and Medicaid exclusions. In November 2010, OIG asked the industry for ideas on updating the 1999 Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs, and comments were due by Jan. 5. San Francisco attorney Judy Waltz, with Foley & Lardner

LLP, thinks it’s likely OIG will provide guidance on how often providers and suppliers should perform checks for excluded provider status. (CMS has recommended to the states that Medicaid require checks every month.)

Waltz also thinks that OIG may explain its views on how repayments should be calculated when an excluded provider contributes to the service that is billed without directly related billing — for example, a nurse

<b>The Current Status of HITECH Act Regulations</b>			
<b>Description of Regulations/Statutory Section</b>	<b>HITECH Act Deadlines for Regulations</b>	<b>Status of Regulations</b>	<b>Effective Date of Statutory Provision/Regulation</b>
Breach notification provision §13402	Aug. 18, 2009	Interim final rule published Aug. 24, 2009 (74 Fed. Reg. 42740)*	Sept. 23, 2009 (Effective 30 days after publication of the interim final regulations, as required)
Temporary breach notification provisions for personal health records §13407  (Federal Trade Commission)	Aug. 18, 2009	Final rule published Aug. 25, 2009 (74 Fed. Reg. 42962)	Sept. 24, 2009
Tiered penalties §13410(d)	Feb. 18, 2010	Interim final rule published Oct. 30, 2009 (74 Fed. Reg. 56123)	Statutory provision: Feb. 18, 2009 Regulation: Nov. 30, 2009
Accounting for disclosures provisions when the entity has electronic health records (EHRs) §13405(c)	Not later than six months after the date on which the HHS Secretary adopts standards on accounting for disclosure	May 3, 2010: OCR issued a request for information	If the organization uses EHRs before Jan. 1, 2009, the effective date is Jan. 1, 2014.  If the organization starts using EHRs after Jan. 1, 2009, the effective date is Jan. 1, 2011.
Expanding organizations that are business associates §13408	Not specified	Proposed rule published July 14, 2010 (75 Fed. Reg. 40868); final rule expected early 2011	180 days after final rule is published
Extension of HIPAA security rule and certain privacy provisions to business associates §§13401, 13404	Not specified	Proposed rule published July 14, 2010; final rule expected early 2011	Statutory provision: Feb. 18, 2010  Final rule enforced 180 days after publication
Willful neglect §13410	Aug. 18, 2010	Proposed rule published July 14, 2010; final rule expected early 2011	Feb. 18, 2011 (24 months after enactment of HITECH Act).
Marketing and fundraising §13406	Not specified	Proposed rule published July 14, 2010; final rule expected early 2011	Statutory provision: Feb. 18, 2010  Final rule enforced 180 days after publication
Patient’s right to request restrictions on disclosures §13405(a)	Not specified	Proposed rule published July 14, 2010; final rule expected early 2011	Statutory provision: Feb. 18, 2009  Final rule enforced 180 days after publication
Prohibition on sale of EHRs or PHI without authorization §13405(d)	Aug. 18, 2010	Proposed rule published July 14, 2010; final rule expected early 2011	Effective six months (180 days) after publication of final rule
Sharing civil money penalties or settlements with harmed individuals §13410(e)	Feb. 18, 2012  (A report by the Government Accountability Office was due Aug. 18, 2010)	Not yet released	On or after the effective date of the regulation
*NOTE: A final rule on notification of breaches of unsecured PHI was submitted for regulatory review May 14, 2010, but was withdrawn July 29 for further review by OCR.			

who cares for a patient during a hospital stay but whose services are not billed separately.

Another exclusion trend is “increased use by OIG of its exclusion authority, particularly as it relates to corporate executives,” says former OIG senior attorney Howard Young, who is now with Morgan Lewis and Bockius in Washington, D.C. Several exclusion actions against executives are pending, although they’re not public yet, he says. OIG set the stage for this crackdown in October when it issued guidance describing the factors it will weigh when considering permissive exclusions against owners, officers and managing employees if their entity is excluded or convicted of certain offenses (*RMC 11/1/10, p. 1*).

### First Compliance Guidance Is Due This Year

Former IG Richard Kusserow calls this the “accountable executive doctrine of OIG,” and notes the government is starting to hold executives and board members accountable for fraud that occurs on their watch. The pressure on health care executives will intensify once CMS issues its compliance-program mandate because executives will be required to certify, in writing, that they have an effective compliance program, says Kusserow, president of Strategic Management Systems, Inc. in Alexandria, Va. They won’t feel comfortable making that attestation without metrics, so compliance officers should expect increasing demands for proof of effectiveness, he says (*RMC 8/16/10, p. 1*).

It’s a good time for executives and board members to pay attention, because “compliance officers are probably the largest contingency of whistleblowers in the hospital setting,” says White, now an attorney with the law firm Nolan & Auerbach. “It makes sense. Compliance officers raise issues to their bosses, who [sometimes] say ‘stop looking.’ Compliance officers are alienated, isolated, terminated — and then they call me.” Lately, hospital compliance officers have been calling him because the incipient Medicaid recovery audit contractor (RAC) program has prompted internal scrutiny of claims, and compliance officers have identified pervasive problems, such as missing admission orders and physicians signing off on care that wasn’t provided, White says.

Speaking of compliance programs, the first CMS regulation to come from the health reform law will appear by year’s end. The health reform law has two general mandates in this area: (1) compliance and ethics programs for skilled nursing facilities that must be effective at preventing and detecting criminal, civil and administrative violations and promoting quality of care, and (2) compliance programs that will be a condition of Medicare and Medicaid enrollment for other providers and suppliers.

CMS specified only a deadline for the nursing facility compliance program, and it’s staggered. By Dec. 31, 2011, HHS must implement a quality assurance and performance improvement program for nursing facilities that will address best practices, says Kim Brandt, CMS’s former director of program integrity. Within a year, nursing facilities have to submit a plan to HHS that describes how they will fulfill the best practices. By March 23, 2012, CMS is required to issue compliance-program guidance for nursing facilities.

There’s no deadline for compliance-program regulations for other providers and suppliers, but CMS asked the industry for input in the proposed anti-fraud provider screening regulation issued Sept. 23, 2010. However, CMS made it clear that it would not finalize the compliance-program requirements until some later point in time. When it happens, says Brandt, the guidance is expected to be issued on a “rolling” basis.

### More Audits to Come

Brandt predicts an increase in the amount of Medicare and Medicaid auditing. On the Medicare side, CMS will complete the transition from 15 program safeguard contractors (PSCs) to seven zone program integrity contractors (ZPICs), which investigate fraud and abuse across Parts A, B, C and D, says Brandt, the new chief investigative counsel for health care issues for Sen. Orrin Hatch (R-Utah), ranking minority member of the Senate Finance Committee.

ZPICs are a force to be reckoned with because each ZPIC is assigned to one region of the country and is not restricted by Medicare claim type. It’s much easier for ZPICs to detect, for example, when a retail pharmacy bills Medicare Part D for medication for a beneficiary who is in intensive care, an obvious error or perhaps fraud.

Brandt says in the physician practice arena, ZPICs will focus on the following:

- ◆ *Home health and hospice* length of stay;
- ◆ *Freestanding labs and independent diagnostic testing facilities* with respect to frequency of testing and number of tests performed; and
- ◆ *Durable medical equipment orders*, with an emphasis on orthotics (a shift away from oxygen, diabetic supplies and wheelchairs).

The reason for the scrutiny, she says, is that earlier this year, Medicare published a regulation that bans payments for these services unless ordering and referring providers (e.g., physicians or nonphysician practitioners) are enrolled in Medicare. Though CMS has delayed this crackdown (see change requests 6417 and 6412), Brandt expects it to take effect this year.

Watch out for ZPICs during the appeals process in particular. Until recently, only providers attended appeals of claims denials before administrative law judges (ALJs), Brandt says. But the tide is starting to turn, with ZPICs showing up to support their paperwork arguments, says Brandt. "They are starting to aggressively fight back because ALJs are finding in favor of providers," she says. "It is almost adversarial."

### **Billing Agents Must Enroll in Medicaid**

Hospitals face scrutiny from Medicare administrative contractors (MACs) on the prepayment side and RACs on the postpayment side. In 2011, they will increase their coordination to improve overpayment recovery (*RMC 12/20/10, p. 1*). Medical necessity seems to be the watchword for 2011, as Medicare auditors hammer away at site-of-service errors (inpatient versus observation), CMS's "PEPPER" reports add at least 24 more admission necessity targets (*RMC 12/13/20, p. 1*), and Department of Justice medical-necessity investigations of kyphoplasty (see story, p. 3) and implantable cardioverter defibrillators (see story, p. 1) march on.

On the Medicaid side, CMS's Medicaid integrity contractors (MICs) are showing up in more states — Ohio is a recent addition — and RACs will begin work in April. "Compliance officers should be looking at Medicaid risk areas, especially because there are more people coming on the Medicaid rolls as a result of reform," Brandt says.

2011 will also usher in a new category of Medicaid enrollees. Billing agents and clearinghouses that submit claims on behalf of providers are required to enroll in Medicaid, according to Sec. 6503 of the health reform law.

This is a big deal, Sheehan says, because claims preparation, submission, review and payment are now virtually all electronic. "Almost no one in the provider side of the system has an end-to-end understanding of the process, and errors or fraud once introduced into the system can proliferate (e.g., default diagnosis codes or billing for services incorrectly numbered on a charge-master or superbill).

"Third-party billing companies and service bureaus market themselves as experts in coding, billing, payment and revenue cycle management and promise significant increases in 'recoveries' by using their services, and most get paid a percentage of their recoveries. Thus, they have significant incentives to be aggressive in coding and billing," he says. "Regulation of this business activity is required because the current contracts between these companies and their customers push back all responsibility on the providers, and the

providers tell us that they relied upon the billing companies' expertise."

Across the board, expect to hear more about Medicare and Medicaid recoupment. Executive departments and agencies of the federal government were required to report Jan. 14 to the Office of Management and Budget on their plans to cut erroneous payments through "recapture audits," also known as "recovery audits." President Obama got this ball rolling in a 2009 executive order (13520), when he announced plans to reduce improper payments by identifying duplicate payments, payments for services not rendered, overpayments and fictitious vendors.

Meanwhile, CMS will start flexing its new Medicare payment suspension muscle this year, Brandt predicts. In addition to its existing payment suspension authority, Sec. 6402(h) of the health reform law allows CMS to suspend Medicare payments to providers when there is a "credible allegation of fraud," unless there is "good cause not to suspend payments." A suspension of payments would mean shutting down some or all of a provider's cash flow pending resolution of the investigation (*RMC 9/27/10, p. 1*).

"Medicare contractors said they really want to start using this more," Brandt says.

### **ICD-10 Implementation Is One Year Closer**

Hospitals face all sorts of billing and coding challenges. For one thing, "ICD-10 takes on another level of importance in organizations. We are one year closer to implementation," says Kathy DeVault, manager of professional practice resources for the American Health Information Management Assn. ICD-10 is a sea change in coding diagnoses and procedures, allowing far greater detail and requiring more documentation specificity. Unless hospitals have gotten the ICD-10 ball rolling, "they are potentially behind." CMS pushed the go-live date to Oct. 1, 2013, to avoid overwhelming hospitals, which need to train, budget and reconfigure software. "It looms a little bigger every year."

On a related note, as of Jan. 1, 2011, hospitals also can start using the new 5010 version of the HIPAA transaction standards to electronically report and inquire about certain health care transactions. The "second level" 5010 standard is a prerequisite for ICD-10, but more immediately, it allows hospitals to report 25 diagnosis codes and 25 procedure codes per claim — far more than they can report now, DeVault says. The claim "wasn't telling the full story of what happened to the patient," she says. The new 5010 also allows for automated present-on-admission (POA) indicator reporting, which lets Medicare know whether a condition was hospital-acquired and may affect reimbursement.

But compliance officers will still focus on core issues in 2011, says Beth Hickman, compliance officer for Mercy Health Partners in Toledo, Ohio. One example is physician signatures. Medicare contractors are cracking down because of pervasive noncompliance with Medicare rules. Physician documentation must be dated, signed and timed; verbal orders must be signed within 48 hours (*RMC 9/13/10, p. 1*); hospitals must have admission orders that unambiguously state the physician's intent; and now lab requisitions must be signed as of Jan. 1, 2011 (*RMC 12/13/10, p. 1*), though CMS delayed enforcement of the lab signature rate until the second quarter. "This is a fundamental part of the business," she says. It's easier for an auditor to deny a claim because the physician didn't sign than it is for an auditor to challenge the medical necessity of a pacemaker implantation (see story, p. 1).

On the enforcement side, providers are more likely to feel the "HEAT." The DOJ-HHS's joint enforcement initiative — the Health Care Fraud Prevention and Enforcement Action Team — and its Medicare Fraud Strike Force have investigated and prosecuted hundreds of providers and recovered millions of dollars. Although HEAT has been focused on more egregious fraud, Jay Darden, former assistant chief of the DOJ criminal division's fraud section and a leader of HEAT, says "potentially HEAT information will be used to go after more mainstream providers."

Investigators and auditors are turning the electronic age into the enforcement age. The DOJ fraud section, for example, has two employees dedicated solely to analyzing data for the Medicare strike force. "We will continue to see the government using data as a way to focus limited investigative and prosecutorial resources," says Darden, with Patton Boggs in Washington, D.C. Health care organizations should be mimicking the government's data analytics in some form or fashion. "It is one of the few instances where facilities have the same information the government has and can analyze that information on a regular basis and [use] it to clean house, rather than wait for the government to do it," Darden says.

### More U.S. Attorneys Will Hop On Fraud Bandwagon

Prosecutors also are expected to start deploying the new enforcement tools from the health reform law. There are 32 sections on program integrity and health fraud in the law, making it easier to nail providers for fraud, waste and abuse, including improper hospital-physician relationships. The law also created a CMS self-disclosure process for Stark-only violations, which providers hope is a quid pro quo for reduced penalties (*RMC 11/22/10, p. 1*).

Whistleblower cases will continue to mount, though the big-dollar cases against pharmaceutical

manufacturers have probably run their course, Sheehan says. "I think we will see an increase in the number of provider *qui tam* cases, especially in U.S. attorneys' offices that historically were not known for their health fraud prosecutions," Young says. With all the money being poured into enforcement, "U.S. attorneys around the country understand the importance of being a leader and being proactive in this area." Move over, Boston and Philadelphia. Less-well known fraud-enforcement hubs may get in the game, spurred on by whistleblower lawyers who are tired of waiting for prosecutors to slog through a backlog of cases.

Companies facing enforcement actions will start to benefit from compliance programs in more concrete ways in coming years. "DOJ and other enforcement agencies are going to start acknowledging companies that are given leniency in the settlements because of their compliance programs," says Roy Snell, president of the Health Care Compliance Assn. "That is big news because they haven't done it much." Snell says this development is important because compliance officers can help boards grasp the cost-benefit ratio of compliance programs.

Compliance officers could use the help. "The stress level for compliance professionals will go off the charts" this year, Snell says. With the number of challenges they face, from keeping up with the changes in the health reform law to coping with RACs, ZPICs, MICs and MACs, compliance officers must find ways to manage the flow of information and ensure they remain independent voices in their organizations.

Contact Kelly at [jkelly@fulbright.com](mailto:jkelly@fulbright.com), Sheehan at [jgs05@omig.state.ny.us](mailto:jgs05@omig.state.ny.us), DeVault at [kathryn.devault@ahima.com](mailto:kathryn.devault@ahima.com), Snell at [roy.snell@hcca-info.org](mailto:roy.snell@hcca-info.org), Darden at [jdarden@pattonboggs.com](mailto:jdarden@pattonboggs.com), White at [jeb@whistleblowerfirm.com](mailto:jeb@whistleblowerfirm.com), Young at [hyoung@morganlewis.com](mailto:hyoung@morganlewis.com), Hickman at [beth\\_hickman@mhsnr.org](mailto:beth_hickman@mhsnr.org), kusserow at [rkusserow@strategicm.com](mailto:rkusserow@strategicm.com) and Brandt at [kim\\_brandt@finance-rep.senate.gov](mailto:kim_brandt@finance-rep.senate.gov). ✧

