

Medical Practice Compliance

News, tools and best practices
to assess risk and protect physicians

ALERT

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HIPAA, ICD-10 among 6 compliance trends that will affect you in 2014

Your practice faces several compliance challenges this year, with a greater emphasis on reimbursement issues becoming legal headaches and the protection of patient data in electronic form. Here's a rundown of what our experts say you can expect in 2014:

Prediction 1: HIPAA enforcement activities and litigation will increase. The Office for Civil Rights (OCR) has gone on record that it will aggressively enforce HIPAA, especially now that the omnibus rule implementing much of the HITECH Act went into effect Sept. 23. This uptick in enforcement coincides with the jump in mobile device use, electronic health record adoption and online scheduling, which will cause digital patient data to be less secure since providers will have less control over it, warns attorney Michael Kline with Fox Rothschild in Princeton, N.J.

(SEE PREDICTIONS, P. 2)

HHS asks for input on new National Practitioner Data Bank guidebook

Practices have until at least Jan. 10 to shape how the National Practitioner Data Bank (NPDB) should be used by giving feedback on its draft guidebook.

The guidebook incorporates new legislative, regulatory and other changes affecting the NPDB, which is the government's clearinghouse of information about adverse actions taken against health professionals, such as medical malpractice actions and licensure or medical staff privileges suspension. In May 2013, the Healthcare Integrity and Protection

(SEE COMPLIANCE GRAB BAG, P. 3)

IN THIS ISSUE

Predictions

1, 4

HIPAA, ICD-10 among 6 compliance trends that will affect you in 2014

Predictions of HIPAA compliance, increased auditing come true

Compliance Grab Bag

1

HHS asks for input on new National Practitioner Data Bank guidebook

HIPAA

5

OCR: Be ready for 'aggressive' HIPAA enforcement

News briefs

6

Compliance Toolbox

8

Medicare delays key provisions in 2014 fee schedule

BY MARLA
DURBEN
HIRSCH

More patients also will become emboldened and sue providers for invasion of privacy under state law, using HIPAA as the standard of care. Patients don't have the right to sue — called a “private right of action” — for violations of HIPAA. However, complying with HIPAA is increasingly being used as a “best practice” in state courts, and patients are winning damages. “People [will] learn that they can sue [for privacy and security breaches]. This area is growing,” he notes.

Prediction 2: The ICD-10 conversion will create new compliance risks. The transition to ICD-10 code sets on Oct. 1 will create significant problems for practices, warns attorney Robert Markette with Hall Render in Indianapolis. “ICD-10 is a lot more work than people realize. Software companies are not ready, and providers are not taking it seriously enough,” he warns. That means that practices may not be prepared and adequately trained; even those who are will make coding errors that will not only affect reimbursement but put the practice at risk of improper billing. “Anything new has hiccups, and this is a sea change in how we code,” he notes.

Prediction 3: Whistleblower activity will increase. Fraud enforcement is going to rise because it gives the government a great return on investment. Many of those actions will be spurred by whistleblowers who go for the money — they receive a percentage of the money recouped — or believe it's the right thing to do. “[Former National Security Agency contractor Edward] Snowden will encourage people to whistle blow,” says Kline. “A trusted consultant can have an employee that decides whistleblowing is the right thing as a matter of public policy,” he explains.

Prediction 4: The Affordable Care Act will create billing compliance headaches. The ACA's problems in 2013 mainly stemmed from the roll out of the exchanges. In 2014, the providers will be dealing with the burdens of coping with its operational problems. For instance, many of the newly insured will not be familiar with the rules of managed care, which will lead to billing and collections

issues and allegations that the practice is billing the patient incorrectly.

Moreover, the ACA loophole that allows for unpaid care for health exchange patients gives patients a three-month grace period before the insurance policy is canceled (*MPCA 8/5/13*). But it's still unclear when and how practices can bill patients directly once insurers determine the patients are no longer covered, putting practices at risk of not only revenue loss but violating debt-collection practices, warns attorney Elizabeth Litten with Fox Rothschild in Lawrenceville, N.J.

Prediction 5: Meaningful use audits will increase. The federal government has paid more than \$1.7 billion in incentives to providers under the Medicare and Medicaid meaningful use program, amid concern by the Government Accountability Office and HHS' Office of Inspector General that CMS has not adequately policed whether providers were entitled to the payments. “The government will start audits to get a lot of this money back,” says Kline. Several providers have already had to return incentive payments that they had received.

Prediction 6: Provider integration and realignment will trigger compliance concerns. As practices work with other providers in new collaborative arrangements spurred by health reform and new payment models, such as accountable care organizations (ACO) and patient-centered medical homes, they will come under increased government scrutiny for problems such as scope of practice issues or referral patterns that might violate the Stark and anti-kickback laws.

In addition, other providers will challenge new alliances, claiming that they violate the antitrust laws, warns attorney Michael Callahan with Katten Muchen Roseman in Chicago. “Not everyone will be able to play in the sandbox, so you'll see economic battles,” he warns. That will spillover and affect other provider relationships. For example, a practice that aligns with a particular ACO may not be able to join a different one.

“There's a lot going on. These are difficult times for physicians,” warns Callahan.

Data Bank, which contains information about adverse actions taken by Medicaid fraud control units, state law enforcement and others merged into the NPDB.

Being reported to the NPDB can have very serious repercussions on a physician.

However, the draft revisions contain provisions that may be overbroad and make more actions reportable, warns attorney Michael Callahan with Katten Muchen Roseman in Chicago.

According to Callahan, the HHS' Health Resources and Services Administration is concerned that it's receiving fewer reports from hospitals than it used to. But that doesn't mean that more actions need to be reported; it reflects the fact that hospitals are trying more remedial measures to help physicians get back on track, such as monitoring, Focused Professional Practice Evaluations (FPPEs) and re-education. "Hospitals prefer not to take away privileges and will try other things unless the doctor has crossed a line," he explains.

For instance, the draft guidebook states that it's a reportable event when a hospital puts a FPPE in place; Callahan says that's too early in a hospital's process of dealing with the physician to be a reportable event. "An FPPE plan isn't an investigation," he explains.

Another potentially problematic area in the draft guidebook is when hospitals require proctoring of a physician who hasn't been suspended from the medical staff. "That's just sending a message to the physician. Why should that be reportable?" he asks.

Callahan suggests that people comment. "The more clarity there is, the better. It's guidance. They really want substantive comments," he says.

4 tips to handle the NPDB

Callahan also recommends that physicians take these steps when dealing with the NPDB:

▶ **Query yourself to see whether the NPDB has reports on you and if so, what the reports say.** Typically, a physician will know about reports, but in some instances — say if a physician has changed addresses — the physician doesn't receive the report.

▶ **Comment on a report being submitted** by a hospital, health plan or other entity so others who later query the NPDB about the physician will be able to read your comment/position as well as the report.

▶ **Ask the hospitals you're affiliated with to let you view your quality file periodically.** "Many hospitals will let you look at it out of fairness," says Callahan. Often an action by a hospital against a physician occurs because of a number of issues that are cumulative, and then one event is the straw that breaks the camel's back, he says. If a physician knows earlier that a patient or nurse has complained, the physician has the opportunity to police himself and improve his performance or behavior.

(SEE COMPLIANCE GRAB BAG, P. 7)

BY MARLA DURBEN HIRSCH

“The HHS' Health Resources and Services Administration is concerned that it's receiving fewer reports from hospitals than it used to.”

Predictions of HIPAA compliance, increased auditing come true

BY MARLA
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As you ring in the new year with your first 2014 issue of *Medical Practice Compliance Alert*, see how our experts' predictions stacked up for 2013:

Prediction: HIPAA compliance, especially regarding patient data in electronic form, is key. **Result:** True. Our experts predicted that compliance with HIPAA will be paramount, especially with the surge of electronic health record (EHR) use. HHS' Office for Civil Rights (OCR) has ramped up enforcement, imposing its first fine for a small security breach and entering into settlement agreements with several additional entities (*MPCA 3/4/13*). OCR also has stated publicly that "aggressive enforcement" will continue (*see story, p. 5*). The majority of security breaches affecting 500 or more patients required to be reported to HHS and posted on its website's "wall of shame" have been with electronic data; 50% of which had been theft of laptops, smartphones and other items where patient data is stored.

Prediction: Regulations will be delayed. **Result:** Inconclusive. Our experts predicted that the HIPAA "mega-rule" would be released in 2013, but they didn't expect the rule until later in the year. It was published in January, although entities had until Sept. 23 to comply with it. The experts also predicted that the final rule implementing the Sunshine Act would be delayed, and that also came out ahead of schedule. However, other eagerly anticipated rules, such as the HITECH Act's accounting of disclosures rule proposed in 2011 has been delayed; HHS has received so much negative feedback about it that it has gone back to the drawing board and HHS is considering revamping the rule significantly (*MPCA 10/28/13*). The proposed rule implementing the Affordable Care Act's (ACA) requirement that overpayments be returned within 60 days has also been delayed. HHS also has yet to issue a proposed rule on mandatory compliance programs, as required by the ACA.

Prediction: The government will increase its auditing. **Result:** True. CMS finished its first set of HIPAA audits under its pilot program and is currently evaluating it to determine how to roll out its permanent HIPAA audit program. CMS also has been conducting both pre- and post-payment meaningful use audits to assess whether attestors earned incentive payments in the meaningful use EHR incentive program and announced it will conduct audits of providers' EHR billing practices (*MPCA 4/15/13*). CMS' move to add a fifth recovery auditor is also expected to increase RAC audits (*MPCA 4/15/13*). And the use of extrapolation in audits are becoming the norm.

Prediction: The ACA will progress despite continued opposition. **Result:** True. Experts warned that practices will need to include the ACA's requirements in their compliance efforts because attempts to derail it will not succeed. While the health insurance exchange websites experienced a rocky roll out, thousands of newly insured individuals — many of whom are unfamiliar with managed care and likely sicker than practices' established patients — are about to descend on practices for care. At the same time, parts of the ACA are still in litigation, which means that some provisions — such as mandatory coverage for contraception — are still up in the air.

“CMS finished its first set of HIPAA audits under its pilot program and is currently evaluating it to determine how to roll out its permanent HIPAA audit program.”

OCR: Be ready for ‘aggressive’ HIPAA enforcement

Providers should make sure that they’re complying with all aspects of HIPAA, including the omnibus rule implementing much of the HITECH Act, now that HHS’ Office for Civil Rights (OCR) has made it clear that it’s ramping up enforcement.

“We have significantly stepped up enforcement, and that aggressive enforcement will continue,” said Iliana Peters, OCR health information privacy specialist, speaking at the American Bar Association Health Law Section’s Annual Washington Health Law Summit in Washington, D.C.

Of the 115 covered entities audited during the pilot audit program, only 11% were in good HIPAA compliance shape (*MPCA 7/9/12*). OCR had expected better compliance. “You’ve had 10 years to come to compliance; it’s time,” she pointed out.

“The security rule is the most vulnerable place for covered entities and business associates. There’s often a complete lack of a risk analysis [as required by the security rule]. People don’t know where their data is so they don’t encrypt and they don’t safeguard,” Peters stated.

Peters did not address that OCR’s recent criticism of its performance by HHS’ Office of Inspector General (OIG) likely will spur OCR to ramp up its investigative and enforcement activity of HIPAA violations (*see box, right*).

HIPAA audits a ‘big priority’

Peters revealed that the settlement amounts agreed to with plans and providers for alleged HIPAA violations are a “fraction” of what could have been imposed by the government. (*To view the settlements, known as “resolution agreements,” go to OCR’s website at www.hhs.gov/ocr/privacy/hipaa/enforcement/examples*).

More than 84,000 reports of small breaches affecting fewer than 500 individuals have been reported to HHS since security breach reporting was required, added Anna Watterson, another OCR privacy specialist speaking at the presentation. More than 700 reports of large breaches have been reported and posted on HHS’ “wall of shame.”

Peters also revealed that the audit program, which is now permanent, is a “big priority” for OCR and that it may be used as an enforcement tool.

OCR expects to release additional guidance on the right to request restrictions, access rights, research and other provisions to help entities comply. In particular, the right to request restrictions of patient treatment when the patient pays out of pocket in full, a new provision of HIPAA courtesy of the HITECH Act, will take a lot of work and will be difficult for providers to implement, Peters acknowledged (*MPCA 2/18/13*).

The agency also has developed a Notice of Privacy Practices in Spanish, which should be published soon, she says.

BY MARLA DURBEN HIRSCH

Are HIPAA audits in jeopardy?

While the Office for Civil Rights (OCR) may view its HIPAA audit program as a “big priority,” it seems to have temporarily run out of financial steam. The HHS Office of Inspector General (OIG) recently chastised OCR for failing to meet federal requirements “critical” to the oversight and enforcement of HIPAA, including failure to assess risks, establish priorities and implement controls for audits and staff inconsistencies in following audit policies, such as document retention and missed opportunities to educate entities. The OIG recommended, among other things, that OCR establish priorities and implement controls for its audits, which are required by the HITECH Act, and provide for periodic audits to ensure security rule compliance.

OCR agreed with the OIG’s recommendations but pointed out that it does not have the funding to conduct the audits.

“We remain concerned about OCR’s ability to comply with the HITECH audit requirement and the resulting limited assurance that ePHI is secure at covered entities because of OCR’s comment regarding limited funding resources for its audit mandates,” the OIG stated in its report.

OCR has the funding to investigate HIPAA violations; the HITECH Act also allows OCR to use money recovered from entities paying penalties to fund future enforcement efforts.

(To read the OIG report, go to <http://oig.hhs.gov/oas/reports/region4/41105025.pdf>.)

► **HHS “strongly encouraging” plans to treat providers as in-network.** If you thought you had been dis-enrolled from the health insurance exchanges by a plan or voluntarily chose to no longer participate, you may be in for a surprise. The government, as part of its overall effort to soften the transition to health insurance exchanges, is “strongly encouraging” insurers to treat out-of-network providers as in-network to ensure continuity of care for acute care or if the provider had been listed in the directory when the individual signed on. For more information, visit www.hhs.gov/news/press/2013pres/12/20131212a.html.

► **HHS’ Office of Inspector General (OIG) releases its top challenges.** OIG has posted its most important performance and management challenges, which indicate what OIG will be focusing its enforcement efforts on in the coming year. Several of the challenges highlighted include fighting fraud and waste in Medicare Parts A and B, overseeing the health insurance exchanges, ensuring appropriate use of prescription drugs in Medicare and Medicaid and monitoring transitions to value-based payments. For more information, visit <http://oig.hhs.gov/reports-and-publications/top-challenges/2013>.

► **GlaxoSmithKline to stop paying physicians for certain services.** The pharmaceutical giant has announced that it will no longer provide “financial support” to health care professionals to attend medical conferences or to speak publicly on its behalf. It will continue to pay for research and advisory activities. To see the press release, visit www.gsk.com/media/press-releases/2013/gsk-announces-changes-to-its-global-sales-and-marketing-practice.html.

► **Malware compromises 90,000 patient records.** Seattle-based UW Medicine suffered a breach of its electronic patient records when an employee opened an email attachment that contained malicious malware. About 90,000 records were affected. For more information, visit www.uwmedicine.org/Global/News/Announcements/2013/Pages/UWMedicine-Notice-of-Computer-Security-Breach.aspx.

► **File informal review requests of e-prescribing (e-Rx) payment adjustments by Feb. 28.** Eligible professionals (EPs) and group practices that think they met e-Rx program requirements but received the 2% pay cut should file informal review requests via email at eRxInformalReview@cms.hhs.gov. CMS will notify providers if they did not meet the 2012 or 2013 e-Rx program requirements. For other questions related to the e-Rx program, call the QualityNet Help Desk at 866-288-8912 or email qnet-support@sdps.org.

► **Feb. 28 meaningful use deadline approaching.** EPs who participated in the electronic health records (EHR) incentive program in 2013 must attest that they demonstrated meaningful use by Feb. 28 to avoid pay cuts. The payment adjustments will be applied starting Jan. 1, 2015, for those who have not met meaningful use requirements. CMS notes in its Dec. 19 MLN Connects Provider eNews that 2014 is the last year EPs can start attesting for meaningful use and earn an incentive.

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► **If disciplinary action may be taken against you by a hospital, consider filing a rebuttal letter to it.** “Everyone makes mistakes. Maybe remedial measures would be better. Seventy percent of hearings could have been unnecessary if the doctor merely said ‘I made a mistake,’” says Callahan.

Resources:

- Access to the draft guidebook and opportunity to comment:
www.npdb-hipdb.hrsa.gov

Lost credentialing challenges can cost docs both sides’ attorney’s fees

Expect more push back from hospitals if they are challenged by a physician who disputes adverse action taken against him or her. Since a suspension or other adverse action by a hospital against a physician has such serious consequences, it’s often tempting to legally challenge the action. But before proceeding, make sure you know all of the risks — not just of losing the challenge but having to pay the hospital’s costs of defending itself.

The Delaware Supreme Court recently upheld an order requiring a surgeon to pay a hospital more than \$425,000 in attorney’s fees after the surgeon’s claims against the hospital for suspending his privileges were dismissed under the immunity provided by the federal Health Care Quality and Improvement Act. The surgeon filed the lawsuit against the hospital after it suspended his privileges for disruptive conduct. The Act allows a hospital to recover its attorney’s fees if the claim or the physician’s conduct during the litigation of the claim was frivolous, unreasonable, without foundation or in bad faith.

The hospital’s credentialing policy was even broader, requiring reimbursement for any reason if the hospital won the lawsuit. The hospital prevailed and asked the court to enforce the credentialing policy’s fee-shifting requirement, which it did.

Resources:

- Sternberg v. Nanticoke Memorial Hospital:
<http://courts.delaware.gov/opinions/download.aspx?ID=185790>

Join our HIPAA Watch forum

Network with your compliance peers, post questions and quickly receive answers to your most pertinent HIPAA issues by joining our free discussion forum at <http://listserv.ucg.com/cgi-bin/listserv/listserv.pl/hipaawatch>.

BY MARLA DURBEN HIRSCH

“The Act allows a hospital to recover its attorney’s fees if the claim or the physician’s conduct during the litigation of the claim was frivolous, unreasonable, without foundation or in bad faith.”

Medicare delays key provisions in 2014 fee schedule

CMS has given you and itself a little breathing room by delaying the effective date for provisions in the 2014 physician fee schedule. Most of the delayed provisions, including those for incident-to and overpayment recoupment periods, go into effect Jan. 27. However, a handful of provisions, such as e-prescribing standards, will be on hold until Jan. 1, 2015.

The chart below provides a list of the delayed provisions by date. The titles and section numbers are from the Code of Federal Regulations.

Provisions effective or applicable Jan. 27	
Amended section title	Amended section number
Individual's liability for payments made to providers and other persons for items and services furnished the individual	§405.350
Waiver of adjustment or recovery	§405.355
Services and supplies incident to a physician's services	§405.2413
Services and supplies incident to nurse practitioner and physician assistant services	§405.2415
Services and supplies incident to clinical psychologist and clinical social worker services	§405.2452
Ultrasound screening for abdominal aortic aneurysms: Condition for and limitation on coverage	§410.19
Services and supplies incident to a physician's professional services: Conditions	§410.26
Colorectal cancer screening tests: Conditions for and limitations on coverage	§410.37
Clinical psychologist services and services and supplies incident to clinical psychologist services	§410.71
Physician assistants' services	§410.74
Nurse practitioners' services	§410.75
Clinical nurse specialists' services	§410.76
Certified nurse-midwives' services: Qualifications and conditions	§410.77
Adjustments to the Clinical Laboratory Fee Schedule based on Technological Changes	§414.511
Physician self-referral prohibitions (Applicability date)	§411.351
Physician Compare website (Applicability date)	§425.308
Provisions effective Jan. 1, 2015	
Amended section title	Amended section number
Scope of subpart and definitions. Investigational device exemption	§405.201
FDA categorization of investigational devices	§405.203
Coverage of a Category B (non-experimental/investigational) device	§405.205
Services related to a non-covered device	§405.207
Payment for a Category B (non-experimental/investigational) device	§405.209
Coverage of items and services in FDA-approved investigational device exemption (IDE) studies	§405.211
Medicare Coverage IDE study criteria	§405.212
Re-evaluation of a device categorization	§405.213
Particular services excluded from coverage	§411.15
Standards for electronic prescribing	§423.160

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