G2 INTELLIGENCE

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Labs Face Multiple Medicare Threats in New Legislative Year

While aiming to fend off reforms that cut reimbursement, lab groups also are primed to push for legislation giving the Centers for Medicare and Medicaid Services the lead authority over regulation of lab-developed tests.

With Medicare sure to be targeted this year during deficit reduction battles in Congress, the clinical laboratory industry is keen to ward off three major threats: further cuts to the Part B lab fee schedule, introduction of a lab copay, and competitive bidding.

The imminent threat is the cut of 2 percent under automatic across-the-board sequestration cuts set to take effect in March. This affects all Medicare providers, and whether Congress will heed calls from hospital and medical groups to repeal the cut is too hard to call, say industry sources.

On a recurring reform proposal, namely, imposition of a 20 percent Part B lab copay, there are conflicting reports. At present there is not much Democratic support, while some GOP members of the House are reportedly looking into it as part of making copays uniform across all Medicare services. Lab services have had both the deductible and copays waived since the Part B fee schedule was established in 1984.

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New HIPAA Rule Expands Patients' Rights, Privacy and Security Protections

The Office for Civil Rights of the Department of Health and Human Services (HHS) on Jan. 17 released an omnibus final rule updating provisions of the Health Insurance Portability and Accountability Act (HIPAA).

In a statement, HHS said, "The rule greatly enhances a patient's privacy protections, provides individuals new rights to their health information, and strengthens the government's ability to enforce the law."

Noting that much has changed in health care since HIPAA was enacted over 15 years ago, HHS Secretary Kathleen Sebelius said the new rule meets privacy and security needs in an ever-expanding digital age. It also incorporates increased civil monetary penalties and caps maximum annual penalties at $1.5 million, up from an existing $25,000 cap.

Business Associates' Compliance

While HIPAA privacy and security rules have concentrated on health care providers, health plans, and health clearinghouses, the changes in the new rule expand many of the requirements to business associates of these entities that receive protected health information, such as contractors and subcontractors. Some of the largest data breaches reported to HHS have involved business associates.

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New HIPAA Rule, *from p. 1*

Data Breach Incidents

HHS replaces the harm standards for data breach incidents, requiring notification to individuals unless there is a low probability the data were compromised. This may be the biggest change, analysts say, since the interim final rule required entities to notify individuals that their protected health information had been breached only if they determined through a risk assessment that the individuals could suffer financial, reputational, or other harm.

Patients' Rights

Individual rights are expanded in the new rule as follows:

- ❑ Patients can ask for a copy of their electronic medical record in an electronic form.
- ❑ When individuals pay by cash they can instruct their provider not to share information about their treatment with their health plan.
- ❑ New limits are set on how information is used and disclosed for marketing and fund-raising purposes.
- ❑ An individual's health information cannot be sold without his or her permission.

Effective Dates

The rule becomes effective March 26, but covered entities and their business associates have until Sept. 23 to comply with most provisions. In the case of existing business associate agreements, covered entities have until September 2014 to make changes.

The rule is based on statutory changes under the HITECH Act, enacted as part of the American Recovery and Reinvestment Act of 2009, and the Genetic Information Nondiscrimination Act of 2008, which clarifies that genetic information is protected under the HIPAA privacy rule and prohibits most health plans from using or disclosing genetic information for underwriting purposes.

HHS Approves 106 New ACOs Under Medicare for 2013

In a major expansion of the Medicare Shared Savings Program, 106 new accountable care organizations (ACOs) have been approved for 2013, the U.S. Department of Health and Human Services (HHS) announced Jan. 10.

ACOs have increased rapidly in two years, covering 10 percent of the population, or millions of patients both under Medicare and in the private health care sector, according to a recent report from the consulting group Oliver Wyman, headquartered in New York City.

The expansion brings the total number of ACOs established since 2012 under terms of the health care reform law to more than 250, serving about 4 million Medicare fee-for-service beneficiaries, the department said in a press release.

ACOs are legal entities formed by physicians and health care providers to furnish coordinated, quality care and disease management programs to beneficiaries (a minimum of 5,000). ACOs share the risk and rewards for keeping patients healthy. Beneficiaries in ACOs can choose health care providers within or outside their ACO.

Payment Incentives and Quality Standards

While Medicare continues to pay individual health care providers and suppliers for specific items and services as it currently does under Part A and Part B reimbursement, CMS sets a benchmark on per capita spending for each ACO against which its performance is measured to assess whether it qualifies to receive shared savings

or to be held accountable for losses. Medicare could save up to $940 million over four years as a result of the initiative, HHS said.

The Centers for Medicare and Medicaid Services (CMS) has established 33 quality standards that ACOs must meet on care coordination and patient safety, appropriate use of preventive health services, improved care for at-risk populations, and patient and caregiver experience of care.

Profile of the New ACOs

The new ACOs include a diverse cross-section of physician practices across the country. Roughly half of all ACOs are physician-led organizations that serve fewer than 10,000 beneficiaries. Approximately 20 percent of ACOs include community health centers, rural health clinics, and critical-access hospitals that serve low-income and rural communities.

The group also includes 15 Advance Payment Model ACOs. These are physician-based or rural providers who get access to capital to invest in staff, electronic health record systems, or other infrastructure required to improve care coordination. Medicare will recoup advance payments over time through future shared savings.

In addition to these ACOs, last year CMS launched the Pioneer ACO program for large provider groups able to take on greater financial risk for the costs and care of their patients over time.

The next application period for organizations that wish to participate in the Shared Savings Program beginning in January 2014 is summer 2013. A final rule addressing provider concerns was published in the *Federal Register* for Nov. 2, 2011 (*NIR 11, 20/Nov. 3, pp. 4-5*).

More information about the program is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html?redirect=/sharedsavingsprogram/*. For a list of the 106 new ACOs, visit: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/News.html*.

Ohio State Lab Settles CLIA PT Referral Case

The Wexner Medical Center at Ohio State University (OSU) in Columbus has avoided the worst that can happen to a clinical laboratory for violating proficiency testing (PT) referral rules under the Clinical Laboratory Improvement Amendments (CLIA): revocation of the certification required to legally perform any diagnostic testing on human specimens and cancellation of approval to receive Medicare and Medicaid payments.

The Centers for Medicare and Medicaid Services (CMS) had imposed these sanctions last summer after PT samples were sent to the Mayo Clinic and to another OSU lab for testing. The sanctions, however, were put on hold when OSU appealed (*NIR 12, 16/Sept. 6, pp. 4-5*).

In a settlement reported in the Jan. 16 *Columbus Dispatch*, the center has agreed to pay $268,000 to resolve allegations that it violated CLIA PT referral rules. The lab will remain open under OSU control, but the center also agreed to appoint a new lab director and provide additional training to the lab staff.

"We are grateful to CMS for its willingness to work toward a resolution that best meets the needs of our patients and the community," said Larry Anstine, CEO of the Ohio State University Hospital, in a prepared statement. In 2011, Ohio State's medical laboratory network performed 9.1 million patient tests, 7.24 million of

which were performed at the lab previously under threat, central Ohio's only fully automated hospital lab, noted the *Columbus Dispatch*.

Background of the Case

The lab threatened with CLIA certificate revocation performs more than 60 percent of tests ordered for the center's patients, according to OSU. At issue were six PT referrals that the center self-reported as accidents, noting that corrective action had been taken.

In February 2012 the lab sent a PT sample of Lyme disease to the Mayo reference lab for Western Blot confirmation. A subsequent review found that five more blood-culture specimens had been improperly referred to another OSU lab with a different CLIA certificate number between November 2009 and November 2011.

Staff from the Ohio Department of Health and CMS conducted a complaint survey of the center's lab on March 28, 2012. In a follow-up letter on June 11, CMS told the lab's director that the lab was out of compliance with federal rules on PT referrals. The lab responded with more than 100 pages of documents addressing this conclusion, but in a July 12 reply, CMS said this was not enough to change its opinion.

Accordingly, it revoked the lab's CLIA certificate and Medicare and Medicaid approval, effective Aug. 10, if the lab did not appeal. The lab did appeal, thus blocking the sanctions while the matter was pending.

Perspectives on the Settlement

In comments on the case to G2Intelligence, attorney Robert E. Mazer with Ober/Kaler in Baltimore, said, "The required payment is a significant amount. But all things considered, this would appear to be a very favorable resolution for the hospital because its lab can continue to provide testing and bill Medicare and Medicaid for its services.

"The settlement may indicate that, in appropriate cases, CMS will accept lesser sanctions than revocation. However, the settlement is not precedent on which another lab can legally rely. Additionally, it's very difficult to determine what factors CMS will consider important in determining whether to accept a sanction other than revocation based on a single settlement."

A recent legislative change gives the agency leeway to impose lesser sanctions for PT referral violations, Mazer noted, "but the agency continues to have authority to revoke a CLIA certificate based on findings that a lab intentionally referred PT samples to another lab for testing which it is certified to perform. A laboratory can challenge CMS' findings but an administrative law judge cannot require that a less severe penalty be imposed for such conduct."

The new enforcement discretion granted to CMS was enacted in the bipartisan Taking Essential Steps for Testing (TEST) Act (Pub. L. 112-202), signed into law last Dec. 4. It amends the CLIA statute to revise sanctions for labs that unintentionally refer PT samples to other labs. CMS has the discretion to make the one-year CLIA certificate revocation optional rather than mandatory and to impose intermediate sanctions instead of the two-year prohibition against common lab ownership or operation that would otherwise apply (*NIR 12, 22/Dec. 13, p. 8*).

Being able to consider PT referral sanctions on a case-by-case basis is a change that CLIA officials have welcomed. Under previous policy, CMS maintained that the law gave it no choice but to impose the most severe sanctions, even for violations that were accidental or inadvertent.

Independent Payment Advisory Board Draws New Fire From House GOP Opponents

At the opening of the first session of the 113th Congress, the House Republican leadership lost no time in registering opposition to the Independent Payment Advisory Board (IPAB) created by the health care reform law and scheduled to begin operations in 2014.

On Jan. 3, in passing procedural rules for the coming two years, the GOP leadership asserted that it can ignore any recommendations from the board. In 2012, the GOP-controlled House voted to repeal the IPAB but the Senate took no action on the bill.

The IPAB snub is symbolic since the statute's requirements trump any rules set by congressional chambers. The battle over the board is likely to begin in the Senate since the panel's 15 members, appointed by the president, require confirmation.

The Board's Duties and Limits

The IPAB by law is required to make recommendations to Congress on reductions in Medicare spending, beginning in 2014, in any year when the per capita growth rate exceeds a target growth rate. Congress would have to give the recommendations fast-track consideration and they would take effect unless lawmakers approved an alternative with the requisite savings.

The law also limits the IPAB. It is barred from making any proposals that would ration care, increase Medicare beneficiary cost sharing, or otherwise restrict benefits or modify eligibility criteria.

The Congressional Budget Office has said the spending targets governing IPAB action are unlikely to be triggered until at least 2022, so the board might not make recommendations before then.

Arguments For and Against

Supporters of the IPAB say it is a fail-safe mechanism to control Medicare spending growth if Congress fails to act and it removes politics from decisions affecting Medicare providers. Opponents, including the American Medical Association and pathology and clinical laboratory groups, say the board's unelected officials would have power over spending that historically has been reserved to Congress.

Critics also charge that since the board cannot make recommendations on restricting Medicare benefits, the savings it seeks would have to come from cutting provider payments, which in turn could threaten beneficiary access to care. In fact, hospital payments are not slated to come under the IPAB purview until at least 2020, so before then the board would have to look to clinical labs, pathologists, and other health care providers to capture savings.

Gift Cards in Exchange for Health Services OK, Says OIG

Gift cards are widely used to drive recipients to particular retailers, so without risking federal sanctions, can a health care provider offer the same for grocery purchases in exchange for receiving a health screening or other clinical service that it furnishes?

Yes, said the Health and Human Services Office of Inspector General (OIG) in Advisory Opinion No. 12-21, released Jan. 3 and based on the particulars of the proposed arrangement.

Though implicating the anti-kickback statute, it would present a low risk of fraud and abuse, the OIG concluded, "and thus we would not impose administrative sanctions on the provider."

The Proposed Arrangement

The party requesting the opinion is a federally qualified health center that proposes to offer a $20 grocery store gift card to certain patients in capitated Medicaid managed care plans as an incentive to receive screening tests or other clinical services.

Eligible enrollees would get a letter from the center informing them of the chance to receive the gift card. Letters would be sent regardless of the health status of enrollees, and the center would not engage in additional promotion or marketing of the arrangement.

The gift cards could not be cashed in, and receipt of the cards would not hinge on patients selecting a particular clinical service at the center. Patients would be limited to one gift card per year, and each card would include information on nutrition, health care, and the health center.

The OIG's Analysis

The OIG found a minimal risk of fraud and abuse and thus declined to impose sanctions for a number of reasons:

- The arrangement would not result in higher costs to the federal health programs nor would the center have an incentive to provide unnecessary care. All eligible recipients would be enrolled in Medicaid managed care plans reimbursed on a capitated basis. Medicaid would not change the capitated payments to the plans based on the nature or number of services the center provides to those eligible. The center, in turn, would be compensated by the Medicaid managed care plans on a similarly capitated basis.
- The arrangement would not be advertised or marketed to the general public. "Additionally, it would limit the annual amount of incentives offered to an enrollee to one gift card of relatively modest value. In a different context remuneration of such value could have a substantial potential to steer patients. Given the facts here, however, we regard the offer as unlikely to harm the center's competitors or result in a destructive race to the bottom among competing providers," the OIG said.
- The arrangement would provide a benefit to members of the largely poor community that the nonprofit health center serves, "engaging beneficiaries and educating them about the center and its potential role to both improve health outcomes and make best use of resources in connection with capitated managed care plans." G2

Take Extra Care When Disposing of Medical Records

That's the lesson that four pathology groups and the former owners of a medical billing practice in Massachusetts learned the hard way.

They have agreed to collectively pay $140,000 to settle allegations that sensitive medical records and confidential billing information for tens of thousands of patients were improperly disposed of at a public dump.

The settlement was announced Jan. 7 by Martha Coakley, the state's attorney general (AG). In a statement, she said, "Personal health information must be safeguarded as it passes from patients to doctors to medical billers and other third-party contractors. It is the obligation of all parties involved to ensure that sensitive information is disposed of properly to prevent this from happening again."

The data breach came to light in July 2010 when a *Boston Globe* photographer, dropping off his trash at a public dump, observed a large mound of papers which, upon closer inspection, he determined were medical records. His discovery was first reported in the *Globe* shortly thereafter. The medical records contained information for more than 67,000 state residents, including names, Social Security numbers, and medical diagnoses that were not redacted or destroyed, the AG said.

The pathology defendants in the settlement are Dr. Kevin Dole, former president of Chestnut Pathology Services, P.C. (Boston); Milford Pathology Associates, P.C. (Milford); Milton Pathology Associates, P.C. (Milton); and Pioneer Valley Pathology Associates, P.C. (Holyoke).

The AG faulted them for two reasons:

- Violating regulations under the Health Insurance Portability and Accountability Act by failing to have appropriate safeguards to protect the personal information they provided to the billing contractor, Goldthwait Associates (located in Marblehead and formerly owned by Joseph and Louise Gagnon, who retired in 2010).
- Violating state data security rules by not taking reasonable steps to select and retain a service provider with appropriate security measures to protect confidential information.

In May 2012 the AG reached a $750,000 settlement with South Shore Hospital (South Weymouth), resolving allegations that it failed to protect the confidential health information of more than 800,000 patients when it sent unencrypted computer tapes off-site to be erased but did not inform the contractor about the data exposure.

Medicare *Claims Advisory*

Interest Rate Increases for Overpayments, Underpayments

The rate of interest that Medicare will pay you for claims that were underpaid, or collect from you for claims that were overpaid, has risen to 10.625 percent, effective Jan. 17, 2013, up from the 10.375 in effect since Oct. 18, 2012, but down from rates in place for most of last year (11 percent as of July 18 and 10.875 percent as of April 18).

The Centers for Medicare and Medicaid Services (CMS) announced the latest update in Transmittal 217, Change Request 8201. Medicare Regulation 42 CFR §405.378 provides for the assessment of interest at the higher of the current value of funds rate (1 percent for calendar year 2013) or the private consumer rate as fixed by the Department of the Treasury. The Treasury has notified the U.S. Department of Health and Human Services that the private consumer rate has been changed to 10.625 percent.

The highest interest rate in the past decade was in early 2001, 14.125 percent, but for most of the years since, the rate has hovered between 10.50 percent and 12 percent.

The interest rate fluctuations have taken on even greater importance to clinical laboratories, pathology practices, and other Medicare providers because their period of exposure to attempts by CMS to recover any overpayments plus interest has been extended from three years to five years, effective Jan. 2, 2013, under the "fiscal cliff" tax law (*NIR 13, 1/Jan. 9, p. 8*).

Labs Face Multiple Threats, *from p. 1*

Advocacy for lab competitive bidding has come from circles outside Congress, including academic journals, research reports, and a think tank position paper, so it is hard to gauge interest among lawmakers to revive this payment approach.

Regulation of laboratory-developed tests (LDTs) is also a big concern for clinical lab and pathology groups. The Food and Drug Administration (FDA) has yet to finalize its plan to use its enforcement discretion to conduct oversight of LDTs based on the level of risk they present.

To oppose this, lab and pathology groups are expected to pursue reintroduction of a bill, similar to the bipartisan one proposed in the previous Congress by Rep. Michael C. Burgess (R-Texas), that would give the Centers for Medicare and Medicaid Services (CMS), not the FDA, the lead authority over LDT regulation.

The groups also face challenges in CMS payment policy for 2013, in particular, ensuring that reimbursement, to be determined by the gap-fill method based on local pricing patterns, is appropriate for 114 new molecular pathology codes added to the Part B lab fee schedule and getting relief from the 52 percent cut in payment for the technical component of CPT 88305, the most commonly ordered surgical pathology code.

Upcoming G2 Events

Webinar *(1 p.m.-2 p.m. Eastern)*

Jan. 29

How to Build, Grow, and Error-Proof Your Laboratory Outreach Program

Featured speaker: Susan Stegall, owner and CEO of M.S. Stegall & Associates, LLC

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