



# NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

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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.

**W**ith 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

**T**he 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. **G2**

## **HHS Approves 106 New ACOs Under Medicare for 2013**

**I**n 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

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