



Week of 6/24/2013

## ***This week's regulatory and legislative news***

- Hospitals brief Senators on cost of audit program compliance
- Supreme Court shields generic drugmakers from lawsuits
- New guidance on shared responsibility and minimum essential coverage
- Reports predict turbulent exchange rollout
- JAMA study sheds new light on low-income uninsured
- Tenet deal puts focus back on consolidation
- *HRI as we see it* will not publish the week of 07/01/13

### **Hospitals brief Senators on cost of audit program compliance**

The Senate Finance Committee this week heard from hospital directors about compliance costs and the appeals process associated with Medicare's Recovery Audit Contractor (RAC) program. The hearing comes one week after the American Hospital Association pressed CMS for new restrictions on the independent contractors Medicare uses to review hospital payments. Jennifer Carmody, director of reimbursement services for Billings Clinic in Montana, told the Senate panel her hospital has appealed about \$3.3 million of the \$8 million in claims flagged for audit. What's more, Billings spends about 8,600 work hours and roughly \$740,000 per year for internal and external staff to manage audits and appeals, Carmody said in written [testimony](#). And Suzie Draper, vice president of business ethics and compliance at Intermountain Health in Utah, [said](#) her facility has added about 22 additional full-time workers to help navigate the audit process.

**HRI impact analysis:** The hospital association asked CMS to financially penalize RACs for incorrectly denying an inpatient stay. On a conference call last week, association officials said that the independent auditors have become more organized, even hiring a public relations firm that has put an emphasis on Medicare fraud and abuse in its messaging. It's unclear how the added attention will affect future regulations. The hospital group made its comments in a response to the proposed inpatient payment rule. A final version of that rule could give hospitals some leeway, especially surrounding what constitutes an inpatient stay.

### **Supreme Court shields generic drugmakers from lawsuits**

For the third week in a row, a Supreme Court [ruling](#) has significant implications for the pharmaceutical industry. In a 5-4 decision, the justices ruled that generic drugmakers cannot be sued under state liability laws. At issue was whether injured patients could sue a manufacturer for design defects. [Previously](#), the high court ruled that generic drugmakers couldn't be sued for failing to update a drug's warning label because the FDA requires a generic's label to be the same as its branded counterpart. The court followed that same logic this time around. Since generic companies cannot change the design of a drug under the FDA's rules, they can't be held accountable for design defects, according to the Court.

**HRI impact analysis:** According to the pharmaceutical analytics group [IMS](#) Health, 84% of all prescriptions filled in the United States are for generic medications. Consumer advocates are concerned that patients will be left with no recourse if they are injured. Some in Congress have already [petitioned](#) the FDA to change its rules for generic drugs in light of the court's decision. With generic drugmakers shielded from liability, branded manufacturers are worried that patients may try to sue them for problems with products they didn't manufacture—one state [court](#) has already ruled that way.

### **New guidance on shared responsibility and minimum essential coverage**

With a little over three months remaining before October 1 open enrollment, HHS released a [final rule](#) Wednesday that clarifies individual mandate exemptions and provides detail on how "other" types of individual insurance—such as self-funded student health plans—may satisfy essential benefit requirements. The final rule

contains some technical updates, but is mostly unchanged from the proposed rule. A summary is available [here](#).

The IRS also [released two notices](#) related to exchanges on Wednesday. The first provides temporary relief from the individual mandate for enrollees who are eligible for employer-sponsored plans that do not begin on the calendar year. Individuals who do not have coverage beginning January 1, 2014, will be otherwise required to pay a penalty of at least \$95. The other notice lays out rules for determining when individuals are eligible for minimum essential coverage through programs such as Medicare Part A and CHIP, which could affect their eligibility for exchange premium tax credits.

### **Reports predict turbulent exchange rollout**

Two new reports from the Government Accountability Office (GAO) cast doubt on the administration's ability to fully stand up health insurance marketplaces known as exchanges by the October 1, 2013 open enrollment deadline. GAO researchers reviewed regulations and planning documents and conducted interviews with federal officials on both [small business](#) (SHOP) and [federal individual exchange](#) preparation. The reports reveal that 44% of states' key SHOP implementation dates were behind schedule by the end of March 2013, and many components of the program had been postponed altogether for a year. In addition, many key activities—including navigator funding and training—had been delayed for the federally facilitated exchange. The reports also noted, however, that HHS was "extremely confident" that the marketplaces would be ready to open on schedule. Just this week, the department rolled out its newly revamped [HealthCare.gov](#) website, which will serve as the one-stop enrollment site for individuals in partnership or federally facilitated states.

**HRI impact analysis:** The GAO reports voice what some in government and industry have long suspected: exchange implementation is running behind schedule, so some components may not be fully operational by the enrollment deadline. Some states and industry stakeholders are pursuing contingency plans—including paper processing—in case certain critical functions such as electronic enrollment systems are not ready. For more on state exchange and Medicaid decisions, please visit [HRI's website](#).

### **JAMA study sheds light on low-income uninsured**

Last year, [HRI reported](#) that the 2014 Medicaid expansion population, with a median age of 31, will be healthier than current enrollees. Now, a [new study](#) from the *Journal of the American Medical Association* (JAMA) confirms that the low-income uninsured who could gain Medicaid coverage under the ACA are less likely to suffer from a range of ailments—including obesity and mental illness—than the current Medicaid population. They are also 7.5% less likely to endure multiple chronic conditions such as hypertension, high cholesterol, and diabetes. But the study did show the uninsured were less likely to be aware of and control their multiple chronic conditions than their insured counterparts.

**HRI impact analysis:** The results may foretell a complicated future for the health industry. While potential Medicaid-eligibles appear to be healthier overall than current Medicaid recipients, those struggling with chronic health issues could be significantly worse off. Healthcare providers and Medicaid managed care companies may be challenged to help the sick newly insured bring their illnesses under control. Some individuals may also cycle back and forth between Medicaid and exchange plan eligibility, further complicating disease management efforts. Health plans with robust care management programs and the capability to handle both Medicaid and exchange enrollees will be better equipped to deal with the health challenges of the new population.

### **Tenet deal puts focus back on consolidation**

Nearly two years after it rejected a takeover bid by Community Health Systems, Dallas-based Tenet Healthcare Corp. this week said it would acquire Vanguard Health Systems for a total of \$4.3 billion. If approved by federal regulators, the deal would greatly expand Tenet's hospital portfolio. According to published [reports](#), the deal would boost Tenet's holdings from 49 hospitals in 24 markets to 79 hospitals in 30 markets. This could be part of a larger consolidation trend spurred on by the ACA. Hospital consolidation increased after Massachusetts passed a universal health coverage law as HRI's recent [look](#) into the Massachusetts healthcare market illustrates.

### **HRI as we see it will not publish the week of 07/01/13**

Due to the Independence Day holiday on Thursday, HRI will not publish a newsletter for the week of 07/01/13. Publication will resume on Friday, July 12.

## Upcoming events & deadlines

- **July 12** – Comments [due](#) on the proposed rule delineating a methodology for reducing Medicaid DSH allotments.
- **July 22** – Comments [due](#) on the interim final rule setting payment rates for healthcare services provided to individuals in the Pre-Existing Condition Insurance Plan.
- **July 30** – Comments [due](#) to the FDA on new models of antibacterial drug development.
- **July 31** – CMS receives state recommendations and final plan data for state partnership exchanges.

## Quote of the week

“We intend to do rate negotiation and make sure that the plans are going to offer consumers the best possible choices, as opposed to the law in some states ... where a company comes in with the plan rates and you take what you get,” [said](#) HHS Secretary Kathleen Sebelius about the federal government’s intention to take a more active role in the selection of plans for the federally facilitated health insurance exchanges.

## In the news

A [brief](#) by the Kaiser Family Foundation takes a look at California’s transition of beneficiaries with complex care needs from fee-for-service to Medicaid managed care. As part of its “Bridge to Reform” Medicaid waiver, the state has moved over 200,000 seniors and individuals with disabilities to managed care.

## Factually correct

4.5% - the 2014 net healthcare spending growth rate, after accounting for likely adjustments to benefit design such as higher deductibles, projected by HRI. To learn more about the 2014 spending trend and the factors shaping it, visit HRI’s Behind the Numbers [website](#).

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