



Week of 11/4/2013

This week's regulatory and legislative news

- **States make accommodations for exchange website delays**
- **For-profit hospitals report higher revenues, but challenges mount**
- **New plan and early warning rule from FDA to reduce drug shortages**
- **Physician ownership of device companies may influence cost, outcomes**
- **IRS releases new guidance on flexible spending accounts**

States make accommodations for exchange website delays

In response to continuing problems with health exchange websites, some states are extending existing plans and protections to help consumers avoid gaps in coverage. [Indiana](#), which is using the troubled federal exchange site, recently announced that it will extend its high-risk pool through Jan. 31—at a cost of \$6.3 million to the state. [Vermont](#), whose state-run site is experiencing significant technical problems, will allow individuals and small businesses to stay on their current plans until March 31. Prompted by the California Department of Insurance, [Blue Shield of California](#) also has agreed to allow individuals to extend non-grandfathered plans through March 31. Individuals have until Dec. 15 to enroll in an exchange health plan in order for coverage to begin on Jan. 1.

HRI impact analysis: While the federal government has stepped up efforts to encourage individuals to enroll via phone or paper application, system-wide technology challenges have slowed the process. Of the 35 states with high-risk pools, [more than a dozen](#) are slated to close shop by Jan. 1. Some states may extend coverage, but many could face budgetary challenges and political opposition. Extending current coverage also may dissuade some young, healthy people with bare-bones coverage from signing up immediately for an exchange plan at a time when their involvement is critical to controlling premium costs for all.

For-profit hospitals report higher revenues, but challenges mount

The nation's four largest investor-owned health systems reported increased third-quarter revenues despite fewer inpatient admissions and emergency room visits, according to publicly reported financial data released during the past three weeks. [Revenues for HCA Holdings Inc.](#) increased 4.9% to \$8.4 billion, while [Tenet Healthcare Corp.](#) stated an 8.4% increase, to \$2.4 billion. [Community Health Systems](#) reported a 0.2% increase, to \$3.2 billion, and [LifePoint Hospitals](#) saw a 9.7% increase, to about \$900 million. For three of the four health systems, inpatient admissions fell from 0.5% to 3.9%, thanks to shrinking ER visits and plummeting readmission rates. HCA, however, continued to buck the trend, reporting a 1.1% increase in admissions and a slight increase in ER visits. All four systems experienced a boost in outpatient utilization.

HRI impact analysis: The [shift from inpatient care to outpatient clinics](#) likely will accelerate as more individuals obtain insurance coverage either through Medicaid or the ACA's new exchanges. Hospitals should shore up clinical staff in [anticipation of the shift](#) and focus on growth and development in areas likely to experience an increase in insured patients. Hospital executives said they expect inpatient volumes to remain soft through the balance of the year, but they added that growth in outpatient services has offset some lost revenue. Additionally, some hospitals will be affected by reductions in Medicare and Medicaid disproportionate share payments, known as DSH, in the fourth quarter of 2013. Several systems reported an increase in hospital "bad debt," and at least one—Community Health Systems—estimated a loss of about \$5 million due to [Medicare's "two midnight" rule](#), which went into effect last month.

New plan and early warning rule from FDA to reduce drug shortages

As required by the 2012 FDA Safety and Innovation Act ([FDASIA](#)), a 19-member FDA task force submitted to Congress [a new plan](#) to reduce drug shortages. The plan has twin goals—to improve FDA procedures, data

infrastructure, and expectations from manufacturers once a drug shortage has been reported, and to enhance measures aimed at preventing shortages in the first place. The preventive measures include incentives for manufacturers to maintain quality, [risk-based monitoring](#) to detect manufacturing and quality problems early, and stronger partnerships with professional organizations and others to increase understanding of underlying causes of shortages. Providers eventually will be able to track shortages through a mobile app, and consumers are being asked to report shortages via email. A separate [proposed rule](#) also would require biologics manufacturers to notify the agency at least six months before halting manufacturing.

HRI impact analysis: The FDA continues to impact drug shortages, reducing them by 53% from 2011 to 2012. This plan represents a more ambitious vision for eliminating drug shortages, encompassing areas beyond healthcare delivery, such as clinical trials in which drug shortages can slow progress or cause harm. Of particular concern is that a significant portion of shortages still hit [therapies and nutritional supplements for newborns and children](#). Also, the proposed incentives may not be sufficient to prevent shortages caused by drug manufacturers' decisions to end production of older or less-profitable products.

Physician ownership of device companies may influence cost, outcomes

Physicians with an ownership stake in medical device companies may wield influence over the number, cost, and quality of certain surgeries, according to a new [report from HHS's](#) Office of the Inspector General (OIG). Prompted by a Congressional inquiry, the study found that surgeons using physician-owned distributors for spinal implants performed more spinal fusions at a higher cost to Medicare than hospitals that chose vendors not owned by doctors. The study, which examined 1,000 Medicare claims including spinal surgeries, also found that providers had varying policies about whether physicians were required to disclose ownership interests.

HRI impact analysis: The OIG raised concerns that physician-owned distributorships are "inherently suspect" under the anti-kickback statute, as spinal implants are considered physician preference items, meaning that a doctor has strong influence over brand and device choices. Providers should have uniform disclosure policies so that hospitals and patients can identify potential conflicts of interest. Additionally, the [Sunshine Act](#) requires most medical businesses to disclose physician ownership. According to the final rule, CMS will list these companies and their payments publically by June 30, 2014.

IRS releases new guidance on flexible spending accounts

Last week, the IRS released guidance that modifies the "use it or lose it" rule for flexible spending accounts (FSAs). Under the amended rule, employees with health FSAs will be able to carry over up to \$500 in unused money to the next plan year. For more analysis, read's [PwC's HRS insights analysis](#).

Upcoming events & deadlines

- **November 12** – [Webinar](#) on the effects of health insurance exchanges on hospitals, including strategy for new exchange customers and [research by the Health Research Institute](#)
- **November 13** – Centers for Medicare & Medicaid Services (CMS) Special Open Door [online forum](#) on rural health
- **November 18** – Comments [due](#) on proposed rule for new prospective payment system for Federally Qualified Health Centers
- **November 21** – Centers for Medicare & Medicaid Services (CMS) Special Open Door [online forum](#) on the ACA Quality Reporting Program for Long-Term Care Hospitals
- **November 25** – Comments [due](#) on the proposed rule on the Basic Health Program. The program gives states the option to establish a health benefits coverage program for low-income individuals who would otherwise be eligible to purchase coverage through health insurance exchanges.
- **November 25** – National Institute on Aging Special Emphasis Panel [meeting](#)
- **November 27** – [Final notice](#) from CMS that allows the Accreditation Commission for Health Care to become a "deemed" organization for accrediting hospice healthcare facilities.

Quote of the week

"We had been hearing more and more from members their general frustration of all the different report cards," said Kathleen Ciccone, director of the Healthcare Association of New York State Quality Institute. "It's so time-consuming for them to be able to respond to the reports, to be able to see what's useful about them. They're really looking for some guidance on how to use the information." This is in response to an effort of the state of New York to turn around and [grade the quality of hospital graders](#).

In the news

A recent article from *NPR* reports that while the federal government is making strides to win people back after the technical problems that occurred with the launch of the federal health insurance exchange, state health insurance exchanges, such as the one in Oregon, [are facing their own enrollment difficulties.](#)

Factually correct

493 – the number of active [private and public accountable care organizations](#) (ACOs) as of September 2013.

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