



Week of 10/28/2013

This week's regulatory and legislative news

- Exchange enrollment file issues could signal future tech challenges for plans
- Final program integrity rule addresses risk adjustment, reinsurance standards
- FDA moves to reduce painkiller abuse
- Proposed bill would reduce FDA oversight in health software and information technologies
- In some states, Medicaid “woodwork” population emerges
- FDA focuses on patient safety as medical devices go wireless

Exchange enrollment file issues could signal future tech challenges for plans

While the federal exchange website's problems continue to dominate the headlines, insurer readiness has slipped under the radar. The challenges with exchange implementation are not just restricted to the government: some issuers are still struggling to fully process exchange enrollment files. In New York, for example, industry sources report that exchange plans underwent minimal testing on enrollment file transfers before October 1. The insurer processing challenges are one major reason that some states and the federal government are reluctant to share final enrollment numbers, preferring instead to highlight the number of applications and accounts created. HHS Secretary Kathleen Sebelius, appearing before the House Energy and Commerce Committee earlier this week, reiterated her reluctance to share enrollment figures. “We do not have any reliable data around enrollment, which is why we haven't given it to date,” she said.

HRI impact analysis: Internal problems processing exchange applications could be just the tip of the iceberg for insurers, who will face many more technical hurdles as individuals start accessing services on January 1. Some health plans, especially those without experience, could be overwhelmed by a sudden surge of claims. Plans could also struggle with hefty state and federal exchange reporting requirements. In a survey prior to open enrollment, HRI found that 63% of insurers participating on the exchanges ranked technology integration as their biggest concern. To learn more about HRI's findings, [read our recent report](#).

Final program integrity rule addresses risk adjustment, reinsurance standards

Last week, HHS released a [final rule](#) on program integrity standards. One key component focuses on the risk adjustment and reinsurance programs, spelling out standards for reporting requirements, payments, and federal access to data. It allows insurers to submit reinsurance contributions in two installments: one at the beginning of the year and one at the end. It also exempts some self-insured, self-administered plans from making reinsurance payments in 2015 or 2016, with more direction to follow in later guidance.

HRI impact analysis: In 2014, HHS will give insurers a break by not imposing financial penalties if they make a good faith effort to comply with reporting requirements. The department will work with insurers to help them remain in compliance and will adjust penalties according to the seriousness of the problem. Insurers that don't submit reinsurance payments simply won't receive payments in return. In the case of risk adjustment, insurers will face a financial penalty based on the insurer's enrollment numbers. Although health plans will have some leeway in the first year, they should already have in place a strong compliance program to track reporting requirements. For a detailed analysis of the full rule, visit the [Health Affairs blog](#).

FDA moves to reduce painkiller abuse

Hydrocodone prescription abuse has reached “epidemic proportions” in certain parts of the US, according to FDA Center for Drug Evaluation and Research director, Janet Woodcock. In response, the FDA is recommending hydrocodone be moved to a [Schedule II drug with other narcotics such as oxycodone and fentanyl](#), which have a “high potential for abuse.” The DEA has long identified hydrocodone [as a major source](#)

[of abuse](#) and illicit activity across all age groups. For their part, researchers recently [tested a vaccine](#) that mitigates the effects of hydrocodone, which could help abusers recover from addiction.

HRI impact analysis: Hydrocodone is the most widely prescribed medication in the US, with about 135 million prescriptions [written each year](#). Physicians' administrative load will increase because prescriptions will be limited to 90-day supplies instead of six-month supplies, and physicians cannot issue refills. The [CDC estimates](#) that painkiller abuse visits to the ER have doubled in the past five years to almost 500,000, resulting in \$72 billion in additional healthcare costs. Patients who experience chronic pain may end up switching to easier-to-obtain, but potentially less effective, drugs.

Proposed bill would reduce FDA oversight in health software and information technologies

During a month in which health software has taken center stage, a proposed bipartisan House bill would reduce FDA authority over certain medical software apps and technologies. The [SOFTWARE Act](#), recently referred to the Energy and Commerce committee, would limit FDA oversight to only medical software that may change the "structure or function" of the body. The FDA recently provided final guidance on [mobile medical apps](#), outlining a limited scope focused on safety risks but inclusive of consumer-oriented EHRs and disease management. The agency does not intend to regulate "app stores" or off-the-shelf tablets and devices.

HRI impact analysis: Health information technology and subcategories such as mobile apps are one of the fastest growing areas of healthcare investment and innovation. Some traditional medical technology companies [are already pivoting](#) toward new products and services that use social, mobile, analytics, and cloud computing technologies. The proposed bill provides specificity about the types of medical software that would be regulated, possibly reducing barriers to innovation in the rapidly evolving industry.

In some states, Medicaid "woodwork" population emerges

Medicaid has seen its numbers swell since October 1, a sign that the open enrollment period for exchanges has helped shift eligible low-income individuals to the joint federal-state insurance program and that a new, streamlined process to determine eligibility is working. The surge in Medicaid numbers, coupled with uncertainty over exchange enrollment data, has providers and insurers worried that private health plans may not immediately see the mix of healthy and unhealthy individuals needed to keep premium costs low. More than 31,000 residents of Washington State enrolled in Medicaid, as did 21,000 Kentuckians, 25,000 New Yorkers, and about 26,000 Coloradoans, according to an analysis by the [Wall Street Journal](#).

HRI impact analysis: While there is demographic data on the newly Medicaid eligible, known as the "woodwork" population, little is known about why they did not previously pursue coverage. Some could be more reclusive and sicker, since they would have been enrolled in a government program if they had recently sought care. Conversely, they could be healthier, younger Americans who did not require significant medical attention in recent years. Either way the boost in Medicaid enrollment will likely be welcome news for hospitals and physician groups who benefit from new paying consumers. The higher enrollment numbers may also reflect a [coordinated outreach effort](#) by "navigators" and other personnel tapped to help find and educate individuals about the law's new coverage options. The enrollment process for subsidized coverage, by comparison, is much more complex—and so far has been hindered by technical glitches.

FDA focuses on patient safety as medical devices go wireless

As more medical devices include remote technology, the FDA is advising manufacturers to ensure their products remain safe and effective. Check out our [latest Spotlight](#) report for a quick update on how recent guidances from the FDA affect wireless networks, mobile apps, and medical devices at provider offices and hospitals.

Upcoming events & deadlines

- **November 7** – PwC [webinar](#) on new plans, progress, and pain points associated with the new state insurance exchanges
- **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 18** – Comments [due](#) on proposed rule for new prospective payment system for Federally Qualified Health Centers
- **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.

Quote of the week

"The health care law is making health insurance more affordable for young adults," said HHS Secretary Kathleen Sebelius. "With nearly half of single, marketplace-eligible uninsured young adults able to get coverage at \$50 or less per month, the healthcare law is delivering the quality, affordable coverage people are looking for."

In the news

In a recent article from Minnesota Public Radio, efforts to [provide outreach](#) to minority patients to sign up for healthcare coverage through Minnesota's health insurance exchange 'MNSure' have had a slow start, [signaling the importance](#) of navigators to assist consumers.

Factually correct

40% - the percentage of medical devices in the global market that are [manufactured in the United States](#).

Contacts

Benjamin Isgur

Director

benjamin.isgur@us.pwc.com

(214) 754-5091

Bobby Clark

Senior Manager - Pharma/Life Sciences

robert.j.clark@us.pwc.com

(202) 312-7947

Matthew DoBias

Senior Manager - Provider

matthew.r.dobias@us.pwc.com

(202) 312-7946

Caitlin Sweany

Senior Manager - Payer

caitlin.sweany@us.pwc.com

(202) 346-5241

Christopher Khoury

Senior Manager

christopher.m.khoury@us.pwc.com

(202) 312-7954

[HRI Online](#)