



Week of 11/18/2013

This week's regulatory and legislative news

- **Health plan extensions meet with mixed reception**
- **For hospitals, penalties outpace bonuses in Medicare program**
- **Drug safety measure passes Congress**
- **A trickle of breakthrough therapies reaches consumers**
- **Moving oral care outside the dentist's office can lower costs, increase access**
- **Medicaid numbers high, but enrollment concerns persist**
- ***HRI as we see it* will not publish the week of 11/25/13**

Health plan extensions meet with mixed reception

President Obama's extension of non-ACA-compliant insurance plan renewals has met with mixed reaction from state insurance commissioners and industry executives. [Some states](#), such as Kentucky, Ohio, and Florida, will allow insurers to re-file rates for current individual health policies. Others, such as Washington, have nixed the idea. The [National Association of Insurance Commissioners](#), [America's Health Insurance Plans](#), and the [American Academy of Actuaries](#) have all advised against the extension, noting that it could undermine the new exchange market. The assumption is that younger, healthier individuals may choose to stay on their current plans—upsetting the balance needed in the new exchange risk pools.

HRI impact analysis: This late development is yet another example of healthcare reform decisions falling to the states. In addition to concerns about how the renewals will affect premiums, some states may not have the bandwidth to review and approve rate filings before the new year. Insurers extending current plans will likely have to prioritize, choosing only their most popular plans to renew—and consumers on those plans could be in for [substantial rate hikes](#). The pressure to renew existing plans comes as HHS implements technological improvements, such as allowing subsidy-eligible consumers to enroll directly with insurers.

For hospitals, penalties outpace bonuses in Medicare program

More hospitals will see a decrease in overall Medicare payments than will see an increase under an ACA measure meant to reward providers that deliver high-value, top-quality care. Under the Value Based Purchasing (VBP) program, about 1,451 hospitals will be paid less this year, while another 1,231 will see payments rise, according to a [Kaiser Health News analysis](#) of just-released [CMS data](#). In a [blog post](#), Patrick Conway, CMS chief medical officer, said the agency was "pleased with this round of results" despite a lower number of higher-end performers this year. The program holds hospitals to about two dozen quality measures, including patient satisfaction scores and clinical outcomes. Now in its second year, the program allows Medicare to hold back about 1.25% of payments, or roughly \$1.1 billion. That money is then redistributed to hospitals that achieve high scores on quality measures.

HRI impact analysis: The quality measures can vary year-to-year, and Conway hinted that the next set could be vastly different from the current ones. The actual payment reductions, which went into effect October 1, may be relatively small for larger health systems. Still, it's another reduction in reimbursement amid a [growing list of financial cuts](#). Overall, about 7% of all hospital Medicare payments could be at risk by 2017. The latest VBP round included measures meant to gauge patient satisfaction—a perennial trouble-spot for health systems. While most of the reportable measures have been a part of hospital quality improvement initiatives in the past, providers could gain higher scores by [concentrating on the patient experience](#).

Drug safety measure passes Congress

Congress has approved a new law intended to protect consumers from counterfeit drugs. [The Drug Quality and Security Act](#) targets counterfeit medicines by establishing a national "track and trace" system over the next ten

years. Manufacturers, wholesalers, distributors, and pharmacies will be required to maintain a record for every time a drug changes hands as it makes its way from the factory to the pharmacy counter. The legislation also clarifies FDA's oversight of compounded drugs, which are tailored to meet the needs of specific patients, such as those with allergies. The law establishes a new voluntary program for compounders that produce medicines in bulk to register with the FDA and undergo inspections. The increased oversight was prompted by a [fungal meningitis outbreak](#) last fall caused by tainted steroid injections that killed more than sixty people.

HRI impact analysis: The nationwide track and trace system will preempt a patchwork of state programs, including [California's](#) pending tracking law, which was slated to take effect in 2015. Companies that were preparing to comply with the California measure will now have to assess the new federal standards and the timeline for complying. Most large-scale compounding operations, such as those that supply hospitals, are expected to comply with the voluntary program due to market pressures. [Pharmaceutical customers](#) will want drugs that are produced under the watchful eye of the FDA.

A trickle of breakthrough therapies reaches consumers

In the span of two weeks, the FDA has approved its first and second "breakthrough therapy" drugs for patients with certain types of leukemia and lymphoma. The approvals are the first since the enactment of new faster regulatory approval pathways for drug development in [the 2012 FDASIA law](#). Both approvals were based on clinical trials conducted on small populations of 100-400 participants, and one approval was for a combination of two drugs that are more effective when used together.

HRI impact analysis: The recent approvals highlight FDA's commitment to streamline the approval process for drugs that treat serious or life-threatening conditions. Drug makers are also learning how to meet FDA requirements, aided [by draft FDA guidance](#) released earlier this year that addresses accelerated approval paths. Extra attention from top FDA leadership and speed of approval is a boon for drug manufacturers. But the [burden of proving comparative effectiveness](#) is high, because the [law stipulates](#) that a drug must demonstrate "substantial improvement over existing therapies."

Moving oral care outside the dentist's office can lower costs, increase access

Fewer dentists are taking new Medicaid patients citing [low reimbursements](#), so moving basic dental care out of the traditional office may be more effective, according to a study by the Journal of the American Medical Association. Studies show that community-based preventive dental care provided by dental hygienists, without supervision from a dentist, can greatly [improve access and lower costs](#). Telemedicine efforts, such as the [Virtual Dental Home pilot](#) in California, can also be cost effective. "By focusing on prevention and early intervention, the virtual dental home model can help to drive down the total cost of oral and general health care," a National Institutes of Health study found. The project gives dentists the ability to electronically review patient's records remotely with help from dental hygienists and assistants in underserved communities.

HRI impact analysis: This is another example of preventive care moving closer to consumers and lowering costs. A study by the Agency for Healthcare Research and Quality found that Medicare beneficiaries who [used preventive oral care](#) had lower overall dental costs. As care moves closer to patients through the use of e-visits and retail clinics, some costs may decline due to less time spent with the dentist and the utilization of supporting staff and technology.

Medicaid numbers high, but enrollment concerns persist

While exchange enrollment continues at a slow pace, Medicaid is proving a surprise hit: Upwards of [400,000 people](#) have qualified for Medicaid, more than a quarter of which were previously eligible but had not enrolled. While interest in the program is strong, back-end enrollment file transfers from the federal exchange website could cause problems. The federal government has repeatedly delayed the transfer of Medicaid files, meaning that states and managed care plans may be left scrambling to finalize enrollment by January 1. For the latest on state Medicaid decisions, see [HRI's updated health reform map](#).

HRI as we see it will not publish the week of 11/25/13

HRI will not publish a regulatory newsletter for the week of 11/25/13. Publication will resume on Friday, December 6.

Upcoming events & deadlines

- **November 29** – Comments [due](#) on interim final rule for changes to Medicare programs, including the Inpatient Prospective Payment System and Disproportionate Share Hospital Uncompensated Care Payments.

- **November 30** – Deadline for eligible hospitals to register and submit attestation to receive incentive payments in fiscal year 2013 for the Medicare electronic health record [“meaningful use” incentive program](#).
- **December 5** – Joint online [conference](#) of America’s Health Insurance Plans (AHIP) and PwC on the topic of plans, progress, and pain points in health insurance exchanges.
- **December 10** – [Public workshop](#), sponsored by the Federal Trade Commission, that will examine the impact of recent regulations and legislation on competition in the biologic drug market.

Quote of the week

“While this marked slowdown (in healthcare spending) likely has many causes, and these causes are not yet fully understood, the available evidence suggests that the ACA is [contributing to these trends](#), and, moreover, is helping to improve quality of care for patients,” said Jason Furman, chairman of the Council of Economic Advisers to President Obama, commenting on a recent medical cost trend study.

In the news

A recent article from the *The New York Times* outlines a recent proposal by the FDA to [downgrade certain medical devices from their “high-risk” status](#), which include external pacemakers, access tubes implanted in blood vessels, and screw systems used in spinal surgery, among many others.

Factually correct

34% - the percentage of uninsured Americans, recently surveyed by the Gallup poll, who had a [positive or very positive experience](#) so far with state and/or federal health insurance exchange websites.

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