



Week of 1/20/2014

This week's regulatory and legislative news:

- With Obama's signature, spending package reaches across health sectors
- New year brings renewed Medicaid expansion debates
- Docs adopt EHR use, but Stage Two readiness a ways off
- FDA releases long awaited guidance on social media
- Google reveals development of smart contact lens

With Obama's signature, spending package reaches across health sectors

The \$1.1 trillion, [far-reaching spending package](#) passed by Congress and signed by President Obama late last week includes a number of provisions that directly impact funding and policy for the health industry. Broadly, it allots \$156.8 billion in discretionary spending for HHS, about \$100 million less than the agency received last year. Of that, CMS will have \$3.7 billion to cover its day-to-day operations, about \$200 million less than last year—and far shy of what some agency officials say is needed to manage the complexities of Medicare, Medicaid, and ACA implementation. Still, some agencies will get budget increases this year, including the National Institutes of Health (\$29.9 billion, about \$1 billion more than 2013), and the CDC (\$6.9 billion, or \$567 million above last year).

HRI impact analysis: While the ACA was largely shielded from Congressional negotiations, some parts of the massive law will see fewer dollars this year. For example, lawmakers siphoned away \$1 billion from its Prevention and Public Health Fund. [Other critical areas affected include:](#) \$6 million to tighten lax compliance standards within the 340B Drug Pricing Program, which requires pharmaceutical companies to offer outpatient drugs at steep discounts; \$1.1 billion to promote programs that reduce chronic illnesses; and \$265 million for graduate medical education in children's hospitals. The legislation also requires CMS to address longstanding payment issues in its Recovery Audit Contractors program, as well as address workforce shortages in rural hospitals.

New year brings renewed Medicaid expansion debates

Just weeks into the new year, state officials and interest groups are already renewing the debate on Medicaid expansion, 19 months after a Supreme Court ruling made state expansion to 138% of the federal poverty level optional. Twenty-five states and the District of Columbia are expanding their programs in 2014, leaving a number of states open to future changes. In [Maine](#), legislators planned to take up the issue again, despite strong opposition from Gov. Paul LePage. [Alabama](#) Gov. Robert Bentley sharply defended his decision not to expand Medicaid in his State of the State address last Tuesday. [Virginia](#) Gov. Terry McAuliffe voiced support for the expansion, kicking off a contentious debate with the state's House of Delegates. In other states, such as [Georgia](#) and [Kansas](#), pro-Medicaid interest groups revived their push. In some states, compromise may take the form of premium assistance programs that send Medicaid-eligible residents to the exchanges: [Arkansas](#), [Iowa](#), and [Michigan](#) are already moving down this path. Other states considering the expansion alternative include [Pennsylvania](#), [Tennessee](#), and [Indiana](#).

HRI impact analysis: Many hospitals and physicians, especially those with high uncompensated care debt, are likely to continue their push for Medicaid expansion this year. Providers - especially those in underserved communities - face the double-sided pressure of rising uncompensated care costs and

shrinking insurer reimbursement. [Rural advocacy groups](#) in particular cite potential closures once federal payments to disproportionate share hospitals decrease in just under two years. Insurers are also likely to continue their support for Medicaid expansion, especially as more states consider options to funnel eligible consumers into private health plans.

Docs adopt EHR use, but Stage Two readiness a ways off

Use of electronic health records (EHR) among office-based physicians jumped to 78% last year, up from 48% in 2009 when federal financial incentives were offered. Yet 81% of physicians who plan to participate in Medicare's incentive program do not have a system supporting the [core objectives](#) needed to advance to the second stage of the initiative, according to [data released last week by the CDC](#). There are three stages to show "[meaningful use](#)," with each portion increasingly more rigorous around outcomes than the next. But the low number of physicians eligible to move to Stage Two, which requires an EHR that orders prescriptions electronically, calls-up guideline-based clinical support and is readily accessible to patients, could hinder health IT progress.

HRI impact analysis: Providers face a number of hurdles on the road to EHR adoption, including high upfront costs that may not have a significant financial return immediately following the investment. But an equally pressing problem is centered on EHR vendors—many of which do not have the [resources](#) to help providers upgrade and re-certify systems as required under the CMS program. Federal health authorities last month said they [would extend Stage Two adoption requirements](#) by one year, through 2016. The move allows CMS to focus on the second-stage requirements and use what it learns to further develop the goals for Stage Three.

FDA releases long awaited guidance on social media

[The FDA recently released draft guidance](#) on the regulation of "interactive promotional media," such as blogs, social networking sites, online patient forums, and podcasts. The guidance applies to drug and biologic makers, as well as packers and distributors. The FDA makes clear that companies are responsible for promotional content that it controls through online media that it owns or operates, as well as third party sites. However, a drug maker generally won't be accountable for content that it has no control over, such as postings to online message boards by individuals who have no affiliation with the company. The recommendations are meant to help industry comply with the agency's [rules on product promotion](#) when using modern-day communication tools.

HRI impact analysis: [According to HRI's report, "Social media likes healthcare,"](#) 42% of consumers have used social media to access health-related consumer reviews of treatments or physicians. But drug makers have been hampered by the lack of guidance on how to use these tools without running afoul of FDA regulations. Manufacturers have been worried they could be held responsible for false or misleading information shared through interactive media which they have no control over. As the new guidance is finalized and those concerns are addressed, the industry may use social media more to communicate with patients. Manufacturers will need to understand how demographics and preferences for social media may impact the [customer experience in pharmaceuticals](#).

Google reveals development of smart contact lens

Google shook up the healthcare world when word spread that its innovation lab, [Google\[X\]](#), was developing a new smart contact lens that will measure blood glucose levels. The project is meant to improve health outcomes of diabetics by alleviating the burden that comes with current tracking methods, such as repeated finger pricks for a blood sample. The product would be regulated as a [medical device](#) and would have to be approved by the FDA before it could be sold to consumers. Company representatives reportedly met with agency officials recently, but it's unclear how soon the company might submit an application for approval.

HRI impact analysis: Google's announcement is another example of how technology companies are entering the healthcare world. In the new health economy, [organizations are rethinking their roles](#) in an effort to provide consumers with new solutions that satisfy their demands for convenient, cost-effective care. Organizations such as Google that are focused on [wearable technology](#) will also have to think about patient privacy [as sensitive data is transmitted](#) from one device to another. While privacy is important to

consumers, according to [HRI's report on customer experience in healthcare](#), consumers may be willing to trade some privacy for easier access to information.

Upcoming events & deadlines

- **January 27** – Comments [due](#) for Medicare hospital outpatient prospective payment system and the Medicare ambulatory surgical center payment system rates for 2014.
- **February 3** – Comments due on FDA's draft guidance on compounded pharmaceuticals.
- **February 4** – Federal Trade Commission [workshop](#) on naming conventions for biologics.
- **March 3** – Start of [CMS testing week](#) for ICD-10.
- **March 31** – Extended deadline for those in the Pre-Existing Condition Insurance Plan to gain coverage through exchanges. [HHS](#) announced the two-month extension last week.
- **March 31** – Open enrollment in health insurance exchanges scheduled to end for 2014.

Quote of the week

"Physicians have an obligation to keep up with the latest in their field of practice, listen to their patients, look at their practice and improve," says Dr. Richard Boran, chief executive of the American Board of Internal Medicine, in response to new credentialing requirements for physicians, called [maintenance of certification](#).

In the news

Last week's JPMorgan Healthcare Conference led to a flurry of discussions around [potential healthcare deals in the pharmaceutical arena](#), the New York Times reports. Among the notables were Bristol-Myers Squibb, which expressed interest in buying new drugs, Teva Pharmaceuticals, which is looking into strategic deals, and Covidien, which is exploring strategic acquisitions.

Factually correct

37% - The percentage of Americans who feel they have enough information on pricing for lab tests, according to HRI's [Top Health Industry Issues of 2014 report](#).

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