



Week of 12/16/2013

This week's regulatory and legislative news

- **Budget deal includes temporary 'doc fix,' hospital payment changes**
- **Young adult exchange enrollment provides cautious optimism for some**
- **Drugmaker shifts gears on drug promotion**
- **FDA approves new Hepatitis C treatment**
- **HRI as we see it will not publish the weeks of 12/23/13 and 12/30/13**

Budget deal includes temporary 'doc fix,' hospital payment changes

Physicians will get a three-month reprieve from steep reductions in Medicare payments, while hospitals will see an extension of across-the-board cuts in federal reimbursement under a bipartisan budget deal approved by Congress on Wednesday. Under the agreement, physicians will receive a 0.5% pay increase through March 2014, a stopgap move that buys lawmakers more time to craft a permanent overhaul of Medicare's reimbursement formula. But the deal also extends by two years a 2% reduction in hospital payments, which was originally part of the budget cuts in 2011. Even so, the legislation offers a number of provider wins: The bill temporarily extends higher payment rates to rural hospitals, and it delays by two years the Medicaid disproportionate share hospital (DSH) pay cuts. The package also changes patient admissions criteria for long-term care hospitals.

HRI impact analysis: The budget deal includes about \$85 billion in spending reductions and new revenue, which replaces about \$63 billion in cuts from the 2011 budget. As a result, it allows higher spending levels for domestic programs, such as funding for the National Institutes of Health (NIH), which in turn could benefit teaching hospitals that rely on government research grants. Under the previous budget cuts known as the sequester, teaching hospitals lost about \$1 billion a year as the NIH was forced to tighten spending. The temporary "doc fix" means that Congress will have more time to potentially create a permanent change to physician Medicare payments known as the sustainable growth rate, or SGR. National hospital groups said they would press to include a delay in the so-called "Two Midnight Rule" as part of any SGR legislation.

Young adult exchange enrollment provides cautious optimism for some

In spite of public concerns that young people aren't enrolling in health plans, early evidence from some state-based exchanges has elicited cautious optimism from state officials. In the District of Columbia, the largest proportion of paid enrollees is between 26 and 34 years old, said DC Health Link's Mila Kofman last week at an AHIP event for insurers. She did note, however, that the reference pool is very small—only about 600 enrollees. About thirty-five percent of Connecticut's early exchange enrollees are under 35, noted Access Health CT's CEO Kevin Counihan, at the same event. In California, 21% of the enrollees in October and November were between the ages of 18 and 34—this group makes up about 42% of the state's uninsured population. Yet the highest percentage of California enrollees is still the 45-and-up crowd, with 36% of the total enrollment.

HRI impact analysis: Exchange enrollment extends through March 31, so it's still too soon to make a final assessment of enrollee demographics. Young, healthy enrollees are essential for insurers to help balance out the financial risk of older, less healthy individuals. Early indicators seem to show that some young people are buying coverage—and their numbers are likely to grow as states smooth out technological glitches, boost outreach, and approach the coverage deadline. The same may prove true in states using the federal exchange, as former Microsoft exec Kurt DelBene takes the helm at HealthCare.gov with the promise of bringing deep technology experience from the tech sector to the exchange roll-out.

Drugmaker shifts gears on drug promotion

This week the British pharmaceutical company GlaxoSmithKline (GSK) announced two significant changes to its global sales and marketing programs. By 2016, the drugmaker will stop paying healthcare professionals to promote its drugs—although GSK will still provide fees to physicians who consult on clinical research, market research, and other advisory activities. The other announced change is the implementation of a new compensation model for sales reps starting next year. Compensation will no longer be based on the number of prescriptions written, but instead sales reps will be evaluated and rewarded for their technical knowledge, the quality of the service they deliver to support improved patient care, and the overall performance of GSK's business.

HRI impact analysis: The move by GSK comes as drugmakers are taking a closer look at their sales and marketing operations. Some may simply want to reduce costs while others may implement changes to fulfill compliance obligations, or to avoid them. The Physician Payment Sunshine Act, which was passed as part of the ACA, requires data collection on payments drugmakers make to physicians. That information will be made public on a website starting September 2014. Drugmakers that halt certain payments to physicians may have fewer reporting requirements under the new law.

FDA approves new Hepatitis C treatment

For the second time in as many weeks, the FDA has approved a new drug as a breakthrough therapy—a designation given to medications that offer major advancements over existing treatments. Products approved as breakthrough therapies may receive an expedited review process. The agency recently cleared Gilead's application to market Sovaldi to treat Hepatitis C. The current standard of care for the illness involves weekly injections of interferon, a drug that can produce flu-like side effects. Sovaldi offers patients the choice of taking a pill over an injection, and it may shorten the treatment period.

HRI impact analysis: The approval of Sovaldi marks the third time that the FDA has applied the breakthrough designation to a new drug since it was established under the 2012 Food and Drug Administration Safety and Innovation Act. Winning FDA approval marks a critical step in the marketing of any drug, but getting reimbursed by purchasers is equally important. Although new drugs typically command high prices, recent news reports highlight how some insurance plans may exclude medications as a way to keep monthly premiums low, especially if they aren't proven better than existing therapies. For a more detailed understanding of how health insurance exchanges may impact drugmakers, see HRI's FAQs document.

HRI as we see it will not publish the weeks of 12/23/13 and 12/30/13

HRI will not publish a regulatory newsletter for the week of 12/23/13 and 12/30/13. Publication will resume on Friday, January 10.

Upcoming events & deadlines

- **December 23** – Deadline for individuals to enroll in federal exchange coverage for January 1.
- **December 26** – Comments due on proposed HHS rule that sets payment parameters and oversight provisions for the 2015 open enrollment period.
- **December 31** – Federal exchange enrollees must pay first month's premium for coverage beginning January 1.
- **January 1** – Exchange plan and expanded Medicaid coverage begins.
- **January 1** – New rules governing electronic fund transfer: Doctors, hospitals, and health plans must follow new rules for electronic fund transfer and remittance advice transactions.
- **January 1** – Medicare Advantage Plan Loss Ratios: Medicare Advantage plans are required to have medical loss ratios no lower than 85%.
- **January 1** – Providers must attest to Meaningful Use Stage 2: Providers participating in the EHR Incentive Programs who have met Meaningful Use Stage 1 for two or three years will need to meet Stage 2 criteria to qualify for incentive payments.
- **February 3** – Comments due on FDA's draft guidance on compounded pharmaceuticals.
- **March 31** – Open enrollment in health insurance exchanges closes for 2014.

Quote of the week

"This is the first significant step in dealing with this important public health concern in 20 years," said former FDA commissioner David Kessler on a new policy phasing out the use of antibiotics to make animals grow bigger. "No one should underestimate how big a lift this has been in changing widespread and long-entrenched industry practices."

In the news

A recent article from *The New York Times* reveals that children who go to preschool or day care in New York City will soon be required to obtain mandatory influenza vaccinations. The New York City Board of Health voted on this measure on December 13th, and the initiative will take effect in mid-January, 2014.

Factually correct

27% - the percentage of surveyed physicians who encourage their patients to use mobile health applications to help them manage their own healthcare, according to a survey conducted by HRI.

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