HRI as we see it

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Week of 12/2/2013

This week's regulatory and legislative news

- **FDA swiftly issues guidance on compounded drugs**
- **Outpatient rule adopts single payment code, new 'bundled' services**
- **HHS proposes tweaks to premium stabilization, exchange subsidy programs**
- **IRS releases final rules on health insurance industry, Medicare taxes**
- **Federal SHOP online enrollment delayed to 2014**

FDA swiftly issues guidance on compounded drugs

The FDA is moving quickly to implement parts of a new drug safety law signed by President Obama last week. On Monday, the agency issued several draft guidance documents to begin phasing in the Drug Quality and Security Act. The new law reforms the way the FDA regulates compounded drugs, which are tailored for patients with specific needs such as medication allergies. The guidance documents provide details regarding the creation of a voluntary registration program for large-scale compounders. The FDA will keep a public list of those companies that sign up for the program and conduct inspections to ensure they are complying with standard manufacturing practices. The FDA is also asking the public to nominate drugs that compounders should be prohibited from developing due to their complexity.

HRI impact analysis: Upon releasing the new guidance, FDA Commissioner Margaret Hamburg urged providers to only purchase compounded drugs from facilities that have registered with the agency. Since the registration program is voluntary, it relies on market forces to encourage participation. This is the latest step in a broader effort by the FDA to improve the quality of prescription drugs. As drugmakers are faced with increasing demands to demonstrate value, quality should be considered part of that equation. Manufacturers should invest in appropriate systems to meet regulatory requirements and customer expectations.

Outpatient rule adopts single payment code, new 'bundled' services

Hospital outpatient centers may see lower reimbursements for services provided to some medically complex patients under a final payment rule released by CMS in late November. The rule streamlines five separate outpatient clinic visit codes into a single, comprehensive one. CMS said the rule, which goes into effect January 1, is more "administratively simple for hospitals," and it better reflects the resources used while treating a patient. The rule does not extend to hospital emergency departments, which CMS previously proposed. In a statement to its members, the American Hospital Association said it is concerned that the single payment rate "will harm hospitals that provide care for large numbers of complex patients, with payment falling well below the cost of treating these patients." Hospitals have until January 27 to submit comments.

HRI impact analysis: The new single code and packaged payment methods could challenge hospitals that rely on outpatient payments to compensate for lower inpatient volume. Some of the largest health systems have seen between a 1% to 5% decline in adjusted admissions even as outpatient services have increased. But as Medicare continues to shift payment models, the cost of treating sicker patients may not be fully covered.

HHS proposes tweaks to premium stabilization, exchange subsidy programs

Last week, HHS released its proposed 2015 Notice of Benefit and Payment Parameters, an annual guideline for health plans in the private insurance market. The notice lays out the 2015 payment structure for the premium stabilization and cost-sharing programs, and makes a number of adjustments for the recent allowance of non-compliant "transitional" plans through 2014. For example, HHS proposes changes to the risk corridor program that would raise the limit for insurers on profits and administrative costs. Among the many other provisions in the rule are changes to cost-sharing limits, a proposed "meaningful difference" standard for

insurers that offer multiple similar health plans on the exchanges, and requirements that health plans must meet to demonstrate that their contracted providers meet patient safety standards.

HRI impact analysis: There's optimism among some in the industry that the proposed changes to the premium stabilization programs may lighten the financial load for health insurers. Some of the updates, such as risk corridor profit and cost limit changes, would likely be applied on a state-by-state basis, since only some states allow transitional plan renewals. It's still too early in the rollout, however, to fully gauge the impact on insurers. Comments on the proposed rule are due December 26.

IRS releases final rules on health insurance industry, Medicare taxes

On Tuesday, November 26, the IRS released final rules related to ACA fees and taxes. One rule implements the health insurance industry tax, a yearly assessment on certain health plans that starts at $8 billion in 2014 and increases to $14.3 billion by 2018, with adjustments based on premium growth in the following years. The tax applies not just to commercial health plans, but also to those offering Medicaid, Medicare Advantage, and Part D coverage. Multi-Employer Welfare Arrangements, which are designed to provide small businesses with access to healthcare benefits on similar terms to large employers, are also subject to the tax. Stop-loss insurers aren't specifically included, but the IRS leaves the door open for future regulation of these plans.

The IRS also issued a final rule on the ACA's Medicare tax, which went into effect in 2013. The rule requires married couples making more than $250,000 and single individuals making more than $200,000 a year to pay an additional 0.9% tax on wages and self-employed income.

HRI impact analysis: The industry tax is expected to be passed along to consumers in the form of higher premiums. While insurers have already adjusted for the tax in 2014 premium rates, the annual increase will nonetheless put added cost pressure on the industry in future years. As consumers gain more control over how their healthcare dollar is spent, health plans will be forced to look for ways to keep down prices to stay competitive. For more on how the health industry is changing in response to reform, see HRI's *Health Exchanges: Open for business* reports.

Federal SHOP online enrollment delayed to 2014

The Thanksgiving holiday came with another ACA implementation delay: this time for small business exchange enrollment. The SHOP online purchasing experience has been delayed until November 2014. States running their own exchanges may offer online enrollment if they are ready, but they aren't required to do so until next year. In 2014, small employers in states without working online enrollment may use a broker, agent, or insurer to enroll in coverage via a paper application.

Upcoming events & deadlines

- **December 9** – Measure Applications Partnership (MAP) preliminary comments due on provider experiences for proposed new measures for Medicare quality and performance assessment.
- **December 10 –** Public workshop sponsored by the Federal Trade Commission examining the impact of recent regulations and legislation on competition in the biologic drug market.
- **December 19** – CMS Special Open Door Forum on discussion of the Hospital Inpatient Admission Order and Certification and 2 Midnight Benchmark rules for Inpatient Hospital Admissions.
- **December 23** – Extended deadline for consumers to sign up for health insurance coverage through the health insurance exchanges for coverage beginning January 1.
- **December 26** – Comments due on proposed HHS rule that sets payment parameters and oversight provisions for the 2015 open enrollment period.
- **January 27 –** Comments due for Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system rates for CY 2014.

Quote of the week

"The United States should be at the forefront of new discoveries into how to put HIV into long-term remission without requiring lifelong therapies, or better yet, eliminate it completely," President Barack Obama said during the unveiling of a new $100 million commitment to find new therapies for HIV.

In the news

A recent article from the *The New York Times,* outlining the ongoing conversation on opaque hospital billing practices in the United States, stated that an average inpatient hospital one-day stay in the United States costs $4,000 or more—five times the charge in many other developed countries.

Factually correct

1.46 million – the number of people who applied and were found eligible for Medicaid or the Children's Health Insurance Program in October, far more than had selected a private health plan in the new insurance marketplace, according to *The New York Times*.

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