HRI as we see it
Weekly insights from the Health Research Institute pwc.com/hri

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Week of 5/19/2014

This week's regulatory and legislative news:

- **Final exchange rule aims to temper 2015 premium increases**
- **CMS proposes one-year reprieve for providers on meaningful use requirements**
- **Hospitals, suppliers struggle with saline shortage**
- **Pharma deals focus on fortifying product lines**
- **CMS scales back rule for Part D plans**
- **Hispanics a growing force in the New Health Economy**
- ***HRI as we see it* will not publish the week of 05/26/14**

Final exchange rule aims to temper 2015 premium increases

Federal health officials last week released a final set of rules for insurers offering exchange coverage in 2015, addressing questions regarding risk corridors, quality reporting measures, and the role of "navigators" who help individuals enroll in coverage. Released on May 16 by CMS, the final rule cements more than a dozen policies introduced this year in its Notice of Benefit and Payment Parameters for 2015 and in other proposed rules. The directive arrives as states rethink investments in the new marketplaces. Nevada Gov. Brian Sandoval last week said he would scrap the state's exchange in favor of the federally-run HealthCare.gov, joining Oregon, Maryland and Massachusetts in making the switch this year.

HRI impact analysis: In its more than 400-page rule, CMS aims to boost insurers' comfort level with exchanges as they head into the second full year of operation and to help tamp down expected premium increases. The rule creates a second stream of funding for the ACA's temporary risk corridor program, allowing insurers to recoup money if they incur financial losses covering more sick people than healthy ones. The rule also finalizes a 2% increase in administrative costs and profits in the risk corridor formula, another move that could alleviate pressure on insurers. The rule also could diminish the impact of the ACA's small business exchanges, delaying until 2016 the employee choice provision on the so-called SHOP exchanges and greatly reducing the incentive for employers and their workers to participate.

CMS proposes one-year reprieve for providers on meaningful use requirements

Hospitals and physicians will have an extra year to meet more rigorous requirements under CMS' Electronic Health Record (EHR) incentive program. Under the program, healthcare providers can qualify for grants to help purchase and implement EHRs, but must first meet federal "meaningful use" requirements. There are three stages to illustrate meaningful use, with each one meant to demonstrate providers' increasing ability to use the technology. CMS issued a proposed rule this week extending the second stage of the program's obligations in response to providers who have had difficulty meeting stage two requirements. The proposed rule also allows providers to qualify for incentive payments using 2011 EHRs. Providers were expected to upgrade to newer EHR technology, but have been hampered by vendor backlogs. Providers can continue to use older versions but will be expected to update them by 2015.

HRI impact analysis: The meaningful use delay was cheered by providers struggling with the program. The use of EHRs among office-based physicians jumped from 48% in 2009 to 78% last year. Yet eight in 10 physicians planning to participate in Medicare's incentive program lack systems supporting the core objectives to meet the second stage of the initiative, according to data released by the CDC. For

example, one core objective is to generate and transmit prescriptions electronically. Effective use of EHRs is a linchpin of better care delivery in the value-based New Health Economy. Hospitals and physicians must invest in the equipment and software necessary to comply and in personnel able to make it work.

Hospitals, suppliers struggle with saline shortage

Hospitals are running low on saline solution, one of the most common products used to deliver care. During the past six months, two primary suppliers have experienced manufacturing problems that temporarily halted production of the product, used to hydrate patients intravenously, among other uses. The problem was compounded by harsh winter conditions in the US, which hampered distribution, and a spike in demand during flu season. The FDA is working with manufacturers to speed production and find alternate sources, including importing saline solution from foreign facilities.

HRI impact analysis: The saline shortage is one of many US drug shortages. As part of the 2012 Food and Drug Administration Safety and Innovation Act, Congress requires manufacturers to notify the FDA as they become aware of shortages. While advance notification can speed the FDA's response, the agency and industry continue to grapple with preventing shortages. In the meantime, the FDA has inspected overseas facilities producing saline, allowing some importation. Some hospital resource managers are negotiating deliveries directly with manufacturers, and some are cutting back where they can on its use or sharing supplies across departments.

Pharma deals focus on fortifying product lines

In recent weeks, drugmakers have sought deals with competitors to form strategic partnerships and bolster product portfolios. Following a strong 2013, pharma/life sciences deals have continued to rise, with merger and acquisition volume increasing 53% during the last two fiscal quarters. Recently, Pfizer proposed to purchase UK-based AstraZeneca for $119 billion, Bayer is selling its device unit to Boston Scientific, Valeant offered to purchase Botox-producer Allergan, and a series of transactions were announced among pharma giants Eli Lilly, GlaxoSmithKline, and Novartis.

HRI Impact Analysis: According to PwC's quarterly report on deals in the pharmaceutical and life sciences sector, deal activity is expected to continue to climb as economic conditions stabilize and drugmakers assess core capabilities. Manufacturers are aiming to cut costs and add value for patients by eliminating underperforming business units and scaling up existing marketing, research and operations capabilities. Increased expertise in specific therapeutic areas may lead to greater understanding of disease states and patient needs, improving the efficiency of R&D. Drugmakers also may pursue transactions for other reasons, such as using cash overseas. US manufacturers may use capital to purchase a foreign competitor and take advantage of lower corporate tax rates abroad, a practice referred to as inversions.

CMS scales back rule for Part D plans

A series of proposals have been scrapped by CMS after an outcry from lawmakers, insurers and consumer advocates. On Monday, CMS issued a final rule for Medicare prescription drug plans offered in 2015. The rule backs away from CMS's proposal to further limit the number of drug plans offered in each service area, allowing insurers to continue to offer a basic plan and two enhanced plans under the program known as Part D. The agency also is leaving intact a longstanding policy requiring insurers to cover drugs—such as antidepressants—in six protected classes. CMS also reversed course on a proposed requirement that health plans offer the same level of cost-sharing for prescriptions filled by preferred or non-preferred pharmacies after critics argued that the agency was interfering in negotiations between insurers and pharmacies.

HRI Impact Analysis: While CMS backed away from some controversial policies, it is moving forward with other significant changes. The agency will require prescribers to be enrolled in the Medicare program to have prescriptions covered. In a June 2013 report, the OIG reported that the Part D program inappropriately paid for drugs ordered by individuals without the authority to prescribe them. Prescribers also can have their enrollment revoked for engaging in abusive prescribing practices, such as

overprescribing painkillers. The agency also will grant greater access to pharmacy, prescriber, and prescription drug data to increase transparency.

Hispanics a growing force in the New Health Economy

More than 10 million Hispanics are eligible to gain health insurance coverage under the Affordable Care Act, representing unparalleled opportunity for businesses aiming to succeed in the New Health Economy. But netting the Hispanic consumer and their dollar will not be easy. Learn how in HRI's new report.

HRI as we see it will not publish the week of 05/26/14

HRI will not publish a regulatory newsletter for the week of 05/26/14. Publication will resume on Friday, June 6.

Upcoming events & deadlines

- **May 28** – PCORI/PwC webinar on exploring new models for research using health data
- **June 16** – Deadline to submit policy and legislative ideas on how the government can support technology adoption in healthcare programs
- **June 27** – 2015 federal exchange premium rate filing deadline for health insurers

Quote of the week

"We have to understand what went wrong…we need to make sure that we both learn from the mistakes of the exchanges that aren't working and learn from the exchanges that are," said Sylvia Mathews Burwell, the HHS secretary nominee, before the Senate Finance Committee. Burwell was approved by the committee on May 21, and a full Senate vote on her nomination is expected the first week of June.

In the news

A new JAMA Surgery study found that surgery patients covered by Medicaid arrive sicker, have more complications, and experience longer hospital stays than patients with private health insurance. The study highlights potential financial and clinical implications for hospitals in states that expanded Medicaid as part of the ACA.

Factually correct

4.8 Million – the number of people newly enrolled in Medicaid and CHIP since open enrollment began for the health insurance exchanges in October 2013.

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