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Weekly insights from the Health Research Institute pwc.com/hri

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Week of 7/14/2014

This week's regulatory and legislative news:

- **Medicaid investment to help spur state innovation**
- **CMS proposes tweak to 'two-midnight' rule**
- **'Predictive analytics' could raise ethical issues, researchers warn**
- **FDASIA hits two-year mark as Congress mulls new reforms**
- **FDA sheds light on social media rules for pharma**

Medicaid investment to help spur state innovation

HHS announced on Monday the launch of a new initiative, the Medicaid Innovation Accelerator Program, to support states in improving Medicaid payment and service delivery systems. HHS is investing more than $100 million in technical support over five years to pay for state innovation and strengthen specific program areas, including new care delivery models, data analytics, quality measurement, and program evaluation. The agency hopes to share lessons learned among states in real time.

HRI impact analysis: As Medicaid enrollments continue to increase due to the ACA's Medicaid expansion, states are looking for ways to stretch already limited dollars. Even states that did not expand Medicaid are experiencing increased enrollment under existing programs due to outreach to previously eligible beneficiaries. Looking for innovative ways to improve care delivery, access, and outcomes is one idea being discussed. States are particularly focused on targeting areas of critical need, such as beneficiaries with high disease or spending burden and populations with large heath disparities. New care delivery models that provide services beyond traditional healthcare settings, such as mobile apps and retail clinics, may help manage patients' health outside of costly care settings and improve access to services. According to an HRI survey, 35% of respondents reported that they had sought care at a medical clinic in a pharmacy or retail store within the last year.

CMS proposes tweak to 'two-midnight' rule

Physicians would not have to certify "medical necessity" for short inpatient admissions under a measure included in Medicare's recently proposed hospital outpatient payment rule. As is, CMS requires physician certification and an admission order for all inpatient stays. The proposed rule, however, says the admission order alone is sufficient to support admitting a patient. If approved, the measure would effectively loosen a provision in Medicare's controversial "two-midnight" rule, which altered short-term admission requirements more than a year ago. Physician certification, however, would still be required for admissions that last 20 days or more, or for some outlier cases.

HRI impact analysis: Some policy analysts believe the proposed change may ultimately lead to CMS scrapping its current policy that requires a patient to spend two nights in a hospital in order to qualify for hospital payments. In May, CMS officials told lawmakers that it would ask hospital groups for alternatives to the two-midnight rule. Even so, the proposal could have a more immediate impact. In response to the rule, many hospitals and health systems spent a significant amount of time developing an electronic response for physician certification, which would not be needed if the provision goes away.

'Predictive analytics' could raise ethical issues, researchers warn

Health systems across the US are adopting predictive analytics programs as a way to manage the care of a specific patient population to keep them healthier and reduce the rate of hospital readmissions. But now some of the industry's biggest champions of these data-driven programs are raising legal and ethical concerns that could arise when doctors look past the individual patient in favor of treating populations. For example, since predictive models are designed to make recommendations for a wide swath of patients, an algorithm may suggest withholding a potentially beneficial treatment from some people because there is a lower probability that they will benefit from it. Researchers also raised concerns that the reliance on analytics programs could work against sicker or uninsured individuals across a large population of patients.

HRI impact analysis: Writing in the journal *Health Affairs*, clinical and legal experts say it is critical that health systems that adopt predictive modeling include "patients and other stakeholders" from the start and ensure that collected health data is de-identified and in compliance with federal privacy laws. Additionally, the authors say that predictive programs should allow physicians the option to override or appeal recommendations when needed. These types of programs, and others that seek to harness the power of "big data," enable the medical advances of the new health economy and clear a path for non-traditional healthcare companies to compete for a share of the more than $2.8 trillion spent annually within the sector.

FDASIA hits two-year mark as Congress mulls new reforms

Two years after Congress passed a law overhauling the FDA, the House Energy and Commerce Committee is contemplating additional changes to the agency and its review process. July 9th marked the second anniversary of the Food and Drug Administration Safety and Innovation Act, known as FDASIA. The law primarily reauthorized the drug and device user fee programs that help fund FDA's reviews of medical products. And it required a number of other significant reforms, such as new rules to combat drug shortages, secure the global supply chain, and improve patient engagement. The agency developed a three-year plan to implement 137 different provisions, most of which are new guidance documents, rules, and reports. Continued implementation of the 140-page law will keep the FDA busy, even as Congress shifts to developing new legislation it's aiming to pass next year as part of its 21st Century Cures Initiative.

HRI impact analysis: Dr. Janet Woodcock, director of the Center for Drug Evaluation and Research at the FDA, recently spoke of progress on the patient-focused drug development program. The initiative solicits patient's perspectives on various diseases, such as sickle cell disease and fibromyalgia. The program looks at how a disease impacts a patient's daily life, the treatment benefits that matter most to patients, and the adequacy of available therapies. Drugmakers must also find ways to better incorporate patient views in the development process. In the new health economy, consumers are more engaged in every aspect of healthcare. Pharmaceutical companies that engage patients at every stage of the product lifecycle can create longer-lasting consumer relationships and improve chances of product success when they're more in tune with consumer needs. For a better understanding of the customer experience in pharmaceuticals, see HRI's report: Getting closer to the patient.

FDA sheds light on social media rules for pharma

A new Spotlight from HRI examines recent draft guidance from the FDA on the use of social media by device and drugmakers. Life sciences companies may still face challenges as they explore working with social media. But the time and effort could be worth it, as social media offers organizations a unique opportunity to tap into the mindset of customers.

Upcoming events & deadlines

- **August 6** – PCORI application system opens for Fall 2014 cycle of funding announcements
- **August 12** – Deadline to submit ideas to the Senate Finance Committee on how to increase the transparency of healthcare data
- **August 15** – PCORI matchmaking app challenge application deadline
- **August 27** – Deadline for physicians and teaching hospitals to review and dispute data submitted by the drug industry under the Sunshine Act's Phase 2 of Open Payments

- **September 2** – Comments due for Medicare's proposed home health payment rule and quality reporting initiatives
- **September 5** – Comments due for Medicare's proposed Hospital Outpatient and Ambulatory Surgical Center payment rules

Quote of the week

"This really brings high technology and combines it with biology – and that's a very exciting combination for us," said Novartis CEO Joe Jimenez on the recent partnership with Google to create smart contact lenses for people with diabetes. The lenses would measure glucose levels in tear fluid and send data to a wireless device, enabling patients to manage their chronic condition through a non-invasive sensor.

In the news

In its latest long-term economic forecast, the CBO projects that Medicare will grow at a rate slow enough to avoid triggering cost-cutting recommendations from the Independent Payment Advisory Board (IPAB). The controversial panel, which has yet to take shape, was born out of the ACA and is charged with slowing the growth of Medicare spending.

Factually correct

6.8% – The projected healthcare spending growth rate in the employer-sponsored market in 2015 prior to benefit design change, according to HRI's Behind the Numbers report.

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