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

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Week of 3/31/2014

This week's regulatory and legislative news:

- **ICD-10 delay leaves industry with new questions**
- **More states move forward with 'alternative' Medicaid expansion**
- **Generic drug labeling proposal sparks debate**
- **FDA updates food labels to help consumers**
- **Industry firsts: J&J, Sanofi Aventis create new C-suite roles for design, patients**

ICD-10 delay leaves industry with new questions

Hospitals, health systems, and technology associations are looking for additional guidance after President Obama signed legislation delaying the move to the ICD-10 coding set. ICD codes are used by the health industry to classify patient diagnoses. The long-awaited move from the older ICD-9 to the newer ICD-10 set will allow more specification of diagnosis because the coding set is larger. Many health system leaders balked at the one-year delay, warning government officials that it will cost time, money, and even personnel. Under the new law, the delay—which extends to at least October 1, 2015—could cost the industry up to $6 billion, according to the American Health Information Management Association. Meanwhile, the move has led to new questions: hospital executives want to know whether they can use the ICD-10 codes with private insurers while using the older set for their Medicare patients, and they are unsure whether or not they can continue to "dual code" using both sets. As of midweek, however, CMS had yet to update its ICD-10 transition page.

HRI impact analysis: Many hospital systems have already purchased expensive new software and signed contracts with insurers, coders, and other vendors as part of the move to ICD-10. In addition, hours have been spent training coders, physicians, and other staff on how to bill using the newer code set. Even with the one-year delay, many health systems will continue to move forward with the planned transition schedules to ICD-10. Though it costs money, hospitals who have the budget may want to continue to dual code procedures, which will give them additional time to fully master the new codes. The delay could offer some relief to smaller practices—especially those not yet ready for the cost or efforts associated with ICD-10 implementation.

More states move forward with 'alternative' Medicaid expansion

Both New Hampshire and Utah are moving forward to expand Medicaid through private insurance—but only on a temporary basis. New Hampshire Gov. Maggie Hassan signed legislation to expand Medicaid, pending federal approval of a two-and-a-half year pilot program that would cover about 50,000 residents through subsidized employer-based coverage and managed care. The program will end automatically once the federal government no longer covers 100% of the cost in 2018. In Utah, state leaders recently pitched their "Healthy Utah" program to federal officials—a three-year demonstration which would block grant $258 million toward private health plans for low-income individuals. Twenty six states and the District of Columbia are expanding Medicaid under the ACA, and six states are pursuing alternative expansion models.

HRI impact analysis: The temporary pilot programs pursued by New Hampshire, Utah, and other states are a stopgap solution to an ongoing dilemma—some state officials are politically wary of supporting the ACA, but are cognizant that their residents are financing other state expansions through federal taxes.

The federal government will continue to pay at least 90% of Medicaid costs for states that expand the program. The alternative expansions, even if temporary, will be a likely win for managed care companies, which stand to pick up thousands of additional customers per state.

Generic drug labeling proposal sparks debate

The FDA's proposal to allow generic drugmakers to update their warning labels is drawing interest across the pharmaceutical sector. Currently, generic drugmakers are not allowed to change their labels because the law requires generic and branded drug labels to be identical. The proposed rule would allow generic manufacturers to update their labels if new safety data becomes known. On Tuesday, a key Congressional committee held a hearing to examine the issue and hear from stakeholders including FDA drug chief, Dr. Janet Woodcock. The comment period on the proposal, which closed on March 13, generated submissions from 63 organizations, including industry and consumer groups.

HRI impact analysis: The FDA was prompted to change its regulations for generic drug labels after the Supreme Court ruled last summer that generic manufacturers couldn't be held liable for failure to warn patients about drug risks. If the proposed rule is implemented, it would reverse the Court's ruling and could once again make generic drugmakers susceptible to lawsuits under state tort laws, forcing them to beef up safety and reporting efforts. Some groups are concerned that the proposal could lead to confusion among patients and providers if branded and generic drugs have different labels. According to HRI's report on the customer experience in pharmaceuticals, 13% of patients are frustrated by confusing medication information.

FDA updates food labels to help consumers

The FDA made headlines when it issued a proposal to update the nutrition facts box found on packaged foods. The proposal marks the first major revision to the nutrition content requirements since they were first mandated more than 20 years ago. According to agency officials, consumers' eating habits have changed significantly since then, necessitating the revision. Some of the label changes proposed by the FDA would require information about the amount of added sugars in a food product. The FDA also wants to update serving sizes and calorie counts to accurately reflect typical portion sizes—steps the agency views as important in addressing public health problems such as obesity and heart disease.

HRI impact analysis: This is the latest effort by the FDA to provide consumers with more information about the food and beverages they consume. The agency previously issued two proposed rules to ensure calorie labeling on menus in restaurants and on food dispensed from vending machines, which was a requirement under the ACA. In the new health economy, consumers will have access to more information that empowers them to make informed decisions about everything from the food they eat to the hospitals at which they are treated. The push for greater transparency is giving rise to a crop of new players that specialize in turning cost and quality data into something much more user-friendly. During a three-year span, more than $400 million in venture capital has flowed to start-up companies eager to jump into the transparency business.

Industry firsts: J&J, Sanofi Aventis create new C-suite roles for design, patients

Within the past two weeks, two pharmaceutical giants have created leadership positions previously unheard of in the industry. Johnson & Johnson's new chief design officer will integrate design into product development and marketing, focusing on prescription drug packaging that improves adherence and more appealing product designs for over-the-counter drugs. This week, Sanofi Aventis also announced an appointment for their new chief patient officer role. The chief patient officer will be responsible for ensuring patient and caregiver needs are represented and met throughout all stages of product development and marketing.

HRI impact analysis: While many drug companies have touted their patient-centricity, there has been debate about what that means. Creating new leadership positions is one way to prioritize consumer needs. Consumers are becoming increasingly empowered and participatory in their care, and they want more information and engagement with drug companies; in fact, a majority (57%) of consumers surveyed by HRI said they want online medication support along with their prescription. In response, innovative drug companies will be looking "beyond the pill" by investing in consumer oriented services and solutions.

Upcoming events & deadlines

- **April 15** – Deadline for the uninsured to sign up for health insurance on federal exchanges by indicating that they had previously attempted to enroll. This "special enrollment period" allows individuals to complete their enrollment.
- **April 30** – Extended deadline for those in the Pre-Existing Condition Insurance Plan to gain coverage through exchanges.
- **May 31** – 2015 exchange premium rate filing deadline for health insurers.

Quote of the week

"Access to meaningful price information is more important than ever as consumers continue to take on a rising share of expenses," said Suzanne Delbanco, executive director of the Catalyst for Payment Reform. The center's annual report card, which measures consumer access to health pricing information on a state-by-state basis, gave 45 states an "F" rating in this past year, up from 29 "F" ratings in 2012. No states received an "A" rating.

In the news

A large study published by the Journal of the American College of Cardiology found that a simple blood test combined with an electrocardiogram is 99% accurate in diagnosing heart attacks, allowing emergency rooms to confidently determine which patients can be safely discharged. Study contributors believe that they can avoid 20-25% of hospital admissions related to chest pain.

Factually correct

7.1 million – The total number of Americans who signed up for health insurance by the end of the March 31 enrollment deadline.

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