



Week of 4/21/2014

This week's regulatory and legislative news:

- FDA announces expedited access program for medical devices
- New insurance payment option underscores retailer opportunities in healthcare market
- Social factors determine readmissions more so than quality
- Providers reap billions in EHR incentive payments
- Social media amplifies patient voices

FDA announces expedited access program for medical devices

On Wednesday, the [FDA released a guidance document](#) outlining its plans for a new program intended to speed approval for innovative medical devices. According to an [agency press release](#), the program “[features earlier and more interactive engagement with FDA staff](#)”—including the involvement of senior management and a collaboratively developed plan for collecting the scientific and clinical data to support approval.” Devices that are eligible for participation must be intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition. For example, the device could be a genetic test that serves as an alternative to surgically removing tumors for sampling. [In a separate guidance](#) also released on Wednesday, the agency spelled out its policy on data collection for medical devices. The guidance clarifies the type of data needed to win approval versus the data FDA might seek to ensure the long-term safety of a medical product once it’s marketed to patients.

HRI impact analysis: The new program builds on existing FDA initiatives that speed access to treatments for unmet medical needs. In 2012, the [Food and Drug Administration Safety and Innovation Act](#) established a similar program for breakthrough pharmaceutical therapies. According to HRI’s report, [Medtech companies prepare for an innovation makeover](#), industry leaders anticipate a more balanced focus between incremental innovation and radical breakthroughs during the next three years. But the new FDA program may alter that balance and spur the industry to develop more radically innovative devices.

New insurance payment option underscores retailer opportunities in healthcare market

Last week, [CVS announced](#) that it will allow shoppers to pay their health insurance premiums at the store’s registers with cash, credit, and debit cards with special customer-specific barcodes. The company isn’t disclosing its insurance partners yet, but it is expected to offer the service for a variety of health plans. Although retail health insurance bill-paying isn’t unique—some already offer cash-only bill pay through vendors such as MoneyGram—CVS’s move is another indicator that retailers can be a primary contact point for healthcare consumers. Last year, [Walgreens teamed up](#) with the Blue Cross Blue Shield Association to educate consumers on health insurance enrollment, and other [similar partnerships](#) followed. Retail clinics may also gain customer popularity as access to traditional providers becomes more limited by cost and bandwidth: [a 2013 HRI survey](#) found that 23% of consumers had sought treatment at a retail clinic.

HRI impact analysis: Retailers and other non-traditional healthcare companies are likely to capture a bigger part of the [\\$2.8 trillion healthcare market in the new health economy](#). They already have an advantage over other players in sheer number of physical retail locations, convenient hours and vast troves of customer data. These factors may position them to lead in delivering an efficient, integrated healthcare experience in an industry historically plagued by fragmentation, waste, and inefficiency.

Social factors determine readmissions more so than quality

Hospital readmission rates may have less to do with the quality of care being provided than they do with the location of a provider and a range of other community factors. According to a new [Commonwealth Fund study](#), nearly 60% of the variation in readmissions can be attributed to factors such as age, employment, marriage status, and physician access. In fact, individual hospital performance accounts for only two-fifths of the readmissions for patients treated for heart attacks, heart failure, or pneumonia. The study found that hospitals in communities with a high percentage of Medicare-aged seniors and high unemployment rates tend to readmit patients more frequently. CMS has tracked readmissions since the late 2000s, but has just recently begun to impose financial penalties on hospitals that fail to reduce preventable return visits. [Despite fewer overall readmissions](#), CMS fined about 2,225 hospitals a total of \$227 million last year. But the study's authors suggest that the penalties may be misguided, since community factors appear to explain much of the variation in readmission rates.

HRI impact analysis: Physicians and nurses have long raised concerns about their limited ability to affect patients once they leave the hospital. Providers are beginning to gauge the types of patients that are likely to be readmitted [through the use of clinical informatics](#), which assesses risk based on medical conditions. Now data specialists are beginning to track social factors as well, such as where a patient lives or his or her insurance status to determine medical risk. Some providers are using predictive analytics to reach patients before they become sick. For example, Carilion Health System [uses computer software to search physicians' notes](#) for information that may not make it into the patient's electronic medical record, such as the number of cigarettes a person smokes each day. In one year, the program identified about 3,500 patients out of 8,500 who were at risk of heart disease.

Providers reap billions in EHR incentive payments

CMS has paid more than \$13.7 billion to 297,466 physicians and hospitals enrolled in the three-year-old Medicare and Medicaid electronic health record (EHR) incentive programs, [according to new data released this month by the agency](#). Under the program—which requires the “meaningful use” of EHRs—eligible physicians and hospitals can potentially earn tens of thousands of dollars if they achieve certain benchmarks during the course of six years. The program has shown increased enrollment, with about 90% of eligible hospitals and about 65% of participating physicians receiving a bonus payment. Depending on the program, Medicare or Medicaid pays physicians, nurse midwives, dentists, nurse practitioners and others to purchase and [implement electronic health records](#). Providers must then demonstrate that they are using those systems to improve the quality of care through electronic prescribing, medication reconciliation, electronic lab test results, and other clinical benchmarks.

HRI impact analysis: The relatively high EHR adoption rates show increasing comfort among providers in the use of electronic records. Clinicians most commonly used electronic records to conduct formulary checks, submit data to immunization registries, and maintain patient lists. The least used electronic capabilities, however, deal with care coordination and reportable lab results. CMS officials say that on average, physicians greatly exceeded each of the benchmarks. Skilled nursing facilities, rehab centers, and long-term care programs are excluded from the program, stoking concerns that care may continue to be fragmented for lack of electronic data sharing across all settings.

Social media amplifies patient voices

Patients and their families are harnessing the power of social media to gain access to experimental treatments from drugmakers and the FDA. The parents of a seven year-old Virginia boy suffering from a life-threatening infection recently convinced a biotech company to provide their son with a new treatment after [soliciting the public's support on Facebook and Twitter](#). After denying a request for access to the drug through its [compassionate use program](#), the company worked with the FDA to set up a new clinical trial to investigate how the medicine works in children. The agency is [reportedly working out a similar agreement](#) with another drugmaker for a novel medication for Duchenne muscular dystrophy after families used online and social media tools to raise awareness.

HRI impact analysis: Patients advocating for access to experimental therapies is not a new phenomenon. But the tools at their disposal have evolved. HRI's report, [Social media “likes” healthcare](#),

explains how platforms such as Twitter and Facebook are changing how consumers interact with healthcare organizations and regulators. Patients and advocacy groups have traditionally used these forums to gather and share information about treatments and clinicians. Now they are using crowdsourcing techniques to also influence regulatory and payment decisions about new medicines. Organizations across the health industries must engage with consumers online as social media becomes increasingly important. That may be challenging for drugmakers whose communications with consumers are tightly regulated. But there can be benefits, such as better targeting of patients for [recruitment into clinical trials](#) and access to patient-reported outcomes.

Upcoming events & deadlines

- **April 30** – [Extended deadline](#) for those in the Pre-Existing Condition Insurance Plan to gain coverage through the exchanges.
- **May 8 & 9** – FDA's [public workshop on implementation of the Drug Quality and Security Act](#) (i.e., track and trace for Rx drugs).
- **May 13-15** – FDA's [public workshop](#) on the risk-based regulatory framework and strategy for health information technology.
- **June 27** – 2015 federal exchange premium rate filing deadline for health insurers.

Quote of the week

"We have been trying to keep our eyes and ears attuned to what the news is, and we have not gotten anything official," said American Health Information Management Association (AHIMA) CEO, Lynn Thomas Gordan, in an interview. AHIMA, among other organizations, is still [looking to CMS for guidance on the ICD-10 delay](#) that was included in a bill passed two weeks ago.

In the news

A new study by the Robert Wood Johnson Foundation found that the [number of uninsured children](#) has decreased greatly over the past four years—from 9.7% to 7.5%, or approximately 1.8 million children through 2012. Researchers attribute the increase to the expansion of public programs such as Medicaid and CHIP.

Factually correct

\$65 billion – A conservative estimate of the value of the [pharmaceutical deals](#) that have taken place in the last month, including a joint venture deal between Novartis, GlaxoSmithKline, and Eli Lilly.

Contacts

Benjamin Isgur
Director
benjamin.isgur@us.pwc.com
(214) 754-5091

Bobby Clark
Senior Manager - Pharma/Life Sciences
robert.j.clark@us.pwc.com
(202) 312-7947

Matthew DoBias
Senior Manager - Provider
matthew.r.dobias@us.pwc.com
(202) 312-7946

Caitlin Sweany
Senior Manager - Payer
caitlin.sweany@us.pwc.com
(202) 346-5241

Aashima Kapoor
Research Analyst
aashima.kapoor@us.pwc.com
(973) 236-4798

[HRI Online](#)

© 2014 PricewaterhouseCoopers LLP, a Delaware limited liability partnership. All rights reserved. PwC refers to the US member firm, and may sometimes refer to the PwC network. Each member firm is a separate legal entity. Please see www.pwc.com/structure for further details. This content is for general information purposes only, and should not be used as a substitute for consultation with professional advisors.