



Week of 6/16/2014

This week's regulatory and legislative news:

- **FDA details new social media requirements**
- **Early 2015 exchange rate filings show modest increases**
- **Health data breaches nearly doubled during two years**
- **Lawmakers ask healthcare groups to take lead on transparency efforts**
- **Key advisory body examines Medicaid's future**

FDA details new social media requirements

At the recent Drug Industry Association's annual conference, FDA officials released new social media guidance for the industry. The draft guidance follows an [initial document](#) released in January that provides recommendations on how to submit information to the FDA via interactive websites, blogs, and online patient forums. The guidance released this week covers two new topics. In [one document](#), the FDA provides industry recommendations on how to appropriately share product information on platforms that have specific length limits, such as Twitter's 140-character maximum. The [second document](#) tells manufacturers how to correct misinformation on third-party sites. For example, Wikipedia pages that rely on content generated by third parties may overstate the benefits or risks of a drug. Stakeholders have 90 days to submit comments on both draft documents.

HRI impact analysis: The pharmaceutical industry has been awaiting the FDA's guidance on using social media in a way that does not violate the agency's rules on advertising and promotion. The new guidance answers many questions, but it also raises new ones. For example, the FDA guidance suggests how a company can correct misinformation posted on social media, but it does not specify when a company should act. Manufacturers will need to consider a range of topics that go beyond FDA compliance as they confront issues that may arise as a result of social media use, such as assigning product liability. Eighty-five percent of young adults report they are influenced by information found on social media sites. But an [HRI survey](#) found that less than 30% of pharmaceutical companies have Facebook pages in which patients can post questions or experiences.

Early 2015 exchange rate filings show modest increases

Health exchange plan rates in 2015 could increase by an average of 7%, according to new analysis by [HRI](#). The preliminary numbers were arrived at by analyzing the early rate filings of more than a dozen states. Actual rate filings in individual states vary widely, ranging from a 23% decrease in Arizona to a 46.3% increase in Indiana. Though posted monthly rates are in the mid-\$300s on average, most consumers will pay significantly less. An [HHS report](#) this week indicated that consumers who bought plans in 2014 paid about 76% less than the full premium, reducing their out-of-pocket payments to below \$100 a month.

HRI impact analysis: Initial 2015 filings show that the overall exchange market avoided a widely anticipated double-digit rate hike. However, the large variation among states indicates that some insurers are experiencing growing pains as they adjust to the needs of their new members. Insurers were required to submit 2015 bids just months after their new enrollees started accessing coverage, so these rates are limited in how accurately they reflect insurers' true costs, and may still be revised. Prices are expected to

normalize during the next few years as the exchange market stabilizes and health plans are better able to predict their costs. In the meantime, many consumers are unlikely to see a major impact on their wallets.

Health data breaches nearly doubled during two years

Confidential health information on more than 15 million people may have been lost, stolen, or mistakenly disclosed between 2011 and 2012, according to a new [report](#) by HHS's Office of Civil Rights. Federal health officials were alerted to more than 458 cases in which a breach occurred that affected 500 people or more, and about 47,000 cases in which sensitive information about a smaller group was mishandled. The latest data shows a significant spike in both the number of breaches and people affected. Legislation passed in 2009 [greatly expanded](#) who is required to notify individuals, HHS, and even the media when protected health information is acquired, used, or disclosed in a manner not permitted under HIPAA.

HRI impact analysis: Hospitals, doctors, and clinicians accounted for about 65% of the reported breaches, while business associates and health plans were a distant second and third, respectively. The majority of those breaches were related to theft, either of an electronic or portable device, or of paper health records, the government found. Unauthorized access or disclosure of data and the loss of health records were also cited. The increase in the number of breaches puts increased focus on risk analysis and management—especially on potential vulnerabilities among [providers and others](#) who house protected patient data.

Lawmakers ask healthcare groups to take lead on transparency efforts

A key Senate panel is asking hospitals, physicians, and consumer advocacy groups for ideas on how to make cost and quality data clearer and more readily available to the general public. The Senate Finance Committee, in a [letter](#) sent June 12 to more than 200 healthcare stakeholders, asked for recommendations regarding what type of data should be made public, what form disclosures should take, and how to make cost and quality information from insurers and providers consistent. Stakeholders were asked to respond to the committee by August 12.

HRI impact analysis: Americans are paying more and more each year for their healthcare, yet few of them have the tools needed to make [educated choices](#) based on accurate pricing and quality data. Even so, new mobile technologies and novel approaches to primary care are changing how individuals shop for medical services—providers that are slow to adapt could lose patients to more tech-savvy practices. [HRI research](#) shows a growing willingness by consumers to seek care in non-traditional settings—and much of that movement is grounded in new medical technology.

Key advisory body examines Medicaid's future

An expert panel is urging Congress to extend the Children's Health Insurance Program (CHIP) for an additional two years. The [report from the Medicaid and CHIP Payment and Access Commission](#) (MACPAC) cites the critical role that CHIP plays in insuring eight million children. But the program is slated to end in 2015 with no plan to transition those currently enrolled into other coverage. Once CHIP ends, beneficiaries may be eligible for coverage in exchange plans, but they may also face enrollment challenges and changes to their benefits. The commission examined other issues that are important to the future of Medicaid, including long-term care and population health. The report notes that only six percent of Medicaid enrollees utilize long-term care, but they account for almost half of Medicaid spending. That amount is likely to grow as the population ages and people with disabilities live longer.

HRI impact analysis: The commission's recommendation to extend CHIP is necessary to investigate the implications of moving children out of the program. For example, it is not well known how benefits, copayments, and provider networks for [exchange plans](#) compare to existing CHIP plans. The landscape is equally complex when it comes to long-term care. Long-term care services and supports are provided through a patchwork of programs that vary by state. One area the commission plans to focus on in the future is the growth of managed long-term care programs. [According to HRI's top health industry issues report](#), 26 states are expected to have managed long-term care programs in place this year to help control costs. MACPAC announced that they will be visiting some of these states to learn more about how these programs operate.

Upcoming events & deadlines

- **June 27** – 2015 federal exchange premium rate filing deadline for health insurers
- **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

Quote of the week

“What we want to make sure is that patients know how their information is being used, how it’s being exchanged, and they need to be assured that all their information is going to continue to be private,” said Peter Ashkenaz, director of content and media in the Office of the National Coordinator for Health Information Technology.

In the news

After signing up millions in the first open enrollment period, CMS outlined the top two priorities for Year Two: helping newly insured individuals understand their coverage benefits and building on outreach strategies to capture those still uninsured. CMS says this will maintain momentum for new enrollments and ensure that covered people re-enroll in their plans. HHS recently launched a new initiative, “From Coverage to Care,” to help the newly insured navigate the healthcare system.

Factually correct

11 – The US ranking in overall health system quality when compared to 10 other western, industrialized nations in a recent report by The Commonwealth Fund.

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