



Week of 5/5/2014

This week's regulatory and legislative news:

- **New guidelines refine exchange enrollment and reporting**
- **Proposed payment rules tie higher rates to quality**
- **CMS to hospitals: Don't forget to disclose your charges**
- **Lawmakers, regulators seek ideas to spur medical innovation**
- **FDA examines communications with consumers**
- **Mobile behavioral health tracking provides insights to patients, providers**

New guidelines refine exchange enrollment and reporting

Late last week, HHS and IRS released guidance on special enrollment periods, insurance enrollment outside of the normal sign-up, mandate exemptions, and exchange reporting. Among those [now eligible](#) for a special enrollment: individuals with COBRA coverage after leaving their employer and those with plans that renew outside of the standard calendar year. People who mistakenly purchased coverage from the public exchanges in April—after the March 31 deadline—will be granted a hardship exemption. The final exchange reporting rule also details the specific personal information and health plan status that states need to [collect and report](#), both on “tax filers” and “responsible adults”—individuals who are in the same family but don’t request tax credits.

HRI impact analysis: While the official open enrollment season has recently ended, health insurers and exchanges must now shift to planning for next season and also managing current reporting requirements. The final reporting rule is intended to make it easier to reconcile advance premium tax credits—which are sent directly to insurers to offset health plan premiums—with consumers’ actual year-end tax credits. Since consumers are required to repay the difference when they file their taxes, the new rules may mean fewer financial challenges but more administrative work for the exchanges. For insurers, the expansion of special enrollment periods may add new complications to manage alongside rate submissions, technology upgrades, and other 2015 open enrollment planning.

Proposed payment rules tie higher rates to quality

Three proposed rules released earlier this month by CMS not only set fiscal 2015 payment rates for [skilled-nursing](#) facilities, [inpatient psychiatric](#) departments, and [hospice](#) care, but also underscore the government’s effort to improve outcomes through the reimbursement process. CMS is proposing to increase payments by 2%, 2.1%, and 1.3% respectively, but the agency wants to tie those higher rates to programs meant to improve the care coordination and management of Medicare patients. Hospice providers, for example, are required to begin using an experience of care survey next year, and some inpatient psychiatric facilities will participate in a new ACA-created quality reporting program.

HRI impact analysis: Industry stakeholders have 60 days to comment on the proposed rules, which are typically finalized in November. Each one includes a number of potential changes. For example, CMS is seeking feedback on a new proposal to coordinate drug coverage for hospice patients. [A 2012 report](#) found that Medicare drug plans were improperly billed for \$33 million worth of prescription drugs that should have been paid by hospice providers. Collectively, the proposed rules demonstrate a continued trend by CMS to use its [leverage as a purchaser](#) of care to drive quality improvement across a number of provider settings.

CMS to hospitals: Don't forget to disclose your charges

CMS is pushing hospitals to make [public how much they charge for routine medical procedures](#) in an effort to boost price transparency and provide consumers with the tools needed to make better informed healthcare decisions. Within the nearly 1,700-page proposed inpatient payment rule are guidelines requiring hospitals to either publicly display charges or produce a list on demand. The rule harkens back to the original provision that was included in the ACA. CMS wants the data to be updated at least annually. In the proposed rule, CMS said it wants hospitals to "undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be ... and to enable patients to compare charges for similar services across hospitals."

HRI impact analysis: Medicare is serious about its push for greater pricing transparency. Last year, [CMS released payment data](#) that showed significant variation in what hospitals charge for a number of common procedures across the US and even within the same community. The data also revealed that hospitals generally charge more for procedures than the amount set by Medicare. The [demand for clearer hospital pricing is expected to increase](#) as more Americans shoulder a higher share of their healthcare costs. Businesses, too, are pushing transparency initiatives.

Lawmakers, regulators seek ideas to spur medical innovation

Earlier this week, a bipartisan group of lawmakers hosted an innovation roundtable with top officials from the FDA and NIH. The event is part of a larger effort dubbed the [21st Century Cures](#) initiative, which will solicit ideas on how Congress can accelerate the discovery, development, and delivery of new treatments to patients. Citing advancements in genomics, digital technology, and personalized medicine, policy makers want to ensure that the nation's laws and regulations are not barriers to medical innovation. The initiative will examine funding for basic research, regulatory approval processes for drugs and devices, economic incentives, and other policy areas.

HRI impact analysis: The FDA review process is one area that could get increased attention. The agency has implemented programs to help get novel therapies into patients' hands quicker. Last week, the FDA [unveiled a pilot program](#) that will enable device companies to submit certain applications electronically, which could make the review process more efficient. Research and development remains a costly and time-consuming undertaking, forcing industry and regulators to look for ways to improve the [clinical trials process](#). Industry must take a more hands-on approach to managing its innovation agenda. According to [HRI's medical technology innovation scorecard](#), only 26% of pharmaceutical/life sciences and 14% of medtech companies manage innovation formally for maximum efficiency.

FDA examines communications with consumers

A key FDA advisory panel [held a two-day meeting](#) this week to examine how the agency communicates with consumers. The Risk Communication Advisory Committee discussed whether FDA's consumer updates are reaching the targeted population, and whether they are increasing awareness and understanding of risk messages. For example, the agency recently sent out an update educating consumers about the impact of [aspirin on reducing the risk of stroke](#) or having a heart attack. The panel will look at specifics such as the terminology and graphics it uses. It will also examine the use of different communication channels including social media.

HRI impact analysis: Regulators and healthcare organizations must have a strategy that accounts for consumers' communication preferences and information needs in the 21st century. To facilitate their decision making, consumers want timely access to accurate and easy-to-understand information. The rise of email, text messaging, and social media has [raised consumers' expectations](#) for speedy information on treatments. And [new entrants](#) are flocking to healthcare to help patients decipher complicated pricing and quality information.

Mobile behavioral health tracking provides insights to patients, providers

Designed to engage the patient, "[digital therapeutic](#)" mobile applications are emerging to help consumers manage chronic and behavioral illnesses that require consistent at-home monitoring. One example is an [app](#) that records inhaler puffs for asthmatics to help identify patterns of asthma attacks and potential

triggers. Similarly, [Recovery Record](#) helps patients with eating disorders self-monitor their food intake and their thoughts about eating, and connects them directly to dieticians.

HRI impact analysis: The increased use of [mobile medical devices](#) is a result of consumer demand for more insight into their health status and medical care. According to an [HRI survey](#), 59% of physicians and insurers believe that the use of mobile health applications will be widespread in the future. This technology would be especially effective for chronic and behavioral disease patients, whose long-term symptoms and care needs often go beyond the occasional physician check-up. The [CDC](#) reports that chronic disease accounts for the highest percentage of preventable healthcare cost and that effective disease management must begin in the home.

Upcoming events & deadlines

- **May 13-15** – FDA's [public workshop](#) on the risk-based regulatory framework and strategy for health information technology.
- **June 16** – Deadline to [submit](#) policy and legislative ideas on how the government can support technology adaptation in healthcare programs.
- **June 27** – 2015 federal exchange premium rate filing deadline for health insurers.

Quote of the week

"[W]ithout actuarial analysis, we really are shooting in the dark," said Wellpoint CEO Joe Swedish in a recent [Wall Street Journal](#) article about rate-setting in a post-ACA environment. Swedish is referring to the process in which actuaries calculate the pricing and premiums for insurance plans and products.

In the news

CMS announced this week that only four hospitals and 50 doctors have attested to [Stage 2 meaningful use](#) of electronic health records as of May 1. Hospitals that have completed two years of Stage 1 must meet stage 2 meaningful use criteria during FY2014 or face a reduction in Medicare reimbursements; physicians must do the same by the end of 2014.

Factually correct

8 million – The number of enrollees who [signed up on the public exchanges](#) between October 1 and April 19. The majority, 65%, selected a silver plan.

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