



Week of 2/24/2014

## ***This week's regulatory and legislative news:***

- CMS proposes Medicare Advantage cuts, methodology changes
- FDA turns attention to drug quality
- CMS faces opposition over Part D rule
- Cloud technology presents new challenges to providers
- Trauma patients less likely to be transferred if insured, study finds
- Samsung and UCSF announce center for digital health innovation

### **CMS proposes Medicare Advantage cuts, methodology changes**

Last Friday, CMS released its [2015 Medicare call letter](#)—an annual announcement that describes payment and program changes to Medicare Advantage (MA), Part D, and other specialized programs. Also covered are employer group waiver plans, retiree prescription drug plans that are offered only through employers or unions. The agency proposed payment changes that would cut reimbursements by at least 1.9%, according to industry analysts. The updates reflect a variety of changes, some precipitated by the ACA, which influence how plans are paid. Actual rates will be published on April 7. Among the changes faced by MA plans in 2015: the end of a three-year demonstration process giving plans more leniency on payments linked to quality scores and the integration of ICD-10 codes into 2015 plan risk scores.

**HRI impact analysis:** Industry advocates such as [America's Health Insurance Plans](#) oppose the payment cuts, arguing that they would hurt more than 15 million MA beneficiaries by causing higher premiums, sparser benefits and fewer plan and provider choices. Last year, CMS made an abrupt decision to [change its proposed 2.2% rate cut](#) to a 3.3% increase after experiencing strong pressure from the industry. With such precedent, CMS again may change course in its final rate release.

### **FDA turns attention to drug quality**

The FDA recently announced a spate of initiatives that will increase its oversight of drug quality. The agency plans to consolidate its enforcement of existing standards under a new Office of Pharmaceutical Quality. Currently, enforcement is spread throughout the agency among various centers and departments. The announcement came during [FDA commissioner Margaret Hamburg's visit to India](#). Upon returning home, Hamburg announced that the agency plans to increase inspections in India, acknowledging the growing importance India plays in supplying the [US drug market](#). The agency also unveiled [a new \\$20 million program to test generic drugs](#) for impurities and to ensure the medicines perform properly. The program will initially focus on five categories of medications: heart drugs, ADHD treatments, immunosuppressants, anti-seizure medicines, and antidepressants.

**HRI impact analysis:** The heightened vigilance follows mounting concerns from lawmakers about the safety of the nation's drug supply. [The House Energy and Commerce Committee](#) held a hearing on the issue this week. And late last year, Congress passed the Drug Quality and Security Act, which will be phased in over 10 years, culminating in an interoperable drug tracing system for the entire country. According to [HRI's top health industry issues report](#), the program could cost between \$10 and \$50 million per manufacturer. With FDA's new focus on quality enforcement, pharmaceutical and biotech

manufacturers should not waste time establishing executive-led governance structures focused on supply chain security and regulatory compliance.

### **CMS faces opposition over Part D rule**

Medicare officials are facing significant resistance over [a proposed rule](#) that would make several changes to the prescription drug program for seniors, known as Part D. The proposal would limit the number of drug plans insurers can offer to two plans in each service area with the aim of reducing confusion among beneficiaries during the enrollment process. But the proposed change has drawn the ire of lawmakers and industry officials who are concerned about limiting choice and stifling competition. The rule also removes protections guaranteeing access to certain categories of drugs, including anti-depressants and immunosuppressants. A key Congressional committee [held a hearing](#) on the controversial proposal this week and a group of legislators are threatening to introduce legislation blocking the rule if it is not withdrawn.

**HRI impact analysis:** Consumer advocates are concerned that removing the protections for classes of drugs could reduce options for patients. While insurers may be tempted to stop covering certain drugs, they'll need to weigh those decisions against the risk that beneficiaries may be drawn to plans with more generous coverage. [According to HRI's report on the customer experience in pharmaceuticals](#), 44% of consumers cited high costs as their number one frustration when it comes to treatment experience. Consumers have weathered prescription drug price increases averaging about 3.2% per year since 2005, according to the Consumer Price Index. As prices continue to climb, patients will be on the hunt for drug plans that cover the drugs they need, reducing their financial risk.

### **Cloud technology presents new challenges to providers**

As more health systems begin to store [private patient data](#) on [remote computer networks](#) known as the "cloud," legal experts warn that contracts between technology firms and healthcare providers—if not written correctly—could expose hospitals to greater liability if any private data is misused. "When you're looking at contracts—HIT contracts, cloud contracts—vendors are not your friends," Steven Fox, chair of the information technology practice group at the law firm Post & Schell, told attendees at the annual HIMSS conference this week. "They are your business partners." Fox, who also co-chairs the firm's data protection and breach practice group, said that in most cases contracts between providers and vendors are comprehensive. "But if it does go wrong, which happens plenty of times, you want the contract to reflect what the deal is and to give you some protection," he added. Fox said that some cloud vendors may not have fully secure servers or recovery programs if their data warehouses are damaged.

**HRI impact analysis:** As cloud technologies grow, so do risks. Providers should be extra careful during the due diligence process and when negotiating with cloud-based companies, because in many cases, they won't see the physical location where their private data is being stored, Fox said. Many cloud vendors are relatively new and may not have extensive security protocols in place. Others may not be able to cover the costs of recovery if a data breach occurs. Health system executives should ask tech companies where the data will be stored—overseas or in the US—and whether or not they plan to use the de-identified patient information. But, "just because it's de-identified doesn't mean there's no liability there," Fox warned, adding that contracts should be written to indemnify the hospital if the vendor uses the data.

### **Trauma patients less likely to be transferred if insured, study finds**

In a [new study published by JAMA Surgery](#), researchers found that in 4500 emergency room trauma cases across the US, insured patients taken to non-trauma hospitals were less likely to be transferred to trauma centers than their uninsured counterparts. Medicaid patients were 14% less likely and privately-insured patients were 11% less likely to be transferred to trauma facilities than those who were uninsured. Type of injury, hospital location, and age also appeared to influence transfer decisions. [Critics](#) say that other factors not considered by the study, such as patient preference, may have confounded the results.

**HRI impact analysis:** Though insurance status is likely not the sole decision for transferring trauma patients, the study suggests that it may be a contributing factor. While doctors often don't know a patient's insurance status, others—such as care managers—do, and they may help guide treatment decisions.

Previous research has shown that patients who receive care at a designated trauma center have a [25% lower risk of death](#). Providers and insurers can do a [better job of coordination and education](#) in this area to improve patient outcomes.

### **Samsung and UCSF announce center for digital health innovation**

Samsung Electronics Co. Ltd. and UCSF announced last week that they are forming a partnership to develop the [UCSF-Samsung Digital Health Innovations Lab](#) to develop new preventive health applications. Located at UCSF's Mission Bay campus, the lab will enable health and technology researchers to run clinical trials on mobile health technologies. The announcement follows a series of other healthcare announcements by technology leaders such as [Apple](#), which was granted a patent for an embedded heart rate monitor, and Verizon, which received FDA approval for a [remote health monitoring solution](#).

**HRI impact analysis:** The emergence of health partnerships with [technology companies](#) such as Samsung represents a shift toward new entrants into the healthcare arena. Strong partnerships, particularly in the [lucrative digital healthcare space](#), could accelerate innovation, define market place and customer segments faster, and further separate the winners in healthcare from their [competitors](#). More than 80% of medtech executives surveyed by HRI reported that [innovation](#) will be a competitive necessity in the next five years.

### **Upcoming events & deadlines**

- **March 7** – Deadline to submit letter of intent for latest round of [PCORI funding opportunities](#).
- **March 31** – Deadline for drug and device makers to [report payments](#) made between Aug. 1, 2013 and Dec. 31, 2013 under new sunshine rules.
- **March 31** – Open enrollment in health insurance exchanges scheduled to end for 2014.

### **Quote of the week**

"As people file their income taxes, tax preparers may be able to help enroll those who are eligible for marketplace plans," said [Robert Wood Johnson Foundation](#)'s Kathy Hempstead. "Since the majority of eligible filers use a tax preparer and file before March 31, this could be an effective route to boost enrollment."

### **In the news**

The obesity rate for children has decreased dramatically, *The New York Times* reports. The study, conducted by the CDC, found that childhood obesity has decreased 43% over the last decade. Representatives from the CDC noted that it is the first time they have seen any significant decrease in obesity in any group.

### **Factually correct**

37% - Americans who prefer an insurance plan that [costs less money](#) but offers a more limited provider network, according to a recent [Kaiser poll](#).

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