HRI as we see it
Weekly insights from the Health Research Institute pwc.com/hri

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This week's regulatory and legislative news:

- **FDA releases draft biosimilar guidance**
- **2015 individual plan rates in Virginia and Washington reveal modest changes**
- **Compliance hurdles may arise as CMS reduces regulatory burdens**
- **Public weighs in on plan to regulate HIT**
- **Apple set to enter healthcare market with new Healthbook application**
- **Hospitals face compliance, financial challenges under 'two-midnight' rule**

FDA releases draft biosimilar guidance

After years of waiting, drugmakers have a better understanding of some of the clinical testing requirements for biosimilar approval in the US. Biosimilars are replicas of biologics -- drugs that are derived from living organisms. This week, the FDA released draft guidance on clinical studies that can help demonstrate that a biosimilar has comparable characteristics to its biologic counterpart. To have a biosimilar approved, drugmakers must show that it has no clinically meaningful difference from the product it is based on in terms of safety, purity, and potency.

HRI impact analysis: Congress authorized the FDA to review and approve biosimilars as part of the ACA. But to date, no biosimilar has been approved in the US, in part because of a lack of guidance regarding clinical requirements. Comparatively, 18 biosimilars have been approved for use in Europe. The release of the FDA guidance may move drugmakers a step closer to eventually marketing biosimilars in this country. As regulatory requirements become known, development programs may accelerate. Having the right R&D talent in place will be critical. Purchasers are hopeful biosimilars can reduce costs by competing against high-priced innovative specialty drugs, though biosimilars may carry a high price tag themselves. Biosimilar manufacturers might be hesitant to offer the same steep discounts purchasers enjoy with traditional generic products due to development costs and regulatory hurdles.

2015 individual plan rates in Virginia and Washington reveal modest changes

Early 2015 proposed rate filings offer a glimpse at future rates for individual coverage on and off the public exchanges. In Washington, the weighted average rate change was 8.25%, the lowest average requested change in seven years. Individual plan changes ranged from -6.8% to 26%. Molina Healthcare submitted the state's only rate cut, due to competitive pressure, conservative pricing in 2014, and anticipation of healthy enrollees in 2015 as the mandate penalty increases. In Virginia, rate increases were reported from 3.3% to 22.4%. While the first batch of proposed rate changes seem on par with industry expectations, there will likely be significant variation across state markets. Rate submission due dates vary, but insurers in the 20 or so states that rely entirely on the federal government to review and approve marketplace plans must submit their applications by June 27.

HRI impact analysis: Health plans are basing their 2015 rate forecasts on member volume, early claims, and historical modeling. Substantial rate fluctuations either up or down could be related to lack of experience in the individual commercial market and pricing pressure from competitors. Other factors influencing 2015 rates include higher ACA fees, reduced protection from reinsurance, and overall medical

cost trend—a measure of healthcare spending growth. Insurance commissioners will also have to approve the proposed rates, which could impact final pricing.

Compliance hurdles may arise as CMS reduces regulatory burdens

An effort by CMS to lighten the regulatory load on health systems across the US may save about $660 million a year for rural hospitals, transplant centers, and a range of healthcare providers, according to the report. In a 201-page final rule released last week, CMS laid out plans to amend, alter, or otherwise scrap existing policies under its Conditions of Participation—the guidelines hospitals must follow to participate in Medicare. Under the rule, critical access hospitals, health centers, and rural clinics would no longer be required to have a physician onsite at least once every two weeks. Another provision would allow the radioactive dyes used during imaging procedures, radiopharmaceuticals, to be delivered without the supervision of a pharmacist or doctor. The rule also simplifies the accreditation process for certain transplant centers. In all, the rule includes more than two dozen changes to current regulations.

HRI impact analysis: Hospital groups lauded the move to provide regulatory relief regarding rules it sees as redundant or overly burdensome. Still, the changes could impact hospitals that must remain compliant with a host of accreditation organizations. For example, provisions that eliminate direct physician oversight of certain medical procedures could shift the compliance responsibility to staff who may not be as familiar with the health system's internal policies and procedures. And while technological advances led CMS to lift the requirement for rural hospitals and clinics to have a physician on-site every two weeks, they still have to comply with new telemedicine guidelines.

Public weighs in on plan to regulate HIT

Federal officials may need to revise a recent government proposal to regulate health information technology (HIT) after listening to feedback from industry representatives and consumers. Last month, the FDA, the Federal Communications Commission, and the Office of the National Coordinator for HIT released their recommendations to coordinate the government's oversight of HIT, including the growing mobile health market. Under the proposal, health technology would be subject to varying degrees of scrutiny from regulators based on its function and level of risk to patients. For example, the FDA would continue to oversee technology that works with medical devices such as remote alarms.

HRI impact analysis: The proposed framework attempts to balance the competing demands of promoting innovation, protecting patient safety and minimizing regulatory duplication. Industry, however, wants more concrete rules established under law by Congress. They cite concerns that future regulators could alter the proposed framework. Uncertain and complex regulations can be a significant barrier for new entrants as they try to navigate the regulatory maze. Consumer advocates are also concerned that manufacturers of products deemed low-risk might skimp on safety if they know they are not subject to FDA oversight.

Apple set to enter healthcare market with new Healthbook application

Apple is expected to move into the healthcare market with the release of its new application, Healthbook. Similar to Apple's Passbook application that stores travel and ticket information, Healthbook provides a centralized location for health and fitness data, including heart rate, blood pressure, activity levels, nutrition, blood sugar, and emergency contact information. Apple recently hired a number of medical and fitness professionals with experience in health monitoring and filed several patents for wearable devices. While the Healthbook will store health information, it is still unclear whether the data will come from third-party applications and devices and/or Apple's own wearable device, such as the much anticipated iWatch.

HRI impact analysis: Traditional technology companies are continuing to increase their focus on the healthcare market by expanding their product offerings and services. These new technologies collect data from healthcare professionals and consumers and then create a more convenient way for users to track and monitor health and fitness information. According to a recent HRI survey, 54.5% of consumers would be likely to check their vital signs at home with a device attached to their phone if it was less costly than a traditional office visit. Consumer-driven healthcare focusing on transparency, timeliness, and quality will

continue to attract new entrants to the healthcare market and provide a way to reshape how data is received and managed.

Hospitals face compliance, financial challenges under 'two-midnight' rule

Chief executives at some of the nation's largest health systems say Medicare's two-midnight rule may cost them millions of dollars in higher payments, further exacerbate a decline in inpatient admissions, and strain compliance as medical staff shoulder much of the reporting responsibility under the new policy. PwC's Health Research Institute (HRI) examines how hospital executives can mitigate its impact in a new Spotlight brief.

Upcoming events & deadlines

- **May 19** – Next cycle of PCORI pragmatic clinical studies funding opens
- **May 20** – House Subcommittee on Health hearing on current hospital issues in the Medicare program
- **May 28** – PCORI/PwC webinar on exploring new models for research using health data
- **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
- **August 15** – PCORI matchmaking app challenge application deadline

Quote of the week

"We are a Samsung company. Our mandate is to become No.1 in everything we enter into, so our long-term goal is to become a leading pharmaceutical company in the world," said Samsung Bioepis CEO Christopher Hansung Ko in a recent Bloomberg article. Samsung plans to invest at least $2 billion in biopharmaceuticals over the next several years and capitalize on the growing healthcare market for new entrants in technology and social media.

In the news

A new economic analysis suggests that allowing young adults to remain on their parents' insurance plans leads to higher wages by providing flexibility in long-term financial decisions, such as staying in school or pursuing better job matches.

Factually correct

$4 billion – The amount the US healthcare system saved during two years after hospitals greatly reduced adverse drug events, falls, infections and other forms of patient harm that historically have driven up costs, according to HHS.

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