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Weekly insights from the Health Research Institute pwc.com/hri

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This week's regulatory and legislative news:

- **CMS backtracks on Medicare Advantage payment reductions**
- **New painkiller faces opposition from elected officials**
- **Federal agencies emphasize risk-based regulation for HIT**
- **Focus shifts from design to enforcement under HIPAA audit program**
- **Innovative 'new entrants' vie for healthcare consumers**

CMS backtracks on Medicare Advantage payment reductions

In a final 2015 call letter released Monday, CMS estimated that Medicare Advantage rates would increase by 0.4% — a sharp contrast to the proposed 1.9% decrease released in late February. The proposed cuts were expected under the ACA, which gradually reduces Medicare Advantage payments over time. The rate increase reflects tweaks to CMS's new risk adjustment methodology and a decision to make no further changes to home risk assessments. CMS also decided not to change weighting measures in its star ratings program, which could have dropped many plans below the threshold for receiving a 5% quality bonus.

HRI impact analysis: The revised estimates come as a welcome — if temporary — relief for many managed care plans. Industry advocates and analysts still note, however, that the changes are not a net positive for the industry. Some of the larger health plans will see their base payment rate reduced by 4% next year, and analysts predict that insurers will experience an average rate drop upwards of 3%, compared with the anticipated 5-6% under the proposed changes. Despite the cuts, Medicare Advantage still has a promising outlook. Enrollment is projected to rise by more than 6% over the next eight years, from 15.6 million in 2014 to 16.6 million in 2022, according to CMS's Medicare trustees report. Medicare Advantage continues to be one of the more profitable businesses for health insurers, and plan benefits are generally considered better than what enrollees would otherwise receive under traditional Medicare.

New painkiller faces opposition from elected officials

A powerful new painkiller approved by the FDA has raised concerns among elected officials. The drug, Zohydro, is a pure form of hydrocodone. Other common painkillers contain smaller amounts of hydrocodone and are often combined with ingredients such as acetaminophen. The manufacturer of the drug argues that its product can help treat chronic pain and avoid liver damage that acetaminophen can cause. But elected officials are more concerned about the new narcotic being abused. Senator Joe Manchin (D-WV) introduced legislation to revoke the FDA approval of the drug. In Massachusetts, Governor Deval Patrick banned the drug as a response to a public health emergency he declared regarding opioid addiction.

HRI impact analysis: Regulators and manufacturers are struggling to develop treatments for chronic pain that do not worsen the nation's prescription drug epidemic. Tighter controls and strict enforcement on how painkillers are stored, prescribed, and dispensed could impact stakeholders up and down the supply chain. Some drugmakers are attempting to develop products that deter abuse, such as pills that can't be crushed. But in a recent hearing before Congress, the FDA Commissioner said the current

technology is not adequate. Physician and patient education about proper prescribing and use will also be important.

Federal agencies emphasize risk-based regulation for HIT

Three federal agencies have released a new report with recommendations on how health information technology (HIT) should be regulated by the federal government, including mobile health apps. The strategy was developed by the FDA, the Federal Communications Commission, and the Office of the National Coordinator for HIT. The report classifies HIT into low-, medium-, and high-risk categories impacting patient safety, each requiring different levels of oversight. Administrative technology such as billing and claims processing are deemed low risk and require no additional regulation, while technology that works with medical devices such as remote alarms is deemed high risk and would be regulated by the FDA under its existing authority.

HRI impact analysis: The report is the latest attempt by the FDA to clarify its role in regulating HIT and the growing mobile health market. Last year, the agency issued guidance indicating it does not intend to regulate smart phones or apps that pose little risk to consumers, such as educational wellness apps or those that help patients connect with caregivers. According to HRI's top health industry issues report, 40% of consumers said that they would be willing to use mobile health apps to communicate with a doctor, nurse, or caregiver. And a majority (59%) of providers and insurers believe widespread adoption of mobile health apps is unavoidable in the near future.

Focus shifts from design to enforcement under HIPAA audit program

Federal auditors this summer are set to expand the number of privacy and security audits that were previously part of a HIPAA pilot program that wrapped up last year. The latest round could spell trouble for hospitals that are unaware of or unprepared for random inspections. The HHS Office for Civil Rights (OCR), which oversees the HIPAA program, plans to audit hundreds of providers, insurers and data warehouses, including business associates, to ensure they comply with new risk assessment and notification requirements and a number of other regulatory provisions that went into place last year. This year's audits will be the first conducted outside of the government pilot program, which wrapped up in 2013. The first phase focused primarily on the implementation of security and privacy protocols, while the second phase focuses on enforcement of those measures.

HRI impact analysis: The OCR said it plans to launch pre-survey questionnaires to about 800 entities this summer and to use the results to select 350 covered entities and business associates to audit in the fall. The differences between the pilot program and the permanent audit program are significant. Most noticeably, the OCR will conduct "desk audits" rather than on-site ones, meaning covered entities and business associates must ensure their documentation in response to the data request is clear, up to date, and concisely addresses the organization's adherence to HIPAA protocols. The stricter desk audits mean providers may have little opportunity to add additional color or clarification. The audits will also focus on regulatory provisions that were the source of a high number of compliance failures during the pilot program, such as the lack of a complete and accurate risk assessment, access to protected health information, authorizations for the disclosure of protected health information, privacy notices, and tax breach notification protocols.

Innovative 'new entrants' vie for healthcare consumers

Retailers, technology and telecommunications companies, makers of consumer products, and even automotive companies are making a major play to capture a share of the nation's annual $2.8 trillion medical tab — and they're doing so by putting the consumer first. A new study by HRI found that consumers are willing to sidestep traditional care settings for more affordable and convenient alternatives, putting at risk at least $64 billion of revenue that now flows to the traditional health system. It's this shift in thinking that has propelled a majority of the nation's top businesses to develop ways to cater to the health needs of an increasingly tech-savvy, cost-conscious consumer base. To find out who these "new entrants" are, and how they already are shaping the New Health Economy, please see, "Healthcare's new entrants: Who will be the industry's Amazon.com?"

Upcoming events & deadlines

- **April 18** – Enrollment deadline for organizations to be considered for Models 2, 3, and 4 of the Medicare Bundle Payments for Care Improvement initiative
- **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 31** – 2015 exchange premium rate filing deadline for health insurers

Quote of the week

"How are we supposed to manage these complex diseases when a third of our patients can't afford food, medication, or both?" said Dr. Seth Berkowitz, the lead investigator for a study on food insecurity and chronic disease published this month in the American Journal of Medicine. The researchers found that nearly one in three US adults with a chronic disease has problems paying for food, medicine, or both.

In the news

Ophthalmologists and cancer specialists were among some of the highest-paid physicians in the US, accounting for nearly a quarter of the $77 billion that Medicare reimbursed doctors in 2012, the New York Times reports. The Medicare physician reimbursement data published this week is some of the most detailed ever to be released by CMS, and comes only after a lengthy legal battle. The data details Medicare payments for over 6,000 types of services and procedures and allows comparisons by physician, specialty, location, and type of service or procedure. Prior to this, CMS released hospital payment data in 2013 in an effort to boost its transparency initiatives. HRI has cited price transparency as a key issue as the healthcare system becomes more focused on the consumer.

Factually correct

$267 billion – the estimated amount Americans spent on fitness and wellness-related goods and services in 2012 (in addition to the $2.8 trillion they spent in 2012 on traditional healthcare)

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