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

pwc

Week of 3/24/2014

This week's regulatory and legislative news:

- **Federal government, states extend exchange sign-up period**
- **House-passed 'Doc Fix' includes key Medicare program delays**
- **FDA releases guidance on labeling for accelerated approved drugs**
- **Concern over rising prices for specialty drugs**
- **Congress sets sights on antibiotic resistance**

Federal government, states extend exchange sign-up period

On Tuesday, HHS announced that it would allow individuals who start the enrollment process on healthcare.gov before the March 31 deadline to complete their applications online by mid-April. HHS will rely on self-attestations, so enrollees could theoretically begin their applications after March 31 and still obtain coverage. The administration has yet to release firm deadlines on the extension. Some state-based exchanges, including Maryland and Minnesota, also announced that they would allow shoppers to complete applications after March 31. The announcements come at a time when insurers, states, and the federal government have increased marketing and outreach to draw as many last-minute customers as possible.

HRI impact analysis: As open enrollment wraps up, the healthcare industry will closely watch to see which states met their goals and which health plans swept up the most enrollees. Just 13 states hit their projected five month enrollment targets for October 1 through March 1. More than six million people selected a plan through the exchanges nationally, enough to dispel concerns about a widespread collapse of the market, with more enrolling off exchanges directly through insurers and sites such as eHealth. The enrollment deadline extension could be a win for insurers, as last-minute enrollees may be younger, healthier, and have less incentive to purchase insurance than individuals who signed up earlier.

House-passed 'Doc Fix' includes key Medicare program delays

With a 24% reduction in Medicare physician payments set for April 1 and little chance Congress will advance legislation repealing the reimbursement formula anytime soon, the House on Thursday passed a 12-month, roughly $17 billion plan that delays the cuts until March 2015. Under the stopgap bill, Medicare payment would stay at the same level through the first quarter of next year, and about a half-dozen payment provisions that favor rural providers would also be extended. The bill would affect several other key Medicare programs: it would partially enforce Medicare's controversial two-midnight rule through the first six months of fiscal 2015, and it would delay the adoption of ICD-10 codes for another year, to October 1, 2015. While lawmakers agreed to a broader package that fully repeals Medicare's sustainable growth rate formula, known as the SGR, they have yet to coalesce around a way to pay for the $180 billion expense of higher Medicare rates.

HRI impact analysis: The bill now moves to the Senate, where it could come up for a vote early next week. If approved there, both hospital and physician groups would see the delay they have been calling for in moving to the more comprehensive ICD-10 codes. Additionally, hospitals would get a longer reprieve from Medicare's two-midnight rule. Under the provision, Medicare recovery auditors would not conduct post-payment status reviews of inpatient claims from October 1, 2013 through March 2015. It would also mark the third time the rule has changed since being finalized in August 2013. The intent is to

prevent Medicare auditors from reducing payments if they find a medical service could have been performed in a lower-cost outpatient setting. Hospitals and health systems contend that CMS' enforcement of the rule would result in lower Medicare inpatient payments. Congress would pay for the bill, in part, by reducing payments for what it are deemed "misvalued codes," or medical procedures that have wide variations in cost, and services that have seen rapid growth, such as the administration of certain cancer drugs and the increased use of imaging procedures. Additionally, the bill extends the Medicare cuts under the automatic budget sequester by one year, to 2024, and extends Medicaid disproportionate share hospital reductions from 2017 through 2024.

FDA releases guidance on labeling for accelerated approved drugs

The FDA recently released draft guidance on labeling standards for drugs approved through accelerated approval pathways, a process that expedites the approval of drugs for certain life-threatening conditions. The recommendations are meant to mitigate the risks associated with fast-tracked drugs, which may have been reviewed with less extensive data. The FDA states that labeling on drugs approved through accelerated pathways must clearly indicate that the drug was approved under fast track conditions. Drugmakers should provide a "succinct description" of the drug's intentions and limitations, while stating that further testing is ongoing and long-term approval will be determined by the results.

HRI impact analysis: More stringent labeling is one way to help consumers and providers understand risks and benefits associated with drugs that haven't gone through the usual review process. As the new guidance is finalized and those concerns are addressed, pharmaceutical companies should be prepared to modify labels for accelerated-approval drugs in a timely manner as new data surfaces. Some consumers may need additional help understanding the new labels. According to HRI's report on customer experience in the pharmaceutical sector, 13% of consumes said they were frustrated by confusing medication information.

Concern over rising prices for specialty drugs

A longstanding debate about the affordability of prescription drugs in the US is intensifying around a new spate of specialty medications. A trio of Democratic lawmakers recently sent a letter to one drugmaker of a new hepatitis C treatment requesting a briefing on its pricing strategy. The high cost that specialty drugs command has some insurers debating whether to cover the therapies. At the same time, consumers purchasing healthcare coverage through the new exchanges are discovering they may be liable for a substantial share of their drug costs. In order to keep costs down, some health plans are increasing patient cost-sharing requirements for specialty drugs, or not covering certain drugs at all.

HRI impact analysis: The price for specialty medicines is contributing to the nation's rising healthcare costs. According to HRI's most recent report on medical cost trend, approvals of new biologics now outpace traditional therapies. Biologics are medicines derived from living organisms. The shift toward specialty products will continue throughout the year as research efforts target complex cases such as cancer. Insurers will need to weigh the prices for these drugs with the benefits they offer, such as shorter treatment times and reduced hospitalizations. Drugmakers may be expected to continue prescription assistance programs to help offset consumer cost-sharing, such as co-pay coupons.

Congress sets sights on antibiotic resistance

The growing problem of antibiotic resistance is getting more attention from lawmakers in Washington. A recently introduced bill with bipartisan support includes additional Medicare payments for new antibiotics developed for hospital inpatient use. The incentive payment is intended to overcome low reimbursement rates that discourage drugmakers from developing new antibiotics. Another proposal would set up an expedited process for FDA to review new antibiotics and antifungals. The proposal would give the agency more flexibility regarding the clinical evidence it needs to approve the drugs, such as limited data sets.

HRI impact analysis: The added flexibility for FDA could help speed new antibiotic drugs to market. But it could come with additional post-market safety requirements to ensure the drugs are being prescribed and used properly by providers and patients. One idea being considered is to include a logo on the label indicating that antibiotics approved under the expedited process should only be used in a limited patient

population. The new effort follows the Food and Drug Administration Safety and Innovation Act of 2012, which provides manufacturers with an additional five years of exclusivity for developing new antibiotics.

Upcoming events & deadlines

- **March 31** – Official deadline to begin the process of enrolling in in health insurance exchanges for 2014. The White House announced a "special enrollment period" for those who indicate that they attempted to get insurance before mid-April. Such individuals will have an unspecified amount of time to complete their enrollment.
- **March 31** – Extended comment period deadline for HHS's proposed rule on emergency preparedness requirements for Medicare and Medicaid providers.
- **April 30** – Extended deadline for those in the Pre-Existing Condition Insurance Plan to gain coverage through exchanges.
- **May 31** – 2015 exchange premium rate filing deadline for health insurers.

Quote of the week

"We need to add value—life-prolonging or quality-of-life benefits—that are meaningful enough for payers around the world to say, 'Yes, I'm willing to pay a premium over generic opportunities,' " said Novartis chairman, Joerg Reinhardt in a recent interview. Reinhardt is pushing Novartis to invest in research and development for new drugs, especially as patents expire for old medications and less expensive generics become available.

In the news

A recent study published by the Annals of Emergency Medicine found that expanding insurance coverage increased emergency department use. The study, which analyzed more than 13 million emergency room visits over a five year period, estimates that the implementation of healthcare reform nationally will increase emergency room visits by up to 2.2%.

Factually correct

35% - The percentage of 25-44 year olds who report having health and wellness applications on their phone, according to HRI's consumer insights report.

Contacts

Benjamin Isgur
Director
benjamin.isgur@us.pwc.com
(214) 754-5091

Bobby Clark
Senior Manager - Pharma/Life Sciences
robert.j.clark@us.pwc.com
(202) 312-7947

Matthew DoBias
Senior Manager - Provider
matthew.r.dobias@us.pwc.com
(202) 312-7946

Caitlin Sweany
Senior Manager - Payer
caitlin.sweany@us.pwc.com
(202) 346-5241

HRI Online