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This week's regulatory and legislative news

- **State exchange websites postpone some noncritical functions**
- **Congress eyes FDA funding fix**
- **Drug industry will voluntarily disclose clinical trial data**
- **Home health provider enrollment halted in two cities; more possible**
- **Major partnership exchange milestone this week**
- **Supreme Court rulings add clarity for pharmaceutical sector**
- **CMS grants hospitals broader role in exchange enrollment**

State exchange websites postpone some noncritical functions

After months of heads-down implementation, state-run insurance exchanges are beginning to unveil the first glimpses of their websites. For many, meeting the October 1 launch will mean functionality but few frills. Minnesota, for example, is on track to be operational—minus a few applications such as the ability for enrollees to update their coverage to reflect major life events such as childbirth and marriage. Nevada's exchange site won't have a virtual assistant, which is tech speak for a dynamic online tool that helps users navigate a website. The website will also not allow consumers to sort insurance plans based on whether their prescriptions are covered. Earlier this month, Connecticut exchange officials said they would delay about 30% of their website's functions, such as technology that tracks when shoppers quit midway through the application process.

HRI impact analysis: While many state-run exchange sites may end up delaying some less critical functions, most are still on track to meet basic requirements. However, it is unclear exactly how far along HHS is in its overhaul of the healthcare.gov website, which will serve as the one-stop enrollment spot for federal and state partnership exchanges. HHS is also relatively quiet on the progress of the federal data hub, which will connect exchanges to various federal agencies to verify applicant information. Technological delays on the federal side may be likely, especially with customer data verification, making the enrollment process more challenging. Most health plans and state exchanges are investing in safeguards such as expanded call center capacity and extra staff to process paper applications in anticipation of technology glitches.

Congress eyes FDA funding fix

The pharmaceutical and device industries paid $85 million to help fund the FDA, but that money is sitting in the US Treasury unspent. The money comes from "user fees" manufacturers pay to have their applications reviewed and factories inspected by FDA, and it is combined with money that Congress appropriates annually to keep the agency operating. When FDA's budget was trimmed as part of the automatic spending cuts known as "sequestration," it didn't differentiate between the fees paid by industry and the money that comes from Congress. FDA recently announced the fees for 2014 and unless lawmakers act, industry will continue to pay millions to the agency only to see it redirected elsewhere. A bill recently introduced in Congress with bipartisan support would exempt the industry fees from being caught up in future budget cuts, but doesn't address the money already cut this year.

HRI impact analysis: The budget cuts could impact FDA's ability to meet its performance goals for reviewing new drug and device applications required under the Food and Drug Administration Safety and Innovation Act. Inspections to ensure drugmakers are complying with good manufacturing practices may be delayed. The cuts could impact changes the agency was planning such as advancing research in regulatory science—a key priority for the FDA commissioner. Those investments could help reduce the time it takes to bring a drug from the lab to a patient's bedside.

Drug industry will voluntarily disclose clinical trial data

In an effort to satisfy increasing calls for greater transparency, the drug industry recently announced that it will make more clinical trial information publicly available starting January 1. The industry's US trade organization, the Pharmaceutical Research and Manufacturers of America (PhRMA), and its European counterpart outlined principles that drugmakers will use to voluntarily disclose data to researchers, patients, healthcare providers, and others. Researchers must submit a proposal to review boards established by individual drug companies. If approved, they will receive anonymous clinical data to protect patient privacy. Manufacturers have also agreed to make summaries of clinical studies publicly available for newly approved drugs.

HRI impact analysis: The announcement comes after some individual companies, such as GlaxoSmithKline, have already moved to make clinical trial data available. Regulators on both sides of the Atlantic continue to consider proposals that would make disclosure of clinical trial results compulsory, such as the Trial and Experimental Studies Transparency (TEST) Act, which was introduced in Congress earlier this year. The push for more transparency is partially due to increasing interest in comparing new drugs to existing therapies. In the new health economy, the value of drugs will be determined by a combination of innovation, price, and performance.

Home health provider enrollment halted in two cities; more possible

The decision last week by CMS to halt for six months new home health provider enrollment in the greater Miami and Chicago areas may only be a start. An industry source says he expects CMS to ultimately expand the moratorium to other markets flagged by the agency as potential fraud "hot spots." CMS officials said they targeted the Miami and Chicago areas due to increased evidence of potential fraud, including a high number of providers relative to beneficiaries, a spike in enrollment applications, and "extremely high utilization" rates. Under the moratorium, existing providers can continue to deliver and bill for services, but new applications will not be approved. Additionally, CMS also stopped enrollment of new ground ambulance suppliers in the Houston metropolitan area. An ACA provision allowed the agency to take the measures.

HRI impact analysis: Though it's temporary, the moratorium could cool the number of joint ventures and acquisitions between hospitals and home health providers in the affected markets, even though the federal restrictions do not extend to sales or co-ownership deals. Traditional hospitals still see home health as a core component of a fully integrated care model—one that helps reduce the number of inpatient readmissions and generally improve overall healthcare quality. But high rates of fraudulent activity and increased CMS scrutiny could make health systems anxious about purchasing standalone facilities. And if CMS extends the moratorium past the six-month window, then acquisition prices could tick up. Higher-than-average rates of fraudulent billing could put more scrutiny on due diligence and feasibility studies for new or acquired home health agencies.

Major partnership exchange milestone this week

Federal-state partnership exchanges were required to submit documentation of their qualified health plan reviews on Wednesday, July 31. This applies to both traditional partnership exchanges and "unofficial" partnerships—where states conduct the same exchange plan management functions as partnership exchanges, but do not have a formal partnership agreement. The deadline marks yet another milestone in the countdown to the October 1 go-live date for state health insurance exchanges. CMS will review state plan decisions in August, and insurance carriers will have the opportunity to review their plan data online and submit corrections by August 23.

Supreme Court rulings add clarity for pharmaceutical sector

In recent weeks, the Supreme Court issued several rulings providing greater clarity to the pharmaceutical industry on three key issues—gene patents, "pay-for-delay" agreements, and product liability. The court's decisions provide more certainty about how the pharmaceutical industry will be treated by lower courts and regulators. For more information, see HRI's new Spotlight.

CMS grants hospitals broader role in exchange enrollment

CMS issued final regulations outlining the different tasks that consumer assistance personnel—including navigators, non-navigators, and certified application counselors—may conduct to help with health plan enrollment in the new marketplace known as exchanges. Under the rules, hospitals are allowed to play an extensive role in helping uninsured or under-insured individuals understand their new insurance options. Read HRI's new Spotlight for more on CMS' final rule and hospitals' role in exchange enrollment.

Upcoming events & deadlines

- **August 8** – Health insurers planning to offer coverage in partnership and federally facilitated exchange states will be able to preview their data online.
- **August 23** – Partnership and federally facilitated exchange plans must submit corrected data to CMS.
- **September 4** – CMS will notify issuers in partnership and federally facilitated exchanges of final qualified health plan certification decisions.
- **September 6** – Comments due on the proposed rule on 2014 payment policies for the Medicare physician fee schedule.
- **September 6 –** Comments due on the proposed rule on the outpatient prospective and ambulatory surgical center payment systems.
- **October 1 –** Health insurance exchange open enrollment begins.

Quote of the week

"Me just making more speeches explaining it in and of itself won't do it. The test of this is going to be, is it working? And if it works, it will be pretty darn popular," said President Obama of the ACA and his belief that naysayers will be assuaged once the law proves successful.

In the news

A new report from the GAO lays out the median premiums that individuals and families pay to get insurance today. The state-by-state numbers, which reflect January 2013 rates, offer a baseline to assess the impact of coverage expansion on premiums as the ACA is fully implemented.

Factually correct

$7 billion – the amount of money more than 6.6 million people with Medicare have saved on prescription drugs in the Medicare Part D donut hole since the enactment of the ACA, according to a recent HHS press release.

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