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

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**Week of 7/21/2014**

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

- **New rule may expand 340b pharmaceutical discounts**
- **Insurance commissioners eye revised 'narrow network' guidelines amid access concerns**
- **Article defends Arkansas alternative Medicaid expansion**
- **FDA ramps up transparency efforts with recalls database**

### New rule may expand 340b pharmaceutical discounts

Drugmakers could be on the hook for millions of dollars in discounts for orphan drugs due to a new rule issued this week by the Health Resources and Services Administration (HRSA). The division within HHS administers the 340b program, which requires manufacturers to discount medications to providers that serve needy populations. These organizations, known as "covered entities," predominantly care for uninsured populations and include federal qualified health centers, Medicare and Medicaid disproportionate share hospitals, and critical access hospitals. The program has grown substantially over the years to include over 10,500 covered entities according to a recent OIG report. The rule issued this week requires manufacturers to provide discounts for orphan drugs that are used off-label, or to treat an illness for which the drug was not originally developed. Drugmakers argue that this interpretation is at odds with the law, which has exempted orphan drugs from the 340b program. That exemption was part of the ACA.

**HRI impact analysis:** The new rule is the latest development in a larger court battle between drugmakers and the administration. Earlier this year, a federal judge overturned a previous rule issued by HRSA attempting to implement the same policy on orphan drugs. The court ruled that the agency did not have the authority to issue such a rule because Congress had not specifically given the agency the authority to do so. In issuing the rule this week, HRSA is attempting to find a workaround to the court's ruling by using its authority to interpret laws as it implements them. Many stakeholders anticipate another lawsuit by the drugmakers challenging these latest actions. The issue of drug pricing is of significant concern to stakeholders across the US health system, particularly as specialty drugs contribute to a larger share of medical costs.

### Insurance commissioners eye revised 'narrow network' guidelines amid access concerns

The National Association of Insurance Commissioners (NAIC) is revising its nearly two-decades-old guidance on provider network adequacy amid concern that some insurers don't have enough hospitals and specialists in their exchange health plans. About 30 stakeholder groups thus far have suggested changes, including ways to increase flexibility regarding differences in populations and to improve consumer education about health plan design. NAIC officials are also considering guidelines on medication formularies, provider access for people with disabilities, the quantity of mental health providers in a given health plan, and measures that more explicitly name doctors and hospitals that are in a particular network. The association expects to release its revised guidelines in November.

**HRI impact analysis:** Narrow or tiered networks, in which insurers design a plan that may exclude or discourage the use of higher-cost providers, have been around since the 1990s. These types of plans have proven an effective—albeit controversial—way to lower premium costs. Some providers—especially those affiliated with an academic medical center or pediatric practice group—were excluded from insurer

networks during the first open enrollment period under the ACA. HHS officials said they would consider ways to broaden some networks even as state and federal lawmakers prepare legislation to do the same. But insurers caution that forcing them to expand network design could increase premiums. Consumers have become savvier purchasers of healthcare in the new health economy as they take on more financial responsibility.

### Article defends Arkansas alternative Medicaid expansion

A new *Health Affairs* article suggests that concerns over the future of Arkansas' alternative Medicaid expansion may be unfounded. The alternative "private" option adopted by Arkansas and other states allows federal Medicaid funds to be used for low-income residents to enroll in health exchange plans. Arkansas' decision to accept federal Medicaid money drew criticism when it was revealed that the state would have to pay back $7.7 million to HHS for exceeding the annual budget cap it agreed to in negotiations. Some said the program was poorly designed and speculated it would lead to long-term cost overruns. The *Health Affairs* article explains that additional costs were due to slightly older-than-expected enrollees and individuals purchasing the most expensive silver plans with built-in coverage for dental and vision benefits. HHS is expected to issue a rule later this year that will require enrollees in the private option to only select plans that cover the essential health benefits, which could help curb future costs for Arkansas' program. Iowa and Pennsylvania are also pursuing similar premium assistance programs.

**HRI impact analysis:** Alternative programs could become more popular as the 21 or so states not expanding Medicaid to individuals earning up to 138% of the federal poverty level face growing political pressure to accept federal funding. If Arkansas is able to bring its spending under control next year, it could encourage other states to pursue private expansions. Besides requiring enrollees to select a plan with just the essential health benefits, Arkansas is also considering implementing a pricing limit and setting quotas on how many people may enroll with a particular insurance carrier. Exchange plans should consider offering basic policies that are priced competitively if they hope to attract new Medicaid-eligible enrollees.

### FDA ramps up transparency efforts with recalls database

The FDA, through its openFDA transparency initiative, unveiled a new data set to plumb: food, drug, and device recalls. The online program lets users chart recall trends—May 2014 represented a 10-year high for prescription drug recalls—and drill down to specific companies and products. In addition to recall enforcement reports, openFDA also houses an adverse events database for drugs, with a third database—for product labels—coming soon. Separately, FDA's Mini-Sentinel pilot program, which uses electronic health data to identify adverse events and other post-market risks, is slated to deliver the results of several studies next year.

**HRI impact analysis**: FDA's release of enforcement recall data and tools for analysis will make it easier for researchers to recognize trends—in manufacturing practices, for example—across the industry and at the individual company level. Pharmaceutical companies are watching FDA's transparency initiatives closely, which include Mini-Sentinel, a powerful database representing 178 million individuals as of July 2014, with 358 million person-years of observational time. Several Mini-Sentinel adverse events studies – on flu and HPV vaccines, for example, are due for completion by spring 2015. While some additional risk is intrinsic to any post-market drug study, opportunities exist for companies able to respond quickly to an issue with real-time analysis.

## Upcoming events & deadlines

- **August 6** – PCORI application system opens for Fall 2014 cycle of funding announcements
- **August 12** – Deadline to submit ideas to the Senate Finance Committee on how to increase the transparency of healthcare data
- **August 27** – Deadline for physicians and teaching hospitals to review and dispute data submitted by the drug industry under the Sunshine Act's Phase 2 of Open Payments
- **September 2** – Comments due for Medicare's proposed home health payment rule and quality reporting initiatives
- **September 5** – Comments due for Medicare's proposed Hospital Outpatient and Ambulatory Surgical Center payment rules

## Quote of the week

"[It's] a big deal. It's a huge shift in terms of transparency and driving quality improvement," said Dr. Patrick Conway, Medicare's chief medical officer, on plans to release quality measurements for large healthcare group practices by the end of the year in order to help consumers choose a doctor based on high-quality care.

## In the news

In separate cases, two US appeals courts issued conflicting rulings on the legality of consumer subsidies in the ACA's federal exchange. In *Halbig v. Burwell*, a three-judge panel in DC concluded that the 2010 healthcare law only allows state-run exchanges to provide subsidies. In the *King v. Burwell* decision released just a few hours later, a Virginia appeals court found that the IRS correctly interpreted the healthcare law to offer subsidies through both federal and state exchanges. The Justice Department indicated that it will likely file an appeal to the *Halbig v. Burwell* decision. The ruling affects approximately 6.5 million people who qualified for a tax credit in 2014 and may forgo coverage in the next enrollment period without subsidies.

## Factually correct

8.2% – The average increase in health insurance exchange premium rates from 2014 to 2015. Twenty two states have reported premium rate filings for 2015, with more expected during the coming weeks.

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