



Week of 7/22/2013

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

- **HHS issues final rule on drug discount program**
- **New caps on out-of-pocket costs for specialty drugs**
- **Humana extends coverage to Mississippi counties without exchange plans**
- **Report estimates \$314B in new hospital payments if all states expand Medicaid**
- **CMS again cautions against use of electronic health records for 'upcoding'**
- **ACA tax provisions dominate IRS agenda**

### **HHS issues final rule on drug discount program**

A final [rule](#) released this week sets up a system in which some hospitals will pay more for orphan drugs, which treat rare diseases such as neurodegenerative disorders, under the federal program known as "340b." The program was created in 1992 to help hospitals treating underserved populations purchase drugs at reduced rates. Congress expanded the types of hospitals eligible for the program when it passed the ACA, but said orphan drugs specifically would not be discounted for new entrants. Hospitals that were eligible for the program before it was expanded can still purchase orphan drugs at the lower prices.

**HRI impact analysis:** The final rule on orphan drugs adds more complexity to a program already under scrutiny. Policymakers fear some hospitals and the doctors affiliated with them are profiting from the program by purchasing drugs at reduced rates while being reimbursed for them at commercial prices. Regulators likely will monitor how newly eligible entities comply with the requirements. Hospitals may need to bolster accounting systems for how drugs are purchased.

### **New caps on out-of-pocket costs for specialty drugs**

Starting next year, Delaware residents will enjoy new limits on out-of-pocket costs for specialty prescription drugs. This week, the state's Democratic governor, Jack Markell, signed into law a [bill](#) limiting patients' copayments or coinsurance to \$100 per month for up to a 30-day supply of any *single* specialty drug or \$200 per month for *all* specialty drugs. Often expensive, specialty drugs are used to treat serious conditions such as cancer. Monthly spending per patient for a specialty drug typically exceeds \$1,200, according to one [study](#). HRI's [report](#) on medical cost trend revealed that the use of specialty drugs is increasing, as are FDA approvals of them.

**HRI impact analysis:** The ACA also [limits](#) out-of-pocket spending, but there's a caveat for insurance plans using pharmaceutical benefit managers to administer their drug benefits. In 2014, consumers enrolled in these plans may face two caps—one for medical services and another for prescription drugs. Because each cap could amount to \$6,500, a patient could have to pay \$13,000 in annual out-of-pocket spending on top of monthly premiums. In 2015, plans will have to use a single cap for medical and pharmaceutical benefits combined.

### **Humana extends coverage to Mississippi counties without exchange plans**

For nearly 54,000 Mississippians, one insurer's decision may be a lifesaver. Last Friday, Mississippi insurance commissioner Mike Chaney [announced](#) that insurance giant Humana will expand its health insurance exchange offerings from four counties to 40. Before the announcement, no insurers offered coverage on the new marketplace for 36 of the state's poorest counties, leaving thousands of exchange-eligible residents with no way to access ACA tax credits for affordable coverage. Residents of those counties are among the nation's poorest, sickest, and most difficult-to-cover. Humana is one of only two insurers participating in Mississippi's exchange market in 2014.

**HRI impact analysis:** Humana's decision to fly solo in much of the state's exchange market could be a gamble for the company, which already covers nearly 200,000 Mississippi residents. Early identification of chronic disease and robust disease management programs likely will help keep costs manageable, but consumers may face higher premiums than in other parts of the country. Humana's decision also may indicate confidence in the risk adjustment process. Risk adjustment, which will be run primarily by the federal government in the first years of the exchanges, shifts revenue among health plans based on member risk. While Humana could face challenges in covering the new exchange population, its decision to offer coverage in these poor counties is unlikely to be financially catastrophic due to safeguards put in place by the ACA.

### **Report estimates \$314B in new hospital payments if all states expand Medicaid**

Since the Supreme Court's decision a year ago made Medicaid expansion optional for states, many hospitals have worried about the impact on their bottom lines. A new [report](#) from the Kaiser Family Foundation supports those concerns. According to the report, if all states expanded Medicaid, US hospitals would receive \$314 billion more in payments during the next ten years. Two-thirds of that money—\$210 billion—would come from the 27 states that have decided against expansion, or remain undecided. Kaiser also reported that 6.4 million uninsured will go without coverage if all 27 states opt out of expanding their Medicaid programs.

**HRI impact analysis:** Safety-net hospitals in states not expanding their Medicaid programs will face financial hardship as disproportionate share hospital funding is reduced (scheduled for FY2014) while the number of uninsured remains high. Hospitals will need to find other revenue sources, including private insurance purchased through the exchanges. As HRI recently reported, hospitals will have more flexibility in certifying their own exchange application counselors to help enroll patients in exchange plans on-site.

### **CMS again cautions against use of electronic health records for 'upcoding'**

Federal health officials have increased audits monitoring hospitals' use of electronic records to "upcode" certain Medicare-covered procedures. CMS also [proposed](#) ways to ensure hospitals properly document patient visits. The agency said it wants to replace the five levels of outpatient visit codes with a single system. The move comes 10 months after HHS Secretary Kathleen Sebelius and US Attorney General Eric Holder jointly warned hospital groups that law enforcement would pursue providers misusing electronic health records (EHRs) to bill for services never provided.

**HRI impact analysis:** Health systems that have adopted electronic records say that any incident of upcoding is the result of more accurate coding compliance, not an effort to game the system. Some EHR systems link a hospital's clinical arm to its financial division, capturing codes missed under the old paper system. Hospitals should conduct back-end compliance reviews to ensure the right codes are being used.

### **ACA tax provisions dominate IRS agenda**

The IRS' federal regulations [agenda](#) is dominated by ACA provisions, from additional Medicare taxes to guidelines for large companies required to disclose employee coverage options. All told, the agency has either finalized rules—or plans to do so soon—on more than 30 ACA [measures](#) concerning employers, insurers, and healthcare providers. Earlier this week, the IRS released its semiannual regulatory agenda, including recent and expected guidance and rules under review. Further guidance on how the 0.9% Medicare tax for high earners impacts employers and employees has moved into the final rulemaking phase. The tax went into effect this year, and employers are seeking clarification on how to file a claim for refunds on over- or underpayments.

## **Upcoming events & deadlines**

- **July 30** – Comments [due](#) to the FDA on new models of antibiotic development.
- **July 31** – CMS receives state recommendations and final plan data for state partnership exchanges.
- **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.

## **Quote of the week**

"What physicians are trying to tell us is that they don't see themselves as necessarily any more responsible for healthcare costs than all those stakeholders," [said](#) Dr. Jon Tilburt, associate professor at the Mayo Clinic, about

his recently published [study](#). Tilburt's research indicates that doctors feel they bear some responsibility in controlling healthcare costs, but that other stakeholders—like lawyers, insurers, drugmakers, and hospitals—bear more.

## In the news

Atul Gawande's new [article](#) in *The New Yorker* examines why some medical innovations are adopted while others are ignored.

## Factually correct

82% – The percentage of insurers who want to see proof of a drug's significant clinical benefit compared to current treatments for the drug to be considered for favorable formulary placement, according to a HRI survey. To learn more about how drugs are valued in the new health ecosystem, read the new [10Minutes report](#).

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