



Week of 6/2/2014

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

- **OIG: Improper coding cost Medicare \$6.7 billion in one year**
- **Hospital charges see moderate growth, yet wide variation**
- **Amid high cancer treatment costs, insurers seek ways to control spending**
- **FDA issues final guidance for expedited approval**
- **FTC recommends more transparency from data brokers to consumers**

### **OIG: Improper coding cost Medicare \$6.7 billion in one year**

More than half of the claims filed by physicians for evaluation and management services in 2010 were inaccurate or incomplete, costing the federal government nearly \$7 billion, according to [a report](#) released by HHS' Office of Inspector General in May. One quarter of those claims resulted in higher payments to physicians, known as "upcoding," resulting in \$4.6 billion in payments. Fifteen percent of claims resulted in lower payments. Nineteen percent lacked sufficient documentation. The OIG, however, did not suggest that the improperly billed codes were a result of fraudulent claims.

**HRI impact analysis:** While the report is based on 2010 data, OIG found that over a decade—from 2001 to 2010—physicians increased their billing for higher-level evaluation and management codes for all visit types. While payment rates for individual evaluation services are small—about \$100 on average—they add up quickly. In 2010, for example, 370 million evaluation services were billed by physicians, accounting for \$32 billion in Medicare payments. The OIG recommends that CMS more closely scrutinize high-coding physicians during payment reviews. Physician executives should increase education about appropriate coding and documentation for clinical staff. Nearly 20% of improper claims failed to include physician documentation supporting the care delivered.

### **Hospital charges see moderate growth, yet wide variation**

The cost of treating chest pain, back ailments, and certain joint replacement procedures grew by nearly 10% during one year, according to [new hospital charge data](#) released by CMS last week as part of an initiative to shed light on utilization and hospital costs. The CMS data compare average charges for about 100 inpatient and outpatient medical services billed to Medicare by more than 3,000 hospitals. Overall charges increased on average by less than 5% from 2011 to 2012, and some medical services, such as treatment for certain head injuries, grew by less than 1%. Even so, differences in hospital charges across the US—and even within the same community—continue to vary widely.

**HRI impact analysis:** The high-profile release of hospital charges—the second time CMS has done so in as many years—underscores an increased commitment to making price and charge [data more transparent](#). CMS has released similar data for physicians, and it has also set its sights on pharmaceuticals. With two years of data available, CMS is encouraging health policy experts and entrepreneurs to develop better ways to help consumers compare cost and quality and, ultimately, make better-informed decisions about their care. While insurers and employers have made some price and quality data available, few comprehensive services exist for the general public. But as consumers [pay more out-of-pocket](#) for medical care, the demand for healthcare to look and feel more like a [retail environment](#) will increase. In addition, HHS also announced the launch of [OpenFDA](#), a website that allows users to openly search millions of adverse events reports filed during the drug approval process.

### **Amidst high cancer treatment costs, insurers seek ways to control spending**

As cancer treatment costs continue to rise, health insurers are using creative new techniques to curb spending. As *The Wall Street Journal* [noted](#), WellPoint soon will begin paying doctors \$350 per member per month in bonus payments to follow the insurer's recommended treatment pathways. Cigna, United Healthcare, and Highmark also have programs designed to dampen incentives to use more costly drugs and treatment settings, such as reimbursing doctors a set amount upfront for treatment instead paying fees tied to drug prices. Cancer is a target area with potential for significant cost savings: IMS Health reports that the US spent \$37 billion on cancer drugs in 2013, with newer medications costing up to \$100,000 per treatment round.

**HRI impact analysis:** Insurer efforts to control cancer treatment costs could have a strong negative impact on the pharmaceutical industry. New drug applications were [down 30%](#) in 2013 compared to 2012; specialty drugs for diseases such as cancer comprised more than half of approvals. As health plans put new cost levers in place, pharma companies will face pressure to cut specialty product prices if they hope to encourage doctors to use those products. Such downward pricing pressure could place significant financial strain on R&D. As HRI [previously reported](#), insurers and providers are increasingly requiring pharma companies to demonstrate the value of their therapies over other options.

### **FDA issues final guidance for expedited approval**

Patients with serious or life-threatening illnesses may gain speedier access to new treatments under recently-issued [FDA guidance](#). The document clarifies the agency's expectations for its [four expedited approval programs](#): fast track, breakthrough therapy, accelerated approval, and priority review. Each program has its own unique qualifying criteria, application requirements, and benefits. For example, a drug designated as a breakthrough therapy must be intended to treat a "serious condition," which is defined as a disease or condition associated with illness that has substantial impact on day-to-day functioning. Preliminary evidence must indicate that the drug may demonstrate a substantial improvement over available therapies. Drugs that receive the breakthrough designation receive intensive guidance from FDA on their development programs, enhanced communications with FDA managers, and other benefits that can help speed approval.

**HRI impact analysis:** It remains to be seen whether the guidance document clears up manufacturers' confusion over expedited approval pathways. That's particularly true for the breakthrough therapy program, which was established by Congress as part of the [2012 FDA reform law](#). While drugmakers have filed 189 applications for the breakthrough designation, the FDA has accepted only 50. Manufacturers should examine internal processes to speed drugs to market, such as development and manufacturing programs. [Improving the efficiency of clinical trials](#) through remote technologies and new methods are other means of lowering costs and accelerating the development process.

### **FTC recommends more transparency from data brokers to consumers**

A recent FTC [report](#) detailed concerns over data brokers' collection and use of consumer information, citing the general public's lack of knowledge about what data are collected and what is done with the information. Data brokers use information obtained from sources such as online activities, financial transactions, and mobile apps to create profiles that they sell to marketers. Sensitive health-related data gleaned from healthcare purchases, fitness devices, and medical internet searches enable brokers to lump consumers into health-related categories, such as "diabetes interest" or "cholesterol focus." The FTC noted that categories derived from this information could pose a risk to consumers, marking them as higher-risk to insurers, for example. The FTC recommends that Congress develop legislation to enable consumers to access and control information sought by brokers, including the creation of opt-out tools, centralized data portals, and consent restrictions for sensitive data, such as personal health information.

**HRI impact analysis:** While consumers may want additional transparency and control over their information, many are [willing to share](#) their data in exchange for services or personalized content. Traditional healthcare companies and new entrants have significant opportunities to [invest in new product offerings](#), such as wearable health and fitness devices that allow consumers to track and monitor health information. As the FTC and FDA [continue to review](#) privacy regulations on consumer data, companies

should develop ways to clearly state what information is being used and how consumers will benefit in return.

## Upcoming events & deadlines

- **June 16** – Deadline to [submit](#) policy and legislative ideas on how the government can support technology adoption in healthcare programs to the House Energy and Commerce Subcommittee on Health
- **June 27** – 2015 federal exchange premium rate filing deadline for health insurers
- **August 15** – PCORI matchmaking [app challenge](#) application deadline

## Quote of the week

“These are people who live in communities who don’t have easy access to healthy food or safe ways to exercise. All those things impact health,” [said](#) Steven Glass, executive director of managed care at Cook County Health and Hospitals in Cook County, Ill., after data released in May provided insight into the demographics, health, and habits of 10,000 new enrollees in Cook County’s Medicaid program.

## In the news

A new federal [plan](#) to cut carbon pollution from power plants by 30% by 2030 may have significant health benefits. The new plan estimates that early reductions in air pollution could prevent as many as 100,000 asthma attacks and 2,100 heart attacks in the first year of reduced emission limits. According to the [CDC](#), 1 in 12 Americans have asthma, each costing the nation an average of \$3,300 per year.

## Factually correct

78 – The number of US Senators that voted to approve the nomination of Sylvia Mathews Burwell as the nation's next Secretary of Health and Human Services. The 78-17 vote on Thursday underscores Burwell's bipartisan support among congressional lawmakers, and clears a path for President Obama's handpicked choice to lead the \$960 billion federal health agency. She will replace outgoing HHS Secretary Kathleen Sebelius, who announced her resignation in April after six years in the post.

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