HRI as we see it

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

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This week's regulatory and legislative news

- **California moves forward with biosimilars legislation**
- **Final rule acknowledges direct-to-consumer exchange plan sales**
- **Individual mandate rule provides clarity on exemptions**
- **Hospitals press for changes to CMS' "two-midnight" rule**
- **Medical Care study suggest men in high deductible plans may delay care**

California moves forward with biosimilars legislation

A controversial bill impacting how biosimilar therapies are dispensed has cleared several hurdles in the California legislature. The legislation would place new requirements on pharmacists before they could substitute a biosimilar drug in place of a branded biologic drug. Biologics are specialty drugs derived from living organisms that are often used to treat cancers and other complex diseases. Under the proposal, pharmacists would have to notify doctors and patients when they plan to substitute a generic version, known as a biosimilar. Typically, for traditional chemical drugs, pharmacists may replace a branded drug with a lower-cost generic without having to notify a patient or their doctor. The legislation spells out when a pharmacist is prohibited from making a switch, such as when a physician indicates "do not substitute" on a prescription.

HRI impact analysis: Generic drugmakers and purchasers such as pharmaceutical benefit managers oppose the legislation, saying it will discourage use of biosimilars and force them to pay higher prices for specialty drugs. Opponents also worry that California, a state the size of many countries, could influence other states that are considering similar legislation. Yet the impact might not be felt for some time. The FDA has yet to receive an application to approve a biosimilar. Also, few biosimilars are likely to be dispensed by a pharmacist since specialty drugs, which are often injected, are typically given under the supervision of a doctor in an outpatient setting.

Final rule acknowledges direct-to-consumer exchange plan sales

On August 28, HHS released a grab bag of exchange direction rolled up into one final 300-page rule. The rule—one of the last released before the October 1 open enrollment deadline—covers topics ranging from privacy and security requirements to sanctions for health plans participating in the federally facilitated exchange. One new area covered by the rule focuses on insurers and web brokers that plan to sell exchange plans directly to consumers. Both will be required to meet specific standards, such as placing disclaimers about limited plan choice and links to official federal or state exchanges on their websites. The final rule also introduces a new term—"issuer application assisters"—for health plan customer service staff and brokers who will assist customers in activities such as determining eligibility for insurance subsidies. Issuer application assisters must receive specific training on health plan benefits, eligibility, and other areas and must comply with state licensing requirements.

HRI impact analysis: Changes such as the website disclosure requirements are a nod to the increasing likelihood that customers—especially those in federally facilitated exchange states—may use web brokers or insurer websites to enroll in coverage, instead of shopping directly on the new marketplaces. Though web brokers may be especially well-suited to enroll customers, given their experience selling individual coverage through online sites, some insurers are ramping up their own efforts at direct enrollment through targeted outreach campaigns and sleek new websites.

Individual mandate rule provides clarity on exemptions

Last week, the IRS released a final rule on the individual shared responsibility provision of the ACA, also known as the individual mandate. The final rule clarifies the hardship exemption—which waives the mandate penalty for individuals—by providing example scenarios, and lays out nine specific categories of individuals who are

exempt from the requirement to carry health insurance beginning Jan. 1, 2014. It confirms that individuals are considered "covered" for a month if they have coverage for at least one day in that month, and provides an exception for coverage gaps of less than three months. It also identifies the types of insurance that would qualify as "minimum essential coverage."

HRI impact analysis: The final IRS rule is another piece of the health reform puzzle, and confirms what type of coverage will satisfy the individual mandate and who will be eligible for exemptions. Businesses that create tools and work directly with individuals to help prepare their tax returns and estimate healthcare costs, as well as hospitals and community groups helping consumers navigate the exchanges, could find the regulations especially helpful. For more on provider navigators, read HRI's spotlight.

Hospitals press for changes to CMS' "two-midnight" rule

National hospital groups won some concessions from CMS over inpatient admission criteria, but nevertheless raised concerns that the new policy, finalized in August, would do little to reduce the number of Medicare billing denials. The American Hospital Association noted the changes in an advisory sent to its member hospitals. The CMS rule states that physicians and other practitioners should admit a beneficiary if they expect the patient will remain in the hospital for more than one Medicare "utilization day"—defined as an admission that spans two midnights—or if they require an inpatient procedure. Under the rule, CMS will count outpatient services, observation services, and treatments in the emergency department, operating room, and other treatment areas toward the "two midnight" benchmark.

HRI impact analysis: The rule gives added weight to the physician's decision to admit a Medicare patient. Hospitals have said that Medicare contractors sometimes ignore the medical judgment physicians use to determine who should and should not be admitted to inpatient status. The new rule states that any physician order admitting a patient must be clear, concise, and documented in the record. External audit contractors, however, will continue to focus on medical reviews for inpatient admissions lasting fewer than two midnights, which account for the largest portion of improper payments under Medicare Part A. In such cases, Medicare contractors will focus on the physician order and the medical documentation supporting the expected two midnight stay.

Medical Care study suggest men in high deductible plans may delay care

A new study in the journal Medical Care suggests that when men switch to high-deductible health plans they avoid using emergency departments for treatment, including for serious problems. Researchers discovered a 34% reduction in ER visits by men the year after they enrolled in a high-deductible plan compared to men who remained in a managed care plan such as an HMO. Women on the other hand did not reduce ER visits for serious problems, such as an irregular heartbeat, when they switched to a high-deductible plan.

HRI impact analysis: As more employers switch to high-deductible plans, patients may put off seeking treatment in order to avoid paying medical bills. That could be a good thing if Americans are overusing treatments, as some health economists have long asserted. Others argue that patients may be forgoing needed care, which could lead to worsening, more expensive healthcare problems down the road. In the new health economy, consumers may look for alternative providers such as retail clinics and telehealth companies to bridge this gap by providing care at a lower price. Increased insurance coverage may also reduce ER visits. HRI's Massachusetts Experience series found that ER use declined as insurance coverage expanded.

Upcoming events & deadlines

- **September 11 –** CMS eHealth webinar - 2013 Physician Quality Reporting System Program: What providers need to know about upcoming deadlines.
- **September 12 –** Office of the National Coordinator and National eHealth Initiative Health IT week webinar series - webinar on privacy and security at http://www.nationalehealth.org/onc-initiatives.
- **September 17 –** PwC webcast on serialization and ePedigree regulations and the current state of readiness in the pharmaceutical and biotech industries.
- **October 1 –** State health insurance exchange open enrollment begins.
- **October 15 –** Last day for individual and group providers participating in the Group Practice Reporting Option to avoid a payment adjustment in 2015. This is a program that allows group practices to report on CMS quality measures in order to earn an incentive payment.

Quote of the week

"Today's ruling provides certainty and clear, coherent tax filing guidance for all legally married same-sex couples nationwide," said Treasury Secretary Jacob J. Lew. The new ruling will give same-sex married couples the same tax filing status options as heterosexual couples, which will now be considered when determining enrollment eligibility for the Medicaid expansion and insurance exchange subsidies.

In the news

A recent article in the *Washington Post* takes a look at how Google is using data analytics and behavioral research to curb unhealthy snacking among its employees.

Factually correct

$43 billion – the sum of money that could have been saved if commercial insurers had paid claims correctly since 2010, according to a survey by the American Medical Association.

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

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