Federal Issues

Regulatory

HHS Finalizes Strategy to Reduce Health IT Burdens
The Department of Health and Human Services released a comprehensive strategy to reduce regulatory and administrative burdens for health care providers using electronic health records and other health information technology. Reflective of public comment, the Strategy on Reducing Regulatory and Administrative Burdens Relating to the Use of Health IT and EHRs aim to give clinicians more time to focus on caring for their patients.

Required by the 21st Century Cures Act of 2016, the report by HHS’ Office of the National Coordinator for Health IT outlines a series of policies the agency may enact over the next several years to reduce burdens related to clinical documentation, health IT usability, and EHR and public health reporting. The report is a collaborative effort between ONC and the Centers for Medicare & Medicaid Services.

Based on input received through several wide-reaching listening sessions, written input, and stakeholder outreach, the strategy outlines three overarching goals designed to reduce clinician burden:

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1. Reduce the effort and time required to record health information in EHRs for clinicians;
2. Reduce the effort and time required to meet regulatory reporting requirements for clinicians, hospitals, and healthcare organizations; and
3. Improve the functionality and intuitiveness (ease of use) of EHRs.

**Industry position:** Commenting on the draft report last year, the American Hospital Association (AHA) urged the agency to look at EHR clinical documentation, prior authorization and the ongoing lack of interoperability between EHR systems, among other concerns.

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**CMS Proposes Changes to Hip and Knee Bundled Payment Program**

The Centers for Medicare & Medicaid Services issued a rule proposing changes to the Comprehensive Care for Joint Replacement model, which bundles payment to acute care hospitals for hip and knee replacement surgery.

Under this model, hospitals in which a joint replacement has taken place are held financially accountable for episode quality and costs. The episode begins when the patient is admitted and encompasses all care provided for 90 days following patient discharge.

Among other proposals, CMS would extend the CJR model for an additional three years, through December 31, 2023, beyond its current five-year timeline. However, this extension would apply only to hospitals in the 34 metropolitan statistical areas in which participation was mandatory. Hospitals participating in the 33 “voluntary” MSAs, as well as all low-volume and rural hospitals that have elected to participate, will continue to see the model end on December 31, 2020.

The agency is also floating a major change to cover outpatient replacements, as the model currently only covers inpatient procedures. This would allow facilities to perform total knee and hip replacements in the outpatient setting.

**Why this matters:**

- The goal of the model, which was created in 2016, was to improve care coordination between the initial admission and through recovery. The first two years of the model generated a modest reduction in spending per hip and knee replacement episode, according to a study in the New England Journal of Medicine. The introduction of outpatient replacement procedures could result in more substantial savings to the program.
CMS' decision to propose an extension for the joint replacement model comes as other models await word of their fate. Chief among them is the Next Generation Accountable Care Organization program, which also sunsets after this year.

**Industry position:** The AHA has long been supportive of voluntary participation in alternative payment models as a pathway to potentially improve care coordination and efficiency. As such, the association is disappointed that CMS is not proposing to extend voluntary participation options in the CJR model.

### FDA Finalizes Rule to Regulate Insulin as Biological Product

The Food and Drug Administration released a final rule regulating certain protein products, such as insulin, as biological products rather than drugs effective March 23.

Authorized by the Biologics Price Competition and Innovation Act of 2009, the change will allow new insulin products, and certain other protein products, to apply for marketing approval through the abbreviated pathway for biosimilar or interchangeable products in an effort to increase market competition and lower prices.

The FDA has taken many steps to date to establish the framework for this new pathway, including issuing the 2018 Biosimilars Action Plan (BAP), which aims to improve the efficiency of the biosimilar and interchangeable product development and approval process and to maximize scientific and regulatory clarity for the biosimilar product development community. The agency has accomplished many of the projects outlined in the Biosimilars Action Plan and is continuing our work on others to enhance patient access to needed medicines in the period leading up to the transition.

This action includes the publication of a final rule and frequently asked questions documents for patients and health care providers explaining more about the transition. These documents clarify that the transition should not affect existing prescribing or dispensing practices and that patients should not notice any difference in their medications, or how they receive their medications, among other topics.

**Background:** Insulin is generally regarded as an ‘old’ product; it was discovered in 1921 and animal-sourced until 1982, when human insulin was the first product brought to market using recombinant DNA technology. Subsequently, analogs have been designed with specific desired clinical properties. For all insulins, monitoring in individual patients must occur multiple times a day and doses need to be carefully titrated to avoid life-threatening variations in blood sugar levels. With one in 12 adults affected, insulin is one of the most commonly used biological medicines worldwide.

The incidence of diabetes is increasing worldwide, especially type 2 diabetes, which is estimated to be the seventh leading cause of death. Historically, unlike many other specialty medicines, the drug cost has been a comparatively low part of the total cost of care for patients with diabetes. This has been changing in the United States in recent years and the cost of insulin, especially for the uninsured, is now a subject of active discussion in the midst of the broader drug pricing debates.

**Why this matters:**
- Insulin is an example of the products impacted by these changes but they are not the only products affected, although they will likely impact the greatest number of patients. **This transition in the United States from ‘drugs’ to ‘biologics’ is expected to increase patient access and potentially lower prices on products** such as insulin.
Education of stakeholders by the FDA will be extremely important due to the potential for patient confusion, and uncertainty by their healthcare providers.

State Issues

Pennsylvania
Legislative

Highmark Testifies Against Bill Banning Mid-Year Insurance Benefit Changes
The House Consumer Affairs Committee met on Tuesday, February 18 for a public hearing to discuss House Bill 853, legislation that would prohibit insurers from making changes to a health insurance plan in the middle of a policy year, including, but not limited to raising premiums, cost-sharing or otherwise failing to provide continued coverage for a benefit that was previously included.

Highmark Vice President for State Government Affairs, Michael Yantis, presented testimony opposing House Bill 853 and how we incorporate necessary changes, including:

- Would prevent Highmark’s ability to adapt a policy to reflect current scientific data;
- Our pharmacy team meets quarterly to review and update prescription drug formularies; and
- When decisions are made to change a medication's formulary status, we notify health care providers and our members, who have the right to submit prior authorization requests.

Capital Blue Cross, Independence Blue Cross and the Insurance Federation of Pennsylvania offered similar remarks, noting how insurers' formularies are reviewed by state regulators.

- Proponents of House Bill 853, including representatives from the Practicing Physicians of America and Thomas Jefferson University Hospitals, shared examples of how some benefit changes have impacted prescriptions and out-of-pocket costs.

State Issues

West Virginia
Legislative

West Virginia Legislative Session Enters Final Two Weeks
The West Virginia Legislature is entering its final two weeks of the 60-day legislative session. The following proposals received consideration last week:

Senate Bill 284, WV Healthcare Continuity Act—WV Attorney General Patrick Morrissey continues to promote his legislation that proposes to maintain sections of the Affordable Care Act (ACA), particularly
protections for pre-existing conditions – should the law be ruled unconstitutional. The bill is pending action by the full Senate.

**Senate Bill 279, Assignment of Dental Benefits**—The Senate voted this week in favor of Senate Bill 279. Further action is pending next week in the House by the Banking and Insurance and the Judiciary Committees. The bill permits:

- Assignment or direct payment to non-participating or out-of-network dentists; and
- Requires dentists to “conspicuously” provide notice to patients about the terms of being treated by an out-of-network dentist, which includes being billed charges and balance billing.

**Senate Bill 291, Mental Health Parity Requirements**—This proposal addresses mental health coverage provided by the Public Employee Insurance Agency (PEIA) and commercial health plans and their perceived limitations as compared to physical health benefits. The Senate approved the bill 34-0. It is slated for consideration by the House Finance Committee.

**Senate Bill 689, Pharmaceutical Transparency and Reporting Act**—The Senate Health Committee has given its approval to Senate bill 689, which requires pharmaceutical manufacturers and health plans to disclose and report a wide variety of data on prescription drug costs and utilization. The full Senate is expected to take up the bill next week.

**Senate Bill 762, Patient Stability Act**—The Senate Health Committee also gave its approval to this proposal, which awaits a Senate floor vote. The measure would prohibit a health plan from changing a patient's existing medication for non-medical reasons or “freeze the formulary.” The bill also requires that the same terms apply as the original prescription, even if the individual or group plan coverage changed. The proponents of Senate Bill 762 are the West Virginia State Medical Association and an affiliate association representing Rheumatologists.

**Senate Bill 787, Pharmacists Reimbursement for Care**—The Senate Health Committee endorsed this measure and it is now scheduled for a floor vote. The bill would require insurers to reimburse pharmacists for all services rendered to patients that are permitted under the scope of practice for pharmacists.

**House Bill 4583, Pharmaceutical Transparency and Reporting**—House Bill 4583 would require pharmaceutical manufacturers and health plans to disclose and report data on prescription drug costs and utilization. The bill is currently under review by the House Government Organization Committee, however, there is a chance the committee may not consider this legislation.

**House Bill 4543, Insulin Cost Cap**—The House of Delegates voted 94-4 to advance House Bill 4543, which would cap the cost of all forms of insulin at $25 per month for each patient. The bill now moves to the Senate, where some members view this bill as government “price fixing.”

The Pennsylvania General Assembly is in recess February 24-28.

The Delaware Legislature returns to session March 17.

The West Virginia Legislature is in session January 8 - March 7.
Congress

The U.S. Senate is in session February 24. The U.S. House and Senate are in session February 25-28.

Interested in reviewing a copy of a bill(s)? Access the following web sites:

Pennsylvania Legislation: www.legis.state.pa.us.
West Virginia Legislation: http://www.legis.state.wv.us/
For copies of congressional bills, access the Thomas website – http://thomas.loc.gov/.

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