Issues for the week ending October 13, 2017

Federal and National Issues

Legislative
- President Trump Signs Executive Order to Direct Tri-Agency Consideration of Expanded Health Insurance Options
- Trump Administrations Announces It will Cut Off CSR Payments
- Committee Leaders Seek Bipartisan Deal on Budget Offsets for CHIP Bill
- Congressional Committee Hears How Hospitals Use 340B Drug Pricing Program

Regulatory
- Hargan Named Acting HHS Secretary
- National Data Demonstrates Hospital Community Benefits Exceed Value of Federal Tax Exemption
- FDA Approves First Zika Screening Test for Blood Donors
- CMS Determines First Qualifying APM Participants for 2018
- GAO Report Highlights the Need for Federal Action to Address Neonatal Abstinence Syndrome
- CMS Issues Bulletin About Segregation of Abortion Funds

State Issues

Pennsylvania
Legislative
- Senate Committee to Consider Bill Allowing Direct Payment to Non-Participating Dentists
- Governor Wolf Signs Right to Try Legislation

Regulatory
- Guidance on Addressing Saline Solution Shortfalls
- Court Denies United's Protest of Community HealthChoices Awards
- PA Department of Health Issues Advisory about Testing Recommendations for Pregnant Females

Industry Trends

Insurance / Market Trends
- California Governor Signs Drug Transparency Measure Into Law

Federal and National Issues

Legislative Issues
President Trump Signs Executive Order to Direct Tri-Agency Consideration of Expanded Health Insurance Options

On October 12, President Trump issued an executive order that directs the Departments of Labor (DOL), Health and Human Services (HHS), and Treasury to promulgate rules covering Association Health Plans (AHPs), Short-Term Limited Duration Insurance (STLDI), and Health Reimbursement Arrangements (HRAs).

- **Association Health Plans**: The order directs the Secretary of Labor to propose regulations within 60 days that consider expanding access to AHPs through a broader interpretation of the Employee Retirement Income Security Act (ERISA). The broader interpretation would allow employers in the same line of business, regardless of state, to form an association that could either purchase a health insurance policy for its employees or self-fund a health plan.

- **Short Term Policies**: The order directs the Departments to propose regulations within 60 days that consider expanding the duration of STLDI products. Currently, STLDI products can be sold alongside individual market coverage but are limited to a period of 3 months or less under a final rule issued by the Obama Administration in October 2016. The EO directs the agencies to consider permitting STLDI products to span a period of up to 12 months. While STLDI products do not meet the definition of a HIPAA-excepted benefit, they are not subject to ACA requirements (e.g., no annual limits, coverage of 10 essential health benefits).

- **Health Reimbursement Arrangements**: The order directs the Departments to consider changes to the usability of HRAs within 120 days, whose deposited funds from an employer are not taxed as income. Existing guidance governing the use of HRAs effectively prevents employers from depositing funds to be used for the purchase of an individual health insurance policy. Should guidance be altered, employees may be able to purchase a health plan on or off an exchange using pre-tax dollars from their employer, in lieu of employer-sponsored coverage.

- **Other Provisions**: Finally, the order also discusses how government rules and guidelines should prioritize competition by limiting excessive consolidation in the health care system, expanding alternatives to ACA compliant health plans, limiting barriers to entry, and increasing data and quality transparency.

Trump Administrations Announces It will Cut Off CSR Payments

On October 12, the Administration announced that payment of cost-sharing reduction (CSR) benefits will end immediately. This will impact advance payments of CSRs for November 2017, which are scheduled to be paid in October, for issuers in all states, including those with Federally-facilitated Marketplaces, State-based Marketplaces, and State-based Marketplaces using the Federal Platform. The White House issued the following statement:

“Based on guidance from the Department of Justice, the Department of Health and Human Services has concluded that there is no appropriation for cost-sharing reduction payments to insurance companies under Obamacare. In light of this analysis, the Government cannot lawfully make the cost-sharing reduction payments. The United States House of Representatives sued the previous administration in Federal court for making these payments without such an appropriation, and the court agreed that the payments were not lawful. The bailout of insurance companies through these unlawful payments is yet another example of how the previous administration abused taxpayer dollars and skirted the law to prop up a broken system. Congress needs to repeal and replace the disastrous Obamacare law and provide real relief to the American people.”

Friday morning, the Administration informed the Court of Appeals of its decision as part of its status report for the House lawsuit challenging the authority of HHS to continue to make CSR payments to health plans without an appropriation from Congress. In August, the Court granted the request
by several state attorneys general to intervene in the case and some have already announced they will seek an injunction to compel the Administration to continue to make payments while the case remains active.

**Committee Leaders Seek Bipartisan Deal on Budget Offsets for CHIP Bill**

House Energy and Commerce Committee Chairman Greg Walden (R-OR) has released a statement indicating that House floor action on legislation to extend federal funding for the Children’s Health Insurance Program (CHIP) will be delayed to allow time for negotiations on budget offsets that would be supported by both Republicans and Democrats.

While stating that he is open to pursuing a bipartisan agreement, Chairman Walden also stated: “We have a responsibility to move quickly to ensure children continue to have access to high-quality affordable coverage. If we are unable to reach a deal by the end of this week, I would expect the House to take up the committee marked bill immediately following the [October 16-20] district work period.”

As approved by the House Energy and Commerce Committee, the CHIP funding bill (H.R. 3921) includes budget offsets in three areas: (1) revising the rules for Medicaid third party liability; (2) revising the treatment of lottery winnings for purposes of determining Medicaid eligibility; and (3) expanding the current policy of requiring income-related premiums under Medicare Part B and Part D for beneficiaries who have higher levels of income. During the markup, Democrats offered an amendment that would have replaced these offsets with language that would have altered the timing of Medicare Advantage and Part D payments beginning in January 2019.

**Congressional Committee Hears How Hospitals Use 340B Drug Pricing Program**

In a hearing before the U.S. House Energy & Commerce Oversight and Investigations Subcommittee, health care providers testified to how the 340B Drug Pricing Program helps expand and improve access to care.

The 340B Drug Pricing Program requires pharmaceutical manufacturers to sell outpatient drugs at discounted prices to health care organizations that:

- Care for large numbers of uninsured and low-income patients
- Serve rural communities
- Offer vital services to cancer patients and children

Lawmakers heard testimony from three hospital leaders, as well as federal grantees under the Ryan White HIV/AIDS Program and Federally Qualified Health Centers.

The hearing—**Examining How Covered Entities Utilize the 340B Drug Pricing Program**—served as a follow-up to a July 18 hearing by the Oversight and Investigations Subcommittee that explored oversight of the 340B Drug Pricing Program by the Health Resources and Services Administration (HRSA).

Ahead of the hearing, the American Hospital Association (AHA) and Association of American Medical Colleges (AAMC) sent a letter to the Energy & Commerce Committee reinforcing the intent of the program and offering examples of how the program works within hospitals.

Hospitals in Pennsylvania have cited that the program allows them to reach more patients and provide more comprehensive services. Many hospitals that participate in the program use the savings to help patients by offering their prescription medications at significantly reduced costs, or no cost at all. Additionally, the program supports initiatives such as providing transportation services to get patients to their doctor appointments, or expanding access to wellness and medication management programs.
Earlier this week, a group backed by the pharmaceutical industry released a disingenuous report that misrepresents how hospitals use the savings from the program to reinvest in care for their community. The AHA highlighted how the report misses the mark in a recent blog.

Setting the record straight, in 2015, 340B hospitals provided $23.8 billion in uncompensated care—62 percent of all uncompensated care provided by hospitals. Uncompensated care includes “bad debt” (services for which hospitals anticipated but did not receive payment) and charity care (services for which hospitals neither received nor expected payment because they determined, with help from the patient, the patient’s inability to pay).

In late September, ten members of the Pennsylvania Congressional delegation signed a letter urging the Centers for Medicare & Medicaid Services (CMS) to abandon a proposed payment policy that will limit the ability of hospitals to use the 340B Drug Pricing Program to better serve their patients and communities. Senator Casey (D, PA) joined 56 colleagues in the U.S. Senate in sending a similar letter that raises concerns about the proposed payment policy, and restates the importance of the 340B program.

**Regulatory Issues**

**Hargan Named Acting HHS Secretary**

President Trump last week named Eric Hargan as Acting Secretary of Health and Human Services. Confirmed as HHS deputy secretary two weeks ago, Hargan previously served on the president’s transition team and as HHS deputy general counsel, principal associate deputy secretary and acting deputy secretary under President George W. Bush.

Tom Price, M.D., resigned as HHS secretary on Sept. 29. Acting Assistant Secretary for Health Don Wright, M.D., has served as acting secretary in the interim.

**National Data Demonstrates Hospital Community Benefits Exceed Value of Federal Tax Exemption**

According to a new analysis prepared by Ernst & Young, not-for-profit hospitals’ and health systems’ community benefit activities outweigh the value of their federal tax exemption by a factor of 11 to one.

The analysis, prepared for and released by the American Hospital Association (AHA), shows that for every dollar invested in hospitals and health systems by means of their federal tax exemption, they deliver $11 in benefits back to their communities.

During 2013, the most recent year for which information was available, the estimated value of federal tax revenue foregone due to the tax-exempt status of non-profit hospitals, was $6 billion. In comparison, tax-exempt hospitals provided $67.4 billion in community benefits to their communities.

Tax-exempt hospitals are exempt from most federal, state, and local taxes because of the community benefit provided by these institutions. They report publicly about their community benefit activities, through Internal Revenue Service Form 990s, as well as through community benefit reports.

In Pennsylvania, both not-for-profit and investor-owned hospitals and health systems are helping local governments and community service agencies address health-related challenges from drug abuse and gun violence to obesity and heart disease. Their commitment reaches beyond buildings and campuses to inner-city neighborhoods and remote rural areas.
Hospitals provide free and reduced cost care for the most vulnerable populations and make up for the gap between Medicare and Medicaid payments and the full costs of delivering care. But there are many more ways that hospitals deliver community benefits. Most people do not realize the extent of the services hospitals support beyond acute care and emergency services. They provide shelter, meals, and other supports during natural disasters such as the recent hurricanes. Hospitals host clinics for underserved communities and programs to help individuals manage chronic illnesses. They are educating the next generation of nurses, physicians, and other health care professionals. Many hospitals mentor young persons through school-based initiatives, often introducing low-income students to health care opportunities. Pennsylvania hospitals, like so many across the country, are establishing partnerships to fight the opioid epidemic and taking mental health services to at-risk individuals. They are implementing programs that address social problems including violence, homelessness, and hunger.

Across Pennsylvania, hospitals are improving health and the quality of life for many citizens. Some hospitals run mobile dental and eye care services for the needy, while others provide remote care for veterans. In efforts to promote wellness, many hospitals operate exercise classes in remote communities or partner to develop bike and walking paths and offer healthy cooking classes.

The study provides estimates for 2013, the most recent year for which community benefit information is available for non-profit hospitals. The analysis does not account for other non-profit specialty hospitals, such as psychiatric or long-term acute care. The analysis reviewed source materials including IRS Form 990 Schedule H, community benefit reports and Medicare cost reports from nearly 3,000 non-profit general hospitals from across the country.

FDA Approves First Zika Screening Test for Blood Donors
The Food and Drug Administration has approved the first blood donor screening test for Zika virus. The agency last year recommended blood centers screen donors for the virus using an investigational test until a licensed test was available. The new licensed test was found effective by several blood centers that used it as well as studies performed by the manufacturer, FDA said.

Zika is transmitted primarily by mosquitoes but also can be spread through blood transfusions and sexual contact. Infection during pregnancy can cause serious birth defects.

CMS Determines First Qualifying APM Participants for 2018
The Centers for Medicare & Medicaid Services has identified the first clinicians eligible to participate in 2018 advanced alternative payment models, based on their participation in qualifying APMs in first-quarter 2017.

Clinicians can use an online tool to look up their 2018 participation status, which will be updated soon based on service claims for second-quarter 2017. Qualifying APM participants are excluded from the Merit-based Incentive Payment System quality reporting program for 2017 and will receive a 5% lump-sum Medicare incentive payment in 2019.

For more information, see CMS’s factsheets on the Quality Payment Program’s methodology and supplemental service payments.

GAO Report Highlights the Need for Federal Action to Address Neonatal Abstinence Syndrome
The rising opioid crisis has increased the number of infants born and diagnosed with neonatal abstinence syndrome (NAS)—a withdrawal condition that affects infants and their families, hospitals, health care providers who treat them as well as federal and state taxpayer who pay for more than 80 percent of NAS-related medical and other treatment costs.
The Government Accountability Office (GAO), as directed by requirements included in the Comprehensive Addiction and Recovery Act of 2016, examined NAS in the United States and related federal government response. For this study, GAO reviewed the U.S. Department of Health and Human Services (HHS) documentation and interviewed HHS officials. GAO also conducted site visits to four states—Kentucky, Vermont, West Virginia, and Wisconsin—selected based on several factors, including incidence rates of NAS and geographic variation. GAO interviewed stakeholders from 32 organizations, including health care providers and state officials in the selected states. GAO’s culminating report describes the hospital and non-hospital settings for treating infants with NAS and how Medicaid pays for services, describes recommended practices and challenges for addressing NAS, and examines HHS’s strategy for addressing NAS.

Key Report Findings and Recommendations
GAO’s report finds that while experts consider NAS to be an expected and treatable result of women’s prenatal opioid use, to date, there currently is no national standard of care for screening or treating NAS. In interviewing stakeholders and reviewing literature, GAO identified several recommended practices for addressing NAS, including the following:

1. Prioritizing non-pharmacologic treatment, such as allowing the mother to reside with the infant during treatment, to facilitate the mother-infant bond
2. Educating mothers about prenatal care, treatment for NAS, and available resources for after an infant’s discharge
3. Educating health care providers about the stigma faced by women who use opioids during pregnancy and about how to screen for and treat NAS
4. Using a protocol in a hospital or non-hospital setting for screening and treating infants with NAS

Additionally, in examining the federal government’s efforts to address NAS—prevent and treat this syndrome by promoting the aforementioned recommended practices, GAO noted that HHS identified key recommendations to help guide its efforts—such as providing medical education to health care providers about how to treat these infants. However, in GAO’s evaluation of the HHS’ strategy to address NAS, GAO found that HHS had no timeline for developing an implementation plan. GAO concluded that it is unclear how the HHS will implement these recommendations, if at all.

The GAO recommended that HHS expeditiously develop a plan to implement these recommendations related to addressing NAS. In response to this recommendation, HHS concurred that it should expeditiously address NAS, but noted implementation of the strategy is contingent on funding.

CMS Issues Bulletin About Segregation of Abortion Funds
The Centers for Medicaid and Medicare Services’ (CMS’) recent bulletin reminds Qualified Health Plan (QHP) issuers about their requirement to comply with Section 1303 of the Affordable Care Act, which prohibits the use of certain federal funds to pay for QHP coverage of abortions, pursuant to the Hyde amendment. The Hyde Amendment bars the use of federal funds to pay for abortions except to save the life of the woman or if the pregnancy was caused by rape or incest. CMS reminds issuers that they must charge and collect no less than $1 per enrollee per month for coverage of non-Hyde abortion services, and deposit the collected amounts into a separate allocation account used exclusively to cover non-Hyde abortions. Issuers should also provide notice to enrollees informing them that a portion of the total premium amount owed is a separate payment for non-Hyde abortion services.

Beginning in the 2018 plan year and future plan years, CMS will directly enforce these statutory requirements in FFM states where it has enforcement authority and calls upon States operating
their own exchanges to do the same. If a State does not enforce these requirements, CMS would step in to substantially enforce them. If CMS finds that an issuer failed to comply with these requirements, civil monetary penalties could result, beginning in the 2018 plan year. CMS is also evaluating whether additional steps should be taken to ensure compliance with the requirements of Section 1303 and its implementing regulations and is exploring options for the FFM to provide more meaningful notice to consumers at the point of sale, beyond the SBC, to more prominently display on healthcare.gov whether a plan includes non-Hyde abortion services.

State Issues

Pennsylvania

Legislative

Senate Committee to Consider Bill Allowing Direct Payment to Non-Participating Dentists

The Senate Banking and Insurance Committee has scheduled for consideration Senate Bill 373. As currently drafted, this measure would allow dental patients to “assign” their insurance payments for dental services directly to a non-participating dental provider. Highmark opposes certain initiatives that provide direct payment to out-of-network providers in part because they negatively impact health care provider networks. Timely, direct payment is a benefit of being part of a dental network. Senate Bill 373 also adds to the cost of claims administration, exposes our members to balance billing, an anti-consumer practice that contributes to the cost of dental care, and would prohibit dental insurers from being able to audit the services delivered by non-network providers.

Governor Wolf Signs Right to Try Legislation

Governor Tom Wolf has signed House Bill 45, the Right to Try Act, into law. Act 33 of 2017 would allow eligible patients to request and use investigational drugs, biological products and devices not yet approved by the U.S. Food and Drug Administration (FDA) as long as the patient has a terminal illness and meets other requirements. The term "terminal illness" is defined as a disease or condition that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely. Act 33 does not require a patient’s health insurance plan or their health provider to pay for these investigational treatments.

Regulatory

Guidance on Addressing Saline Solution Shortfalls

The hospital and health care community have been working with the Pennsylvania Department of Health (DOH) to assess and address shortfalls in the supply chain of sterile saline solution and related products. Manufacturers have limited the allocation of some products. As a result, some facilities have received less than half of their normal baseline orders. Data collected by DOH indicates that small-volume presentation of these products (≤250 mL) are most affected.

The federal U.S. Food and Drug Administration (FDA) is working to ease these supply chain issues by:

- Temporarily licensing products currently being manufactured in Europe
- Working to enhance production and distribution from the Baxter Puerto Rico manufacturing facility affected by recent hurricanes

Meanwhile, clinicians and facilities:

- Should consider using common sense approaches to managing shortfalls
• May wish to order **saline products** being temporarily imported by Baxter Healthcare Corporation in conjunction with the FDA
• May wish to adapt **guidance** for conserving limited IV solution supplies, originally created by the American Society of Health-System Pharmacists to address shortages of large-volume IV fluids

Key points from this **guidance** include:

• Use oral hydration whenever possible.
• Implement an organization-specific action plan to conserve IV fluids where possible. Allow flexibility as the shortage status of specific products may change frequently.
• Develop medical staff-approved policies for substitution of IV solutions based on product availability within the organization.
• Frequently evaluate the clinical need to continue intravenous fluid.

DOH is expected to issue similar guidance shortly.

Concern about supply chain availability of sterile saline solution and related products has been a national issue since 2014. The hurricanes, and recent FDA action regarding another manufacturing plant, have exacerbated the shortage. Tax breaks and incentives made Puerto Rico the Caribbean’s economic powerhouse two decades ago, helping attract dozens of drug and device makers that built state-of-the-art manufacturing facilities. The industry accounts for roughly a quarter of the island's gross domestic product, with more than 70 medical-device manufacturing operations and 49 U.S.-approved pharmaceutical plants.

DOH’s [Bureau of Public Health Preparedness](#) is continuing to monitor and share information regarding this shortage. Information currently is being shared on the Knowledge Center Health Care Incident Management System (KC-HIMS) and through emergency preparedness channels.

**Court Denies United’s Protest of Community HealthChoices Awards**

On October 4, 2017, the Pennsylvania Commonwealth Court denied UnitedHealthcare’s challenge to the Pennsylvania Department of Human Services’ contract awards for **Community HealthChoices**, Pennsylvania’s **managed long-term services and supports program**.

United argued that:

• Other insurers should not have been allowed to submit performance scores from other states
• The qualifications of the small and diverse businesses in the bids were incorrectly evaluated

The court rejected all of United’s arguments for failure to meet deadlines and lack of merit.

Implementation of Community HealthChoices currently is scheduled to begin in **14 counties** in the southwestern part of the state on January 1, 2018.

**PA Department of Health Issues Advisory about Testing Recommendations for Pregnant Females**

The Pennsylvania Department of Health (DOH) has issued a statewide health advisory to health care providers. **Health Advisory 389** encourages OB/Gyn providers to review testing recommendations for pregnant females. This advisory follows recent reports indicating increases in sexually transmitted diseases and opioid addiction among this population. Testing recommendations follow the U.S. Centers for Disease Control and Prevention **treatment guidelines**.
The DOH health advisory provides general recommendations for testing of pregnant females, including:

- Offering pregnant women a test for syphilis and HIV at the time of first examination
- Routinely screening for the hepatitis B surface antigen HBsAg during the first prenatal visit, or within 15 days of the first visit, but no later than the time of delivery
- At time of admission to the hospital for delivery, testing patients who were not screened prenatally, and retesting those with signs and symptoms of hepatitis B, or those at high risk for infection behaviors
- Creating a special note for high-risk females
- Creating a special note about Syphilis treatment with Benzathine penicillin G, and how to obtain treatment assistance

Health care providers interested in receiving DOH health alerts health advisories and health update notifications, can sign up with the PA Health Alert Network.

### Industry Trends

#### Insurance / Market Trends

**California Governor Signs Drug Transparency Measure Into Law**

California has a new drug transparency law. Despite efforts by the drug manufacturing industry to defeat Senate Bill 17, Governor Jerry Brown (D) signed the measure, which addresses drug manufacturer reporting on price increases and on new drugs, health plan reporting, and reporting by the California Research Bureau. The new law also includes the following requirements:

- Manufacturers of prescription drugs with a wholesale acquisition cost (WAC) of more than $40 per course of therapy must notify specified purchasers (state agencies, health plans, insurers, and PBMs) 60 days in advance of a planned increase that will result in a cumulative WAC increase of 16 percent or more over the previous two calendar years.

- For each drug that meets the law’s advance notice threshold, the manufacturer must report specified information to the Office of Statewide Health Planning and Development (OSHPD) on a quarterly basis.

- Manufacturers must notify OSHPD within three days after release of a new prescription drug to the commercial market if the WAC qualifies as a specialty drug under Medicare Part D.

**State**

The Pennsylvania General Assembly is in session the week of October 16.

The Delaware General Assembly has adjourned for the year.

The West Virginia Legislature has adjourned for the year.

**Congress**

The U.S. Senate is in session the week of October 16.
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/.