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Federal and National Issues

Legislative Issues

Congress Returns from Summer Break
Congress is back in Washington this week for the first time since mid-July. They face an abbreviated pre-election session which will include consideration of a “continuing resolution” (CR) to provide temporary funding to support government operations during the initial part of the new fiscal year that begins on October 1.

House Majority Leader Kevin McCarthy (R-CA) has outlined more than a dozen issues that may see legislative action in September, including two health-related issues: (1) a $1.1 billion
supplemental funding package to address the Zika crisis; and (2) legislation that would change the threshold for the medical expense tax deduction back to its pre-ACA level of 7.5 percent – down from its current level of 10 percent.

While there are a relatively small number of legislative days in this Congress there are a few issues that could still see action in September or during a post-election lame duck session:

- **21st Century Cures:** The House approved major legislation addressing 21st Century Cures in July 2015, with the goal of advancing the discovery, development, and delivery of new cures and treatments. The Senate HELP Committee approved a series of 19 medical innovation bills addressing these same priorities, in three separate markups held in February 2016, March 2016, and April 2016. While this legislation faces significant challenges, the leaders of the House Energy and Commerce Committee and the Senate HELP Committee will be pushing for final congressional action by the end of this year.

- **Mental Health Reform:** Separate bills addressing mental health reform were approved earlier this year by the full House and by the Senate HELP Committee. Both bills would direct federal agencies to issue guidance that provides illustrative examples of compliance and non-compliance with the parity requirements of the Mental Health Parity and Addiction Equity Act (MHPAEA), and methods that insurers may use for disclosing information to ensure that they are in compliance. Other priorities addressed by this legislation include the development of evidence-based treatment programs, workforce issues, and guidelines on the appropriate use and disclosure of protected health information.

- **Health Insurance Tax:** Last year, Congress suspended the ACA health insurance tax for 2017. Unless action is taken before the end of the year, the tax will be reinstated for 2018 and beyond.

**Clinton Announces Agenda on Mental Health Issues**

Democratic presidential nominee Hillary Clinton has announced a comprehensive agenda for addressing the needs of Americans with mental health problems.

Secretary Clinton’s agenda focuses on six priorities: (1) promoting early diagnosis and intervention, including launching a national initiative for suicide prevention; (2) integrating the nation’s mental and physical health care systems and significantly enhancing community-based treatment; (3) training law enforcement officers in crisis intervention and prioritizing treatment over jail for low-level, non-violent offenders; (4) enforcing mental health parity “to the full extent of the law”; (5) improving access to housing and job opportunities for individuals with mental health problems; and (6) investing in brain and behavioral research and developing safe and effective treatments.

With respect to mental health parity, Secretary Clinton’s agenda calls for randomized audits to detect parity violations, requiring health plans to specifically disclose how their non-quantitative treatment limitations comply with the parity law, strengthening federal monitoring of health insurer compliance with network adequacy requirements, and directing federal officials to work with the National Association of Insurance Commissioners, state leaders, patient advocates, and other stakeholders to “set milestones and hold one another accountable to improve parity enforcement across-the-board.”

**California Passes Surprise-Bill Legislation**

California medical consumers will enjoy strong new protection against surprise out-of-network medical bills starting July 2017, under a hard-fought bill overwhelmingly approved by the state legislature this week.
Under the bipartisan bill, AB 72 (PDF), patients who received care in in-network facilities by out-of-network providers would have to pay only in-network cost sharing. This would apply just to non-emergency care, since emergency physicians in California already are barred from balance billing patients. The bill’s provisions would not apply, however, to self-insured employer health plans, which are shielded from state regulations by the federal Employee Retirement Income Security Act. Health plans would pay non-contracting physicians the plan’s average contracted rate or 125% of the Medicare rate, whichever is greater. Doctors could appeal that through a binding independent dispute resolution process, which the state Department of Managed Health Care will establish.

Florida enacted a similar law this year, joining New York, while Georgia and other states are studying the issue or considering legislation.

Insurers and other payers faced pressure to come up with a legislative solution because shocker out-of-network bills have undermined public support for narrow-network health plans, which have become a primary method of keeping premiums affordable.

**Regulatory Issues**

**CMS Issues 2018 Notice of Benefits and Payment Parameters Proposed Rule**

The Centers for Medicare and Medicaid Services (CMS) on August 30th released the proposed Notice of Benefit and Payment Parameters (NBPP) for 2018, which includes provisions related to risk adjustment, rating factors and QHP certification, among others. In addition, CMS released the draft [actuarial value (AV) calculator](#) (Comments on the calculator are due September 30, 2016) and methodology for 2018. Throughout 2017, both trade associations, America’s Health Insurance Plans (AHIP) and the Blue Cross and Blue Shield Association (BCBSA) met extensively with the Administration offering recommendations, based upon industry input, to ensure that the 2018 requirements focus on marketplace sustainability and affordability.

While CMS *did not* include the industry’s recommended priority actions to require up-front verification of special enrollment periods or policies to address gaming of grace periods, CMS does comment on potential future steps that could be taken to address these issues. Below is a short list of some standout provisions:

- **Improvement of the Risk Adjustment Methodology:** The proposed rule improves the risk adjustment methodology to incorporate prescription drug data and addresses partial year enrollments. The proposal also includes an update to risk adjustment high risk members with claims in excess of $2 million.
- **Standardized Plan Requirements:** The proposed rule continues to allow insurers to offer standardized plans on a voluntary basis, while widening the scope of the initiative.
- **Updated Child Rating Factors:** The proposed rule updates child rating factors for 2018 and beyond to address insufficient rates and to eliminate the steep, one-time rate increase when a child becomes an adult under the existing factors.
- **Five-Year Market Re-Entry Ban:** The proposed rule changes the parameters of the current five-year ban on companies returning to the individual or small group markets after they have left the market. The proposal would make it easier for an issuer with multiple subsidiaries to avoid the ban at the parent organization level.
- **Direct Enrollment:** The proposed rule includes a number of modifications to existing requirements and establishes new requirements for agents and brokers who use the current direct enrollment process.
- **Binder Payments:** The proposed rule aims to add additional flexibility to binder payment rules and requires agents and brokers to ensure consumers are educated regarding how to make such payments.
- **Special Enrollment Period (SEP):** In the rule, CMS acknowledged competing concerns regarding special enrollment period enrollee impact on the risk pool. CMS proposed to codify several special enrollment periods that it already made available through guidance. It also requests quantitative information on potential “gaming” of current SEPs.

- **Levels of Coverage: Bronze Plans:** The rule proposes to offer greater flexibility for plan design innovation by liberalizing Actuarial Value requirement for bronze plans.

- **Medical Loss Ratio (MLR) Requirements:** The agency is considering changes to liberalize MLR requirements and provide new and growing issuers greater flexibility in calculating MLR.

- **Meaningful Access:** CMS proposes to lessen the administrative burden of “meaningful access” tagline requirements. The agency recognizes that these requirements are duplicative of those in the recent Office of Civil Rights ACA section 1557 regulation, and proposes to streamline dual regulations.

Comments on the proposed notice are due October 6, 2016. Highmark’s Government Compliance area is currently analyzing the proposal and preparing a detailed summary which will be shared with various business units throughout the enterprise. The draft regulation is available at: [https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-20896.pdf](https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-20896.pdf).

**Medicare Periodic Data Matching**

The Centers for Medicare and Medicaid Services (CMS) announced on September 1st that the Federally-facilitated Marketplace (FFM) conducted a data match with Medicare to determine whether consumers aged 65 and older who are enrolled in Marketplace coverage with financial assistance are also enrolled in Medicare coverage that qualifies as Minimum Essential Coverage (MEC). The FFM will send a Medicare Periodic Data Matching notice to the household contact of consumers identified as being enrolled in both Marketplace coverage with advanced payment of the premium tax credit (APTC) or cost sharing reductions (CSR) and MEC Medicare instructing such consumers to end their Marketplace coverage with APTC/CSR. Other consumers in the household who are enrolled in the Marketplace plan may remain on that plan.

Consumers enrolled in Medicare Part A and Medicare Part C, which qualify as MEC, are not eligible for a Marketplace plan with APTC or income-based CSR. If consumers are enrolled in both MEC Medicare and a Marketplace plan with APTC/CSR and they do not end their Marketplace coverage with APTC/CSR, the consumer will likely have to pay back all or some of the APTC received for a Marketplace plan during the months the consumers were also enrolled in Medicare.

**State Issues**

**Delaware**

**Regulatory**

**Delaware Department of Insurance Proposes Four Regulations that Impact Health Insurers**

- **Regulation 1317 relating to Network Disclosure and Transparency:** The proposed regulation establishes the standards for the form and content of network disclosures that are required to be made by out-of-network providers and the written consent that must be obtained by such a provider prior to balance billing an insured. The proposed regulation also requires health insurers to maintain and publish accurate, complete and up-to-date provider directories and to make those directories easily accessible to covered persons.

- **Regulation 1313 relating to Arbitration of Health Insurance Disputes Between Carriers and Providers:** The proposed regulation would amend an existing regulation to make the current arbitration provisions applicable to arbitrations conducted pursuant to 18 Del.C. §§3371 and 3571S. The purpose of this Regulation is to implement 18 Del.C. §§333, 3371 and 3571S.
which requires health insurance carriers to submit to arbitration any dispute with a health care provider regarding reimbursement for an individual claim, procedure or service upon a request for arbitration by the health care provider.

- **Regulation 304 relating to Standards and Commissioner's Authority for Companies Deemed to be in Hazardous Financial Condition [Formerly Regulation 70]:** The proposed regulation would bring the existing regulation in compliance with the National Association of Insurance Commissioners (NAIC Model Regulation 385, as revised 2008). Model Reg. 385 is needed for accreditation purposes and provides additional standards for consideration by the Insurance Commissioner to determine whether the continued operation of any insurer might be deemed to be hazardous to its policyholders, creditors or the general public. The proposed amendments give the Insurance Commissioner additional authority to issue an order requiring companies deemed to be in hazardous financial condition to take corrective action. These amendments should not pose additional burdens on insurers.

- **Regulation 1214 relating to Senior Protection in Annuity Transactions:** The proposed regulation would bring existing regulation in compliance with the National Association of Insurance Commissioners (NAIC) Model Regulation for Suitability in Annuity Transaction (NAIC Model Reg. 275, as revised December 2010). NAIC Model Reg. 275 requires insurers and producers to establish a system to supervise recommendations made in the marketing and sale of annuities, regardless of age (which standards are also consistent with the standards imposed by the Financial Industry Regulatory Authority (FINRA)). This proposed amendment should not pose additional burdens on agents as they should already be doing this.

All proposed regulations can be viewed at the Delaware Insurance Commissioner’s website at: [http://www.delawareinsurance.gov/departments/documents/ProposedRegs/](http://www.delawareinsurance.gov/departments/documents/ProposedRegs/)

**Pennsylvania**

**Regulatory**

**Community HealthChoices Awards Announced**

The Departments of Human Services (DHS) and Aging announced that the Commonwealth is moving forward to negotiate agreements with three managed care organizations (MCOs) for Community HealthChoices (CHC). DHS selected AmeriHealth Caritas, Pennsylvania Health and Wellness (Centene) and UPMC for You to deliver statewide services in Pennsylvania beginning in 2017.

The Pennsylvania implementation is scheduled to occur in three geographic phases: the Southwest on July 1, 2017, the Southeast on January 1, 2018, and the remainder of the state on January 1, 2019.

CHC will coordinate physical health care and long-term services and supports (LTSS), if needed, to enhance the quality of medical care and access to more than 420,000 individuals who are dually eligible for Medicare and Medicaid, older Pennsylvanians and individuals with disabilities.

The MCO agreements will also continue the departments’ increased focus on greater coordination between the physical and behavioral health systems, as well as LTSS. CHC will:

- Enhance opportunities for community-based services and increase access to services
- Strengthen health care and LTSS delivery systems
- Allow for new innovations
- Promote the health, safety, and well-being of enrolled participants
- Ensure transparency, accountability, effectiveness, and efficiency of the program
Industry Trends

Provider / Delivery System Trends

St. Luke’s and Geisinger Seek Permission to Forge Partnership
According to reports from PennLive, St. Luke’s University Health Network and Geisinger Health System unveiled a collaboration that will see St. Luke’s six hospitals and 270-plus medical offices will become clinical partners under the Geisinger Health Plan, in an effort to generate savings and keep them in-house rather than benefitting other insurers, executives from both companies announced. The partnership is projected to take effect Jan. 1, if approved by Pennsylvania Insurance Commissioner Teresa Miller. Additions going forward under the new collaboration include a Medicare Advantage plan sponsored by St. Luke’s and Geisinger and new plans available to commercial and employer groups in the region. St. Luke’s 10,000-plus employees and their families will also become members of the Geisinger insurance plan, in a move projected to save St. Luke’s about $500,000 a year, officials said.

Hospital Pay Rule Would Increase Fraud and Abuse Risks
A proposed rule to update payments for hospital outpatient departments would increase the risks of hospitals and physicians running afoul of fraud and abuse laws, according to a legal analysis prepared for the American Hospital Association. The analysis, prepared by Washington-based Hogan Lovells LLP for the AHA, said so-called site-neutral payments could trigger violations of the physician self-referral law and the anti-kickback statute.

Fraud and abuse laws prohibit hospitals from providing free goods or services to physicians who refer business to the hospitals, such as office space, equipment and nursing staff, yet according to the analysis the proposal would leave hospitals responsible for staffing and operating their outpatient departments while the entire Medicare reimbursement payment would go to the contracting physician. This type of arrangement could be considered a provision of free services to physicians, placing it in violation of fraud and abuse laws, the analysis said.

“Were CMS to adopt the proposed rule, hospitals and treating physicians would be forced to choose between the substantial legal risk of entering into altered financial arrangements subject to scrutiny as well as potentially significant financial and criminal penalties under the fraud and abuse laws, on the one hand, or disrupting the delivery of patient care on the other,” the legal analysis said.

The proposal would implement Section 603 of the Bipartisan Budget Act of 2015, requiring that certain services provided at hospital outpatient departments no longer be paid under the outpatient prospective payment system. The policy, which would equalize Medicare payment rates for hospital outpatient departments and hospital-owned physician offices, intended to address the practice of hospitals acquiring physician offices then billing patients under the outpatient prospective payment system, which has higher reimbursement rates than the Medicare physician fee schedule.

The site-neutral payment provisions were included in the proposed 2017 hospital outpatient prospective payment system rule, which was published July 6. Comments are due Sept. 6. The AHA said it would be submitting formal comments to the Centers for Medicare & Medicaid Services in addition to the legal analysis.

Faced with potential violations of fraud and abuse laws from a finalized site-neutral provisions in the OPPS rule, hospitals would have to restructure their business arrangements with outpatient departments, the analysis said. The restructuring process would involve burdensome negotiations with physicians, the analysis said, and could be viewed with suspicion by the Centers for Medicare & Medicaid Services and the Health and Human Services Office of Inspector General.
According to the analysis, “steadiness of contractual terms is key to satisfying critical protections under the fraud and abuse laws, but the proposed rule would require substantial changes and produce contractual turmoil.”

**Insurance / Market Trends**

**Alissa Fox to Retire**
Senior Vice President of the Blue Cross Blue Shield Association (BCBSA) on September 2d announced her retirement. In her announcement Alissa states:

“I want to let you know that I am retiring from BCBSA – after 30 years of service with the Blues. Just so you know, I started when I was 17!! I will continue in my role until next April to help with the transition to a new Administration and new Congress. I am very appreciative of all of your support and hard work over the years in advocating for our legislative and regulatory priorities and am looking forward to continuing to work together over the next several months on our key issues.”

**Mylan Plans Generic EpiPen to Quell Outcry Over $600 Cost**
Mylan NV will sell a generic version of its EpiPen at half the price of the branded $600 cost for its emergency allergy shots in coming weeks, bowing to pressure after U.S. lawmakers derided earlier steps last week as mere public relations fixes. The drugmaker, whose offer of assistance programs to help patients cover out-of-pocket expenses was blasted as insufficient, will introduce a generic EpiPen identical to the branded product, which includes the drug itself and the handheld pen with a needle that injects the shot. The company also plans to continue to sell the branded version.

Mylan has attracted scrutiny for increasing the treatment’s price 400 percent in nine years; EpiPen cost $57 for a single pen when the drugmaker bought it in 2007. Criticism of Chief Executive Officer Heather Bresch, the daughter of Sen. Joe Manchin (D-W.Va.), quickly intensified last week as members of the Congress called for investigations and the EpiPen became campaign fodder.

Introducing a so-called authorized generic, which does not require formal approval from the Food and Drug Administration, is a fast way for Mylan to get a cheaper version out—without actually cutting the branded EpiPen’s price. “They can just do it. They don’t need approval,” said David Rosen, a lawyer at Foley & Lardner LLP. The move will not block future generics from competitors such as Teva Pharmaceutical Industries Ltd., but it can help Mylan capture some of the market share it would have lost with the introduction of a rival generic, he said.

Meanwhile, a letter from lawmakers on the House Energy and Commerce Committee Aug. 29 questioned the FDA’s speed in approving generic equivalents to the EpiPen. They identified issues in bringing competitors to Mylan’s allergy treatment EpiPen onto the market.

The EpiPen price increases drew particular attention in Washington because Bresch had successfully pushed legislation to encourage use of the EpiPen in schools nationwide. Mylan spent about $4 million in 2012 and 2013 on lobbying for access to EpiPens generally and for legislation, including the 2013 School Access to Emergency Epinephrine Act, according to lobbying disclosure forms filed with the Office of the Clerk for the House of Representatives.

State
The Pennsylvania House of Representatives returns to session on September 19 and the Pennsylvania Senate returns on September 26.

The Delaware General Assembly has adjourned for the year.

The West Virginia Legislature has adjourned for the year.

Congress
The U.S. Congress is in session the week of September 6.

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


Pennsylvania Legislation: [www.legis.state.pa.us](http://www.legis.state.pa.us).

West Virginia Legislation: [http://www.legis.state.wv.us/](http://www.legis.state.wv.us/).

For copies of congressional bills, access the Thomas website – [http://thomas.loc.gov/](http://thomas.loc.gov/).