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Federal and National Issues

Legislative Issues

Post-Recess Agenda Includes Health and Budget Priorities
Congress will reconvene on Monday, June 5, returning from a Memorial Day recess. The legislative agenda in the next stretch of the 2017 session will include continued efforts in the Senate to develop “repeal and replace” legislation, next steps in the budget process for fiscal year
2018, reauthorization of the FDA’s user fee programs, and an extension of federal funding for the Children’s Health Insurance Program (CHIP).

Following the release of CBO’s cost estimate for the House-passed version of the American Health Care Act (AHCA), staffers from the Senate Finance Committee, Senate HELP Committee, and Senate Budget Committee have begun drafting language for various legislative options. The new CBO analysis projects that the number of additional uninsured people (compared to current law) would increase by 14 million in 2018, 19 million in 2020, and 23 million in 2026. To address this concern, senators are weighing alternative approaches to the AHCA’s state waivers, Medicaid provisions, premium tax credits, and market reforms. They also are exploring the need for immediate steps to stabilize the individual health insurance market in the short term.

The overall focus of the Senate bill will be significantly influenced by CBO’s estimate that the AHCA would achieve $119 billion in budget savings over ten years. To comply with budget reconciliation rules, the Senate bill will need to achieve at least the same level of budget savings; this requirement will at least partially limit the Senate’s ability to pursue provisions that involve significant costs. While Senate Republicans will be strongly focused on advancing repeal and replace legislation in June, key senators have acknowledged that reaching a consensus will be difficult and the outcome is uncertain.

The post-recess legislative agenda in Congress also will include the following priorities:

- **FDA User Fee Programs:** The Senate Finance Committee and the House Energy and Commerce Subcommittee on Health have approved similar bipartisan bills addressing reauthorization of FDA user fee programs that are scheduled to expire on September 30, 2017. A markup in the full House Energy and Commerce Committee is expected in early June. Lawmakers are aiming to send a reauthorization bill to the President’s desk before the August recess.

- **CHIP Funding:** The President’s budget for FY 2018 proposed a two-year extension of federal CHIP funding, while the Medicaid and CHIP Payment and Access Commission (MACPAC) has recommended a five-year extension. CHIP supporters in Congress, both Republicans and Democrats, will be pushing for legislative action on this issue well before the current authorization expires on September 30, 2017.

- **Annual Budget Process:** Following the release of the President’s budget for fiscal year (FY) 2018, the House and Senate Budget Committees are preparing to develop a budget resolution that is expected to include reconciliation instructions for tax reform legislation while also providing allocations for the FY 2018 appropriations bills. However, consideration of the FY 2018 budget resolution on the House and Senate floors may need to wait, depending on how the reconciliation rules are interpreted, until after the Senate completes action on the reconciliation bill (i.e., for health reform legislation) that was authorized under the FY 2017 budget resolution.

**Administration and House Urge Denial of States’ Motion to Intervene in CSR Lawsuit**

The U.S. Justice Department has filed a response to the motion to lift the abeyance (i.e., state of suspension of the appeal) that recently was filed by the attorneys general of 15 states in a lawsuit, House v. Price, challenging the Administration’s payment of cost-sharing reduction (CSR) subsidies. The House of Representatives also filed a response to that motion.

The attorneys general filed the motion to lift the abeyance to allow consideration of their motion to intervene in the case. In their motion to intervene, the attorneys general argued that they should be permitted to intervene in this case “to ensure an effective defense against the claims made in this case and to protect the interests of millions of state residents affected by this appeal.”
The response filed by the Justice Department argues that the motion to lift the abeyance should be denied. It further states that the attorneys general's intervention motion should be denied and that the federal government does not “intend to respond substantively to the States' intervention motion unless directed to do so by the Court.”

The response filed by the House argues that the motion to lift the abeyance should be denied “to allow the parties time to seek a negotiated resolution in light of the new Administration and ongoing legislative efforts.” The response states that the attorneys general have not justified lifting the appeal because, among other things, “there is no outcome of this appeal that could yield a judgment barring the Administration from deciding to stop making cost-sharing payments.”

**Federal Circuit Grants Motion to Have Same Appeals Panel Consider Risk Corridor Cases**

Two of the twenty-four risk corridor cases filed in the Court of Federal Claims are currently on appeal to the Federal Circuit: Land of Lincoln (in which the Court of Federal Claims ruled for the government) and Moda (in which the Court of Federal Claims ruled for Moda). Land of Lincoln and Moda both recently filed motions to have the same merits panel consider their appeals. The government opposed these motions and filed its own motion to stay (i.e., delay) the Moda appeal until Land of Lincoln is decided.

On May 30, the U.S. Court of Appeals for the Federal Circuit granted Land of Lincoln and Moda’s motions to have the same merits panel consider their appeals and denied the government’s motion to stay Moda’s appeal. Joint oral argument of the cases will occur in the fall, following the full briefing of Moda’s appeal.

Also on May 30, the Federal Circuit granted a motion by the U.S. House of Representatives to file an amicus brief in Land of Lincoln. The House seeks affirmance of the Court of Federal Claims’ decision in favor of the government, arguing that such a decision is compelled by constitutionally-based appropriations law principles.

**Regulatory Issues**

**Contraceptive Coverage Interim Final Rule at OMB**

The Office of Management and Budget (OMB), on May 23, indicated that it has begun a review of an interim final rule regarding “certain preventive services” (which is the phrase used historically to refer to the market-wide contraceptive services requirements under the Affordable Care Act). The OMB information prompted a group of Democratic Senators to write to OMB Director Mick Mulvaney urging him to cease any efforts in response to a previous Executive Order that directed the agencies responsible to review the contraceptive services mandate and accommodation scheme for conscience-based objections. The plot continued to thicken this past week with a leaked copy of the proposed interim final rule. It is not the likely that the interim final rule will emerge in its current form.

**Social Security Numbers to be Removed from all Medicare Cards by April 2019**

The Centers for Medicare & Medicaid Services (CMS) announced that it will remove Social Security numbers from Medicare cards and is on schedule to begin mailing new Medicare beneficiary cards during April 2018. CMS hopes the initiative will help combat identity theft and will have all existing Medicare cards replaced by April 2019.

The new Medicare cards no longer will use a Social Security-based Health Insurance Claim Number (HICN) but, instead, an 11-character Medicare Beneficiary Identifier (MBI), a combination of upper-case letters and numbers, will be used as a beneficiary’s unique identifier. CMS will allow for a 21-month transition period during which providers may use either the HICN or the MBI number for claims. The transition period will begin no earlier than April 1, 2018, and will extend through December 31, 2019. CMS also has made available its MBI Format specifications.
CMS is required to remove Social Security numbers from Medicare cards as mandated by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. This effort is an important initiative that will help reduce the growing number of identity theft incidents among seniors, which increased to 2.6 million from 2.1 million between 2012 and 2014.

More information about CMS’ Social Security Number Removal Initiative is available at the CMS website.

NIH Researching Opioid Alternatives as It Steps in to Help Combat Crisis

The National Institutes of Health wants to develop alternative painkillers to opioids that are just as effective without causing addiction as one way of combating an overdose epidemic linked to more than 33,000 deaths in 2015. New drug development is part of a three-pronged approach announced on May 31 by the NIH in partnership with the pharmaceutical industry. NIH Director Francis Collins and Nora D. Volkow, director of the NIH’s National Institute on Drug Abuse (NIDA), described their plan in a special report in the New England Journal of Medicine (NEJM).

The NIH announcement falls on the same day Health and Human Services Secretary Tom Price announced that more than $70 million is available in two grant programs to aid first responders, health care providers, and others trying to prevent opioid overdose deaths and treat opioid use disorder. Ending the crisis a top priority for President Donald Trump, Price said, adding the HHS is “committed to bringing everything the federal government has to bear on this health crisis.”

Addressing the epidemic is not as simple as removing opioids from treatment protocols. Otherwise, those patients will rely on opioids from the black market. “If we want to address the opioid crisis, we need to address the needs of patients suffering from pain,” Volkow said.

In addition to developing drugs that will not cause addiction, the NIH also wants to research ways to reverse or prevent an overdose and develop new treatment strategies for opioid use disorders. Representatives from the NIH, the Food and Drug Administration, and research and development heads of major drug companies convened in April to lay out this strategy.

The FDA is “signaling that they’re interested in a regulatory framework that might be more friendly towards the development of new medication,” Collins said. “They recognize that pain medicines need not be completely devoid of any side effects to be approvable when you consider the side effects of opioids which are, sadly, addiction and sometimes death.”

Over the next six weeks, the NIH plans to hold “a series of three very intense workshops” with drug companies to accelerate the process of finding answers in areas where current solutions are inadequate to respond to the crisis.

Regulatory Conflict in HHS Privacy and Lab Rules to Get Review

A new National Academies project aims to tackle a long-standing discrepancy that pits the HIPAA Privacy Rule against laboratory testing requirements for when a research lab can share results with patients. The Health Insurance Portability and Accountability Act Privacy Rule requires research subjects to have access to their data on request. But these data cannot be shared if they are from a research laboratory that is not certified under a 2014 final rule about the Clinical Laboratory Improvement Amendments, which are regulated by the Centers for Medicare & Medicaid Services. Most research laboratories in HIPAA-covered entities such as academic medical centers are not CLIA certified, creating a regulatory conundrum between the two Department of Health and Human Services rules.

More research studies, both academic and industry-sponsored, are using non-CLIA-certified research laboratories to run their tests as part of protocols that have been approved by institutional
review boards. "This conflict between the legal requirements of CLIA and HIPAA—the regulations and interpretations of two offices within HHS—has therefore further complicated an already difficult set of ethical calculations regarding the return of research tests’ results to research participants."

The HHS Secretary's Advisory Committee on Human Research Protections issued recommendations on this regulatory conflict two years ago as part of a larger recommendation on the return of research results. They called on the relevant agencies to clarify what to do when individuals ask for their research tests run through a non-CLIA lab in a HIPAA-covered entity.

On top of the CLIA-HIPAA regulatory conflict the Food and Drug Administration medical device regulations may also require additional measures before returning individual-level research results.

**Trump Administration Wants to Overhaul Drug Discounts for Hospitals**

The Trump administration's 2018 budget envisions big changes to a drug pricing program that offers discounts to hospitals and other providers. The president's budget request for fiscal year 2018 directs the Department of Health and Human Services to work with Congress to develop a legislative proposal to improve the 340B drug pricing program's "integrity and ensure that the benefits derived from participating in the program are used to benefit patients, especially low-income and uninsured populations."

The Health Resources and Services Administration, part of HHS, administers the 340B program, which was created by a 1992 law. However, HRSA has had trouble in the courts with implementing 340B program rules due to a lack of statutory authority.

The 340B program requires drug manufacturers to provide discounts on outpatient prescription drugs to certain safety-net health care providers specified in the statute. Drugmakers must provide the discounts in order to remain eligible for reimbursements through Medicare and Medicaid. The Affordable Care Act expanded the 340B program to include new types of providers, including free-standing cancer, community, and critical access hospitals. Covered entities saved on average between 25 percent to 50 percent on what they would have otherwise paid for covered outpatient drugs. HRSA said it estimates 340B sales are approximately 2.8 percent of the total U.S. drug market.

Given HRSA's repeated difficulty in promulgating new rules or guidances, Congress appears increasingly likely to revisit the 340B program's underlying statute.

Some lawmakers have already said they plan to introduce legislation to change the 340B program. Senator Bill Cassidy (R-La.) said May 2 at an event hosted by AIR 340B he is working on a drug pricing bill that will include 340B overhaul ideas. Representative Peter Welch (D-Vt.) plans to introduce legislation on the 340B program and the orphan drug exclusion the week of June 5. Welch's proposal, the Closing Loopholes for Orphan Drugs Act, would limit the 340B drug discount program's orphan drug exclusion to apply only when drugs are used to treat the rare diseases or conditions they were developed to treat. But it would allow the drugs to be discounted under the 340B program when they are being used for a wider, nonorphan indication. Orphan drugs, which treat rare diseases that affect 200,000 or fewer Americans, are excluded from the 340B program.

In a related matter, Republican leaders of the House Energy and Commerce Committee are investigating the recent expansion of the 340B drug pricing program. The lawmakers sent a letter to the Health Resources and Services Administration, saying they are concerned about the 340B drug pricing program's “rapid growth without additional oversight” and asked HRSA to provide information on its audits of the hospitals and other covered providers participating in the program. The lawmakers, including committee Chairman Greg Walden (R-Ore.), noted that drug sales under 340B more than doubled from 2010 to 2015.
The House lawmakers also said they are concerned that HRSA does not track how much covered entities make through the 340B program and how the covered entities use program savings. “The committee is concerned about reports that uninsured and underinsured patients at 340B hospitals often pay the full list price for a drug while the hospital receives that same drug at a severely discounted price.” Another concern the lawmakers cited is when covered entities receive duplicate discounts on the same drug.

State Issues

Delaware

Legislative

Delaware Enacts Three Laws Designed to Fight Opioid and Heroin Addiction
Delaware is trying something new in the fight against opioid and heroin addiction. The latest package of laws, signed by Governor John Carney on May 30th, is a three-pronged approach to tackling the statewide public health epidemic: treatment, the prescription of opioids, and legal assistance if insurance companies turn down patient claims for care.

- **Senate Bill 41** ensures that insurance companies provide direct access to treatment by removing pre-authorization requirements and requiring insurance companies to fund inpatient residential treatment when deemed medically necessary for those with Delaware plans. The new law, which goes into effect on January 1, also guarantees patients immediate access to 14 days of inpatient treatment before a "utilization review" or determination whether treatment is medically necessary, occurs. New York enacted a similar law last year that has showed success anecdotally for both insurance regulators and treatment providers. Attorney General, Matt Denn, author of SB 41 stated that he is hopeful this new law attracts more treatment providers to the state.

- **House Bill 91** supports the creation of the Delaware Prescription Monitoring Program Advisory Committee, which would make recommendations regarding improvements to the existing program. It would also give the committee the power to make direct referrals to licensing agencies when they see doctors and prescribers not adhering to state requirements. In some cases, as evidenced by arrests and other investigations in the state, doctors will illegally prescribe medications to those with addiction for cash or high prices. This committee would be able to provide investigators with information that would speed up the investigatory process, according to the bill which went into effect at its signing.

- **House Bill 100** grants the insurance commissioner and the state Attorney General’s Office the power and funds to offer legal advice – and even representation – for families and people trying to appeal denials for treatment. The Attorney General’s office would rely on money from the Consumer Protection Fund – which can fluctuate from year to year – to cover the cost of providing medical and legal expertise for these people, Attorney General Denn stated. This law is a first of its kind and goes into effect 120 days after its enactment.

To review these bills go to [http://legis.delaware.gov/](http://legis.delaware.gov/)

Pennsylvania

Legislative

Budget, Pensions to Dominate June Legislative Session
The Pennsylvania General Assembly reconvenes Monday, June 5. Governor Tom Wolf and GOP leadership will continue their negotiations on the 2017-2018 budget, including how to address the current $3 billion deficit. While the House-passed budget is currently in the Senate and does not
include any new taxes, Governor Wolf’s plan incorporates several revenue generating line items, such as a health insurance premium tax expansion and a computer services sales tax. Senate and House Republicans are committed to meeting the statutory June 30 deadline to pass the fiscal measure without any new taxes. As part of the budget discussions, the parties will likely consider pension reform, an issue that has been discussed over the years without resolving the underlying problem—underfunding.

In addition, advocates and proponents are likely to ask the Senate to consider a number of health care bills that recently cleared the House, including Lyme Disease long-term therapy mandate, payment for emergency services without transport and physician credentialing requirements.

**Regulatory**

*Pennsylvania Insurance Commissioner Announces Single-Digit Aggregate 2018 Individual and Small Group Market Rate Requests*

Pennsylvania Insurance Commissioner, Teresa Miller, announced, on June 1, that the five health insurers that sell on Pennsylvania’s individual market will stay in the market and filed plans for 2018 with aggregate statewide rate increases of 8.8 percent for individual plans and 6.6 for small group plans. However, Commissioner Miller warned that significant changes to the Affordable Care Act (ACA) by the federal government would impact insurers’ aggregate proposed rate increases. For example, Miller noted that if the individual mandate is repealed, insurers estimate that they would seek a 23.3 percent rate increase statewide. If cost-sharing reductions are not paid to insurers, the companies would request a 20.3 percent rate increase statewide. If both changes occurred, insurers estimate they would seek an increase of 36.3 percent.

“Information provided by insurers shows the extent to which instability and changes would impact Pennsylvania’s 2018 health insurance rates. This proves what we already know — instability caused by adverse action from the federal government will do nothing but hurt consumers who are stuck in the middle,” said Commissioner Miller. “The 506,000 Pennsylvanians with Affordable Care Act-compliant plans in the individual market deserve single-digit rate increases like the ones most people will see if Congress and the Trump Administration choose not to risk consumers’ health and financial well-being by jeopardizing the stability of these markets.” In April, Commissioner Miller and the chief executives of Pennsylvania’s five individual market health insurers issued a letter to Secretary of Health and Human Services Tom Price stressing the need for stability in the individual market. The letter emphasized that instability could reduce coverage options and increase prices for the individual market population in Pennsylvania and around the country.

Rate filings for 2018 health insurance plans were submitted to the Insurance Department on May 22. All five health insurers filed to continue selling in 2018, and each of Pennsylvania’s 67 counties will have on-exchange coverage options for 2018 based on current filings. Rate change requests vary by plan and region, and complete rate filing requests including plan-specific information, will be available on July 21 at [www.insurance.pa.gov](http://www.insurance.pa.gov).

**Industry Trends**

**Provider / Delivery System Trends**

*Ohio Sues J&J, Teva and Other Drugmakers Over Opioid Epidemic*

Ohio’s attorney general is suing five leading drug manufacturers to recover money spent battling the state's worst-in-the-nation opioid epidemic. Ohio is the second state, following Mississippi, to sue drugmakers for their alleged role in deceptive marketing practices—a type of suit Ohio Attorney General Mike DeWine (R) said has little precedent. At a press conference May 31, DeWine announced the suit against Purdue Pharma, Endo Health Solutions, Teva Pharmaceutical
Industries, Johnson & Johnson, and Allergan, the makers of many pain medicines, including OxyContin, Percocet, Actiq, Duragesic and Norco.

DeWine said drugmakers are partially responsible for the addiction epidemic because they targeted doctors who did not have a specialty in pain management and encouraged those physicians to overprescribe opioids. The suit alleges the drug companies violated the Ohio Consumer Sales Practices Act and created a “public nuisance” in its calls for an injunction against advertising practices it calls “deceptive.”

The complaint also seeks damages for $175 million paid by the Ohio Department of Medicaid and $200 million paid by Ohio consumers that the state’s attorney general says would not have been spent if people were not over-sold on effectiveness, and under-sold on the addictive qualities, of opioid medication.

The suit makes bold claims against the drugmakers, alleging they downplayed risks of addiction, claimed that dependence and withdrawal were easily managed, and denied risks of higher opioid dosages. All the while, the drugmakers allegedly “falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life” without evidence, the suit says.

The complaint alleges drugmakers paid doctors and front groups to carry these misleading messages, “borrowing a page from Big Tobacco’s playbook” to persuade “doctors and patients that what they had long known—that opioids are addictive drugs, unsafe in most circumstances for long-term use—was untrue, and quite the opposite, that the compassionate treatment of pain required opioids.”

DeWine confirmed the suit was intentionally filed in Ohio's rural Ross County, one of the worst-hit regions in the country, where overdose and death has become a sorrowful backdrop to small town life. In 2015, more than 1.6 million opioid pills were dispensed in Ross County, according to the state's computer system which tracks opioid prescriptions. That's enough to give each of the 78,000 people in Ross County 21 pills.

Ohio's suit is the latest in a run of highly publicized actions claiming drug distributors and manufacturers had direct roles in the opioid epidemic. In April, the Cherokee Nation sued major drug distributors, including McKesson Corp., Cardinal Health Inc., CVS, Walgreens, and Wal-Mart, alleging those companies fueled the opioid crisis and profited from opioid sales. The tribe claimed the companies enabled opioids to fall into illegal channels, did not alert regulators to suspiciously large quantity orders, and used financial incentives to increase opioid sales.

Similar legal battles rage in West Virginia, where in January Ohio-based Cardinal Health Inc. agreed to pay $20 million and Chesterbrook, Pa.-based AmerisourceBergen Corp. agreed to pay $16 million to settle state claims that those companies sold their drugs to “pill mills” that then fueled the state's prescription drug abuse problem.

State
The Pennsylvania General Assembly is in session the week of June 5.

The Delaware General Assembly is in session June 6-8.

The West Virginia Legislature has adjourned for the year but continues in special session to address the 2017-2018 state budget.

Congress
The U.S. Congress is in session the week of June 5.
Interested in reviewing a copy of a bill(s)? Access the following web sites:


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/).