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Federal and National Issues

Legislative Issues

Senate Leaders Release Revised Legislative Language for BCRA; Vote Delayed
On July 13, Senate leaders released revised legislative language for the “Better Care Reconciliation Act” (BCRA). Senate Majority Leader Mitch McConnell (R-KY) announced over the
weekend that the vote will be delayed for at least another week as Senator John McCain (R-AZ) is unable to travel to Washington following surgery. An updated analysis from the Congressional Budget Office had been expected on Monday, July 17, but that is also being delayed.

The outlook for Senate action on this revised bill remains uncertain. Senators Rand Paul (R-KY) and Susan Collins (R-ME) have indicated that they plan to vote against a motion to proceed to the revised bill and several others are undecided. In order to begin a Senate floor debate on the bill, Senate leaders need at least 50 senators to vote “yes” on the motion to proceed. Majority Leader McConnell has emphasized that senators will have an opportunity to offer amendments addressing concerns they have raised with the draft BCRA.

The revised Senate bill differs from the previous draft in several important respects:

- An additional $70 billion would be provided in 2019-2026 for the proposed Long-Term State Stability and Innovation Program.
- Would provide an opportunity for insurers to offer off-Exchange plans in state rating areas that do not comply with guaranteed issue, community rating, and essential health benefit (EHB) requirements, among other exceptions. Insurers offering such plans would be required to certify that they will offer one gold level, one silver level, and one benchmark plan in the Exchange market with respect to the rating area in the state. Premium tax credits and the risk adjustment program would not apply to the off-exchange plans.
- The core Medicaid provisions —Would make changes including certain revisions to the per capita cap funding formula, the block grant option, and Medicaid DSH allotments, and a new demonstration project encouraging increased payments for home and community-based services.
- An additional $45 billion would be provided in 2018-2026 to support states in providing substance use disorder treatment and recovery support services.
- The modified premium tax credit could be applied toward the purchase of a catastrophic plan, beginning in 2020.
- Health Savings Account (HSA) funds could be used to pay premiums for a high deductible health plan (HDHP), beginning in 2018.
- Several ACA tax provisions would not be repealed: (1) the net investment income tax; (2) the higher Medicare payroll tax for high-income taxpayers; and (3) the limitations on the tax deduction for health insurer remuneration.

Democrats Outline Stabilization Ideas
On July 10, Senate Democratic leaders addressed a letter to Leader Majority Leader Mitch McConnell (R-KY), urging him to “focus on immediately advancing policies to provide stability and certainty to the health insurance markets.” Their letter identifies four Democratic proposals that they would like to consider immediately:

- S. 1462, the “Marketplace Certainty Act,” would permanently appropriate funding for cost-sharing reduction (CSR) payments while also increasing the amount of CSRs and extending CSRs to all Exchange enrollees up to 400 percent of the federal poverty level.
- S. 1354, the “Individual Health Insurance Marketplace Improvement Act,” would establish an Individual Market Reinsurance Fund that would be used, beginning in 2018, to make reinsurance payments to insurers with respect to high-cost individuals enrolled in qualified health plans (QHPs). The bill would appropriate “such sums as are necessary” for this proposed Fund.
- S. 1201, the “Health Care Options for All Act” would provide, with respect to any counties where no Exchange plans are available, that individuals living in such counties would have access to the coverage options that are available to members of Congress and congressional staff through the DC exchange.
A proposal by Senator Heidi Heitkamp (D-ND) seeks to “help more families afford health insurance in the individual market by smoothing the ‘subsidy cliff’ for people who earn even nominal sums over” 400 percent of the federal poverty level.

On July 19, a group of 10 House Democrats released a white paper that outlines proposals aimed at stabilizing and improving the individual health insurance market. This group was led by the co-chairs of the New Democrat Coalition’s Affordable and Accessible Health Care Task Force. Their proposals focus on five priorities: (1) creating a permanent reinsurance program; (2) reducing co-pays and deductibles for low-income Americans through cost sharing reduction funding; (3) promoting coverage and making sure that people pay their fair share; (4) creating more affordable coverage options; and (5) making additional improvements to the individual market.

**House Approves FDA Reauthorization Act**
On July 19, by voice vote, the House approved an updated version of H.R. 2430, the “Food and Drug Administration (FDA) Reauthorization Act.” The core provisions of this bill would reauthorize FDA user fee programs that generate funds to support, among other activities, the review and approval of new prescription drugs (including generics), medical devices, and biosimilars. Under current law, these programs are scheduled to expire on September 30, 2017.

The White House issued a statement, expressing support for the goals of the bill and for reauthorization of the FDA user fee programs, but also highlighting concerns about certain provisions of H.R. 2430 and indicating that the Administration would like to make “a number of important technical changes.” One notable concern raised by the Administration is that the bill would provide “additional market exclusivity to manufacturers, which could make exclusivity unpredictable and decrease competition.”

Key senators have suggested that the Senate may take action in the next several weeks on the House-passed version of H.R. 2430, thereby avoiding the need for negotiations in a conference committee. Senate HELP Committee Chairman Lamar Alexander (R-TN) stated that the House bill is “a very good bill” and “almost the same” as an FDA user fee bill (S. 934) that was approved by his committee on May 11.

**House Committee Approves Medicare Advantage SNP Bill**
On Thursday, July 20, by voice vote, the House Ways and Means Committee approved bipartisan legislation, H.R. 3168, addressing reauthorization of Medicare Advantage Special Needs Plans (SNPs).

This legislation would provide for a five-year reauthorization of Dual Eligible SNPs and Chronic Condition SNPs, and a permanent reauthorization of Institutional SNPs. Other provisions of the bill focus on increased integration of Dual Eligible SNPs, care management requirements for Chronic Condition SNPs, quality measurement at the plan level for SNPs, a GAO study on state-level integration between Dual Eligible SNPs and Medicaid, and expanded supplemental benefits for chronically ill Medicare Advantage enrollees.

**House Holds Hearing on Medical Product Communications**
The House Energy and Commerce Subcommittee on Health held a hearing on Wednesday, July 19, on two draft bills that address pharmaceutical manufacturer communications on medical products.

The “Medical Product Communications Act” – proposed by Representative Morgan Griffith (R-VA) – would allow drug manufacturers to proactively communicate a broader range of information to health care service providers about uses of their products, known as “off-label” uses, which have not been approved by the Food and Drug Administration (FDA). Specifically, the bill would remove the scientific exchange of off-label uses from the definition of “intended use” of a drug or device,
preventing the FDA from conducting any oversight of the scientific exchange of information about off-label uses of drugs and devices.

The “Pharmaceutical Information Exchange Act” – proposed by Representative Brett Guthrie (R-KY) – would expand the ability of drug and device manufacturers to share health care economic information (HCEI) and scientific information with payors, formulary and technology review committees, and similar entities for investigational use drugs and devices before they are approved by the FDA.

Update on Risk Corridor Appeals
The briefing schedule this fall of the three risk corridor cases before the Federal Circuit (Land of Lincoln, Moda, and Blue Cross & Blue Shield of North Carolina) is as follows: all briefs have been submitted in the Land of Lincoln case. While subject to change, the submission of briefs in Moda is currently due to be completed by September 5, and briefing submissions in Blue Cross & Blue Shield of North Carolina are currently scheduled to be completed by October 10. In addition, a number of risk corridor cases before the Court of Federal Claims have been stayed pending a decision by the Federal Circuit in one or more of the cases on appeal. Most recently, the court in Health Republic has stayed proceedings on the parties cross-motions for summary judgment in the matter. Health Republic is a class action and reports and motions related to the class are proceeding, at least for the time being.

Court Grants HHS Request in Case Challenging Nondiscrimination Rule
On Monday, July 10, the U.S. District Court for the Northern District of Texas granted in part the Department of Health and Human Services’ (HHS) Motion for Voluntary Remand and Stay in Franciscan Alliance v. Price (formerly Franciscan Alliance v. Burwell). This case involves a challenge to portions of the HHS Rule on Nondiscrimination in Health Programs and Activities, sometimes referred to as the “Section 1557 Rule,” that would have prevented discrimination on the basis of “gender identity” and “termination of pregnancy.” On December 31, 2016, Judge O’Connor of the Northern District of Texas issued an order granting a nationwide preliminary injunction of those portions of the rule.

In its motion, HHS had asked the court to send the matter back to the Department, so it can “reevaluate the regulation and address the issues raised in this litigation through proper rulemaking proceedings.” HHS also asked that the matter be placed on hold (stayed) pending completion of the rulemaking proceedings. Plaintiffs in the case had opposed the HHS requests.

The court granted the request for a stay of the matter, but not the request that the matter be remanded back to the Department. The court indicated that “staying the case and resuming consideration of all pending motions when HHS completes reconsideration of the rule will promote judicial efficiency and impose no undue prejudice on the plaintiffs.” It added that “[b]ecause HHS’s authority to reconsider the Rule is unaffected by whether the Court grants a remand or a stay, and Defendants have consented to the Court’s continued jurisdiction and ongoing preliminary injunction, the Court declines to fully remand the case but imposes a stay of all proceedings.”

The court provided a couple of clarifying notes. First, it stated that the preliminary injunction is unaffected by its order and “remains in full force and effect during the duration of the stay until further order of the Court.” Second, it indicated that “to encourage timely review of the Rule, the Court will continue to exercise jurisdiction over the case, requiring periodic status reports on the rulemaking proceedings.”

Since the nationwide preliminary injunction remains in effect, nothing will change immediately in terms of the manner in which the rule has been applied since December 31, 2016. The motion from HHS and the order of the court, however, contemplate potential rulemaking proceedings.
Regulatory Issues

CMS Releases 2018 Hospital Outpatient PPS/Ambulatory Surgical Center and Physician Payment Proposed Rules

The Centers for Medicare & Medicaid Services (CMS) issued the proposed rules governing payment to hospital outpatient and ambulatory surgical centers and the physician fee schedule (PFS).

Key issues include:

- **OPPS/ASC cuts to 340B payment rates:** The Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Centers (ASC) proposed rule calls for significant decreases in the payment rate for certain Medicare Part B drugs purchased by hospitals under the 340B drug pricing program. CMS is proposing payment rates of the average sales price (ASP) minus 22.5 percent rather than ASP plus 6 percent, which is the current practice.

- **PFS cuts to HOPD providers:** The PFS proposed rule dictates the payment rates for non-excepted off-campus providers-based hospital departments paid under the PFS as a result of Section 603 of the Bipartisan Budget Act of 2015. The rule proposes reducing the current PFS payment rate for services and items no longer paid under the OPPS by 50 percent. Currently, CMS pays for these services under the PFS based on a percentage of the OPPS payment rate. The proposal would change the PFS payment rates for these services from 50 percent of the OPPS payment rate to 25 percent of the OPPS rate.

- **Non-enforcement—Direct Supervision:** The proposed OPPS/ASC rule reinstates the non-enforcement of direct supervision enforcement instructions for outpatient therapeutic services for critical access and small rural hospitals having 100 or fewer beds for CY 2018 and 2019.

- **Telehealth:** The PFS rule proposes to add several codes to the list of payable telehealth services and eliminate the required reporting of the telehealth modifier for professional claims. The rule also improves the payment rates for office-based behavioral health services.

CMS has issued fact sheets for the OPPS/ASC proposed rule as well as the PFS proposed rule.

CMS will accept comments about both proposed rules until September 11, 2017.

Rao Confirmed as Trump's Regulatory Chief

Neomi Rao was confirmed by the Senate on July 10, in a bipartisan 54-41 vote, as President Donald Trump's chief regulatory officer and leader of the administration's efforts to deregulate and streamline rules. Rao will serve as administrator of the Office of Information and Regulatory Affairs (OIRA), an agency within the White House Office of Management and Budget that reviews all significant federal regulations.

The position will be critical in implementing Executive Order 13,771 Reducing Regulation and Controlling Regulatory Costs, which requires that any significant regulation issued after noon on January 20 include two deregulatory actions and be completely offset.

For the past decade, Rao has been a law professor at the George Mason University School of Law, renamed the Antonin Scalia Law School in July 2016. Rao founded the Center for the Study of the Administrative State at the university to debate administrative law. Rao previously served in all three branches of the federal government, including as associate counsel to former President George W. Bush, as counsel for nominations and constitutional law to the Senate Judiciary Committee, and as law clerk to Supreme Court Justice Clarence Thomas.

Picture Becoming Clearer on New Trump Regulatory Policy
The Office of Management and Budget said it will release, likely the week of July 17, the Spring 2017 Unified Agenda of Federal Regulatory and Deregulatory Actions, which will list for the first time the regulations that agencies intend to eliminate or modify to offset the costs of their new regulations. The report will provide a long-awaited missing piece of President Donald Trump's new one-in, two-out regulatory policy, which requires agencies to eliminate two regulations and to offset the costs of each new regulation they want to issue.

Trump signed Executive Order 13,771 on Reducing Regulation and Controlling Regulatory Costs, which requires any significant regulation issued to include two deregulatory actions and be completely offset, resulting in a zero net increase in regulatory costs in fiscal year 2017.

To date, Cabinet secretaries have done a good job slowing down the new regulatory burden, but they need to spend more time looking back at existing regulations, said OMB Director Mick Mulvaney.

Since then, a few agencies have come to the OMB and argued that with rules already in the pipeline, they have to impose costs before they can reduce them, or add a new rule before they can get rid of two old ones, Mulvaney said. “We’re going to look at it on a fiscal year,” meaning in practice, agencies won’t have to eliminate two rules before they issue a new rule, he said. “At the same time, we’re allowing them to bank, so if they have a couple of deregs now, they can go ahead and do those and then they don’t immediately have to find a new one to put out; they can build up an inventory of five or six or 10 dereg actions and then use those to offset the new regulatory actions in the future,” he said. Another accommodation is to count, in most cases, the elimination of agency guidance as an offset, Mulvaney said.

Homeland Security Issues Update on Federal Efforts to Strengthen Cybersecurity

The Department of Homeland Security has released an initial update on efforts to strengthen the cybersecurity of federal networks and critical infrastructure, including hospitals and health systems, as required by the president’s May executive order.

With respect to critical infrastructure, the Department of Commerce’s National Telecommunications and Information Administration is accepting stakeholder comments through July 28 on actions that could be taken to address the threat of automated attacks, such as botnets. The President’s National Security Telecommunications Advisory Committee also has been asked to provide recommendations on ways to reduce the threat of botnet attacks.

Among other actions, the National Institute of Standards and Technology plans to issue a request for comments and hold August public workshops on developing a report on the nation’s cybersecurity workforce.

Alaska Section 1332 Waiver Approved

CMS and the Department of Treasury announced on July 11 that Alaska’s Section 1332 waiver request has been approved. The state program will cover claims in the individual market for people with one or more of 33 identified high cost conditions in order to help stabilize premiums. The approval is effective for January 1, 2018 through December 31, 2022. CCIIO also posted a fact sheet and the public comments received during the federal comment period. CMS stated that Alaskans have seen individual market premiums increase 203 percent since 2013. Alaska’s waiver will lower premiums and increase coverage without any additional costs to the Federal Government. The average premium is expected to be reduced by 20 percent in 2018 and cover 1,400 additional individuals. The waiver includes a budget of $59 million for 2018 with pass through funds of $48 million from the federal government and $11 million from the State of Alaska.

Hundreds Charged with Defrauding the Federal Government

More than 400 people, including doctors and nurses, have been charged with defrauding Medicare and other federal healthcare programs of $1.3 billion, with many accused of illegally distributing
opioids and other narcotics, the Justice Department said on Thursday. A total of 412 people, including almost 115 doctors, nurses and other medical professionals, have been charged in sweeping enforcement action, the biggest ever by the multi-agency Medicare Strike Force, the Justice Department said in a statement.

Those charged participated in schemes that billed Medicaid, Medicare and TRICARE - which serves military personnel, veterans and their families - for unneeded drugs and treatments that were often never provided, the Justice Department said. In many cases, healthcare providers paid cash kickbacks to patients and others in exchange for medical data that would allow them to file fraudulent bills to Medicare, the Justice Department said.

State Issues

Pennsylvania

Legislative

PA Budget Becomes Law without Governor’s Signature, Revenue Talks Continue
Governor Tom Wolf and Senate and House leaders continue their quest for an agreement on a $2.2 billion revenue plan necessary to fund the $32 billion 2017-2018 budget. Governor Wolf allowed House Bill 218 to become law without his signature at midnight July 11. While the Senate is scheduled to resume its session on Monday, July 17, the House will remain on call until a revenue plan is agreed upon. Also incomplete are other budget-related code bills.

House Approves Legislation to Alter Medicaid Program
The House of Representatives voted 101-92 to approve an amended House Bill 59, which now includes a number of changes to the state’s Medicaid program, including:

- Establishment of a new Total Population Coordinated Care Management Pilot Program
- Creation of new enrollment processes, including a requirement for individuals to remain enrolled in the same plan for at least 12 months, unless an exemption is available (qualifying life events, moves, specific health conditions)
- A directive for the state to apply for a waiver that would allow for a sliding scale premium requirement for medical assistance provided to disabled children in families with incomes above 1000 percent of federal poverty level
- Creation of a new asset verification system
- New reporting requirements for ambulatory surgery centers including an annual financial data submitted to the Pennsylvania Health Care Cost Containment Council (PHC4)

While House Bill 59 must be sent to the Senate for further consideration, Governor Tom Wolf has weighed in expressing his opposition to the bill. He believes the changes could negatively impact the state’s most vulnerable citizens.

Office of the Inspector General to Become Permanent Government Position
The House and Senate voted overwhelmingly to approve a bill that will make the Office of the Inspector General (OIG) a permanent office in Pennsylvania state government. The legislation, Senate Bill 527 (Ryan Aument, R-Lancaster), will allow for the official creation of an independent OIG who will be charged with investigating and eradicating waste, fraud and abuse in state government agencies.
While the OIG is not a new office, it currently exists under an Executive Order, the first being issued by Governor Robert Casey in 1987. Since 1987, the office has operated only if the current governor continues the Executive Order – which all since Governor Casey have chosen to do. Governor Wolf, who announced that he intends to sign the measure, will have the responsibility of nominating an individual to fill the position, which requires Senate confirmation.

Industry Trends

Provider / Delivery System Trends

Report Proposes National Strategy to Reduce Opioid Epidemic
The National Academies of Sciences, Engineering, and Medicine has issued a report recommending actions to contain and reverse the harmful societal effects of the prescription and illicit opioid epidemics. According to the report, requested by the Food and Drug Administration, it is possible to stem the escalating prevalence of opioid use disorder and other opioid-related harms without foreclosing access to opioids for patients suffering from pain, but that years of sustained and coordinated efforts will be required.

Among other actions, the report recommends promoting more judicious prescribing of opioids, expanding access to treatment for opioid use disorder, preventing more overdose deaths, weighing societal impacts in opioid-related regulatory decisions, and investing in research to better understand the nature of pain and develop non-addictive alternatives.

State
The Pennsylvania General Assembly is in session the week of July 17 (Senate only).

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 July 17.

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

Delaware State Legislation: http://legis.delaware.gov/

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/.