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Thursday, July 7, 2022

With just a few short weeks left until August recess, there is no shortage of items on the congressional to-do list. The latest round of Supreme Court decisions has inspired new action within Congress to pass legislation prior to the month-long August recess. Senate Democrats continue to negotiate a revitalized reconciliation package, while also ironing out differences in the House-passed and Senate-passed versions of USICA, as well as the FDA User Fee reauthorization legislation. Additionally, both the House and Senate Appropriations committees continue their
work in finalizing the budget for FY-2023.

Regulatory rulings are anticipated to be passed down in July, as the final version of the No Surprises Act, the Physician Fee Schedule, and potential updates on the Public Health Emergency could be announced. All of this is in the backdrop of the rapidly approaching Midterm Elections, which are currently 126 days away.

See below for greater detail on key issues and more in this month’s edition of What’s Next in Washington? presented by the Foley & Lardner Federal Public Affairs team.

1. Reconciliation negotiations continue in the Senate

   1. Senate Majority Leader Chuck Schumer (D-NY) and Senator Joe Manchin (D-WV) have been in discussions regarding a reconciliation package, valued at approximately $1 trillion.

      1. All 50 Senate Democrats have agreed on the drug pricing language. The text will now be sent to the Senate Parliamentarian to go through the “Byrd Bath”, to ensure that it meets the reconciliation rules.

      2. Democrats have been looking for means to pass a reconciliation package ever since Manchin announced that he would be unable to support President Biden’s Build Back Better package in December 2021.

   2. The main goal of the package would be to lower prescription drug prices as outlined in Biden’s Build Back Better Act, which would empower the government to negotiate the price of prescription drugs on behalf of Medicare starting in 2023.

      1. The bill would also cap prescription drugs at $2,000 a year, while penalizing drug companies that raise their prices faster than inflation.

      3. Additional portions of the bill would include changes to the original Build Back Better Act regarding international corporate taxes, by potentially carving out a provision that would allow corporations to blend their overseas taxes to meet the 15% minimum.

   4. In the backdrop of reconciliation negotiations, Senate Minority Leader Mitch McConnell (R-KY) tweeted stating should Democrats pass a reconciliation package; he will withdraw support for the U.S. Innovation and Competition Act (USICA).

      1. USICA is currently being negotiated in conference, the bill’s original co-sponsors, Senators Chuck Schumer (D-NY) and Todd Young (R-IN), have expressed their hope that the bill will pass by the end of the summer.

2. The electoral landscape comes into focus as the first half of the Primary Election season wraps up
1. All but 18 states have decided their Democratic and Republican nominees for the 2022 Midterm Elections. All 435 seats in the House of Representatives and 35 seats in the Senate are in play this electoral cycle.

2. Alongside inflation and economic concerns, two key issues are expected to play a role in the elections.
   1. A string of high-profile mass shootings took place at the end of May, prompting Congress to pass the Bipartisan Safer Communities Act at the end of June to combat gun violence.
   2. Also, at the end of June, the Supreme Court overturned Roe v. Wade in its decision of Dobbs v. Jackson Women's Health Organization.
   3. Both issues are anticipated to play a role in deciding the outcome of closely contested seats.

3. In the “toss-up” category, House Democrats are currently defending 25 seats, while Republicans look to defend eight. More seats could come into play as the primaries continue. Hot button issues are now on the ballot, and with a change in the political landscape, the Midterm elections could prove to be close for both parties.
   1. The Foley team has been tracking all congressional retirements, primaries, and close House & Senate races. You can read more about this here.

4. The second half of primaries will begin on August 2nd, when Arizona, Kansas, Michigan, Missouri, and Washington will choose their next candidates for office.

3. Senate Appropriations Markups begin, House eyes floor votes in July

1. The House Appropriations committee spent June marking up and approving all 12 spending bills.
   1. House Appropriators have aimed for floor votes in July.

2. The Senate Appropriations committee have not yet released their spending bills for FY-2023.
   1. Sen. John Tester (D-MT), chair of the Senate Appropriations Defense Subcommittee, told the press that he believes that the Senate Appropriations bills will be “different” than the House versions.

3. Senate Appropriations Chairman Patrick Leahy (D-VT) has announced that the committee will begin its markup the second week of July.
   1. However, Senate Republicans have not yet agreed on a topline spending figure, so it remains to be seen how the budget will be allocated.
4. House Appropriations Chairwoman Rosa DeLauro (D-CT) has expressed confidence that Congress will be able to pass FY-2023 appropriations prior to the end of the 117th Congress, in which both Senate Appropriations Chairman Leahy and Ranking Member Richard Shelby (R-AL) will both retire.

4. January 6th Committee Hearings wrap up

1. The House Select Committee to Investigate the January 6th Attack on the Capitol has held a series of investigatory hearings throughout the month of June.

   1. The committee originally planned for the hearings to last the month of June and then to produce a report in September.

   2. The Committee now plans to hold at least two more hearings as more evidence comes to light. The report timetable could be changed as well.

   1. The Committee will likely complete its hearings by the August recess, which is slated to begin on July 29th for the House.

5. The Food and Drug Administration’s user fee programs, which fund roughly half of their annual budget, are set to expire on October 1, 2022. These include the Prescription Drug User Fee Act (PDUFA), Generic Drug User Fee Amendments (GDUFA), Biosimilar User Fee Act (BsUFA), and Medical Device User Fee Amendments (MDUFA).

1. Last month, the House passed the Food and Drug Amendments of 2022 (FDA22) by a vote of 392-28. This bipartisan bill was introduced by House Energy and Commerce Health Subcommittee Chair Anna Eshoo (D-CA) and Ranking Member Brett Guthrie (R-KY).

2. The Senate Health, Education, Labor, and Pensions Committee (HELP) advanced their version of legislation, the FDA Safety and Landmark Advancements (FDASLA) by a vote of 13-9. This legislation was introduced by Committee Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC).

3. Congress set a goal for themselves to reauthorize the programs by August, but with several differences between the House and Senate legislation, which also include several policy riders, all in addition to Congress’ unhappiness with the FDA for their handling of the infant formula crisis, it is looking likely that an agreement could slip to September.

   1. The FDA is required to issue layoff notices 60 days prior to programs expiring.

4. The relevant committees are pre-conferencing to work out legislative differences prior to any further floor action. They are still on track to finalize reauthorization programming before it expires at the end of the fiscal year.
6. The Department of Health and Human Services’ Public Health Emergency (PHE) is set to expire July 16

1. HHS Secretary Xavier Becerra extended the PHE declaration on April 12th, noting that states and agencies should prepare for an end to the flexibilities that the declaration has allowed throughout the pandemic.

   1. Approximately 15 million people are at risk of losing access to Medicaid or CHIP when flexibilities unwind.

   2. Following a letter from the administration urging them to start planning for an end to the PHE, Governors are planning to return to “normal operations” with regards to Medicaid and CHIP enrollment.

      1. State officials were promised 60 days’ notice of HHS’ intentions to let the declaration expire, so it is highly likely that Becerra will extend the PHE at least once more.

7. Stakeholders are urging the Department of Health and Human Services, Labor, and Treasury to issue the final ruling on the No Surprises Act, which is expected this month.

   1. Last month, Congressman Joe Morelle (D-NY) and Congresswoman Marianette Miller-Meeks (R-IA) sent a bipartisan letter to the agencies urging for its quick passage. A similar letter was sent by dozens of organizations ranging from the AFL-CIO to the National MS Society to the Leukemia and Lymphoma Society, among many others.

   2. Four agencies, including Centers for Medicare & Medicaid Services, the Employee Benefits Security Administration, the Internal Revenue Service, and the Office of Personnel Management, issued the interim final rule in September 2021.

      1. Eight lawsuits were filed challenging the interim final rule on the independent dispute resolution (IDR) process. Only one court decision has so far been made, with the Judge in the Texas Medical Association case invalidating parts of the rule.

   3. New fact sheets on “No Surprises” were released on the CMS website here.

Scott Klug and Michael Crossen also contributed to this article.

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