Federal Policy Update

Federal Budget

- Key messages - fund the government and finalize a bill as close to the House bill as possible. See AIDS Budget and Appropriations (ABAC) Chart.
- Despite all the impeachment investigation hearings, Congress does appear to be moving forward on appropriations.
  - Once top line numbers, or allocations, are agreed to by House and Senate, they will move quickly to finalize the bills.
- There will be another “Continuing Resolution” that essentially keeps the government open until appropriations bills are enacted. Currently the plan is to have the CR run to Dec. 20th
  - If Congress fails to reach a funding agreement, they could pass a full year Continuing Resolution, which would fund all programs at the same level as they’re currently funded.
  - While this means no cuts, it also would mean that no new funding is allocated for the Ending the HIV Epidemic (EtHE) plan
- Funding currently in jeopardy:
  - EtHE because it’s new money, though both House and Senate proposed to fully fund almost all parts of the program, so we expect the final bills to include this funding.
  - EtHE funding for the Indian Health Service was not included in the Senate’s bill, but the House did propose to fully fund the $25 m.
  - Senate proposed to cut HOPWA by $63 million, but the House proposed to increase funding by $17 m, which is the community request.
- Anomalies - A mechanism for providing funding or other changes for a program that would otherwise not receive funding or continue in its current form under a continuing resolution (CR)
  - If a full year CR happens, the community and the administration will advocate for an “anomaly,” which basically says that there should be an exception to flat funding so that a program that desperately needs additional funding can receive it.
    - A good example of an anomaly would be the Census, which would not be able to occur in 2020 at the funding level for 2019
    - The Administration has already said they will push for an anomaly for EtHE if a full year CR occurs
Syringe Services Program (SSP) Language
✓ The House bill completely removed all restrictions on using funds for SSPs
✓ Previously years there has been a ban on using federal funds to purchase syringes, though funding could be used for other aspects of SSPs
✓ The Senate bill still includes the syringe ban, so community is pushing for that removal

Florida targets for advocacy
✓ Marco Rubio - sits on the Senate L-HHS Appropriations Subcommittee and is a very important target for advocacy
✓ Mario Diaz-Balart - sits on the House Appropriations Committee and has a lot of sway on HOPWA
✓ John Rutherford - sits on House Appropriations Committee
✓ Lois Frankel and Debbie Wasserman-Shultz are on the House Appropriations Committee, but have always supported our programs, so thanking them is important
✓ Rick Scott may be someone to lean on next year, but likely won’t be involved in the FY2020 appropriations negotiations

PrEP program
✓ HHS plans to roll out the program in the beginning of December
✓ This will be available nationwide, with focused education and training in the targeted jurisdictions
✓ In order to qualify for this program, a patient must:
  ▪ Lack prescription drug coverage
  ▪ Have a valid PrEP prescription
  ▪ Have a documented HIV-negative test
  ▪ HHS plans to leverage FQHC infrastructure, telemedicine, and other existing infrastructure to get the program off the ground ASAP

Affordable Care Act / Insurance / Co-pay Accumulators
✓ As you all might know, rules issued earlier this year limited when insurance sponsors could use copay accumulators. Plans were only allowed to have copay accumulator adjustment programs for drugs that had a generic equivalent. Otherwise, if there was no generic, or if the patient gained access to the drug through an exceptions or appeals process, the plan had to count copay assistance towards the patient’s out-of-pocket costs.
✓ However, in August, HHS announced that it would not enforce the rule in 2020, and would address the issue further in the Notice of Benefit and Payment Parameters for 2021. We expect to see that proposed rule out soon. Until then, plans are allowed, for the 2020 plan year, to use copay accumulator adjustment programs for any drug.
✓ Here is the copay accumulator information for FL plans
  “Florida 2020 Qualified Health Plans Copay Accumulator Policies”
- Florida Blue plan is a good example of amending their policy after HHS stated they would not enforce the rule.

✓ Legislation requiring plans to count all copay assistance toward a patient’s deductible and cost-sharing (in other words, prohibiting copay accumulators) has been introduced in FL. **SB696** (on pages 6 and 12, or search "third-party" and it should come up) and **HB561**. Identical language in both bills, and same language as in VA and WV laws - which is what the copay state group refers to as a "positive ban" or that it requires third-party payments to be counted towards the insured's out-of-pocket costs.

✓ VA, WV, AZ, and IL enacted similar legislation this year.

✓ ACA open enrollment is on now. We want as many people as possible to sign up or renew their plans, but we are also concerned that people who use copay assistance know whether the plan they’re choosing has a copay accumulator adjustment program.

✓ Medicaid: We’re watching a number of proposals to implement Section 1115 waivers around the country. A number of states have submitted (and gotten approval) for waivers that include work requirements, even though the courts have said that work requirements shouldn’t be allowed in Medicaid. Recently, Tennessee developed a proposal that would block grant its TennCare (Medicaid) program, and would also allow the state to limit the formulary to as little as one drug per class. TAI filed comments in the state’s process opposing the waiver. Nearly all of the comments the state received were in opposition of the waiver, so we’ll watch to see whether it moves forward to the next step, which would be submitting it to HHS.

- Medicaid Expansion?
  - If FL expanded Medicaid, over 837,500 people would gain health coverage in the first 5 years of expansion
  - Due to the enhanced federal matching, the state would net significant savings

✓ Medicare: There are a number of proposals focused on prescription drug costs in Medicare. While the Senate and House prescription drug bills have some important differences, one important provision that is the same is - capping the amount that enrollees have to pay out of pocket (OOP) for prescription drugs in Medicare Part D.

- The Senate bill would cap OOP at $3100/year.
- The House bill would cap OOP at $2000/year
- There are some differences between the bills about how this would be paid for, but both bills share the costs in some way between the government, insurance plans, and pharma. Because there is strong support for this provision, we’re hopeful that it could move forward this year or early next year.
340B Impact
✓ There isn’t currently any legislation specific to restructuring the 340b program. However, there could be impact on 340b, either directly or indirectly, from drug pricing legislation.
   ▪ Indirectly because if the price of drugs really does go down, then there would be less money in the 340b program.
   ▪ Directly because some proposals include changes to what drugs qualify for the 340b program.

Drug Pricing Legislation
✓ Both Senate and House have bills ready to go to the floor for votes. Significant overlap between them, with the exception that the House bill (HR3) includes a barrier for industry, because it would institute international reference pricing for the top 25 most expensive drugs in Medicare (and apply that pricing to the drug for all payors). The bills would also (see link for Commonwealth Fund comparison of the bills):
   ▪ Cap OOP for Medicare Part D enrollees (as mentioned previously)
   ▪ Require manufacturers to pay a rebate to the federal government when the price of a drug rises faster than inflation.
   ▪ Politically, it’s unclear if or when either of the bills will be taken up on the floor. Impeachment hearings and appropriations are the top priorities, and it’s unclear if there will be time or ability to pass significant legislation like this.
   ▪ Moreover, the House bill, if and when it is brought to the floor, is likely to pass along party lines, with little or no Republican support. The White House has said it will not support the House bill. PhRMA is lobbying intensively against it. Leadership plans to bring it up for vote after the full CBO score is released.
   ▪ The Senate bill is interesting politically because it was Chairman Grassley’s bill, but lost many Republican votes in the Finance Committee. To pass the Senate, it would need to pick up Republican support.
   ▪ Even if Congress cannot pass significant prescription drug legislation this year, it’s likely to stay on the legislative agenda for the foreseeable future.
   ▪ And the Administration has made a number of efforts to affect drug prices via regulation. We should expect to see more from them soon, especially with regard to reimportation - we expect to see a proposed rule imminently.
Hepatitis / STD’s

✓ Hepatitis
  - CDC released the *Hepatitis Surveillance Report* which showed continued increases in new hepatitis cases
  - 375% increase in HCV since 2010
  - Hepatitis outbreaks across the country have put a strain on CDC’s already underfunded Division of Viral Hepatitis
  - If there isn’t an increase to the Division, it could mean less money is available to the states because more funds will need to go to outbreak response
  - The House proposed to increase funding by $11 m

✓ STDs
  - CDC released [data](#) showing that STDs are at an all time high
  - There have been significant increases for all reportable STDs, including congenital syphilis which poses severe harm to a baby
  - House has proposed to increase STD funding at CDC by $10 m