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Legislative Days 2024

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First Timers' Session

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Common terms

- **Ask** – the request you are making of your Members of Congress (i.e., “please co-sponsor the MVP Act”).
- **Leave-behind** – informational material you give to the staffer during the meeting; the staffer keeps this material.
- **Sponsor** – the Member of Congress who introduced a bill, also referred to as “leading” the bill.
- **Co-sponsor** – A Member of Congress who has committed to supporting the bill; co-sponsorship is the gold standard of support.
  - A Member who co-sponsored at the time of introduction is called an “original” co-sponsor.

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Common terms

- **Fly-in** – This type of event, where advocates convene in DC for many Hill meetings on the same day. Most groups have their own name for it, but Hill staffers may ask if you're part of a "fly-in."
- **Mark-up** – A committee process where a bill is considered and amended. Considered a step towards passage. More common in the House than the Senate. Staffers may ask if a bill has been "marked up."
- **Score** – The estimated cumulative cost of the bill over 10 years, as determined by the Congressional Budget Office (CBO). Staffers (particularly Republican offices) may ask if a bill has been "scored."

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What if I can't advocate for one of the bills?

Sometimes, an AMCP advocate may have employer restrictions or other reasons that they cannot advocate for a certain bill. This is not uncommon and is easily managed.

- Let AMCP staff know.
- If you have other advocates in your team, turn the conversation over to another team member if possible.
- If you are solo, take the issue brief out of your leave-behind and skip that portion of the conversation.
- Remember that you are here in your individual and personal capacity, not as a representative of your employer.

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Congressional office hierarchies

- In descending order of authority
  - Member of Congress
  - Chief of Staff
  - Legislative Director
  - Legislative Assistant/Policy Aide
  - Legislative Correspondent
  - Staff Assistant
  - Intern
- Other titles you may see:
  - Fellow
  - Scheduler
  - Communications Director

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Getting around the Hill

- Longworth and Rayburn office numbers are 4 digits long, the first digit indicates building and the second indicates floor.
  - 1 means Longworth, 2 means Rayburn.
  - Examples: “1345 Longworth” means Longworth building, 3rd floor, office 45. “2210 Rayburn” means Rayburn building, 2nd floor, office 10.
  - We will always put the building name with the office number. You can ignore the first digit in Longworth and Rayburn addresses.
- Cannon uses 3-digit office numbers and does not have a building identifier.
  - Example: “422 Cannon” means Cannon building, 4th floor, office 22.

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Getting around the Hill

- Easiest method is to walk outside between buildings. This is necessary for going between the House and Senate.
- The Capitol Subway System, connecting Senate and House offices to the Capitol Building, is not accessible by the public. It is for staff only.
- There are hallways on the lowest levels of both the Senate and House office complexes that connect to the other buildings in that complex but do not connect to the other complex.
  - Unless there is an urgent need such as back-to-back meetings, we recommend against using these tunnels. They are difficult to navigate without familiarity.

Questions and discussion

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Legislative Asks Overview

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What are PDTs?

- Prescription digital therapeutics (PDTs) are therapies that primarily use software to deliver a clinical mechanism of action and have been reviewed and authorized by FDA
- There are 24 FDA-cleared PDTs indicated to treat or manage a variety of conditions including PTSD, ADHD, and amblyopia
- PDTs are generally cleared under the 510(k) pathway, considered Software as a Medical Device (SaMD)
- PDTs may help close gaps in care
  - Address geographic disparities by enabling patients to receive treatment at home
  - Enable providers to monitor their patients' treatment without need to schedule a visit

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What does the Access to PDTs Act do?

- Creates a benefit category for PDTs within Medicare/Medicaid
    - Necessary for coverage and reimbursement
    - Limited to digital therapeutics reviewed and cleared/authorized by FDA
    - Prescribed by a healthcare provider
- Does **not** require CMS to cover a specific PDT or PDTs as a class of products under Medicare/Medicaid
- Establishes definition for prescription digital therapeutic
- Directs CMS to establish framework for HCPCS coding

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Legislative History

- *PDTs to Support Recovery Act* introduced in 116th Congress by Sens. Capito and Shaheen
  - Limited definition of a PDT to prescription-only products that use behavioral treatments for the prevention, management, or treatment of a mental health or substance use disorder
  - Only introduced in the Senate
- *Access to PDTs Act* introduced in the 117th Congress
  - Expanded definition to include all prescription-only products that use software to prevent, manage, or treat a medical disease, condition, or disorder
  - Introduced in both chambers
- Reintroduced in the House and Senate on March 8, 2023

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Legislative History

- House version (*H.R. 1458*)
  - Introduced by Reps. Hern, Thompson, Johnson,* and Matsui
  - 21 cosponsors (17 D, 4 R)
  - Referred to the Energy & Commerce and Ways & Means Committees
- Senate version (*S. 723*)
  - Introduced by Sens. Shaheen, Capito, Booker, and Blackburn; Sen. Budd added as an additional cosponsor
  - Referred to the Finance Committee
- June 22, 2023: AMCP and DTA hosted a PDT demo day for Congressional offices
- Sept. 19, 2023: E&C Health Sub hearing on Medicare innovation with CMS and GAO witnesses
- Bill awaiting a score from the Congressional Budget Office (CBO)

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Next Steps

- Continue education on PDTs
  - Second PDT Demo Day
- Build cosponsors in House and Senate
- Identify a new Republican E&C champion
- Hold hearing in Senate Finance Committee/markup in House E&C Committee

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Medicaid Value Based Arrangements

- Medicaid programs are partially limited in how they can cover high-cost specialty medications due to balanced budget rules and the Medicaid Drug Rebate Program
- Prescription drug market dynamics are causing pressure on Medicaid budgets, crowding out other priorities
  - Growth in Medicaid prescription drug spending is driven by specialty drugs, which have higher list prices
  - Cell and gene therapies to treat conditions like sickle cell disease impact populations that are more likely to be covered under Medicaid
- Specialty drugs may have significantly different outcomes between patients
- Value or outcomes-based arrangements could allow states to share risk with manufacturers and tie payments to improved patient outcomes

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Medicaid VBPs for Patients (MVP) Act

- Enhances Medicaid patient access to new, high-cost therapies, such as cell and gene therapies, by modernizing the framework for value-based purchasing arrangements in Medicaid
- Provisions:
  - Codifies the existing “multiple best price” rule that allows manufacturers to report multiple best prices
  - Clarifies that the best price under a value-based arrangement is the maximum possible price paid, assuming all patient outcome benchmarks are satisfied
  - Further updates requirements for manufacturers to report information related to pricing structures for value-based arrangements to CMS

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Legislative History

- MVP Act introduced in the 117th Congress by Reps. Schrader, Guthrie, and Mullin (House only)
- House version (*H.R. 2666*)
  - Introduced by Reps. Guthrie, Eshoo, Joyce, Auchincloss, Miller-Meeks and Peters in April 2023
  - Referred to the Energy & Commerce and Ways & Means Committees; reported out of E&C on May 24, 2023
  - 39 cosponsors (20 R, 19 D)
- Senate version (*S. 4204*)
  - Introduced by Sens. Mullin, Sinema, Scott, and Hassan on April 30, 2024
  - Referred to the Finance Committee

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Next Steps

- AMCP sent a letter of support for HR 2666 to House and Senate leadership on April 29
- Add House cosponsors to build support for a floor vote
- Attract Senate cosponsors to new bill
- Secure hearing in Senate Finance Committee

Questions?