BILLS UNDER CONSIDERATION

E&C COMMITTEE

H.R. 1613, the Drug Price Transparency in Medicaid Act of 2023 (Carter, Allen, Harshbarger, Peters)
- Bans use of spread pricing in Medicaid
- Pass through pricing of ingredient cost and dispensing fee
- Requires Secretary of HHS to conduct NADAC monthly survey
- HHS report to Congress on specialty drug coverage and reimbursement in Medicaid

H.R. 2666, the Medicaid VBPs for Patients (MVP) Act (Guthrie, John Joyce, Miller-Meeks, Peters)
- Adds reporting requirements for manufacturers for VBP pricing structures
- Excludes VBP discounts from AMP reporting and adds VBP to anti-kickback safe harbor

H.R. 2691, the Transparent PRICE Act (McMorris Rodgers)
- Codifies in statute the Transparency in Coverage final rule
- Publicly discloses the average amount paid by a plan (net of rebates, discounts and price concessions)

H.R. 2679, the PBM Accountability Act (Kuster, Guthrie, Carter, Eshoo)
- Requires reporting of drug pricing and coverage to employers
- Very similar to the E&C mental health offset last Congress

H.R. ___, To establish patient protections with respect to highly rebated drugs
- Limits out of pocket cost for 30-day supply to 1/12 of annual net price paid by a plan for drugs with greater than 50 percent price concession in previous year
- Prohibits price concession for highly rebated drug not covered in previous year unless reflected at point of sale to enrollee and any other remuneration is a flat fee not based on volume of sales

H.R. ___, To amend title XVIII of the Social Security Act to promote transparency of common ownership interests under Parts C and D of the Medicare Program
- Requires report on negotiated price for each in-network pharmacy and pharmacy for which plan has ownership interest as well as average per-drug DIR paid by pharmacies to plan sponsor
- Prohibits Part D plan sponsors from contracting with “specified pharmacy or PBM” unless PBM discloses certain information to HHS

H.R. ___, To require the Secretary of Health and Human Services to consider, within the annual rulemaking process, the effect of regulatory changes to certain Medicare payment systems on provider and payer consolidation, and for other purposes
- Requires HHS through rulemaking to seek comment on how changes in payment rates for Parts C and D affect provider and payer consolidation

H.R. ___, To amend title III of the Public Health Service Act to ensure transparency and oversight of the 340B drug discount program
- Requires covered entities to allow audit of expenses and DSH hospitals to submit reports to HHS

H.R. 2816, the Drug Pricing and Transparency Act (Harshbarger – Miller Meeks)

- Amends HHS reporting to include aggregate dollar amount of all rebates, administrative fees, and other revenue the PBM receives from drug manufacturers and healthcare entities; highest, lowest, and total retained rebate percentages; and post-adjudication pharmacy payment reconciliations

H.R. 2880, To amend title XVIII of the Social Security Act to establish certain requirements for pharmacy benefit managers under part D of the Medicare program (Carter)

- No text

H.R. 830, the Help Ensure Lower Patient (HELP) Copays Act (Carter, Barragan, Miller-Meeks, DeGette, Sarbanes, Blunt Rochester, Matsui, Kuster)

- Prohibits use of copay accumulator programs in exchange programs (PHSA)

H.R. 1352, the Increasing Access to Biosimilars Act (Hudson)

- Establishes a shared savings model for biosimilar utilization in Medicare Part B

H.R. 1488,the Affordable Insulin Now Act (Craig, Castor)

- Caps insulin copayments at $35 in the commercial market

H.R. 1503, the Prescription Information Modernization Act (Harshbarger, Peters, Blunt Rochester)

- Allows manufacturers to transmit prescribing information electronically

H.R. 1770, the Equitable Community Access to Pharmacist Services Act (Bucshon, Matsui, Carter, Harshbarger, Bilirakis, Peters, Lesko, Craig)

- Would permanently reimburse for pharmacist-administered testing, vaccinating, and delivery of medications for common respiratory illnesses

H.R. 1790, the Biologics Competition Act (Miller-Meeks, Barragan, Kuster)

- Requires HHS to evaluate system of substitute of interchangeable biologics and therapeutic equivalence ratings

H.R. 2408, the Access to Innovative Treatments Act (Barragan, J. Joyce)

- Establishes a process for review of adverse National Coverage Determinations that includes public input

H.R.2534, the Preserving Rules Ordered for the Entities Covered Through (PROTECT) 340B Act (Spanberger)

- Prohibits insurers and PBMs from discriminating against providers and contract pharmacies that dispense 340B drugs

H.R. 2630, the Safe Step Act (Miller-Meeks, Ruiz)

- Establishes a clear exceptions process for medication step therapy and exceptions process under ERISA

H.R. , (not yet reintroduced), the Increasing Transparency in Generic Drug Applications Act (Kuster)

- Would allow the FDA to provide feedback on proposed drug formulations to generic drug applicants (disclosing amount of inactive ingredient)

Senate

SENATE HELP COMMITTEE (expected markup on 5/2)

Senate HELP Committee's Draft of the Pharmacy Benefit Manager Reform Act

- Based on the section 306 language from the Lower Health Care Costs Now Act
- Prohibits spread and rebate pass-through, and mandates new detailed reporting to clients, prospective clients, and the government

- **Potential Amendments:**
  MAGGIE HASSAN
  - **S.574** — enables the FDA to immediately approve drugs – instead of the normal 30-month approval stay – if the only barrier to approval is a REMS patent

  - **S.775** — Require the FDA to more clearly identify the specific differences between the generic and brand name drug when there is an issue with the composition of the generic, thereby streamlining the approval process, helping more generics reach the market faster, and lowering prescription drug prices overall.

  - **S.1120** — Prevents brand-name manufacturers from withholding drug samples that generic manufacturers need to prove that their generic medication acts the same as the brand

  - **S.1128** — ***Ensuring Access to Generic Medications Act*** prohibits manufacturers from overstating the scope of certain patents to stop the FDA from approving generic competitors.

  TINA SMITH
  - **S.1114** – ***Expanding Access to Low-Cost Generics Act*** prohibits "parking." "Parking" occurs when a brand name manufacturer agrees not to sue the first company that submits an application to create a generic version of that drug—a so-called "first filer"—as long as the generic company agrees to delay bringing that generic drug to market.

  BILL CASSIDY (SHAHEEN)
- **S.1067** — ***Ensuring Timely Access to Generics Act of 2021*** enhances oversight of the FDA's citizen petition process.

- **MIKE BRAUN**
  - **S.1130** — A bill to amend the Public Health Service Act to provide for hospital and insurer price transparency.

  - **S.1131** — A bill to amend title XI of the Social Security Act and title XXVII of the Public Health Service Act to establish requirements with respect to prescription drug benefits.

  - **S.1133** — A bill to amend the Public Health Service Act to clarify rules relating to drug discounts for covered entities.

- **TAMMY BALDWIN**

- **S.1214** — A bill to set forth limitations on exclusive approval or licensure of drugs designated for rare diseases or conditions

The Committee is also considering amendments on:

- PBM fiduciary
- Disclosures for the purpose of selecting a PBM
- Plan sponsors having the option of choosing POS rebates