A CAMPAIGN FOR Transformative Therapies

H.R. 2666- MVP Act

Issue Overview
"Medicaid VBPs for Patients (MVP) Act"

What are VBPs:
Value-Based Purchasing (VBPs) Arrangements are contracts between payers and biopharmaceutical manufacturers where the manufacturer is reimbursed based on their prescription drug's performance and the patient's clinical outcome(s) (i.e. did the drug do what it was supposed to do).

VBPs ensure that payers- like Medicaid- are only paying for therapies that work and patients have greater access to promising therapies.

How do they work (generally):
1. **Contract**: Clear definition of terms and setting of goals for patient populations
2. **Reporting**: Establishment of how data will be collected and managed
3. **Data Analysis**: Calculations based on reported data to provide accurate reimbursement
4. **Payment**: Reimbursement linked to terms based on agreed upon patient outcome(s), which may differ between contracts

AKA
- Outcomes-Based Arrangements (OBAs)
- Value-Based Arrangements (VBAs)
- Value-Based Payment/Purchasing Arrangements/Agreements (VBPs)

Example VBP:
- For a blindness gene therapy, the contract could measure short- and long-term durability of the drug based on vision tests; if the patient's vision does not improve, then the manufacturer refunds a percentage of the cost of the drug back to the payer.

Federal Barriers to VBPs:
Federal price reporting laws (Medicaid Best Price, Average Sales Price [ASP] and Average Manufacturer Price [AMP]) and fraud and abuse laws (Anti-kickback Statute [AKS]) inhibit VBPs. Specifically, if a patient does not respond to a therapy and a significant refund is provided to the payer, the discounts could skew the Best Price, ASP and AMP of the therapy. A skewed Best Price and AMP will result in inaccurate Medicaid rebates and a skewed ASP will result in inacurate Medicare Part B payments. Additionally, manufacturer refunds in this case could potentially trigger AKS because the manufacturer could be viewed as giving an inducement.

CMS, CMMI & Medicaid:
- **CMS**: In 2020, CMS finalized a rule that aimed to eliminate some of the federal barriers to encourage more VBPs in the marketplace. They did this by allowing multiple best prices (for when the Rx works and doesn't work) to be reported for prescription drugs with a VBP. That rule didn't clarify how VBP discounts will count towards certain price reporting requirements , which is why H.R. 2666 is needed.
- **Medicaid**: States have some flexibility to enter into VBPs with manufacturers via state plan amendments (SPAs) or through CMS via the Multiple Best Price Rule (AKA VBP Rule). As of February 2024, more than 20 states have received approval for their SPAs to enable negotiation of VBP contracts with drug manufacturers. But barriers still remain for widespread adoption unless H.R. 2666 is passed.
- **CMMI**: In 2024, CMMI (CMS Innovation Center) announced the first Cell and Gene Therapy (CGT) Model for sickle cell disease gene therpapies in 2025. H.R. 2666 will help VBPs for additional disease states.

Bill Summary
"Medicaid VBPs for Patients (MVP) Act"

H.R. 2666 Summary
Sponsors: Reps. Guthrie (R-KY) and Eshoo (D-CA)

Sec. 2: Codifies VBP Definition and Adds Additional Reforms
- **Multiple Best Prices**- Codifies multiple best prices can be used for drugs that have a VBP
- **AMP**- Excludes VBP discounts (that result from the drug not working) from average manufacturer price (AMP) reporting and adds a special rule that in the case of installment payments (i.e. pay-over-time VBP models) the full price of the drug is reported for AMP and not an individual installment payment
- **Definitions**- Adds VBP definition (same as CMS final rule) to the list of definitions in Medicaid/CHIP
  - ***Justification***: Without multiple best prices, if a drug doesn't work in just one patient, the discount (e.g. 100% refund) would have to be applied to all of Medicaid- which means that nobody would enter into a VBP. Codifying the CMS rule (which is a bipartisan rule that was drafted in the Trump Administration and further refined and implemented in the Biden Administration) adds certainty that state Medicaid programs would have access to multiple best price points for drugs that work and don't work. Excluding the discounts when a drug doesn't work from AMP ensures that AMP is not artificially skewed because of a few non-responding patients.

Sec. 3: ASP Clarification
- **ASP**- Exempts VBP discounts (that are reported through the CMS multiple best price pathway) from Average Sales Price (ASP) calculations
  - ***Justification***: Like the AMP argument above, excluding discounts from non-responding patients ensures that ASP is not artificially skewed. It also helps ensure ASP is correct (and not artificially too low) for calculating inflation rebates as part of the Inflation Reduction Act.

Sec. 4: Guidance on Inpatient Drugs with VBPs
- Mandates that HHS shall issue guidance to State Medicaid agencies on how to enter into VBPs for inpatient drugs and how states can cover Medicaid patients who need to travel to different states (for instances where there's a center of excellence for treatment of a certain disease).
  - ***Justification***: Some gene therapies require inpatient stays and are billed differently so this ensures that states can navigate how to deal with those types of VBPs.

Sec. 5: Anti-kickback statute Safe Harbor
- Adds VBP discounts to the list of safe harbors (i.e. exclusions) to the federal anti-kickback statute
  - ***Justification***: If a non-responding patient triggers a 100% refund, that refund could be considered a kickback or remuneration under the Anti-kickback statute (AKS) so the discounts from non-responders need to be carved out via a safe harbor.

Sec. 6: GAO Study on the effectiveness of VBPs on patient access, health outcomes, and health system costs.