

## Bill Summary “Medicaid VBPs for Patients Act”

### What are VBPs:

Value-Based Purchasing (VBPs) Arrangements are contracts between payers and biopharmaceutical manufacturers in which 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).

### Medicaid, CMS and VBPs:

- **Medicaid:** Eleven states (and counting) have submitted state plan amendments (SPAs) to CMS that allows them to use supplemental rebate agreements for VBPs.
- **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 for multiple best prices to be reported for prescription drugs with a VBP. That rule was delayed until July 2022 and some barriers still remain, which is why H.R. 7389 was introduced.

### AKA

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

### Example VBP:

- **Outcome:** 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.

## H.R. 7389 Summary

### Sec. 1 & 2: Title and Findings

### Sec. 3: Codifies CMS VBP Provisions

- **CMS Rule-** Codifies the provisions of the CMS VBP Final Rule (CMS-2384) related to multiple best price reporting for value-based purchasing arrangements (VBPs)
- **Quarterly Reporting-** Adds reporting requirements for manufacturers related to VBP pricing structures; clarifies that states are not required to enter into any VBPs
- **AMP-** Excludes VBP discounts from average manufacturer price (AMP) reporting and adds a special rule that in the case of installment payments (i.e. pay-over-time models) the full price of the drug is reported for AMP, not an individual installment payment
- **Definitions-** Adds VBP definition (same as final rule) to the list of definitions in Medicaid/CHIP
- **Effective Date-** July 1, 2022

### Sec. 4: Anti-kickback statute Safe Harbor

- Adds VBP discounts to the list of safe harbors (i.e. exclusions) to the federal anti-kickback statute

### Sec. 5: GAO Study

- Studies the effectiveness of VBPs on patient access, health outcomes, and health system costs
- Due 5 years after enactment