Alliance for Regenerative Medicine

The Alliance for Regenerative Medicine (ARM) endorses H.R. 2666, the "Medicaid VBPs for Patients (MVP) Act," sponsored by Representatives Guthrie (R-KY), Eshoo (D-CA), Joyce (R-PA), Auchincloss (D-MA), Miller-Meeks (R-IA), and Peters (D-CA). ARM requests that Members of Congress co-sponsor the "MVP Act" to eliminate barriers to using innovative payment models that will promote access to cell and gene therapies for the Medicaid patients that need them. Similar legislation is forthcoming in the Senate.

Cell and gene therapies (CGTs) are at the next frontier in the fight against some of humankind's most devastating diseases and disorders. Value-based payment (VBP) arrangements[1] can help bring CGTs to more patients. Critically, these arrangements can ensure patient access to new therapies while supporting state Medicaid agencies as they manage their budgets. They can help defray the cost density of the numerous one-time administered, potentially curative therapies coming to market in the next few years – which will likely include therapies for both rare diseases and large patient populations. To this end, value-based payment models can help increase timely patient access to paradigm-shifting technologies. This is particularly important under Medicaid as it will likely be a prominent payer for many of the CGTs that will be approved in the coming years.

The MVP Act helps advance these innovative payment structures, which permit state Medicaid programs to voluntarily enter value-based purchasing (VBP) arrangements with drug manufacturers. VBP arrangements modernize Medicaid reimbursement by basing the treatment price on the effectiveness of the product in providing a clinical benefit rather than the quantity of medicine consumed. Specifically, the MVP Act reflects and codifies the Medicaid Best Price (BP) provisions of the Centers for Medicare & Medicaid Services (CMS) rule.

Before the rule, stakeholders stated that Medicaid's best price requirements severely hindered the use of VBP arrangements in both Medicaid and the commercial space, as the lowest price offered in any market would have to be offered to state Medicaid programs. For example, if a manufacturer sought to offer a commercial plan an outcomes-based contract, where the manufacturer rebates 80% of the drug to the payor if a patient fails the therapy, the manufacturer would have to offer an 80% rebate to all states, regardless of whether the drug produces desired outcomes for Medicaid patients or there was a VBP in place. The rule allows manufacturers to report multiple best prices (BPs) under VBP arrangements without impacting BP for sales outside of the arrangement.

In addition to the codification of the BP provisions in the CMS Final Rule, the introduced bill::

1. Clarifies how Average Manufacturer Price (AMP) is to be calculated for VBP drugs;
2. Establishes a safe harbor to the Federal Anti-Kickback Statute (AKS) for any remuneration from a VBP;
3. Clarifies the calculation of Average Sales Price (ASP) by exempting the price of products sold under a VBP arrangement from the ASP;
4. Provides VBP protections for inpatient-administered therapies; and
5. Requires a GAO study no later than June 2027 on the effectiveness of VBPs on patient access and overall health system costs related to "transformative therapies, including rare disease gene therapies:"

[1] *The Centers for Medicare and Medicaid Services broadly defines VBP arrangements as an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a select population and includes, but is not limited to, evidence-based or outcomes-based measures.*

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The bill also includes a sunset provision beginning five years after the date of enactment. However, the sunset provision will not impact value-based agreements already in place at that time.

It is essential that VBPs be utilized to ensure patient access to transformative cell and gene therapies. We greatly appreciate your support in securing the passage of the MVP Act.