# IGT Supports Passage of the MVP Act

**H.R. 2666, The Medicaid Value-Based Payment Act**, is an important piece of legislation for fostering innovative new ways to pay for potentially curative treatments like gene therapies. The core of the bill codifies a **regulation** establishing a voluntary pathway for manufacturers to report multiple best prices, which opens the door for manufacturers and payers, including state Medicaid programs, to implement and share value-based payment arrangements on a voluntary basis. This ultimately benefits the patients, who gain timely access to these potentially curative treatments. Failure to pass the bill leaves states with insufficient tools at their disposal to finance these treatments.

The multiple best price approach is critical because it is flexible enough to accommodate VBAs for many therapeutic areas where outcomes vary greatly depending on the particular disease. This approach also allows states to pick up VBA terms "off the shelf" without having to enter into a supplemental rebate agreement.

While the Rule has been effective since July 1, 2022, the Institute for Gene Therapies (IGT) supports passage of the MVP Act because it addresses other lingering challenges for VBA implementation that are not addressed directly in the Rule. Passing the MVP Act would significantly improve the regulatory environment for manufacturers and payers, including state Medicaid plans, to implement VBAs in a way the final rule by itself does not.

Below, we have compiled answers to some commonly asked questions and concerns to help ensure this complicated issue is well understood and emphasize why passing the MVP Act creates sound public policy.

## FREQUENTLY ASKED QUESTIONS / CONCERNS

### 1 Why do we need to codify this now?

A) Gene therapies are still a new concept in the reimbursement landscape. Many private payers, state Medicaid programs, and manufacturers are just now working to address the challenges surrounding reimbursement for gene therapies for the first time. There have long been legislative and regulatory barriers to creating value-based payment arrangements that can ensure states do not have to pay for a gene therapy if it either 1) does not work in the short term or 2) proves not to be durable. While the science behind gene therapy is promising, we will not have long-term data on a therapy's lasting impact on functional outcomes for decades.

***Medicaid patients should not be forced to wait decades because Congress did not ensure states have protections in the event a patient does not respond to therapy.***

B) Value-based payment arrangements often take years to develop, negotiate, and implement. Both sides need time to research research the eligible patient population, create financial modeling tools to estimate budgets over time, and then agree to operational elements - starting with broad agreement terms and then contractual specifics such as payment timing, reconciliation, and adjudication. Given the prolonged and complex nature of these agreements, it is critical that manufacturers and payers, including state Medicaid programs, have clarity as to what the rules of the road will be as new gene therapies are approved and become available to patients.

***By passing the MVP Act, Congress will provide additional certainty that will foster additional investment into VBA development.***

### 2 Have states used the current rule? Why haven't they?

To date, we are not aware of manufacturers who are reporting multiple best prices pursuant to a VBA. However, as described above, it takes a long time to establish a new VBA, and the Final Rule has only been effective for less than a year.

With the oncoming wave of gene therapy approvals in the near future, it is a safe bet to assume states and other payers will be looking towards VBAs to help secure larger discounts in the event of failed treatments or to spread their financial obligations over time instead of in one lump sum. The multiple best price approach provides needed flexibility to ensure innovation in VBA design while protecting states and ensuring they are will never receive less than the current statutory minimum rebate.

## 3 This will lead to manufacturers gaming the system and only offering a VBA and charge Medicaid a higher rate.

One of the MVP Act's strongest points is that the new multiple best price approach provides a strong level of security and agency to states to determine how they would like to pay for gene therapies. The Rule specifically ensures that:

**A)** Participation in VBAs is completely voluntary for states.

**B)** States are still guaranteed access to the traditional Medicaid drug rebates they would receive today, if they so choose.

**C)** Manufacturers are ***REQUIRED*** to offer any operationalized VBA to ***ALL*** states, guaranteeing states will have access to the best VBAs available. Manufacturers cannot refuse a state who wishes to utilize the terms of an existing VBA.

**D)** Manufacturers must report a "non-VBA Best Price" for states, even if the therapy is only offered in the commercial market under a VBA; and states are guaranteed to get continued access to the minimum statutory rebate on the non-VBA best price.

## 4 Medicaid programs don't have the operational capacity to track these agreements.

States did raise this concern when the multiple best price rules were first proposed, but their concerns were largely addressed by CMS guidance that provided additional details as to how CMS will support states. Notably, CMS will require manufacturers to report the terms of any agreed upon VBA, and CMS will then proactively provide those VBA terms to the states so they can choose for themselves to accept the conditions.

CMS has also made it clear that states choosing to use the terms of an existing VBA do not have to submit a state plan amendment (SPA) to begin receiving reimbursement via reported multiple best prices, which lowers the burden for states, particularly smaller states, who may not have enough staff to manage the red tape associated with SPA development.

## 5 The bill removes CMS flexibility by codifying the multiple best price rule, which would prohibit CMS from pulling the regulation entirely if they believe it isn't working.

The latest version of the MVP Act includes many revisions requested by CMS in their technical assistance that restores CMS' flexibility to implement changes to the multiple best price program. Notably, the statute refers back to the regulation itself for the underlying definitions upon which the multiple best price policy is based. This gives CMS significant flexibility to manage any problems with the program.

As to whether CMS could rescind the Rule, it is critical that this approach be safeguarded from removal in order to provide certainty for both states and manufacturers who are just entering into VBAs for the first time; and again, the process of VBA development typically takes over a year. So, if CMS were to rescind the Rule, rare disease patient access could be compromised.

***The current CMS has clearly leaned in on VBAs for now, but can we count on future Administrations not to significantly disrupt or remove the program?***

## 6 The bill includes additional parts that weren't part of the Rule, giving manufacturers more ability to manipulate federal drug pricing programs.

While the bill does lean heavily upon the multiple best price final rule, it would provide other elements that "complete" a working environment for VBA development. These elements have largely been made in accordance with CMS' technical assistance, and they also provide additional urgency around passing the bill.

***To be clear, these additional elements address lingering technical challenges that stand in the way of VBA development and gene therapy access; the bill is stronger for including them. These elements are another reason why passing the MVP Act is important.***

**A) AMP Special Rule:** This provision ensures that pay-over-time arrangements will be possible for states to use under the multiple best price approach, while continuing to protect states from rebate erosion.

**B) ASP For All Sales:** This provision fixes how ASP is calculated for a gene therapy provided under a VBA so that physicians and providers are not under water when they provide these therapies to their patients.

**C) Inpatient Guidance:** Many gene therapy patients will require multi-day inpatient hospital stays to prepare for administration of the gene therapy. This provision will give states additional clarity on how to use existing legal authorities to provide a gene therapy that is offered under a VBA in the inpatient setting. These legal authorities again ensure that providers are not underwater when existing MS-DRGs cannot capture the costs of administering a gene therapy that is being provided under a VBA.

**D) GAO Study:** This study provides an additional guardrail for Congress and CMS to inform future policymaking, and acts as a check against any unintended consequences for states that the bill has not already actively worked to address.