August 15, 2023

The Honorable Brett Guthrie
U.S. House of Representatives
Washington, DC 20515

The Honorable Anna Eshoo
U.S. House of Representatives
Washington, DC 20515

Dear Representatives Guthrie and Eshoo,

On behalf of the Alliance for Regenerative Medicine (ARM), which represents more than 475 emerging and established biotechnology companies, academic and medical research institutions, and patient organizations, I thank you for your leadership championing policies to ensure patients can benefit from durable, potentially curative cell and gene therapies (CGTs).

CGTs are at the forefront of the fight against some of humankind's most devastating diseases and disorders. CGTs will soon be available for both rare diseases and large patient populations and will provide major paradigm shifts away from chronic care, especially for historically underserved populations. To this end, it is particularly important that Medicaid programs be equipped with new tools, as Medicaid will likely be a prominent payer for many of the CGTs that will be approved in the coming years.

We strongly support your *Medicaid VBPs for Patients (MVP) Act* (H.R. 2666), currently co-sponsored by Representatives Auchincloss (D-MA), Miller-Meeks (R-IA), Peters (D-CA), Joyce (R-PA), Swalwell (D-CA), Crenshaw (R-TX), Bilirakis (R-FL), Dunn (R-FL), Balderson (R-OH), Phillips (D-MN), Bera (D-CA), Lieu (D-CA), and Thompson (D-CA).

Value-based payment (VBP) arrangements can help bring CGTs to more patients, while supporting state Medicaid agencies as they manage their budgets. Specifically, VBPs can defray the upfront cost of the numerous one-time administered, potentially curative CGTs coming to market in the next few years and ensure that states are only paying for products that provide a benefit to patients.

The *MVP Act* helps facilitate these types of VBPs by modernizing Medicaid payment methodologies for CGTs. Specifically, VBPs can be structured to base the cost of a drug to a Medicaid program on its effectiveness rather than the quantity of medicine consumed. The MVP Act would encourage the use of VBAs by states and manufacturers by codifying recent CMS changes to the Medicaid Best Price (BP) regulations. The legislation also makes critical changes to other legacy provisions that were codified well before CGTs were a reality in order to accommodate VBPs, including those related to the calculation of Average Sales Price (ASP), Average Manufacturer Price (AMP), as well as provisions of the Federal Anti-Kickback Statute (AKS).

Many changes were made to the introduced bill during the Committee process to respond to concerns about scope, product prices, and costs to states. In addition, the bill requires a GAO study on the effectiveness of VBPs on patient access and overall health system costs related to "transformative

therapies, including rare disease gene therapies" to ensure oversight of the changes made in the bill and that the savings projected to the health care system are conceived.

While most of the provisions of the *MVP Act* are focused on products administered in the outpatient setting, the bill also addresses potential access challenges created by CGTs administered in the inpatient setting by directing CMS to issue guidance to states on how current laws apply to VBPs for products carved out of inpatient bundled payments. In many cases, current Medicaid bundled payments are inadequate to cover the hospital's cost of purchasing innovative new therapies, disincentivizing the treatment of Medicaid patients. Some states are beginning to pay hospitals separately (i.e., outside of the bundle) for their acquisition cost of CGTs to improve patient access. Separate payment also allows for the collection of rebates by the states and the use of VBPs because, in these cases, the products are considered Covered Outpatient Drugs in the Medicaid Drug Rebate Program.

In addition to your leadership on the *MVP Act*, we ask that you consider weighing in with CMS on several of its efforts directly impacting the adoption of value-based payment arrangements for CGTs.

- **Proposed rule entitled Misclassification of Drugs, Program Administration and Program Integrity Updates under the Medicaid Drug Rebate Program ("MRDP proposed rule") –** We are deeply concerned that CMS is currently considering changing the interpretation of "covered outpatient drug" to include not only inpatient-administered products paid separately as described above, but also products that are simply *listed* separately on the claim form without any form of separate payment, directly undermining the efforts to provide clarity about inpatient products in the MVP Act. Allowing states to seek rebates on inpatient-administered drugs merely by identifying the product on the claim form, and without actual, separate payment to the provider for the cost of the drug, creates an end-run around the mutually beneficial balance that separate payment arrangements for inpatient CGTs strike where hospitals obtain adequate payment and states obtain rebates. The MVP Act takes a more rational approach to the issue of therapies administered in the inpatient setting, clarifying existing interpretation of the law which provides greater flexibility in the approach to making CGTs available to Medicaid beneficiaries.

- **Center for Medicare and Medicaid Innovation (CMMI)'s proposed CGT Access Model –** ARM members believe that this model should be implemented in a manner that promotes, rather than hinders, access to these important therapies and pilot the model on a small scale and ensure the model is truly voluntary for manufacturers and States. We are closely monitoring CMMI's recently announced CGT Access Model, under which state Medicaid agencies could voluntarily allow CMS to coordinate and administer multi-state, outcomes-based agreements ((OBAs), a type of VBP arrangements), with manufacturers of certain CGTs. We support the overall goals of the Model to provide the resources necessary for State Medicaid programs to negotiate, implement, and operationalize VBAs. However, to ensure that the voluntary model can meet its intent to ensure appropriate, equitable, and sustainable access to CGTs immediately upon their launch, CMS should ensure that the design of each VBA under the model remains the product of negotiations between the relevant state, which would have the greatest knowledge regarding the needs of its state Medicaid patients, and the product's manufacturer, which would have the deepest trove of relevant clinical data.

ARM greatly appreciates your work on the MVP Act, and we will continue to advocate for its enactment to support equitable access to CGTs for Medicaid beneficiaries. We encourage you to follow CMS as it works to finalize the MRDP proposed rule and implement the CMMI demonstration to ensure they both meet this same promise. Thank you again, and if you have any questions, please contact me at ecischke@alliancerm.org.

Sincerely,

Erica Cischke, MPH
Vice President, Government Affairs
Alliance for Regenerative Medicine