



September 25, 2023

The Honorable Charles Grassley
United States Senate
135 Hart Senate Office Building
Washington, DC 20510

The Honorable Michael Bennet
United States Senate
261 Russell Senate Building
Washington, DC 20510

The Honorable Lori Trahan
United States House of Representatives
2439 Rayburn House Office Building
Washington, DC 20515

The Honorable Mariannette Miller Meeks
United States House of Representatives
1034 Longworth House Office Building
Washington, DC 20515

Re: Accelerating Kids' Access to Care Act

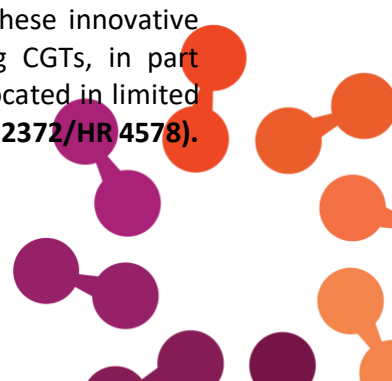
Dear Senators Grassley and Bennet and Representatives Trahan and Miller Meeks:

On behalf of the Alliance for Regenerative Medicine (ARM), I thank you for your leadership championing policies to ensure children with medically complex conditions enrolled in Medicaid can access specialized care across state lines.

ARM is the leading international advocacy organization championing the benefits of engineered cell therapies and genetic medicines for patients, healthcare systems, and society. We represent more than 400 emerging and established biotechnology companies, academic and medical research institutions, and patient organizations.

In recent years, numerous transformative – and sometimes life-saving – cell and gene therapies (CGTs) have been approved by the Food and Drug Administration (FDA) for some of the most difficult-to-treat conditions affecting both children and adults, including cerebral adrenoleukodystrophy, beta-thalassemia, spinal muscular atrophy, hemophilia A and B, Duchenne muscular dystrophy, and various forms of cancer. There are nearly 1,000 CGT clinical trials ongoing in the US to test the next generation of therapies. Many patients who can benefit from CGTs are children or individuals living with disability who rely on Medicaid for their health coverage. Notably, two gene therapies for sickle cell disease patients – many of whom are enrolled in Medicaid – could be approved by the FDA in December 2023.

ARM is committed to ensuring all patients have equitable and timely access to these innovative therapies. However, Medicaid beneficiaries face numerous challenges accessing CGTs, in part because the highly specialized providers administering these novel therapies are located in limited geographic areas. **We strongly support your Accelerating Kids' Access to Care Act (S.2372/HR 4578).**



Because of the specialization required for the administration of CGTs, manufacturers generally contract with providers in a limited number of states that have the appropriate experience and facilities necessary for the administration of their therapies. For this reason, patients seeking CGT treatments, who in many cases tend to be critically ill with medically complex conditions, often are required to travel beyond their home states to obtain care.

This treatment is not limited to single encounters or procedures. The administration of cell and gene therapies can necessitate extensive care in advance of administration of the therapy, along with consistent follow-ups over months and years.

Providers seeking to treat nonresident Medicaid beneficiaries must become enrolled in, and credentialed by, the Medicaid program in the patient's home state. Currently, since each state Medicaid program establishes and administers its own credentialing program, the rules and procedures for credentialing can vary from state to state, resulting in a patchwork of state-specific credentialing requirements. These requirements can be onerous, complex, and time-consuming. As a result, certain providers qualified to administer CGTs may be reluctant to complete necessary credentialing procedures to allow the treatment of nonresident beneficiaries, creating avoidable barriers to care for medically complex patients seeking treatment with CGTs.

The Accelerating Kids' Access to Care Act takes steps to alleviate these potential administrative hurdles by requiring state Medicaid programs to establish a streamlined enrollment process for some out-of-state providers working with children. This process would still maintain important program integrity checks that take into account the standing of providers in their home state and with federal programs, including Medicare.

While passage of the legislation would provide welcome relief for health care providers working with children, providers working with adults travelling across state lines seeking care also face significant administrative obstacles. To that end, we would support amendments to the legislation that broaden the applicability to specialized providers treating Medicaid patients of *all* ages.

ARM greatly appreciates your work on the Accelerating Kids' Access to Care Act, and we will continue to advocate for its enactment to support equitable access to CGTs for Medicaid beneficiaries. 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