Alliance for Regenerative Medicine

June 23, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

Submitted via http://www.regulations.gov

**Proposed Rule on Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality (CMS–2439–P)**

Dear Administrator Brooks-LaSure:

The Alliance for Regenerative Medicine (ARM) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Proposed Rule on Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality (the "Proposed Rule").[1]

The Alliance for Regenerative Medicine (ARM) is the leading international advocacy organization championing the benefits of engineered cell therapies and genetic medicines for patients, healthcare systems, and society. As a community, ARM builds the future of medicine by convening the sector, facilitating influential exchanges on policies and practices, and advancing the narrative with data and analysis. We actively engage key stakeholders to enable the development of advanced therapies and to modernize healthcare systems so that patients benefit from durable, potentially curative treatments. As the global voice of the sector, we represent more than 475 members across 25 countries, including emerging and established biotechnology companies, academic and medical research institutions, and patient organizations.

As of year-end 2022, 1,308 regenerative medicine and advanced therapies developers worldwide are sponsoring 1,200 clinical trials across dozens of indications, including rare monogenetic diseases, oncology, cardiovascular, central nervous system, musculoskeletal, metabolic disorders, ophthalmological disorders, and more.[2]

[1] 88 Fed. Reg. 28092 (May 2, 2023).
[2] https://alliancerm.org/sector-report/2020-annual-report/

1900 L Street NW, Suite 735
Washington, DC 20036
info@alliancerm.org
@alliancerm
www.alliancerm.org

To date, the FDA has approved seven gene therapies – six for rare genetic diseases – and six CAR-T cell therapies for various blood cancer indications. Transformative cell and gene therapies (CGTs) have been approved for the rare genetic pediatric indications spinal muscular atrophy and cerebral adrenoleukodystrophy, and for the pediatric blood cancer indications acute lymphoblastic leukemia. These innovative therapies address high unmet medical needs; they can be life-saving; and many have the potential to reduce the need for burdensome and costly chronic care.

The CGT pipeline for both rare and prevalent diseases is accelerating, with growing impacts on Medicaid. Regarding rare diseases, gene therapies for Duchenne muscular dystrophy, hemophilia A, and sickle cell disease could be approved by the FDA in 2023. There are also transformative therapies advancing in the pipeline for chronic diseases including Type 1 diabetes.

Ensuring Medicaid patients have timely access to the same transformative therapies that will become available to those with other forms of government and commercial insurance is critical to achieving CMS' goal of addressing health equity, including closing gaps in care for underserved populations and eliminating racial health disparities. Medicaid nationwide covered 66 percent of sickle cell disease hospitalizations in 2004 and 58 percent of emergency department visits for the disease between 1999 and 2007.[3] Not only does Medicaid pay for a majority of acute care for sickle cell disease patients, but those patients are overwhelmingly people of color.[4]

We commend CMS for its continued efforts to strengthen access to care, improve care quality and health outcomes, and address health equity issues for managed care enrollees in Medicaid and CHIP. In this letter, we offer specific recommendations to strengthen and clarify language in two sections of the Proposed Rule to protect medically fragile beneficiaries and ensure access to medically necessary CGTs:

- CMS should further address network adequacy to ensure access to specialized providers of CGTs for Medicaid managed care enrollees.
- CMS should expand upon the proposed payment adequacy provisions to ensure access to CGTs by Medicaid MCO enrollees.

**CMS should further address network adequacy to ensure access to specialized providers of CGTs for Medicaid managed care enrollees.**

Consistent with the principles of Executive Order (E.O.) 14009 and E.O. 14070, the Proposed Rule "proposes new standards to help States improve their monitoring of

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8550393/.

[4] https://www.cdc.gov/ncbddd/sicklecell/data.html#:~:text=SCD%20affects%20approximately%20100%2C000%20Americans,sickle%20cell%20trait%20(SCT).

access to care by requiring establishment of new standards for appointment wait times, use of secret shopper surveys, use of enrollee experience surveys, and requiring States to submit a managed care plan analysis of payments made by plans to providers, for specific services, to more closely monitor plans' network adequacy."[5] ARM supports the Administration's efforts to ensure adequate access to providers for Medicaid managed care enrollees, and urges CMS to further address network adequacy for the specialized providers of CGTs, including across state lines.

As noted in the Proposed Rule, current CMS regulations require states to establish uniform credentialing policies for providers, including "acute" care providers. *See* 42 CFR § 438.214(b). ARM supports this requirement as a means to ensure providers can easily and efficiently enroll in Medicaid managed care plans' networks.

However, the term "acute" care provider is not defined anywhere in the Medicaid managed care regulations. To ensure CMS regulations guarantee access to care for patients with complex medical conditions who may seek treatment with CGTs, we urge CMS to clarify that this term includes providers of CGTs, including centers of excellence.

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. Providers seeking to treat nonresident Medicaid beneficiaries must become enrolled in, and credentialed by, the 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.

Consistent with CMS's authority under section 1902(a)(16) of the Social Security, Act, and similar to the standards CMS has already adopted for medically-fragile children,[6] the establishment of a consensus-based credentialing standard for CGT providers treating patients of all ages that state Medicaid agencies may opt to use will help facilitate access to care among some of the nation's most vulnerable patients.

[5] *Id.* at 28095.

[6] https://www.medicaid.gov/federal-policy-guidance/downloads/smd22004.pdf.

**CMS should expand upon the proposed payment adequacy provisions to ensure access to CGTs by Medicaid MCO enrollees.**

As CMS notes in the Proposed Rule, "[t]here is considerable evidence that Medicaid payment rates, on average, are lower than Medicare and commercial rates for the same services and that provider payment influences access, with low rates of payment limiting the network of providers willing to accept Medicaid patients, capacity of those providers who do participate in Medicaid, and investments in emerging technology among providers that serve large numbers of Medicaid beneficiaries."[7] To address this concern, CMS believes that "greater transparency is needed to understand when and to what extent provider payment may influence access in State Medicaid and CHIP programs to specific provider types or for Medicaid and CHIP beneficiaries enrolled in specific plans."

Specifically, CMS is proposing that MCOs, PIHPs, and PAHPs, submit annual documentation to the State that demonstrates a payment analysis showing their level of payment for certain services, if covered by the managed care plan's contract. States would review and include in their assurance and analysis submission to CMS. CMS is also proposing to require each MCO, PIHP, and PAHP to use paid claims data from the immediate prior rating period to determine the total amount paid for evaluation and management current procedural terminology (CPT)[8] codes for primary care, OB/GYN, mental health, and SUD services. CMS is proposing this analysis provide the percentage that results from dividing the total amount the managed care plan paid by the published Medicare payment rate for the same codes on the same claims.

ARM greatly supports CMS's efforts to ensure payment adequacy by Medicaid managed care plans, and agrees that beneficiary access is inextricably tied to provider payment rates.

However, we urge CMS to go further to ensure access to CGTs and related items and services for Medicaid managed care enrollees.

First, we urge CMS to expand the list of services for which MCOs conduct their payment analyses to include the CGT administration and related items and services. As CMS notes, low provider payment rates under Medicaid is associated with reduced investment in emerging technology among providers that serve large numbers of Medicaid beneficiaries. CGTs are some of the newest technologies and involve significant resources to acquire and administer. In addition, as noted above, only certain provider types are qualified to administer these therapies. Without adequate payment, Medicaid beneficiaries are likely to have limited access to these promising new lines of treatment.

Second, we urge CMS to adopt a payment adequacy analysis other than comparison with Medicare payment rates with respect to CGTs and other inpatient-administered

[7] 88 Fed. Reg. at 28,104.

[8] CPT® is a registered trademark of the American Medical Association.

therapies. Many CGTs are administered in the inpatient setting. Under Medicare, this means that the hospital is paid a bundled rate for all items and services furnished during the hospital stay, the amount of which is determined based on the Diagnosis Related Group (DRG) assigned at discharge. Notably, this bundled rate is generally inadequate to cover the hospital's cost of purchasing innovative new therapies, including DRGs. As a result, hospitals can be strongly disincentivized to purchase and administer newly available CGTs products because of significant financial losses.

For CGTs, we therefore recommend that CMS instead direct managed care plans to compare payments to separate payments made for the therapy by certain state Medicaid programs. Specifically, a limited number of states are beginning to pay hospitals separately (outside of the bundle) for their acquisition cost of CGTs through state plan amendments (SPAs) or administrative policies. These policies can significantly advance access to innovative new therapies. CMS should therefore encourage the adoption of such policies by Medicaid managed care plans (in addition to all state Medicaid programs) in an effort to bolster access to these emerging technologies.

While CMS has worked hard to draft improvements to the adequacy assurances in 42 CFR § 438.207, there is an urgent need for an additional safeguard to protect access to treatment for complex conditions.

With the rapid adoption of alternative payment methodologies, including diagnosis and episode-based fees, global payments, bundled payments, sub-capitation, performance incentives, and shared saving arrangements, it is increasingly challenging to hold state Medicaid programs and their MCO, PIHP, and PAHP contractors accountable for assuring access, particularly for complex therapies covered under State Plans or EPSDT. State and Medicaid plans often indicate how a provider receives an all-inclusive fee. At the same time, the hospitals and physicians maintain the fixed fee is either inadequate or does not envision the particular treatment.

State Medicaid agencies cannot delegate ultimate responsibility or accountability for access, quality, and health equity to contracted risk plans. Nor are the contracted plans permitted to defer their duties by passing the buck to providers, regardless of the payment model. Unfortunately, the financial alignment from state capitation payments to the plans and plans paying providers under alternative methods shifts state and MCO-level compliance for service access to the providers. While this effect is unintended, the rules must address this misdirected day-to-day accountability.

Therefore, we strongly urge CMS to revise 42 CFR § 438.207 to require states and their MCO, PIHP, and PAHP contractors to assure CMS that payment methodologies, payment levels, credentialing standards, provider contracts, provider behaviors and clinical decision-making, and utilization management practices do not adversely affect patient access to specialized care and treatment, including gene and cell

therapies and EPSDT treatments and other services under § 1905(r)(5) of the Social Security Act.

The proposed language in 42 CFR § 438.207(f)(1) indicates that the remedy plan requirement applies to "...access to care under the access standards in this part." While we assume CMS intends to encompass all of 42 CFR § 438.207 in the meaning, given the section title and content, we recommend that CMS clarify that 42 CFR § 438.207 applies to the remedy plan requirement.

Thank you, in advance, for considering our recommended improvements to the proposed revisions to 42 CFR Part 438 in CMS–2439–P. We look forward to working with CMS and state Medicaid agencies to establish policies that promote equitable and appropriate access to CGTs. Please feel free to contact me at ecischke@alliancerm.org with any questions.

Sincerely,

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