January 22, 2024

The Honorable Bill Cassidy, M.D.
United States Senate
Washington, DC 20510

RE: Request for Information to Improve Americans' Access to Cell and Gene Therapies and Other High-Cost Drugs

Dear Ranking Member Cassidy,

The Alliance of Community Health Plans (ACHP) appreciates the opportunity to respond to your Request for Information (RFI) seeking input to improve Americans' access to cell and gene therapies and other high-cost drugs. ACHP and its member companies are committed to providing high-quality, affordable access to health care. Clinical and pharmacy leaders, rooted in their communities for decades, continue to stress the need to address the underlying price of prescription drugs, improve care coordination and establish coverage policies that are consistent for consumers regardless of where they live. Recent approvals of life-improving cell and gene therapies, and a litany of others working through the approval pipeline, underscore the need for attention by federal policy makers and swift action. We look forward to working with you and your team to lower the price of prescription drugs, beginning with improving access to affordable and potentially life-saving cell and gene therapies.

ACHP is the only national organization promoting the unique payer-provider aligned model in health care, delivering affordable, coordinated and comprehensive coverage options. ACHP member companies collaborate with their provider partners to deliver high-quality coverage and care to tens of millions of Americans in 40 states and D.C. Deeply rooted in their communities, ACHP member companies understand the value of an integrated system of care, in which providers, payers and community leaders work together to enhance access to services and improve health outcomes.

As the only national payer organization to endorse comprehensive drug pricing reform, we recognize the recent approval of potentially curative, life-extending and life-altering cell and gene therapies as an opportunity to think differently about how we approach coverage and payment. With equity and access as driving forces, we are excited to collaborate with you and your staff to evaluate how we finance emerging and expensive treatments to ensure the sustainability of our health care system. We hope our members' real-world experience can be a resource to policymakers as they deliver on the promise of cell and gene therapies for patients and families facing unfathomable health challenges.

Currently, the health care system cannot withstand the pressure of the price that cell and gene therapies and associated treatment demand, requiring urgent attention from policymakers. Following extensive engagement with clinical and pharmacy subject matter experts from across the country, we urge policymakers consider in any action: (1) the underlying price of these drugs, (2) differences in coverage

across state lines and health insurance products, (3) the need for coordination and (4) the necessity for collaboration.

Addressing the Underlying Price

It is critical to evaluate the underlying issue of price of cell and gene therapies and high-cost therapeutics. The primary challenge to access is the high list price of drugs coming to market. Look no further than the recently approved Casgevy and Lyfgenia. At $2.2 and $3.1 million respectively, and a possible patient population of 100,000 Americans diagnosed with sickle cell disease, the potential cost impact is at least $200 billion, not accounting for the associated treatment. The health care system simply can't afford this cost, especially when considering the full pipeline of other potentially life-changing therapies. Without action to bring down the price, the status quo will limit access, further sociodemographic inequities and could result in significant adverse selection.

Policymakers must also take action that brings transparency to pricing. Absent transparency into the full drug supply chain, like the ACHP-supported PBM transparency efforts working through Congress currently, the exorbitant price tag cell cannot be justified, and value fully measured. Policymakers must prioritize legislation like Senators Braun (R-IN) and Baldwin's (D-WI) *FAIR Drug Pricing Act* to require basic transparency and justification of the price of both cell and gene therapies and high-cost drugs so that access decisions are determined by medical necessity and not colored by the exorbitant price tag.

Differences in Coverage

A major challenge to cell and gene therapy access are the differences in coverage across insurance products and between states. This creates a patchwork landscape that treats consumers differently based on where they live and how they receive their coverage and care. Coverage standards are further complicated as rapid advancements in cell and gene therapy development and approval often requires payers to engage in case-by-case decision making. Federal guidance can create predictability and equity in coverage across the country. Standardization at the federal level will ensure the ability to receive care regardless of geography or how a consumer receives their insurance. Consistent standards, alongside flexibility in designing financing options to account for the differences in payer size, location and line of business, will protect consumers access to cell and gene therapies and allow for innovation in benefit design.

Case for Coordination

Policymakers must act immediately to address the impact of cell and gene therapy costs on the health care system. This begins with bringing manufacturers, providers, payers and the federal government together to determine appropriate, value-based prices for these medical advancements. Appreciating that a long-term financing system will take time to develop and implement, a temporary funding mechanism is necessary to blunt the immediate impact of these high-cost drugs. While ACHP is not prepared to endorse a specific financing mechanism, we strongly support a coordinated funding mechanism administered and governed

by the federal government. Our members encourage models that incorporate value into the price of the therapy, allow for clinical flexibility and reward evidence of efficacy.

ACHP and its members look forward to opportunities to engage with you directly to put together an adequate, sustainable framework, building on the ideas you laid out in 2019 outlining potential models to finance cell and gene therapies. Our initial input and questions on each of the proposed models include:

1) Subscription ("Netflix") model: A subscription model allows predictability for payers by establishing a set payment for a predetermined number of therapies and drugs. However logistical concerns exist. For example, how would the amount each health plan pays be determined? What drugs would be part of the subscription? Who would determine eligibility for therapies to be part of the subscription and how would that be done? If decisions are based on price, meaning a drug costs above a certain threshold, there could be a perverse incentive to artificially inflate, or deflate, the price depending on return on investment.

2) Pay-over-time ("mortgage") model; The "mortgage" model, while predictable in monthly or yearly payments, shifts the responsibility solely to the payer and creates additional logistical concerns. Would a manufacturer allow a health plan to pay a monthly rate directly or would a health plan have to work with the federal government, or some other agency, to secure the financing up front and subsequently pay the money back at a set rate to the third-party loan? Would the monthly payment follow the individual or would the health plan that administers the treatment or drug make payments in perpetuity?

   Regardless, in this situation, a payer is in a difficult position. If the payments follow the consumer, and after a few years the individual moves to a different plan, the originating payer does not see the benefit and the secondary payer takes on payments for a drug or treatment it did not administer. On the contrary, if the "mortgage" stays with the originating payer, and that individual changes payer, the originating payer doesn't realize the value of the treatment. Additionally, this model takes the manufacturer's price and does not link any outcomes or value-based measures to the payment methodology.

3) Federally-funded model: The federal government taking on the responsibility of paying for and dispersing high-cost drugs would eliminate the financial burden for payers, but still poses logistical challenges. At what point would the federal government take over the continuum of care and for how long? How would a payer and provider continue that relationship, and would the patient have to travel to certain sites for the delivery of care? If the federal government takes on the burden of financial responsibilities, there is a challenge in coordinating care for that individual in the long-term.

Regardless of financing option policymakers choose to pursue, we urge wholistic consideration of the treatments including list price, disease prevalence, treatment costs, novelty of the drug, market competition, quality of the evidence and therapy duration.

Call for Collaboration

Financing cell and gene therapies is a comprehensive problem that requires a collaborative solution. Solely placing the financial risk and burden on payers and consumers, as we see today, does not lead to increased access or value. Rather, the status quo often limits access for those who need these therapies the most. Treating cell and gene therapies as a public utility where all parties are invested is necessary to protect equal access.

Manufacturer involvement is necessary to increase access to these therapies. This means being involved in a federally created and designed funding mechanism and incorporating value-based payment arrangements where outcomes are heavily incorporated. Current value-based payment arrangements for blockbuster treatments require significant concessions from health plans, including insights into prior authorizations, that don't always include reimbursement should the treatment not work. Value-based contracts must have clear endpoints that align with clinical value. Requiring greater emphasis on the manufacturers' role in any federal funding mechanism and strengthening value-based contract arrangements will result in improved shared risk and patient access.

Our members recognize the importance of partnering to ensure access to these life-changing therapies and are eager to play a part in finding a solution. They are willing to collaborate with stakeholders across the health care system in pursuit of an answer to the question of accessibility. Additionally, ACHP urges the Senate HELP Committee to hold a hearing to discuss improving access to cell and gene therapies and to ensure pricing of these therapies and drugs are based on value.

ACHP looks forward to a thoughtful conversation with you and your staff in support of innovation, patient access and the financial sustainability of our nation's health care system. Please contact Josh Jorgensen, ACHP Associate Director of Legislative Affairs, at jjorgensen@achp.org with any questions.

Sincerely,

Ceci Connolly

Ceci Connolly
President and CEO
ACHP