



**FILED**  
INDEX DEPARTMENT

MAR 18 2024

IN THE OFFICE OF  
SECRETARY OF STATE

**SPRINGFIELD, ILLINOIS**

March 18, 2024

Executive Order 2024-01

**EXECUTIVE ORDER TO ADVANCE FINANCING AND ACCESS TO  
SICKLE CELL DISEASE TREATMENT AND OTHER HIGH-COST DRUGS  
AND TREATMENT IN ILLINOIS**

**WHEREAS**, sickle cell disease is a group of lifelong inherited blood disorders affecting more than 100,000 people across the United States and more than 5,000 Illinois residents; and,

**WHEREAS**, sickle cell disease disproportionately impacts people of color, particularly Black Americans. It is estimated that sickle cell disease affects 1 in every 365 Black Americans and 1 in every 16,300 Latinos; and,

**WHEREAS**, symptoms and health complications resulting from sickle cell disease appear as early as five months of age and worsen over a person's lifetime. People with sickle cell disease have a life expectancy more than 20 years shorter than the general population and are at higher risk of asthma, acute chest syndrome, chronic pain and fatigue, depression, organ damage and failure, stroke, and other long-term and life-threatening conditions; and,

**WHEREAS**, the cause of sickle cell disease has been known for nearly 70 years, but progress has been impeded by the lack of resources historically dedicated to supporting research and treatments for sickle cell disease due to racial discrimination; and,

**WHEREAS**, people with sickle cell disease often encounter barriers to accessing necessary treatment to improve their quality of life, such as limitations in geographic access to care, high costs of treatment, a high reliance on emergency care, and a limited number of health care providers with expertise in comprehensively managing sickle cell disease. These barriers further exacerbate persistent systemic inequities in healthcare that disproportionately impact communities of color; and,

**WHEREAS**, the cost of managing sickle cell disease over a lifetime is enormous, with an estimated average lifetime cost of \$1.26 to \$2.1 million in health care expenses, of which patients on average contribute \$34,000 to \$53,000 in out-of-pocket expenses. Lifetime health care expenses are reported to be as high as \$4 to \$6 million for the most severely impacted people living with sickle cell disease; and,

**WHEREAS**, more than 40% of Illinoisans with sickle cell disease receive publicly funded health insurance through Medicaid, with an estimated 49% of Medicaid customers with sickle cell disease having a severe form of the disease; and,

**WHEREAS**, under Public Act 102-0004, the Illinois Department of Public Health is investing in organizations to build and grow innovative solutions to improve the health of Illinoisans fighting sickle cell disease, including educational and outreach programs to provide people with sickling disorders and trait, their families, clinical providers, health care professionals, local public health, service providers, educators, and the community, with accurate, up to date, and timely information; and,

**WHEREAS**, on December 8, 2023, the U.S. Food and Drug Administration (FDA) approved two milestone gene therapy treatments for the treatment and potential cure of sickle cell disease; and,

**WHEREAS**, gene therapies are highly expensive, creating concerns about equitable access, the risk of health insurance restrictions, and potential budgeting challenges for public health insurance programs. While final net cost and how widely treatment will be available are to be determined given the recent FDA approval, the importance of equitable access to novel therapies for historically underserved populations is clear; and,

**WHEREAS**, The U.S. Department of Health and Human Services and the Centers for Medicare & Medicaid Services (CMS), having recognized the importance and urgency of supporting states in addressing the high costs of these transformative gene therapies, announced the launch of a new Cell and Gene Therapy (CGT) Access Model. CMS selected sickle cell disease as the first focus of the CGT Access Model; and,

**WHEREAS**, the CGT Access Model will establish greater negotiating leverage with drug manufacturers through a pooled, multi-state bargaining approach that allows CMS to negotiate and administer outcomes-based agreements with drug manufacturers on behalf of participating states. The outcome-based agreements will include multiple avenues for state savings on cell and gene therapies, including savings tied to a patient's clinical outcomes; and,

**WHEREAS**, states may apply to join the CGT Access Model in summer 2024, with the ability to begin participation as early as January 2025. States can help inform CMS' negotiations with participating drug manufacturers by outlining their priorities through a non-binding letter of intent and meetings with CMS; and,

**WHEREAS**, the pipeline for cell and gene therapies has expanded rapidly, including cell and gene therapies for the pediatric population for which Medicaid will be a major payor. The FDA has approved several new cell and gene therapies within the last year and is forecasting a rapidly increasing number of approvals in coming years; and,

**WHEREAS**, the FDA also is increasingly approving other novel and high-cost specialty drugs and treatments through its accelerated approval pathway. Drugs approved under the accelerated approval pathway are approved based on an endpoint that is likely to predict a clinical benefit. Many of these drugs have high list prices and lower rebates compared to other drugs, and some do not have a verified clinical benefit for a decade or more; and,

**WHEREAS**, the federal Medicaid Drug Rebate Program provides federal rebates to states based on the manufacturer's lowest or best price, but state Medicaid programs are required to cover essentially all FDA-approved drugs in return, including drugs approved through the accelerated approval pathway; and,

**WHEREAS**, Medicaid drug spending trends are increasingly driven by high-cost drugs and treatment. From 2018 to 2021, the average cost of a brand drug increased almost 50 percent, reflecting the introduction of new, high-cost specialty drugs and therapies; and,

**WHEREAS**, new cell and gene therapies and other high-cost specialty drugs and treatment for rare and severe diseases impacting a small number of individuals create uncertainty in the number of individuals who might seek treatment in a given year and potential budget volatility from year to year. The approval of each new high-cost drug and treatment can add substantial costs and pressure to the Medicaid budget; and,

**WHEREAS**, the Illinois Department of Healthcare and Family Services (HFS) is actively working with CMS towards approval of a Medicaid State Plan Amendment that will allow HFS to enter into outcomes-based agreements with drug manufacturers to negotiate additional state rebates for high-investment drugs and therapies. HFS is in the early stages of implementing outcomes-based purchasing, with the opportunity to identify best practices through the testing of various approaches to administering outcomes-based agreements with drug manufacturers; and,

**WHEREAS**, this is a momentous opportunity to execute an innovative and sustainable solution to make emerging and transformative gene therapy treatments and specialty drugs affordable and available to Illinoisans with sickle cell disease and other health conditions. Illinois' legacy to future

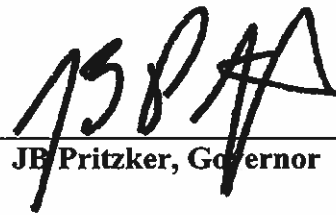
generations should be implementing solutions that show the value we place on the right of everyone to have access to quality and affordable healthcare; and,

**WHEREAS**, forming an Advisory Council is an important and effective tool in expanding access to new sickle cell disease treatments and other high-cost drugs and treatment, bringing together State resources for this common goal, drawing from the deep knowledge and expertise of national, state, provider, and consumer advocates, and prioritizing patient voices and community partnerships in developing and implementing solutions;

**THEREFORE**, I, JB Pritzker, Governor of Illinois, by virtue of the executive authority vested in me by Article V of the Constitution of the State of Illinois, hereby order as follows:

1. HFS is tasked with leading the State's effort to establish payment models and financing structures that support access to new sickle cell disease treatment and other high-cost drugs and treatment within Illinois' Medicaid Program.
2. The Advisory Council on Financing and Access to Sickle Cell Disease Treatment and Other High-Cost Drugs and Treatment ("Advisory Council") is established for the purpose of advising HFS in the development of payment models and financing structures for sickle cell disease treatment and other high-cost drugs and treatment that support equitable access and contribute to national efforts to formulate solutions.
3. The Advisory Council shall meet at least four times and shall:
  - a. Engage in a robust effort that considers the input of subject matter experts, providers, insurers, drug manufacturers, and Medicaid customers living with sickle cell disease or other conditions requiring access to high-cost drugs and treatment.
  - b. Review innovative approaches establishing sustainable payment models and financing structures for high-cost drugs and treatment, with a focus on value and outcome-based models.
  - c. Evaluate the success and challenges of various value and outcome-based payment approaches implemented in other states.
  - d. Make recommendations on financing approaches that could be adopted in Illinois and/or nationally with the support of CMS.
  - e. Identify any state and federal policy, legal, regulatory, and resource changes necessary to successfully implement the Advisory Council's recommendations.
  - f. Provide leadership for and collaborate with those working to make sickle cell disease treatments and other high-cost drugs and treatment accessible.
  - g. Promote effective interagency collaboration and consider related efforts federally and in other states when drafting policy options related to financing, with a focus on ensuring equitable access to sickle cell disease treatment and other high-cost drugs and treatment in the Illinois Medicaid program.
4. The Advisory Council shall develop a report to be delivered to the Governor and the General Assembly by December 31, 2024. The report shall evaluate options for financing new cell and gene therapies and other high-cost drugs and treatment and monitoring patient outcomes within the Medicaid program and shall recommend strategies to equitably provide access to new treatments within the program.
5. The Advisory Council shall consist of diverse stakeholders that represent the goals and population described in this executive order, to be appointed by the Governor. Members should be geographically diverse to represent the needs of urban, suburban, and rural communities across Illinois. Members should include state subject matter experts and may include national experts. HFS may include any State agency staff they deem necessary as ex officio, non-voting members of the Advisory Council.
6. The Advisory Council, to be appointed by the Governor, shall consist of:
  - a. The Director of HFS, or their designee, who shall serve as chair.
  - b. One member representing the Illinois Department of Public Health.
  - c. One member representing the Illinois Department of Insurance.
  - d. One member representing the Governor's Office of Management and Budget.
  - e. One member with lived experience as a person with sickle cell disease.

- f. One member with lived experience as a person with a condition requiring access to new, innovative drugs or treatment.
  - g. One member representing providers treating sickle cell disease patients.
  - h. One member representing providers treating patients with another condition requiring access to new, innovative drugs or treatment.
  - i. Two members with expertise in prescription drug rebate negotiations and outcomes-based agreements.
  - j. Two members with published research in financing new, innovative drugs and treatments within public health insurance programs.
  - k. Two members with health economist or actuarial backgrounds.
  - l. One member representing sickle cell disease advocacy organizations.
  - m. One member representing advocacy organizations for a condition(s) requiring access to new, innovative drugs and treatment.
  - n. Two members representing the health insurance industry.
  - o. Two at-large members, who may or may not meet the qualification requirements for the other appointees.
7. The two members with lived expertise may be provided an honorarium to reimburse them for their time, not to exceed \$250 per meeting.
  8. The Advisory Council shall strive to operate by consensus; however, so long as they each have a quorum, they may approve measures and make recommendations based on an affirmative vote of a majority of the members present.
  9. Members of the Advisory Council shall serve at the will of the Governor. If there is a vacancy for any cause, the Governor shall make an appointment to become immediately effective. The Advisory Council shall sunset on December 31, 2024.
  10. In addition to any by-laws, policies, or procedures that they may adopt, all operations of the Advisory Council will be subject to the provisions of the Illinois Freedom of Information Act (5 ILCS 140/1 et seq.) and the Illinois Open Meetings Act (5 ILCS 120/1 et seq.). This shall not be construed to preclude other statutes from applying to the Advisory Council and its activities.
  11. HFS shall provide administrative support to the Advisory Council.
  12. Nothing in this Executive Order shall be construed to contravene any federal or state law or regulation. Unless specifically referenced in this Order, nothing in this Order shall affect or alter the existing statutory powers of any State agency or be construed as a reassignment or reorganization of any State agency.
  13. This Executive Order supersedes any contrary provision of any prior Executive Order.
  14. If any part of this Executive Order is found to be invalid by a court of competent jurisdiction, the remaining provisions shall remain in full force and effect. The provisions of this Executive Order are severable.
  15. This Executive Order shall take effect immediately upon its filing with the Secretary of State and shall remain in effect until rescinded.

  
JB Pritzker, Governor

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