



Via Electronic Submission

January 20, 2025

Dorothy Fink, M.D.
Acting Secretary of Health and Human Services
U.S. Department of Health and Human Service
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Acting Secretary Fink,

Under the leadership of President Trump during his first term, the U.S. Department of Health and Human Services (HHS) took historic steps towards improving access to care and treatment for Americans living with Sickle Cell Disease (SCD), including funding the National Academies of Sciences, Engineering, and Medicine to develop a blueprint for action on SCD. The resulting report, *“Addressing Sickle Cell Disease: A Strategic Plan and Blueprint for Act,”*ⁱ is a landmark publication that outlines steps that federal policymakers can take to improve federal health care programs, policies, and research for SCD.

In 2022, the Sickle Cell Disease Partnership (“Partnership”) was founded under the leadership of Trump Administration former HHS Assistant Secretary for Health, Brett Giroir, M.D. The goal of the SCD Partnership is to support the SCD community in translating the National Academies’ blueprint for SCD into concrete policy improvements by working with Congress and the Administration to effectuate policy and program improvements.

Today, the Partnership is a multi-sector public policy and advocacy collaboration of more than a dozen patient advocates, health care providers, biopharmaceutical manufacturers, and other health care stakeholders committed to advancing policies that will improve the lives of those living with SCD. The Partnership is pleased to see the significant progress made to improve access to care and treatment for Americans with SCD, thanks to bold leadership under President Trump’s first Administration. The Partnership looks forward to supporting the Administration in its efforts to build on this progress over the next four years.

SCD is a chronic, debilitating disease that is also the most common inherited blood disorder in the United States.ⁱⁱ Although it is a rare disease, SCD affects approximately 100,000 Americans. Individuals living with SCD face severe health complications, including recurring and life-altering pain crises, repeat infection, acute chest syndrome, lung problems, severe and chronic pain, leg ulcers, organ damage, and stroke. Due to inadequacies in comprehensive care management, only about 1 in 4 patients with SCD receive a standard of care described in guidelines,ⁱⁱⁱ resulting in individuals with SCD needing to visit the emergency department far more often than the average population.^{iv} These and other factors increase the cost of care for Americans with SCD and on the system overall. As a result of systemic inadequacies and the severity of the disease itself, individuals with SCD ultimately have an estimated life expectancy that is dozens of years shorter than the average expected life expectancy in the United States.



Recognizing the health disparities Americans with SCD face, officials in the first Trump Administration took valiant steps forward to improve SCD care and treatment using various platforms and policy avenues, including:

- Holding a **White House Roundtable**, “Improving the Lives of Americans Living with Sickle Cell Disease” in recognition of National SCD Awareness Month, led by First Lady Melania Trump and HHS.^v
- Expanding the **Centers for Disease Control and Prevention’s (CDC) Sickle Cell Data Collection Program**.^{vi}
- Working with Congress to enact the ***Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act***, which authorized the award of grants for 3 purposes: (1) collection and maintaining of data on SCD health outcomes; (2) education and training of health professionals; and (3) evaluation of best practices for the prevention and treatment of complications.^{vii}
- Supporting **gene therapy research** for SCD^{viii} and progressing SCD gene therapy closer to FDA approval through the Cure Sickle Cell Initiative (CureSCi).^{ix}
- Establishing a pilot program, the **Sickle Cell Disease Training and Mentoring Program (STAMP)**, to educate primary care providers on SCD evaluation and management through web-based trainings offered January – June 2020.^x
- Issuing a **proclamation of Sickle Cell Disease Awareness Month** in September 2020, for the first time since 1983.^{xi}
- Convening a **Sickle Cell Disease Workgroup** that brought together 60 members from 11 HHS agencies to align efforts and prioritize SCD activities, with one priority area being the transition of SCD care from pediatric to adult.^{xii}
- Holding a **Roundtable at the World Health Assembly**, where HHS, African health ministers, the World Health Organization, and SCD experts discussed barriers in SCD care.^{xiii}

Building on the strong foundation laid by the first Trump Administration, the Partnership has worked to carry forward the National Academy’s recommendations by translating them into concrete, actionable improvements in Congressional and Administration policy. These efforts have focused on:

- Increasing comprehensive care available to Americans with SCD served by Medicaid, as outlined in the 118th Congress in [H.R. 7432/S. 5097](#), the ***Sickle Cell Disease Comprehensive Care Act***. The Congressional Budget Office anticipates the bill to save money. This bipartisan legislation was sponsored by Representatives Michael Burgess, M.D., (R-TX) (former member), Danny Davis (D-IL), Darren Soto (D-FL), Eleanor Holmes Norton (D-DC), Terri Sewell (D-AL) and Senators Cory Booker (D-NJ), Tim Scott (R-SC), Bill Cassidy, M.D. (R-LA), and Amy Klobuchar (D-MN).
- Improved data collection through the **CDC SCD Data Collection Program**, which has grown to cover sixteen states and approximately half of the SCD population in the United States.
- Reauthorization of the ***Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act***, which was initially passed in 2018 during the first Trump Administration.
- Access to the transformative **SCD gene therapies** as approved by the FDA, including through the Centers for Medicare and Medicaid Services’ (CMS) Innovation Center’s Cell and Gene Therapy (CGT) Access Model.
- Educational programs, including through the **HHS SCD Summit** and the **SCD Services, Opportunities, Activities, Resources (SOAR) initiative**, a webinar series focused on improving the quality of life for individuals with SCD and their families by connecting them to federal agency programs that support the SCD community.



The Partnership is looking forward to working with the Trump Administration to further advance the recommendations from the National Academies report that was funded in the first term. Towards that end, the Partnership is sharing with you some of the concrete, near-term opportunities that we believe can be effectuated to turn the policy vision enabled by the first Administration into a reality. The Partnership collected these opportunities and put them in our [report](#), “*Progressing Forward: Improvements to Access to Care and Treatment for Persons with Sickle Cell Disease*.”^{xiv} Important policy priorities noted in the report include:

- Reintroducing and passing the bipartisan ***Sickle Cell Disease Comprehensive Care Act*** ([H.R. 7432/S. 5097](#) in the 118th Congress).
- Passing the reauthorization of the bipartisan ***Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act*** ([H.R. 3884/S.1852](#) in the 118th Congress).
- Expanding the **CDC’s Sickle Cell Data Collection Program**.
- Publishing a follow-on report to the **2020 T-MSIS report** that shares data about the characteristics of Medicaid and CHIP enrollees with SCD on a state-by-state basis.
- **Educating providers and state Medicaid programs** on best practices for SCD management and monitoring quality of care. Ensuring providers have easy-access to resources in order to better implement care and coverage opportunities.
- Implementing the CMS Innovation Center’s **CGT Access Model** on SCD, including by taking into account the [recommendations](#) of the Partnership
- Enacting thoughtful, targeted regulation or bipartisan legislation to **clarify a safe harbor** to the Anti-Kickback Statute and Stark Law in order to allow pharmaceutical manufacturers to provide transportation, lodging, and fertility preservation for individuals receiving gene therapy.
- Translating a **SCD-specific research agenda** to inform effective programs and policies across the lifespan.
- Continuing the **HHS SCD Annual Summit** and the **SCD SOAR webinar series** to amplify federal support for individuals with SCD.

We look forward to collaborating with Trump Administration staff over the next four years to continue to improve access to care and treatment for Americans with SCD. Please reach out to Advisors to the Partnership, Josh Trent (Josh.Trent@LeavittPartners.com), Clay Alspach (Clay.Alspace@LeavittPartners.com), or Liz Hassett (Elizabeth.Hassett@LeavittPartners.com) with any questions or to further discuss.

Sincerely,

The Sickle Cell Disease Partnership

ⁱ <https://www.nationalacademies.org/our-work/addressing-sickle-cell-disease-a-strategic-plan-and-blueprint-for-action>

ⁱⁱ <https://www.hematology.org/education/patients/anemia/sickle-cell-disease>

ⁱⁱⁱ <https://minorityhealth.hhs.gov/news/coming-together-confront-sickle-cell-disease>

^{iv} <https://www.iscimedcentral.com/public/assets/articles/hematology-3-1037.pdf>

^v <https://trumpwhitehouse.archives.gov/briefings-statements/readout-first-ladys-roundtable-improving-lives-americans-living-sickle-cell-disease/>

^{vi} https://archive.cdc.gov/www_cdc.gov/media/releases/2019/p0925-cdc-awards-funds-sickle-cell.html

^{vii} <https://www.congress.gov/bill/115th-congress/senate-bill/2465/text>

^{viii} <https://www.nih.gov/news-events/news-releases/nih-launches-new-collaboration-develop-gene-based-cures-sickle-cell-disease-hiv-global-scale>

^{ix} <https://www.nhlbi.nih.gov/science/cure-sickle-cell-initiative>; <https://curesickle.org/>

^x <https://minorityhealth.hhs.gov/news/stamp-providing-pathway-greater-awareness-and-better-health-outcomes-people-living-sickle-cell>

^{xi} <https://www.federalregister.gov/documents/2020/09/03/2020-19754/national-sickle-cell-disease-awareness-month-2020>

^{xii} <https://minorityhealth.hhs.gov/news/coming-together-confront-sickle-cell-disease>

^{xiii} <https://minorityhealth.hhs.gov/news/coming-together-confront-sickle-cell-disease>

^{xiv} <https://www.sicklecellpartnership.org/wp-content/uploads/2024/06/SCD-Progress-Report.pdf>

