Via Electronic Submission

October 22, 2025

The Honorable Mehmet Oz, M.D.
Administrator of the Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

RE: Medicaid Community Engagement Requirements for Americans with Sickle Cell Disease

Dear Administrator Oz,

The Sickle Cell Disease Partnership[i] (Partnership) is a public policy and advocacy collaboration of 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 Sickle Cell Disease (SCD). In 2022, the Partnership was founded under the leadership of Brett Giroir, M.D., who served as HHS Assistant Secretary for Health in the first Trump Administration. The goal of the Partnership is to advance actionable federal health care policies that improve the lives of individuals living with SCD, informed through the Trump Administration-funded National Academies blueprint[ii] for SCD.

The American Society of Pediatric Hematology/Oncology[iii] (ASPHO) joins the Partnership on this letter. Founded in 1981, ASPHO is the professional membership organization for over 2,000 physicians and other health care professionals dedicated to promoting the optimal care of children, adolescents, and young adults with blood disorders and cancer by advancing research, education, treatment, and professional practice. ASPHO sponsors educational and professional development programs and co-sponsors the *Pediatric Blood & Cancer* journal. ASPHO works in partnership with appropriate organizations to advance its health policy and advocacy priorities related to childhood cancer and blood disorders to ensure individuals of all backgrounds receive necessary care.

The Partnership and ASPHO are grateful to see the Trump Administration's continued support of Americans with SCD, including through continuing the Centers for Medicare and Medicaid Services (CMS) Innovation Center's Cell and Gene Therapy Access Model, an innovative payment model for SCD gene therapies. In addition, the Partnership and ASPHO were appreciative to see you and Health and Human Services (HHS) Secretary Kennedy both verbally affirm their support for Americans with SCD during their confirmation hearings. Your commitment to helping Americans impacted by SCD is appreciated.

As your agency works to promulgate regulations implementing the Medicaid community engagement requirements of OBBBA, P.L. 119-21, the Partnership and ASPHO are writing to convey our perspective about how the Administration can best help to protect Americans with SCD and to request a meeting with you to further discuss. Based on our careful review of data and discussions across multiple stakeholders, the Partnership and ASPHO request that in its forthcoming guidance, CMS categorically exclude Americans with SCD from Medicaid community engagement requirements, or otherwise issue practical guidance for states to ensure exceptions for Americans with SCD. The severity of the disease, the importance of continuous coverage to access care, sudden pain crises and complications, and the

disruptions these Americans face to consistently work create legitimate barriers to meeting the requirements for community engagement. The reasoning for such an exclusion is delineated in the following sections below, and the Partnership and ASPHO would like to further discuss with you in a meeting.

The Severity of SCD and the Importance of Medicaid Coverage

SCD is a chronic, debilitating disease that is also the most common inherited blood disorder in the United States.[iv] Although it is a rare disease, SCD affects more than 100,000 Americans – about half of whom are enrolled in Medicaid. Americans 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,[v] resulting in Americans with SCD needing to visit the emergency department far more often than the average population.[vi] 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, Americans with SCD have an estimated life expectancy that is over two decades shorter than the average life expectancy in the nation.

The importance of continuous Medicaid coverage for SCD cannot be overstated. Approximately 52,524 Medicaid enrollees had SCD in 2021,[vii] representing about half of all Americans with SCD. Further, about half of Americans with SCD have severe forms of the disease, requiring more frequent medical care.[viii] When coverage is inconsistent, Americans with SCD face barriers to accessing the medical care they need, leading to heightened health care costs and higher emergency room utilization. For example, without continuous coverage, SCD patients become reliant on emergency services, contributing to $2.4 billion in avoidable annual ED costs according to government data.[ix]

The Partnership and ASPHO are concerned that community engagement requirements may increase churn in Medicaid enrollment for Americans with SCD, meaning enrollees with SCD would cycle on and off of coverage, often due to stringent reporting requirements rather than not meeting the community engagement requirements themselves. In SCD, the disease trajectory makes it difficult to consistently adhere to community engagement requirements, creating more opportunities for coverage loss compared to a healthy individual without the disease.

How SCD Hampers an Individual's Ability to Work

SCD interrupts work primarily through unpredictable, recurrent vaso-occlusive (VOC) pain crises, which occur when sickled cells traveling through small blood vessels get stuck and block blood flow throughout the body.[x] VOC pain crises can occur suddenly and severely, causing pain in the hands, feet, chest, and back, in addition to ongoing chronic pain throughout one's lifetime.[xi] VOC can lead to emergency room or extended inpatient care, which accumulates into repeated absences, reduced on-the-job productivity, and, over time, decreased labor force participation. Lost wages begin in early adulthood and intensify with crisis frequency.

While the specific frequency of VOC pain crises can vary, up to 67 percent of Americans with SCD experience at least three VOC pain crises per year.[xii] The typical hospital admission length for severe pain crises is five days,[xiii] with an average of 1-3 admissions per year.[xiv] One survey found that 17.5 percent of adults with SCD had missed more than ten days of work in the previous year due to SCD complications.[xv] In another survey, adults with at least four VOC pain crises per year missed an estimated 35 percent of scheduled work hours per week.[xvi] Furthermore, employment status declines as disease severity increases:

each additional annual hospitalization raises the odds of being unemployed by 33 percent.[xvii] Ultimately, modeled lifetime earnings are $695,000 lower than for peers of similar demographics without SCD.[xviii]

Given the severity and recurring nature of VOC pain crises – and despite wanting to contribute to the workforce – fewer than one-third of adults with SCD maintain steady work.[xix] Therefore, community engagement requirements tying coverage to work-hour or volunteer or education thresholds for Americans with SCD risks butting up against with the realities clinical needs of Americans SCD. Irrespective of the intent behind community engagement requirements, if CMS guidance does not specifically exempt Americans with SCD, through the varied process of states' implementation, the Partnership is concerned that administrative processes and practical implications from this policy could inadvertently disrupt access to coverage – which would delay access to care and increase crisis frequency, which would increase emergency room and inpatient visits, causing personal and program costs to climb.

Regulatory Request

With these challenges in mind, the Partnership and ASPHO urge CMS to leverage its regulatory authority in implementing the community engagement requirements of OBBBA P.L. 119-21 to exempt Americans with SCD from such requirements. Section 71119 of the Act provides that states must require certain Medicaid enrollees to complete 80 hours per month of qualifying activities (i.e., work, community service, work program, half-time education, or income equivalent) to maintain eligibility. However, the statute also provides for mandatory exceptions from community engagement requirements, to be further defined by the HHS Secretary via regulation, and the statute allows CMS to grant state flexibility in implementation of the requirements. As such, the Partnership and ASPHO urge CMS to take the following actions when it implements OBBBA, listed in order of priority to protect Medicaid enrollees who have SCD:

1. **Exclude Americans with SCD from community engagement requirements under the authority provided to the Secretary to define "medically frail," "special medical needs," "physical [] disability," and/or "complex medical condition."** (Pub. L. 119-21, Sec. 71119(a); (xx)(9)(A)(ii)(V)). Given repeat pain crises, hospitalizations, severe health complications, and the above-delineated impact on activities of daily living, these terms plainly encompass Americans with SCD. Without an exclusion specific to people with SCD, patients will face disruptions in coverage – worsening health outcomes and increasing health care costs. CMS has previously defined "complex medical condition" to include SCD in its letter to State Medicaid Directors regarding the implementation of Section 1945A of the Social Security Act, enacted as part of the Medicaid Services Investment and Accountability Act of 2019 (P.L. 116-16), which authorizes states to cover an optional health home state plan benefit for Medicaid-eligible children with medically complex conditions.[xx]

   Additionally, without an exclusion, the state administrative burden significantly increases in the case of SCD due to frequent good-cause requests, appeals, and verifications through hospitals and enrollees. More broadly, if the Secretary articulates specific conditions, such as SCD, that HHS considers to meet the mandatory exception requirements because they fall under these terms, HHS would reduce the administrative burden for states by simplifying the exceptions process.

   Finally, HHS should emphasize that states should not verify compliance with community engagement requirements for Americans with SCD more than once during the standard determination/redetermination process. (See below, Section 2c, for additional information).

2. **If CMS decides not to name SCD as a condition meeting a mandatory exclusion in full, the Partnership urges CMS to include practical implementation guidance for states that makes clear the following:**

    a. **Specifics on how to deem an individual to have met a specified exclusion.** (Pub. L. 119-21, Sec. 71119(a); (xx)(9)(A)(ii)(V)).
    To ensure Americans with SCD are properly excluded from community engagement requirements when provided for by law, HHS should equip states with the disease criteria and clinical markers that they should use to help determine whether an individual with SCD meets a specified exclusion, including for medical frailty, special medical needs, physical disability, or a serious or complex medical condition. These criteria should reflect the episodic and unpredictable nature of SCD, which can often interfere with the ability to maintain consistent work or community engagement.

    b. **SCD emergency room visits, hospitalizations, pain crises, and transfusions qualify as either "inpatient hospital services" or "other services of similar acuity" under the state-optional hardship exception rules.** (Pub. L. 119-21, Sec. 71119(a); (xx)(3)(B)(ii)(I)).
    The state-optional hardship rules allow a state to except certain Medicaid enrollees from community engagement requirements for the month in which the enrollee experiences a qualifying short-term hardship event. HHS should make it clear that states can automatically except an individual with SCD under the state-optional hardship rules given a documented emergency room visit, hospitalization, transfusion, or other complication due to SCD during a particular month.

    c. **When making ex parte verifications, states should use all information available to it to determine whether an individual with SCD is excluded from community engagement requirements or meets the requirements for a state-optional hardship rule.** (Pub. L. 119-21, Sec. 71119(a); (xx)(5)).
    In making ex parte verifications for the purpose of verifying whether an individual has met the requirements for an exclusion or a state-optional hardship rule, states must follow standards established by HHS and use reliable information available to the state in making such a determination. HHS should emphasize that states should not verify compliance with community engagement requirements for Americans with SCD more than once during the standard determination/redetermination process. HHS should also advise states to work closely with providers to determine applicable diagnosis codes which may exclude an individual from community engagement for a period of time – allowing the state to better determine when an individual meets an exception based on health care services provided without burdening that individual with administrative paperwork to maintain continuity in coverage.

We look forward to collaborating with CMS to ensure Americans with SCD have continuity in care under Medicaid and that they receive the flexibilities permitted by law when subject to community engagement requirements. Please use Liz Hassett (Elizabeth.Hassett@LeavittPartners.com) as a point of contact for the Partnership, and Sally Weir (sweir@aspho.org) as a point of contact for ASPHO.

Respectfully,

The Sickle Cell Disease Partnership
The American Society of Pediatric Hematology/Oncology

[i] https://www.sicklecellpartnership.org/
[ii] https://www.nationalacademies.org/our-work/addressing-sickle-cell-disease-a-strategic-plan-and-blueprint-for-action
[iii] https://aspho.org/
[iv] https://www.hematology.org/education/patients/anemia/sickle-cell-disease
[v] https://minorityhealth.hhs.gov/news/coming-together-confront-sickle-cell-disease
[vi] https://www.jscimedcentral.com/public/assets/articles/hematology-3-1037.pdf
[vii] https://www.norc.org/research/library/spotlight-new-analysis-of-sickle-cell-disease-prevalence-among-medicaid-enrollees.html
[viii] https://pmc.ncbi.nlm.nih.gov/articles/PMC9898623/
[ix] https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Opioid-Prescription-in-Medicare-Beneficiaries-Report.pdf
[x] https://www.cdc.gov/sickle-cell/complications/pain.html
[xi] *Id.*
[xii] https://pmc.ncbi.nlm.nih.gov/articles/PMC8561926/
[xiii] https://hcup-us.ahrq.gov/reports/statbriefs/sb251-Sickle-Cell-Disease-Stays-2016.jsp
[xiv] https://pmc.ncbi.nlm.nih.gov/articles/PMC7153675/
[xv] https://pmc.ncbi.nlm.nih.gov/articles/PMC10909714/
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