

July 31, 2026

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

RE: Medicaid Program; Community Engagement Requirement for Certain Individuals

Dear Administrator Oz,

On behalf of the Sickle Cell Disease Partnership (Partnership),¹ we appreciate the opportunity to provide comments on the interim final rule with comment period (IFC) implementing community engagement requirements in the Medicaid program.

The Sickle Cell Disease Partnership (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 for SCD.²

Thank You For Policies Supporting Americans with SCD

The Partnership is 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 is appreciative to see both you and Health and Human Services (HHS) Secretary Kennedy both verbally affirm support for Americans with SCD during your respective confirmation hearings. Your commitment to helping Americans impacted by SCD is greatly appreciated.

As your agency works to finalize regulations implementing the Medicaid community engagement requirements of OBBBA, P.L. 119-21, the Partnership is writing to convey our perspective about how the Administration can best help to Americans with SCD who rely on Medicaid for coverage and care. We appreciate that the CMS IFC allows states to create lists of serious or complex conditions to identify

¹ <https://www.sicklecellpartnership.org/>

² <https://www.nationalacademies.org/our-work/addressing-sickle-cell-disease-a-strategic-plan-and-blueprint-for-action>

individuals who may be considered medically frail and explicitly cites SCD as an example of a “reasonable” condition for inclusion by states. This specific mention in the IFC is an important signal to states and stakeholders, and we greatly appreciate the specific example and mention by name.

However, we are concerned by the inclusion of the novel requirement that a beneficiary’s condition must “significantly impair the individual’s ability to comply with the community engagement requirement” in order to be exempted from community engagement requirements. We note such requirement is unevenly applied to medical frailty rather than other exemption criteria, and as such it should be removed.

Based on our careful review of data and discussions across multiple stakeholders, the Partnership reiterates our prior request that CMS go beyond what is contemplated in the preamble of the IFC and categorically exclude Americans with SCD from Medicaid community engagement requirements, or otherwise issue actionable 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.

SCD is a Life-shortening Chronic and Debilitating Disease

SCD is the most common inherited blood disorder in the United States.³ 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,⁴ resulting in Americans with SCD needing to visit the emergency department far more often than the average population.⁵ 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 average life expectancy more than 20 years shorter than the general population, with half of SCD patients dying before the age of 54.⁶

Continuous Medicaid Coverage is Crucial for Managing SCD

The importance of continuous Medicaid coverage for SCD cannot be overstated. Approximately 52,524 Medicaid enrollees had SCD in 2021.⁷ Further, about half of Americans with SCD have severe forms of the disease, requiring more frequent medical care.⁸ 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

³ <https://www.hematology.org/education/patients/anemia/sickle-cell-disease>

⁴ <https://minorityhealth.hhs.gov/news/coming-together-confront-sickle-cell-disease>

⁵ <https://www.jscimedcentral.com/public/assets/articles/hematology-3-1037.pdf>

⁶ <https://pubmed.ncbi.nlm.nih.gov/31730182/>

⁷ <https://pmc.ncbi.nlm.nih.gov/articles/PMC9898623/>

⁸ <https://pmc.ncbi.nlm.nih.gov/articles/PMC9898623/>

emergency services, contributing to \$2.4 billion in avoidable annual ED costs according to government data.⁹

The Partnership is 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.

SCD's Uneven Trajectory 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.¹⁰ 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.¹¹ 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.¹² The typical hospital admission length for severe pain crises is five days,¹³ with an average of 1-3 admissions per year.¹⁴ 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.¹⁵ In another survey, adults with at least four VOC pain crises per year missed an estimated 35 percent of scheduled work hours per week.¹⁶ Furthermore, employment status declines as disease severity increases: each additional annual hospitalization raises the odds of being unemployed by 33 percent.¹⁷ Ultimately, modeled lifetime earnings are \$695,000 lower than for peers of similar demographics without SCD.¹⁸

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.¹⁹ Therefore, community engagement requirements tying coverage to work-hour or volunteer or education thresholds for

⁹ <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Opioid-Prescription-in-Medicare-Beneficiaries-Report.pdf>

¹⁰ <https://www.cdc.gov/sickle-cell/complications/pain.html>

¹¹ *Id.*

¹² <https://pmc.ncbi.nlm.nih.gov/articles/PMC8561926/>

¹³ <https://hcup-us.ahrq.gov/reports/statbriefs/sb251-Sickle-Cell-Disease-Stays-2016.jsp>

¹⁴ <https://pmc.ncbi.nlm.nih.gov/articles/PMC7153675/>

¹⁵ <https://pmc.ncbi.nlm.nih.gov/articles/PMC10909714/>

¹⁶ <https://pmc.ncbi.nlm.nih.gov/articles/PMC7253500/>

¹⁷ <https://ashpublications.org/blood/article/132/Supplement%201/4930/262374/Association-between-Employment-Status-and>

¹⁸ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2755485>

¹⁹ <https://pmc.ncbi.nlm.nih.gov/articles/PMC9458333/>

Americans with SCD risks butting up against with the realities of clinical needs for Americans with SCD. Irrespective of the intent behind community engagement requirements, if CMS guidance does not specifically exempt Americans with SCD, through the varied approaches 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.

As Such, We Urge CMS to Categorically Exempt Americans with SCD from Medicaid Community Engagement Requirements

With these challenges in mind, the Partnership urges 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 urges CMS to take the following actions when it implements OBBBA, listed in order of priority to protect Medicaid enrollees who have SCD:

- 1. Exclude *all* 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 work and other 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.²⁰
- 2. If CMS maintains its current stance in not expounding on a minimum set of specific conditions that qualify an individual for an exemption, the Partnership urges CMS to improve upon 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

²⁰ <https://www.medicaid.gov/federal-policy-guidance/downloads/smd22004.pdf>

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.

In general, individuals with SCD want to work and many do work. Yet such individuals may experience periods of stability interspersed with acute episodes, including severe pain crises, hospitalizations, and complications affecting multiple organ systems. In such cases, the ability to engage in work activities may be intermittent and unpredictable. States should account for this variability when evaluating exemptions and should avoid standards that require beneficiaries to demonstrate continuous inability to work. CMS should not permit states to apply rigid or overly narrow criteria that require beneficiaries to prove an absolute inability to work – which would be inconsistent with the statute. Instead, determinations must reflect the clinical reality of episodic and fluctuating conditions, including those characterized by unpredictable exacerbations and varying functional capacity over time.

- b. 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)). We thank CMS for including expectations around state use of ex parte verification through reliable data sources to make determinations on exceptions and compliance. 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, it is crucial that states follow standards established by HHS and use reliable information available to the state in making such a determination. HHS should further 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.
- c. When ex parte data is not available or conclusive, CMS should allow states to utilize a reasonable self-declaration approach.** For individuals applying for Medicaid (or who are currently enrolled in Medicaid but for whom ex parte data is inclusive) who seek to qualify for an exemption based on medical frailty or related criteria, CMS allows states to adopt transitional verification approaches that support timely access to coverage.

- d. CMS should allow states at least a year during a transition to utilize a responsible self-declaration approach to maintain or acquire coverage.** CMS should permit states to rely on beneficiary statements, supplemented by data matching and post-enrollment verification, in order to streamline enrollment and renewal processes and avoid unnecessary denials and appeals. When an individual is determined by a state to have SCD, unless that determination is later identified by the state to be a factual error, the individual should not have to further recertify they have SCD. CMS should ensure that self-attestation policies do not inadvertently disadvantage individuals with serious or complex conditions. In the case of self-declaration, CMS should allow states to allow attestation of medical frailty or other exemption categories, with verification conducted through existing data systems to the extent feasible. States should request additional documentation only when data sources are insufficient to resolve material inconsistencies. States should avoid documentation-heavy processes that shift administrative burden onto beneficiaries rather than leveraging available federal and state data sources.
- e. CMS should take further steps to prevent, monitor for, and remediate unintended disenrollments of Americans with SCD who do meet eligibility criteria for Medicaid.** Given the importance of Medicaid coverage for those living with SCD and the impacts of uneven disease trajectory on work and other activities of daily living, it is critical that communication of the new requirements reaches those living with SCD. Mention of SCD should therefore be incorporated into CMS's nationwide information campaign to support broad awareness of the new requirements and steps that must be taken to maintain coverage to this community. CMS and states should explore ways to partner with organizations and entities that provide care and services to patient communities at the local level, such as SCD community-based organizations, blood centers, and others to further disseminate information on the forthcoming changes. We encourage CMS to provide further guidance to states on redeterminations, including to note that if states are redetermining eligibility with greater frequency as a result of what is allowable in statute, that states will have less claims, diagnoses, and data from which to make a determination – and in such case risk disenrolling individuals who are in fact eligible for coverage. We also ask that CMS monitors outcomes of implementation and administration of community engagement requirements at the state level for any signs of unintended disenrollments for individuals who are actually eligible for Medicaid. CMS should be proactive in identifying and addressing practices that lead to unintended disenrollments within and across states.

We welcome the opportunity to continue dialogue and collaboration 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 contact Victoria Gemme (Victoria.Gemme@LeavittPartners.com) should you have any questions regarding this letter or the Partnership's work more broadly.

Respectfully,
The Sickle Cell Disease Partnership