



www.HaystackProject.org

July 3, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–2439–P
P.O. Box 8013
Baltimore, MD 21244–1850

RE: Medicaid and Children’s Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality (CMS–2439–P)

Haystack Project appreciates the opportunity to provide its comments on the Centers for Medicare & Medicaid Services’ (CMS’) proposed rule on the Medicaid and Children’s Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality (CMS–2439–P) (the Proposed Rule).

Haystack Project is a 501(c)(3) non-profit organization with a membership of 140+ rare and ultra-rare disease patient advocacy organizations. Our core mission is to evolve health care payment and delivery systems with an eye toward spurring innovation and quality in care toward effective, accessible treatment options for all Americans.

Haystack Project’s rare disease communities struggle to navigate health system challenges in disease states where unmet need is high, and treatment delays and inadequacies are both common and potentially catastrophic. Individually, these access challenges can present inconveniences, frustration, and delays in receiving care. Cumulatively, they can present an overwhelming burden for patients and their families. It is, therefore, imperative that beneficiaries have all relevant tools and information available as they seek out effective, efficient care.

Our comments offer insights and recommendations from Haystack Project’s over-140 rare and ultra-rare disease patient advocacy organization members so that CMS can continue to build upon its efforts to ensure that healthcare coverage and benefits confer equally to individuals regardless of their race, financial resources, health care needs, or the rarity of their health condition(s).

Haystack Supports CMS’ Proposal to improve access to care, quality and health outcomes, and better address health equity issues for Medicaid and CHIP managed care enrollees.

Haystack supports all of the proposals CMS puts forth to ensure Medicaid and CHIP beneficiaries have reasonable access to services. All too often, coverage of services may be apparent in benefit design, coverage documents and payer policies, yet the real-world experience for patients is a continuing struggle to find a provider with expertise in treating their condition, ability to schedule a timely appointment, and willingness to accept their coverage. Haystack generally supports CMS' proposals to implement enrollee experience surveys, appointment wait time standards, secret shopper surveys and provider payment analysis as an important first step toward alleviating the struggles our patients face.

However, we note a significant flaw in the proposals related to access in that they are too limited in scope to be relevant to rare and ultra-rare patients. Specifically, the proposals limit inquiry into appointment wait time standards, secret shoppers, and provider payment analysis to four types of services: outpatient mental health and substance use disorder (SUD), primary care, obstetrics and gynecology (OB/GYN), and an additional State-selected service type.

While Haystack agrees that the identified service types are important indicia of access among the general patient population, MCOs could fail rare and ultra-rare patients completely yet appear "perfect" on CMS' measured parameters.

Moreover, we expect that MCOs will focus their resources on maximizing network provider depth to accommodate access to the selected service types and have little incentive to alleviate constricted access to the specialists capable of delivering quality care to our patient communities. In fact, to the extent that MCOs are working with finite resources, they may intentionally or unintentionally reduce access efforts for services not under scrutiny to offset the cost of increasing access to selected service types. This is troubling for all Medicaid beneficiaries. Since rare and ultra-rare patients disproportionately rely on specialist care, however, they could easily become the "unintended consequence" of CMS' well-intentioned access improvement initiative.

Rare disease patients face unique but pervasive struggles with access; starting with the protracted journey from symptom emergence to diagnoses and continuing through treatment and management of their condition(s) through a specialist with disease-specific expertise. These hurdles can be particularly challenging for individuals relying on Medicaid.

- Of the approximately 7,000 rare diseases identified to date, 95% have no FDA-approved treatment option.
- 80% of rare diseases are genetic in origin, and present throughout a person's life, even if symptoms are not immediately apparent.
- Approximately 50% of the people affected by rare diseases are children.
- 30% of children affected by a rare disease will not live to see their 5th birthday; and
- Approximately half of identified rare diseases do not have a disease-specific advocacy network or organization supporting research and development.

We urge CMS to extend the reforms in this rule to capture the patient experience across the full MCO network. In addition, since the challenges confronting individuals with rare and ultra-rare diseases can easily become obscured and/or overshadowed by the experiences within the general patient population, we ask that CMS establish a rare and ultra-rare disease Ombudsman to identify and address barriers rare and ultra-rare patients face in accessing meaningful, quality coverage for their unique healthcare needs. This would include access to specialists with disease-specific expertise as well as on- and off-label treatments accepted as the standard of care for the specific condition.

Haystack Supports Reforms to the Medicaid Managed Care Quality Rating System

Haystack is pleased to see that CMS is advancing the Medicaid Managed Care Quality Rating System (QRS). For too long, Medicaid patients have not had access to information that would help them select the best MCO to meet their healthcare needs. Haystack supports the use of the initial mandatory measure set which would allow patients to compare plans not only within their state, but also across states. This level of uniformity in tracking plan quality will also enable CMS to determine if certain states or MCOs across states are underperforming.

We are particularly supportive of the inclusion of the following Consumer Assessment of Healthcare Providers and Systems (CAHPS®) measures:

- How people rated their health plan.
- Getting care quickly.
- Getting needed care.
- How well doctors communicate.
- Health plan customer service.

We expect that this information will help patients with rare and ultra-rare diseases determine a plan's *relative* ability to provide the care they need when they need it. Haystack Project, however, remains concerned that there are no existing measures capable of capturing the unique challenges faced by patients with rare and ultra-rare diseases and the extent to which those challenges are alleviated.

Haystack acknowledges that it is infeasible to create measures reflecting access to quality care for each rare condition or even related subsets of conditions. However, we urge CMS to work with Haystack Project and the ultra-rare patient communities to develop one or more measure(s) reflecting the main components of quality care for people with ultra-rare disorders, including:

- Recognition of patients at risk for the disease
- Starting the appropriate evaluation
- Making the appropriate diagnosis
- Starting the appropriate treatment
- Scheduling the appropriate follow-up
- Communicating with the patient to ensure compliance/adherence to treatment

We also recommend that CMS require MCOs to include activities addressing health disparities in the Quality Improvement (QI) program. We remain concerned, however, that the metric CMS proposes for evaluation purposes is untested and may overlook disparities and inequities in care for individuals of color not impacted by SDOH, particularly those with rare and ultra-rare diseases. We urge the Agency to engage with the patient and provider communities to review and assess the impact of this health equity initiative.

Finally, we suggest that CMS include a metric related to newborn screening within MCOs that benchmarks plan performance to the “Recommended Uniform Screening Panel” (RUSP) developed by the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) and encourages inclusion of clinical geneticists within the MCO network.

Conclusion

Haystack Project appreciates the opportunity to submit feedback on this important CMS initiative and welcomes the opportunity for a continuing dialogue toward meaningful access to quality care for all patients.

Once again, we thank you for your consideration of our comments. If you have any questions, please contact our policy consultant M Kay Scanlan, JD at 410.504.2324.





