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July 3, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2442-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: Medicaid Program: Ensuring Access to Medicaid Services (CMS-2442-P)

Haystack Project appreciates the opportunity to provide its comments on the Centers for Medicare & Medicaid Services' (CMS') proposed rule entitled "Medicaid Program: Ensuring Access to Medicaid Services" (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. We strive to coordinate and focus efforts that highlight and address systemic reimbursement obstacles to patient access in disease states where unmet need is high and treatment delays can be catastrophic.

The access challenges rare and ultra-rare disease patients face as they struggle to navigate the health system can each present inconveniences, frustration, and delays in receiving care. Cumulatively, they can become an overwhelming burden for patients and their families. It is, therefore, imperative that Medicaid 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 rare and ultra-rare 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).

Medicaid Advisory Committee and Beneficiary Advisory Group

CMS proposes to replace the current Medical Care Advisory Committee (MCAC) requirements with a committee framework designed to ensure the proper and efficient administration of the Medicaid program so that care and services are provided in a manner consistent with the best

interests of the beneficiaries. States would be required to establish and operate the newly named Medicaid Advisory Committee (MAC) and a Beneficiary Advisory Group (BAG). The MAC and its corresponding BAG would serve as vehicles for bi-directional feedback between interested parties and the State on matters related to the effective administration of the Medicaid program. States would maintain discretion on the operation and make-up of the committees but would be required to include individuals with Medicaid beneficiary experience. This means that the BAG would be comprised of people who: (1) are currently or have been Medicaid beneficiaries or (2) individuals with direct experience supporting Medicaid beneficiaries (family members or caregivers of those enrolled in Medicaid). CMS encourages states to take into consideration the demographics of their Medicaid programs, and ensure that proper representation is in place, but ultimately leaves it to the states' discretion.

Haystack is broadly supportive of this proposal. Inclusion of the beneficiary perspective in a Medicaid policy and oversight are critical to ensuring that the Medicaid program is effectively serving patients. However, we believe CMS has missed an opportunity to ensure an appropriate mix of individuals are included in each state's BAG. For example, CMS may consider mandating inclusion of patients with rare or chronic diseases given their unique set of challenges. Approximately 1 in 10 Americans live with one or more of the 7,000 rare diseases that have been identified to date. While each disease is rare, rare-disease patients are relatively common and the challenges they face are significant:

- 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 with a rare disease will not live to see their 5th birthday
- Approximately half of identified rare diseases do not have a disease-specific advocacy network or organization supporting research and development.

Rare disease patients are also uniquely positioned to provide meaningful input to inform policy decisions. Rare disease patients generally:

- See an average of 4.2 primary care physicians and 4.8 specialists before receiving an accurate diagnosis.
- Make an average of 2.4 out-of-state trips related to their diagnosis.
- Visit an emergency room an average of 3.7 times and are hospitalized an average of 1.7 times for reasons related to their rare disease prior to diagnosis.
- Have a very limited set of clinicians with disease-specific expertise, making it difficult for many patients to identify an experienced provider within their network, or even their state.
- Disproportionately rely on off-label use of treatments indicated for more common conditions to address disease symptoms and/or progression. Due to disease rarity, these off-label uses are seldom included within compendia.

We urge CMS to, at a minimum, ensure that members of the BAG and members of the public have an opportunity to submit issues for inclusion on the agenda. The proposed rule limits the

BAG's utility as an independent, patient-oriented voice on policy by granting states full authority to set (and limit) meeting agendas. While we appreciate that the MAC/BAG meetings are not intended as a form of "town hall," we believe there is value in empowering the BAG and the general public to identify and raise issues that are important to patients.

Home and Community Based Services (HCBS)

Patient-Centered Service Plans

CMS proposes to replace existing guidance on person-centered service plans with new regulations directing annual functional need reassessment. Under the proposal, states will be required to demonstrate that they reviewed the person-centered service plan (and revised it as appropriate) at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days.

Haystack generally supports this proposal. HCBS currently serves over 2.2 million Americans, and according to [AHRQ](#), many of the most vulnerable:

- 26% have an intellectual or developmental disability
- 13% have severe mental illness
- 24% have physical disability

Haystack agrees with CMS' assertion that the 86% threshold:

provides States with more latitude than is necessary to account for unexpected delays in the timeframe for conducting reassessments and updating service plans, as States should assume that some delays are likely and account for them as part of their reassessment and service planning processes. Further, media and anecdotal reports indicate that re-assessment and care planning processes are often delayed without valid reasons, which suggests that beneficiaries may be at risk for preventable harm due to unnecessary delays in person-centered planning processes and that [CMS] should establish a more stringent threshold for States to demonstrate compliance with the requirements. (88 FR 27973)

Payment Adequacy

Section 1902(a)(30)(A) of the Act requires state Medicaid programs to ensure that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are as available to beneficiaries as they are to the general population in the same geographic area. CMS proposes to require that state Medicaid agencies demonstrate that payment rates for certain HCBS services are sufficient to ensure a sufficient direct care workforce to meet the needs of beneficiaries. CMS proposes to require that at least 80 percent of all Medicaid payments for homemaker services, home health aide services, and personal care services are spent on compensation to direct care workers.

Haystack supports this new requirement to ensure that HCBS workers are adequately compensated. CMS correctly notes that “Direct care workers typically earn low wages and receive limited benefits, contributing to a shortage of direct care workers and high rates of turnover in this workforce, which can limit access to and impact the quality of HCBS.” (88 FR 27982). We are pleased to see that this provision of the rule applies to both managed care and fee-for-service (FFS) Medicaid.

Haystack Project membership organizations have long described significant difficulties in obtaining the in-home services often required to care for an individual with a rare or ultra-rare condition. In particular, home nursing services are unavailable to Medicaid beneficiaries in many states due to insufficient payment rates. We urge CMS to consider adding these professional services to those subject to the payment adequacy standards. In addition, we strongly urge CMS to hasten the implementation timeline for this proposal.

Payment Rate Transparency

CMS proposes to require that states publish their FFS Medicaid payment rates in a clearly accessible, public location on the state’s website. In addition, the Medicaid payment rates for primary care services, obstetrical and gynecological services, and outpatient behavioral health services would be compared to Medicare rates for those services.

Haystack supports the transparency provisions in this rule. However, as we expressed in our comments on the Managed Care Rule (CMS–2439–P) CMS’ payment comparison proposal is too limited in scope and could have unintended consequences that disproportionately impact individuals with rare and ultra-rare conditions. We expect that the primary purpose of the payment adequacy analysis is to drive states to identify and address payment inadequacies and disparities. Unfortunately, because states have limited funds to operate their Medicaid programs, any increase in payment to one set of providers presents a risk that payments to other providers will be reduced or that funding will be cut from some other part of the program. CMS’ piecemeal approach to ensuring access may end up harming the beneficiaries it intends to protect. This is troubling for all Medicaid beneficiaries but of particular concern to patients with rare and ultra-rare diseases who disproportionately rely on specialist care.

Rare disease patients face unique but pervasive struggles with access; from the protracted journey to diagnoses through treatment and management of their conditions. 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 amend its proposed requirement that states perform a comprehensive payment adequacy analysis to provide for review of a specified percentage of services paid for by the Medicaid program rather than a specified set of service types.

We also reiterate our request that CMS establish a rare and ultra-rare disease Ombudsman to ensure that rare and ultra-rare disease patients are not subject to barriers 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 identified by those experts as within the standard of care.

Additionally, we note that payment is not the only reason providers avoid participating in Medicaid. There is a myriad of other reasons why providers are hesitant, including:

- Burdensome claims submission processes
- Lack of clarity on what services are covered
- Visit limits or limits on the number of CPT codes that can be billed per visit
- Confusing rules on copayments, especially for dual-eligible beneficiaries
- Prior authorization and utilization management. The potential for post-payment reviews is particularly daunting since it reduces physician office trust in results from the prior authorization and claims payment processes
- Lack of clarity on when cash-payment is legal

We appreciate that CMS has done considerable work recently to alleviate some of the administrative burden providers face. We encourage the agency to continue this work to ensure that providers can maximize the time they have to do what they do best: treat patients.

State Analysis Procedures for Rate Reduction or Restructuring

Finally, CMS proposes a two-tiered approach for determining the level of access analysis states are required to conduct when proposing provider payment rate reductions or payment restructurings. The state agency would be required to provide written assurance and relevant supporting documentation that three criteria are met, as well as a description of the state's procedures for monitoring continued compliance. The criteria are that 1) payment in aggregate for a benefit category is at or above 80% of Medicare; 2) the proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the state fiscal year, would result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for each benefit category; and 3) public feedback yielded no significant access to care concerns or yielded concerns that the State can reasonably respond to or mitigate. If any criterion in the first tier is not met, states must document current and recent historical levels of access to care.

Haystack Project is encouraged that CMS proposes to include protections to mitigate the risk that payment reductions will translate into reduced access. While this analysis could be an effective way to determine appropriate payment, we note that CMS has declined to define

“benefit category” in a meaningful way. CMS states that ‘benefit category’ refers to all individual services under a category of services described in section 1905(a) of the Act for which the state is proposing a payment rate reduction or restructuring. This means that extremely large swaths of services can be grouped together for the purposes of conducting the analysis. This can mask the real-world impact of payment cuts on specific provider types. CMS states “[f]or example, if the State is seeking to reduce payment rates for a subset of physician services, the State would review all current payment rates for all physician services and determine if the proposed reduction to the relevant subset of codes would result in an average Medicaid payment rate for all physician services that is at or above 80 percent of the average corresponding Medicare payment rates.” (88 FR 28026).

This presents a dangerous loophole through which states can drastically cut payment for services, including, for example, specialist office visits, without triggering additional regulatory scrutiny. As rare and ultra-rare disease patients disproportionately rely on specialists – a service type that could easily face rate reduction efforts - we are extremely concerned. The only safeguard to this policy is the third criteria of the first tier, which provides that public feedback yielded no significant access to care concerns or yielded concerns that the State can reasonably respond to or mitigate, as appropriate. However, we are not convinced that the subjective inquiry on whether state efforts might be reasonable coupled with the non-specific activity the state would undertake (“respond” or “mitigate”) provides an actual hurdle to payment cuts constricting access for rare and ultra-rare patients.

We urge CMS to take an approach that is more straightforward than the two-tiered proposal. For example, CMS could propose that payment reductions in excess of 5% for any given service or CPT code should be reviewed by CMS to determine if patient access is at risk. While we understand that states need flexibility in operating their Medicaid programs, provider payment adequacy is a sufficiently critical component of a functioning health system to warrant federal oversight and a straightforward mechanism for protecting patient access.

Conclusion

Haystack Project appreciates the opportunity to submit feedback on this important CMS proposal. We welcome the opportunity for a continuing dialogue toward meaningful access to quality care for all patients relying on Medicaid.

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.







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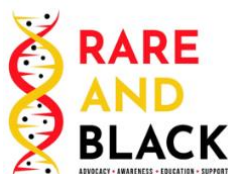
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