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November 7, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1771-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility Determination, Enrollment, and Renewal Processes (CMS-2421-P)

Haystack Project appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS') above-referenced proposed rule streamlining enrollment and renewal in the Medicaid, Children's Health Insurance Program (CHIP), and Basic Health program (BHP) (the Proposed Rule).

Haystack Project is a 501(c)(3) non-profit organization enabling rare and ultra-rare disease advocacy organizations to highlight and address systemic access barriers to the therapies they desperately need. We strive to amplify the patient and caregiver voice in disease states where unmet need is high, and treatment delays and inadequacies can be catastrophic. Our core mission is to evolve health care payment and delivery systems, spurring innovation and quality in care toward effective, accessible treatment options for Americans living with rare or ultra-rare conditions. Haystack Project is committed to educating policymakers and other stakeholders about the unique circumstances of extremely rare conditions with respect to product development, commercialization, and fair access to care.

We applaud CMS for taking this important step toward improving the Medicaid, CHIP and Basic Health Programs for beneficiaries. Improving the ease and efficiency through which beneficiaries can acquire and maintain coverage in these programs will not only ensure better outcomes for the people who rely on them but is also a practical step toward ensuring these programs remain sustainable. Our comments focus on ensuring that efforts to refine Medicaid, CHIP and BHP policies result in improved quality, efficiency, and access for all beneficiaries regardless of the rarity of their medical condition(s).

A. Facilitating Medicaid Enrollment

Haystack broadly supports the policies proposed to ensure enrollment in Medicaid is as efficient as possible and reduces the burden on beneficiaries. Many persons with rare and ultra-rare diseases are disabled or otherwise dependent on carers, and the burden of complying with a continuous cycle of paperwork in order to acquire or maintain coverage can be overwhelming and ultimately lead to loss of or gaps in coverage that significantly impact a patient's health. Individuals who are eligible for Medicaid should be seamlessly and efficiently enrolled so their care can begin immediately. Haystack, therefore, supports CMS' proposals to:

1. *Facilitate Enrollment Through Medicare Part D Low-Income Subsidy "Leads" Data (§§ 435.4, 435.601, 435.911, and 435.952)*

CMS proposes to codify the statutory requirements that States utilize leads data to establish eligibility for Medicaid and the Medicare Savings Program (MSP). The MSP enables use of Medicaid benefits to pay costs associated with Medicare coverage, including premiums, deductibles, and for some beneficiaries, cost sharing. CMS anticipates that requiring states to treat receipt of leads data as an MSP application will address the under-utilization of this program.

Haystack strongly supports this proposal. We urge CMS to require that states use clear, plain language notices that inform beneficiaries that additional benefits are available.

2. Automatically Enroll Certain SSI Recipients into the Qualified Medicare Beneficiaries Group (§ 435.909)

CMS also proposes to ensure that certain beneficiaries of supplemental security income (SSI) be automatically enrolled in the Qualified Medicare Beneficiary group (QMB). The QMB protections from out-of-pocket costs that could otherwise deter patients from seeking the care they need are particularly important to individuals with chronic conditions, disabilities, and rare conditions. We appreciate that CMS seeks to implement processes to ensure that Medicare-eligible Supplemental Security Income (SSI) recipients are automatically considered for and enrolled in the QMB eligibility group. Alleviating the onerous requirement that these beneficiaries complete an additional application for QMB benefits, on top of their SSI application and Medicare enrollment will help to ensure that these beneficiaries are able to access their benefits quickly and efficiently.

3. Facilitate Enrollment by Allowing Medically Needy Individuals to Deduct Prospective Medical Expenses (§ 435.831)

CMS also proposes to allow certain individuals to deduct their anticipated medical and remedial care expenses from their income for the purposes of meeting medically needy income eligibility criteria. Currently, this deduction is permitted only for institutionalized individuals.

Haystack strongly supports this proposal. As the Biden-Harris administration has committed itself to advancing health equity, we applaud this decision to ensure that all persons have the same access to health coverage through the Medicaid program, regardless of whether they are institutionalized or remain within their community. Rare disease patients and their families face exorbitant health care costs year after year and should not have to face yearly struggles of choosing between paying for health care and meeting financial obligations associated with food and housing.

CMS notes that it intends to include in the regulatory language examples of specific types of expenses that would be permitted in the spenddown deduction, while providing additional flexibility for States to identify additional expenses that meet the criteria of being constant and predictable. Haystack strongly recommends that certain drug costs be expressly mentioned in the regulatory language.

Advances in research and development such as regenerative medicine, gene therapy, and other targeted therapy innovations offer a renewed hope that a treatment could be on the horizon for any disease, no matter how rare. And as the vast majority of rare diseases have no available treatment beyond off-label use of therapies approved for other conditions, many patients with rare diseases are left to pay out of pocket for their treatment.

The disruptions in care that result from patients churning off and on Medicaid place patients at high risk for compromised health outcomes, including disease progression, exposure to inappropriate interventions, emergence of comorbid conditions, and even death. They are also costly. Although approximately 70% of rare diseases are genetic, and the costs for genomic sequencing has dropped from \$95,263,072 in 2001 to under \$1,000, the diagnostic journey has remained long and complex. According to an economic study which

included a survey of 1360 patients with 379 rare diseases^{1, 2} cited to in the GAO Report and administered by EveryLife Foundation and Lewin Group, patients:

- Saw an average of 4.2 primary care physicians and 4.8 specialists for their rare disease diagnosis
- Made an average of 2.4 out-of-state trips related to their diagnosis
- Visited an emergency room an average of 3.7 times and
- Were hospitalized an average of 1.7 times for reasons related to their rare disease, and prior to diagnosis.³

The diagnostic and treatment access challenges common to rare disease patients generally can be an overwhelming burden for people of color and other underserved populations, including rural communities. Communities of color face significant disparities in symptom severity, disease progression and mortality for rare diseases such as systemic lupus erythematosus and myasthenia gravis even though these conditions tend to occur across populations. Other rare diseases such as sickle cell anemia, thalassemia, and sarcoidosis disproportionately impact people of color. The growing number of beneficiaries with sickle cell disease (SCD) are primarily young, medically complex, and likely impacted by social determinants of health (SDOH):

- 75.5% utilized the emergency department, and 59.3% had an inpatient stay
- Hospital utilization was higher for individuals aged 18-45
- Common comorbidities in Medicare FFS patients with SCD include:
 - hypertension (65.8%)
 - fibromyalgia (64.9%)
 - depression (51.3%)
 - chronic kidney disease (47.0%).
 - over 70% of Medicare FFS beneficiaries with SCD were dual-eligible
 - over 80% are under 65 years of age.

Haystack recognizes that states only project spenddown amounts based on costs that are constant and predictable enough to predict with reasonable certainty, and drug-related costs may not be appropriate or possible to project for all patients. We urge CMS to include drug-related costs as a potential spend-down expense that would be included if either (1) the patient's treatment regimen includes drugs for which costs are relatively constant and predictable or (2) a new treatment option is available to address the patient's condition and the costs of that treatment are ascertainable.

Additional Medicaid Enrollment Proposals.

Haystack also supports CMS' proposals to clarify the definition of "family size," the effective date for QMBs, the reasonable compatibility standard for resource information and verification of citizenship and identity. These proposals will lower the burden on beneficiaries, speed enrollment and ultimately allow for better health outcomes for persons entitled to these benefits.

B. Promoting Enrollment and Retention of Eligible Individuals

CMS proposes to require States to apply the same Medicaid renewal procedures for MAGI and non-MAGI beneficiaries. Currently, streamlined processes that make it easier for eligible individuals to apply and remain enrolled in Medicaid and CHIP are only available for populations who are eligible for Medicaid based on MAGI. In many states, this has led to a more burdensome process for beneficiaries who qualify for Medicaid on a non-MAGI basis, such as being age 65 or older or having blindness or a disability.

¹ <https://everylifefoundation.org/burden-study/>

² <https://ojrd.biomedcentral.com/articles/10.1186/s13023-022-02299-5>

³ EveryLife Foundation and the Lewin Group, "National Economic Burden of Rare Disease." p 19.

Haystack supports this proposal to ensure equitable treatment of Medicaid beneficiaries regardless of the statutory basis on which they qualify for the program. CMS correctly notes that individuals who are Medicaid eligible based on age, blindness or disability may experience additional barriers related to document retention, communication (for example, limited English proficiency and low health literacy), technology (for example, printing costs, access to a computer or internet) and access to transportation, among others. Further, but nature of the fact that these beneficiaries qualify for Medicaid on non-MAGI criteria, their eligibility is less likely to change in a given year. For instance, while MAGI beneficiaries may see changes in their income year over year which may lead to loss of eligibility, it is less likely that a person who qualifies for Medicaid based on age, blindness or disability will no longer have the qualifying condition. Haystack, therefore, supports CMS' proposal to require that states conduct regularly-scheduled eligibility reviews once, and only once, every 12 months for all Medicaid beneficiaries, including non-MAGI beneficiaries.

Haystack also supports the proposals related to changes in circumstances timeframes and protections (§§ 435.916, 435.919, and 457.344), timely determination and redetermination of eligibility (§§ 435.907 and 435.912); agency action on returned mail (§§ 435.919 and 457.344); transitions between Medicaid, CHIP and BHP agencies (§§ 431.10, 435.1200, 600.330); and optional group for reasonable classification of individuals under 21 who meet criteria for another optional group (§ 435.223). These policies will reduce beneficiary burden and ensure that states process applications in a timely manner and make reasonable efforts to contact beneficiaries who may have moved addresses but remain eligible for benefits.

C. Eliminating Barriers to Access in Medicaid

1. Remove Optional Limitation on the Number of Reasonable Opportunity Periods (§§ 435.956 and 457.380)

CMS proposes to remove the option for states to limit the number of reasonable opportunity periods during which a beneficiary meeting other eligibility requirements can continue to receive Medicaid benefits while the state seeks to verify citizenship or satisfactory immigration status.

Haystack supports this proposal. As CMS notes in the proposed rule, only one state has sought to implement a limit on the number of reasonable opportunity periods Medicaid beneficiaries are entitled to. Given the life-and-death nature of having health coverage we strongly support the proposal to prohibit States from imposing limitations on the number of ROPs that an individual may receive.

2. Remove or Limit Requirement to Apply for Other Benefits (§ 435.608)

CMS also proposes to reinterpret the requirement that all Medicaid applicants and beneficiaries, as a condition of their eligibility, take all necessary steps to obtain other benefits to which they are entitled, unless they can show good cause for not doing so. CMS correctly notes that historically, Medicaid eligibility was closely tethered to other assistance programs and the primary path to Medicaid eligibility at the time was receipt of SSI or Aid to Families with Dependent Children (AFDC). However, numerous eligibility groups have since been authorized under the statute, including groups for children, pregnant individuals, parents and caretaker relatives, and other adults with income higher than the income standard for cash assistance programs. The requirement that beneficiaries complete applications and seek out other benefits is, therefore, outdated and overly burdensome. Haystack supports this proposal to only require beneficiaries to obtain and be evaluated for eligibility based on the resources and income in their immediate control.

E. CHIP Proposed Changes—Streamlining Enrollment and Promoting Retention and Beneficiary Protections in CHIP

In order to retain the alignment with Medicaid and other insurance affordability programs, CMS proposes to adopt the same proposed policies for CHIP as are proposed for Medicaid in this proposed rule. Haystack fully supports the policies proposed for Medicaid as well as their implementation in CHIP. Many of the barriers

faced by Medicaid beneficiaries are felt more acutely for children enrolled in CHIP due to their age, dependence on caregivers, and lack of health literacy.

F. Federal Oversight of Managed Care Organizations

While Haystack appreciates the work CMS has done to improve Medicaid, CHIP and BHP, we note that our members experience barriers to care most frequently when receiving their coverage through Medicaid or Medicare managed care organizations (MCOs). The use of MCOs is widespread, and in theory should serve to simplify the process of navigating Medicaid and CHIP for beneficiaries while potentially resulting in cost saving for the state. Unfortunately, these goals are often not met for individuals with rare and ultra-rare conditions. For patients with rare diseases, the challenges associated with managed care are particularly acute. Narrow networks and restrictions on access to specialists can prevent these patients from seeing the providers they need – often times there is not an alternative provider available.

Our members note considerable frustration and stress resulting from dealing with MCOs. Most recently, as North Carolina completed its transition to managed care, our members noted inconclusive or confusing official communications, missing personal communications (i.e., "welcome packets" that were not sent to all Medicaid recipients), incomplete provider subscription to the new health care plans, and ever-changing timelines. While the challenges faced in North Carolina were significant, they were not unique, as 69% of Medicaid beneficiaries are enrolled in managed care.⁴ Any attempt to make a meaningful difference in the administration of Medicaid and CHIP benefits should address and improve the role of MCOs. We urge CMS to consider future rulemaking(s) that focus on MCOs.

Conclusion

Haystack appreciates the considerable work CMS has undertaken to develop these important policy proposals. Improving the ease and efficiency through which individuals can enroll and maintain coverage in Medicaid, CHIP, and BHP has the potential to significantly improve the health and well-being of some of the most vulnerable populations in the country. Haystack looks forward to continuing to work with the Agency to improve these programs for those who need them most. Please do not hesitate to contact me, or Kay Scanlan, our policy consultant, at 410-504-2324 if you have questions or would like further information.

Sincerely,



Deanna Darlington
Chief Executive Officer
Haystack Project

⁴ <https://www.kff.org/other/state-indicator/total-medicaid-mco-enrollment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>