



March 3, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 212441

RE: CMS-2023-0010 Calendar Year (CY) 2024 Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (the Advance Notice).

Dear Administrator Brooks-LaSure:

Haystack Project appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') Advance Notice referenced above. We appreciate that CMS is implementing provisions of the Inflation Reduction Act of 2022 (IRA) to ease the financial burden that Medicare beneficiaries with rare diseases and other costly conditions have faced in obtaining the treatments they need. Our comments are intended to inform CMS on the challenges our patients face accessing care so that policy refinements designed to improve the MA and Part D programs do not drive unintended consequences for rare disease patients.

Haystack Project is a 501(c)(3) non-profit organization enabling rare and ultra-rare disease patient advocacy organizations to coordinate and focus efforts that highlight and address systemic reimbursement obstacles to patient access unique to rare diseases or particularly pronounced in extremely rare diseases. We are committed to educating policymakers and other stakeholders about the unique circumstances associated with extremely rare conditions with respect to product development, commercialization, and fair access to care. 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 living with or caring for someone with a rare or ultra-rare condition.

We focus on our comments on:

- Urging CMS to ensure that risk adjustment methodologies and updates align with the treatment costs associated with rare and ultra-rare diseases.

- Recommending CMS delay implementation of “universal foundation” quality measures until they reflect high-quality care for rare and ultra-rare disease patients.
- Releasing draft IRA implementation guidance with sufficient time to provide meaningful feedback.

Haystack Project urges CMS to ensure risk adjustment methodologies and updates align with ultra-rare disease treatment costs.

CMS is trying to protect the Medicare program and its beneficiaries from overpayments to MA organizations, driven either by “upcoding” diagnoses and/or otherwise manipulating risk adjustment calculations. However, CMS must consider the potential that many very rare diseases with high health care costs are not factored in or accurately benchmarked for risk adjustment purposes. We recommend that the Agency:

- Engage with patient organizations and other stakeholders in the ultra-rare disease community to identify conditions with heightened risk and benchmark annual care costs for incorporation into CMS’ risk adjustment methodologies. Haystack Project could, for example, work with its 130+ extremely rare disease organizations to contribute information on their diagnostic and treatment journeys.
- Ensure that annual risk adjustment associated with specific diagnoses reflects the costs of new treatments.
 - o Newly-approved treatments targeted to treating extremely rare diseases tend to be more costly than drugs approved for more common conditions. Patients report that plans delay access to these new treatments for 6 months to a year. These treatments are often the only option available for patients, and CMS should (a) require that plans cover them when they are commercially available; and (b) ensure that the payments to the Part D sponsor or MA organization takes into account these new treatments;
 - o MA plans have demonstrated that they will initiate the National Coverage Determination (NCD) process to shift costs of new, high-cost treatments to Medicare fee-for-service. Proactive incorporation of the costs of innovative treatments would eliminate the financial incentives that MA plans now have to trigger the NCD process.

Haystack Project recommends CMS delay implementation of a proposed set of “universal foundation” quality measures until one or more measures are included to reflect high-quality care for rare and ultra-rare disease patients.

System-wide reforms designed to expand equitable access to quality health care without overburdening providers and plans with complex reporting requirements is a laudable goal. However, CMS’ effort to identify a set of “universal foundation” measures to implement across federal programs, perhaps predictably to Haystack Project, does not include any related to rare

and ultra-rare disease patients. We are concerned that failure to address the diagnostic and treatment delays rare and ultra-rare disease patients experience will mean our community will yet again not benefit from the care quality improvements CMS envisions.

Haystack Project suggests delaying implementation until the agency works with Haystack Project and the rare and especially ultra-rare disease patient communities to develop a measure(s) reflecting the main components of quality care for people with ultra-rare disorders. Haystack Project would welcome an opportunity to engage the Agency as it considers:

- 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

Furthermore, we recommend requiring plans to include activities to address health disparities in the Quality Improvement (QI) program to improve their efforts to serve the needs of marginalized populations. We remain concerned, however, that the metric CMS proposes for evaluation purposes is untested and may have unintended consequences for communities of color not impacted by SDOH, particularly those with 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.

Haystack Project asks CMS to release draft IRA implementation guidance with a sufficient comment period for meaningful feedback.

Haystack Project applauds CMS' implementation of IRA provisions to improve access to care for people with costly conditions, thus getting – and staying – on treatment more affordable, including:

- the Part D Low-Income Subsidy program (LIS) includes beneficiaries earning between 135 and 150 percent of the federal poverty level and meet the resource limit requirements. These individuals will, beginning in 2024, receive the full LIS subsidy;
- Removal of deductibles and cost sharing for recommended vaccines;

However, we ask that CMS release guidance on IRA implementation, in draft form, as soon as possible, and to ensure that the comment period is sufficient to enable patient advocacy organizations to provide meaningful feedback.

Conclusion

Once again, Haystack and its member organizations appreciate the opportunity to submit comments as CMS finalizes its refinements to the MA and Part D program requirements.

If you have any questions or would like to discuss the issues raised in our comments, please contact our policy consultant, M Kay Scanlan, JD at (410) 504-2324.

Very truly yours,



