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Submitted electronically to PartDRedesignPI@cms.hhs.gov

March 1, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard Baltimore, MD 21244

RE: Draft CY 2025 Part D Redesign Program Instructions

Dear Administrator Brooks-LaSure:

Haystack Project appreciates the opportunity to provide its comments to the Centers for Medicare & Medicaid Services' (CMS') Draft CY 2025 Part D Redesign Program Instructions.

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. Haystack Project is 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.

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 can be 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. For members of our patient communities relying on Medicare Part D to access treatment, the Inflation Reduction Act's (IRA's) provisions creating the Part D annual $2,000 out-of-pocket (OOP) cap and the beneficiary option to "smooth" out-of-pocket (OOP)

prescription drug costs over the plan year will help address financial barriers to access that have historically pushed patients to abandon prescribed medications vital to managing disease burden.

The IRA also created the Manufacturer Discount Program and changed how financial responsibilities are allocated among enrollees, plan sponsors, manufacturers, and CMS. The IRA changes to Part D may be a double-edged sword with reduced OOP expenses potentially counterbalanced by unintended consequences to formulary decisions as plan sponsors face increased financial liability. We are concerned that plans will be incentivized to narrow formulary access, particularly in areas where plan liability is expected to increase most, such as for drugs with spending that primarily falls in the catastrophic phase. Medications for rare and ultra-rare conditions tend to be relatively costly and our patients have frequently reached the catastrophic coverage phase early in the plan year. We urge CMS to:

- Increase its oversight to ensure that plan formularies include all necessary medications and that expedited formulary exception processes enable access when patients need treatments not included on formulary.
- Provide Part D plans with clear guidelines on coverage, formulary tiers and utilization management (UM) tools, including enforcement of requirements that formulary process be transparent and utilization management strategies be based on clinical evidence.
- Proactively monitor the impact of the Manufacturer Discount Program, the Medicare Drug Price Negotiation Program, and Part D redesign on formulary decisions and UM practices. This should include monitoring of any impact that plan financial liability changes have on access to medications.
- Identify and mitigate any access constrictions, both on the plan and sponsor levels and program-wide.
- Establish a formal mechanism for patients and patient advocacy organizations to communicate their experiences, including barriers to getting their prescribed medications when they need them, directly with CMS. We urge the Agency to create a dedicated communication channel as well as a set of proactive forums for patients and clinicians.

In addition, Haystack Project has long been concerned that the protections that have been codified since 2006 for Part D drugs within the six “protected” classes, i.e., immune-suppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics, has eroded from one year to the next. Individuals with extremely rare conditions, including those with rare forms of epilepsy, often require approaches to treatment that differ from treatment of more common forms of the condition. This could mean that a specific anticonvulsant drug is required, that two or more treatments are needed, or even that drug combinations that include products outside the anticonvulsant class are used to control seizures. Rare, genetic conditions impacting the immune system similarly require distinct, disease-specific treatment regimens to reduce disease burden or extend life. The statutory designation of these classes of drugs as requiring plans to include all or substantially all drugs within the class was designed to ensure that formulary designs do not disadvantage and

discriminate against the vulnerable patients requiring access to specific drugs or combinations of drugs. We urge CMS to enforce this important statutory provision within its Part D redesign efforts, and that it provide a real-time mechanism for patients unable to access treatments within the protected classes due to formulary design or utilization management tools.

Conclusion

Haystack Project understands that CMS has had an extremely narrow timeline for implementing the prescription drug provisions of the Inflation Reduction Act (IRA). We appreciate the opportunity to submit feedback on CMS' Part D Redesign Program Instructions and look forward to continuing to work with you in ensuring that all Medicare beneficiaries, including those with rare diseases, can receive the treatments they need without financial hardships associated with high out-of-pocket costs.

If you have any questions, please contact me at Kara.berasi@haystackproject.org or our policy consultant, Kay Scanlan of Consilium Strategies at mkayscanlan@consilstrat.com.

Sincerely,

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