



The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1734-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

Re: **CMS-1734-P**  
**CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; etc.**

Dear Administrator Verma:

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. 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 amplify the patient and caregiver voice in disease states where unmet need is high and treatment delays and inadequacies can be catastrophic.

The Rare Cancer Policy Coalition (RCPC) is a Haystack Project initiative that brings together rare cancer patient organizations. RCPC gives participants a platform for focusing specifically on systemic reimbursement barriers and emerging landscape changes that impact new product development and treatment access for rare cancer patients. It is the only rare cancer coalition developed to focus on and respond to reimbursement, access and value issues across the rare cancer community. Working within the Haystack Project enables RCPC participants to leverage synergies and common goals with rare and ultra-rare patient advocates and optimize advocacy in disease states where unmet need is high and treatment inadequacies can be catastrophic.

Haystack Project and RCPC (collectively, "Haystack") appreciate the Administration's unprecedented efforts to respond to the health care access challenges within the COVID-19 Public Health Emergency (PHE) with pragmatic flexibilities that have enabled health care providers to maximize resources and minimize the spread of the novel coronavirus. These flexibilities have been especially important to Medicare patients with rare and ultra-rare conditions and rare cancers who are particularly vulnerable to the risk of serious COVID-19



disease and would otherwise struggle to maintain access to health care services that are critical in treating and/or managing their diseases. We support the Centers for Medicare & Medicaid Services' (CMS') proposal to continue many of the flexibilities implemented in response to the PHE, and to consider permanent adoption of telemedicine flexibilities that demonstrate value through improved access to care. We similarly support CMS' proposals to delay implementation of the MIPS Value Pathway (MVP) and enhance the complex patient bonus within the Quality Payment Program.

***Haystack Supports CMS' Proposal to Enhance Access to Care through Telehealth Services Through and Beyond the PHE.***

We appreciate ongoing CMS' efforts to ensure that the nation's most vulnerable patients receive the care they need throughout the PHE. The appropriate use of telehealth services is crucial throughout the COVID-19 pandemic, as it relieves patients of making the difficult decision between continuing their care plan and avoiding heightened risk of exposure to the novel coronavirus. Haystack believes that patients requiring treatment for rare and ultra-rare disorders and rare cancers may remain hesitant to abandon social distancing measures once it becomes acceptable for low-risk individuals in the general public to return to normal activities. We also agree with CMS that broadening access to telehealth beyond the PHE may offer value to patients, clinicians, and the Medicare program so long as the decision on whether or not face-to-face clinician visits should be used is based on the patient's condition, needs and preferences. Ideally, telehealth would function as an adjunct to in-person visits that would, for individuals with rare conditions, enable broader access to a continuity of coordinated care that includes disease-specific expertise from local specialists as well as those outside the patient's geographic area.

Haystack supports CMS' telehealth-related proposals to:

- Add codes to the permanent list of Medicare telehealth services for group psychotherapy, domiciliary, rest Home, or custodial care services (established patients), home visits (established patients), cognitive assessment and care planning services, visit complexity inherent to certain office/outpatient evaluation and management services, prolonged services, and psychological and neuropsychological testing.
- Permanently allow physicians to use telehealth to supervise rural non-physician providers;
- Extend the temporary policy of allowing practitioners to satisfy direct supervision requirements virtually using real-time, interactive audio and video technology until the later of the end of the calendar year in which the PHE ends or December 31, 2021;



- Implement sufficient add-on coding and payment mechanisms to enable participation of ASL or tactile sign interpreters in telemedicine visits; and
- Ensure that the geographic and site of service flexibilities for telehealth service originating sites continues at least through 2021.

Haystack appreciates that CMS is considering additional services for permanent inclusion on the list of Medicare telehealth services. We also agree that abruptly ceasing payment for temporary telehealth services upon resolution of the PHE could disrupt patient care and provider practices. Haystack urges CMS to retain all temporary telehealth services through the end of the calendar year in which the PHE ends, regardless of the Agency's intention to consider a specific service for permanent inclusion on the list of telehealth services.

Several Haystack member organizations have reached out to patients with a survey assessing the patient experience with telehealth services during the PHE. The majority of patients responding to the survey were able to access telehealth with relative ease and felt that the telehealth service flexibilities helped protect them from COVID-19 exposure. For individuals with rare conditions, the increased ease in accessing specialist care underscores the need to continue many of these flexibilities permanently. For example, one patient noted the care they have received through telehealth during the PHE:

Medication changes, local tests were ordered, met with neurosurgeon to determine surgery is needed. We live in Alaska and frequently have to fly to Seattle for care. We have been able to visit with specialists via telehealth and it's saved us considerable money and provided us with additional opportunities to see experts regarding care.

While many patients noted that they found it easier to access a specialist through telehealth, only 8% of surveyed patients stated that they were satisfied with their ability to receive injectable medications within the home setting. Respondents appeared to view telehealth as vital through the PHE, and useful as an adjunct to in-person care thereafter, and many expressed concerns that the ability to receive remote care from out-of-state providers could be restricted once again after the PHE resolves.

Haystack has also heard from patients and caregivers regarding the barriers individuals with hearing and/or visual impairments face in seeking care that enables compliance with social distancing protocols. Usher Syndrome, for example, is a very rare (approximately 25,000 US patients) inherited disease causing combined hearing loss and vision loss from retinitis pigmentosa. For these patients, it is essential that remote care includes access to an American



Sign Language (ASL) interpreter if they have sufficient remaining vision, or a tactile sign interpreter if they do not. We urge CMS to consider incorporating sufficient add-on codes to telemedicine options, on a permanent basis, to enable services of an ASL or tactile sign interpreter.

We urge CMS to engage the rare and ultra-rare disease community and examine Medicare claims data to ascertain the extent to which patients have relied on the telehealth PHE-related flexibilities, the impact on their care, and potential for refinements to improve the patient experience.

***Haystack appreciates CMS' PHE-related flexibility enabling patients to receive in-home administration of Part B medications and urges the Agency to ensure that patients have access through the end of the year in which the PHE ends without increased out-of-pocket costs.***

Haystack applauds CMS for helping patients with rare conditions requiring Part B medications avoid the impossible choice between the high risk of COVID-19 exposure within a provider setting and the known, potentially catastrophic consequences of delaying or stopping the treatments they need to avoid disease progression or worsening symptoms. When CMS implemented its thoughtful approach to making in-home administration of Part B treatments available for Medicare beneficiaries, Haystack had hoped that providers, suppliers, and practitioners would meet CMS' unprecedented set of program flexibilities by adapting their practices and business arrangements to the social-distancing realities of this PHE.

Unfortunately, many patients are finding it difficult to access in-home administration of Part B drugs at all, and others are only able to receive their treatment in their home through the home health pathway. Haystack has significant concerns that as we enter a new plan year for Part D, patients relying on home health agencies for in-home Part B drug administration will encounter significant out-of-pocket expenditures. We are concerned that the choice between stopping treatment or risking COVID-19 disease exposure could be replaced by the similarly difficult choice between a home infusion associated with a very high, immediate out-of-pocket cost, risking exposure to the virus in a clinic or infusion center setting, or foregoing treatment.

We have heard from stakeholders expressing the belief that the PHE presents a short-lived inconvenience and a marginal risk to patients. Although there are ongoing discussions about "re-opening" the nation, individual states, or regions to varying degrees, we are concerned the danger of COVID-19 exposure will remain a significant concern for immune-compromised and other vulnerable patients. Individuals diagnosed with rare and ultra-rare diseases and rare cancers are frequently immune-compromised due to either the nature of their disease or the treatments they require. While the PHE has certainly added to the dangers associated with



exposure to infectious diseases, our patients live with the daily reality that any health care encounter could expose them to a disease they are unable to fight.

We urge CMS to recognize that for Medicare beneficiaries generally, the need for a home infusion option could, and probably should, extend beyond the point at which the general public starts to move toward “normalcy.” Immune-compromised rare disease patients would benefit from a permanent flexibility that offers the peace-of-mind of being able to access care in the setting that offers the lowest risk of exposure to infectious diseases ordinarily present in the general population beyond the PHE. Haystack expects that CMS assurances to clinicians regarding the duration of this flexibility could encourage clinicians to make arrangements within their practices to accommodate patients who feel safer with in-home medication administration.

We urge CMS to:

- Explicitly expand the duration of this flexibility to the end of the calendar year in which the PHE has resolved and consider permanent adoption of the telehealth flexibilities enabling this care setting for in-home Part B drug administration incident to a physician’s service (particularly for immune-compromised individuals);
- Implement sufficient add-on coding and payment mechanisms to enable participation of ASL or tactile sign interpreters in telemedicine visits; and
- Temporarily permit beneficiaries receiving Part B drugs through their Part D plan to seek copayment assistance directly from the manufacturer until the catastrophic benefit is reached, without raising concerns about fraud and abuse violations.

**Haystack supports CMS’ proposal to delay MVP implementation and urges the Agency to refine its QPP to reflect high-value care for individuals with rare disorders and rare cancers.**

Haystack appreciates CMS’ interest in ensuring that the Quality Payment Program drives transformation toward patient-centered care and improved health outcomes. While the Quality Payment Program does not explicitly accommodate the unique care needs of individuals with rare diseases, the underlying policies have a clear potential to shift incentives and impact providers treating rare disease patients. Haystack believes that CMS’ proposed MIPS Value Pathways (MVP) initiative could favor adherence to commonly-held principles for addressing common conditions at the expense of the complex care needs of Medicare patients with rare diseases and rare cancers. We, therefore, support CMS’ proposed delay in implementing the MVP initiative.



Despite dramatically increased availability of novel treatment options, many Medicare beneficiaries with rare diseases and rare cancers still face hurdles accessing lifesaving and life improving FDA-approved therapies. As Medicare's QPP becomes an increasing factor in provider decisions on which patients to treat and how to treat them, we fear that the framework of winners and losers will create risks and uncertainties for clinicians encountering patients with extremely rare conditions in the near-term, and exact a chilling effect on innovation in the long-term. We urge CMS to continue its stakeholder engagement and approach MVP implementation with a goal of devising a flexible framework of value-based incentives that can be adapted to evolving standards of care for all patients, including those with extremely rare disorders and rare cancers.

We urge CMS to improve the QPP and reduce the potential for unintended consequences for patients with very rare diseases and rare cancers. Haystack acknowledges that, from an operational standpoint, the program's shortcomings in addressing very rare disorders and rare cancers may not impact its overall functionality in addressing quality care for the most commonly-encountered conditions in the Medicare population. We also understand that it is infeasible to create measures reflecting care for each rare condition or even related subsets of conditions as the measures would fail to meet both the benchmark and case requirement thresholds. We suggest that CMS develop alternative means to reward clinicians treating patients with extremely rare disorders and rare cancers by including practice improvement and advancing care information measures specific to these conditions, either as distinct measures or within an MVP. This might include incentivizing use of disease-specific patient registries, inclusion of communications regarding clinical trial participation within care planning, and use of FDA-approved therapies when one exists, or standard of care treatment with off-label products in the absence of an FDA-approved treatment. A set of quality measures reflecting the main components of quality care for people with rare disorders and rare cancers would include:

- Recognition/identification of patients at risk for the disease;
- Starting the appropriate evaluation;
- Making the appropriate diagnosis;
- Starting the appropriate treatment;
- Scheduling the appropriate follow-up to assess response to treatment;
- Ensuring appropriate compliance/adherence to treatment.

Finally, Haystack urges CMS to consider the unique needs of patients with rare disease and rare cancers as it transitions toward a system of MVPs. Specifically, we request that CMS not disproportionately remove measures related to care for individuals with rare diseases and rare cancers from MIPS due to an inability to link quality measures with cost measures or a preference for population-level measures.



**Haystack supports CMS proposal to enhance the Complex Patient Bonus by increasing its value from 5 points to 10 points for Performance Year 2020, and urges CMS to continue this bonus until measures are developed to capture quality care for rare diseases and rare cancers.**

Haystack appreciates that CMS continues to recognize the need to ensure that clinicians are not penalized for treating Medicare’s sickest patients. We support CMS’ goals of protecting access to high-quality care for complex patients and avoiding unintended penalties under MIPS for clinicians treating a complex population. Haystack urges CMS to finalize its proposal to double the value of the complex patient bonus and to continue applying this bonus beyond the 2020 performance year.

Haystack believes that patients with rare disorders and rare cancers should be presumptively complex for purposes of calculating a clinician’s eligibility for the complex patient bonus. We ask that CMS monitor application and utility of the HCC in identifying patients with ultra-rare disorders as high complexity.

Finally, given that the complex patient bonus is a temporary policy to account for the lack of measures applicable to high-complexity patients, we strongly urge CMS to engage the patient community in developing system-wide quality measures, practice improvement activities, cost measures, and advancing care information activities that capture the clinical realities associated with caring for complex patients, including those with rare diseases and rare cancers.

## **Conclusion**

Once again, Haystack’s participating patient groups appreciate the opportunity to submit comments as CMS finalizes its update to the Physician Fee Schedule and Quality Payment Program. We look forward to working with the Agency as it continues to address the COVID-19 PHE and determines steps forward on telehealth and the QPP.

We look forward to a continuing dialogue to ensure that all patients are able to receive appropriate care, no matter how rare their disease or condition. If you have questions or need further information, please do not hesitate to contact Saira Sultan at 202-360-9985.

Sincerely,



