

June 26, 2020

The Honorable Lamar Alexander  
United States Senate  
Washington, DC 20510

Dear Chairman Alexander:

Haystack Project and the Rare Cancer Policy Coalition appreciate the opportunity to provide input on the White Paper on “Preparing for the Next Pandemic.” We agree that this exercise is critical for avoiding the disruptions to health care that our community has experienced during the COVID-19 emergency.

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 rare and ultra-rare patients. We strive to amplify the patient and caregiver voice in these 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 just to focus attention on reimbursement, access and value issues across the rare cancer community. Working within the Haystack Project enables RCPC participants and rare and ultra-rare patient advocates to leverage synergies and common goals to optimize advocacy in disease states where unmet need is high and treatment inadequacies can be catastrophic.

We have continually surveyed our members during the Public Health Emergency (PHE) and tried to bring attention to the issues disrupting care for rare and ultra-rare patients.

In particular, the surprise out-of-pocket (OOP) costs for patients requiring in-home injected or infused medications as their care has unexpectedly shifted from Medicare Part B to D has been problematic.

We commend the Administration’s recently published Interim Final Rules during the PHE that allow beneficiaries to receive injectable medicines in the home setting during the emergency period. The Administration’s pragmatic approach in relaxing regulations, devising mechanisms to provide needed

care in a home setting, and using enforcement discretion to protect providers responding to this emergency will undoubtedly save lives. However, the Administration's decision to open more than one channel through which beneficiaries can receive their medications at home needs some critical refinement to mitigate potential beneficiary financial consequences. **Specifically, we need to address the very real financial burden patients face when suddenly and unexpectedly they receive their medications under Part D when they had been receiving it under Part B prior to the PHE.** Part D OOP costs can be significantly higher, and in fact, Congress had been considering a bipartisan proposal to cap OOP costs in Part D prior to the PHE. Our efforts to address high OOP under Part D have been delayed during the PHE, but seniors face increasing economic hardships during this pandemic and need help now. **We would strongly encourage any efforts to reduce or mitigate high Part D OOP costs during this and future PHEs.** This could be done by:

- requiring coverage of clinician-administered medications under Part B even when the technicalities associated with the entity doing the administration or the site of care would shift it to Part D;
- looking at how Medigap policies could support their patients, given that they contracted to cover their Part B OOP costs and are finding that obligation lifted unexpectedly during this time;
- implementing a waiver of enforcement of the antikick back statute during the PHE such that manufacturers could support patients facing these unexpected OOP costs;

We would support these or some other pragmatic and immediate solutions that offer seniors and disabled beneficiaries relief during the PHE or until Congress enacts a cap.

Another critical area for our patients is access to specialists who are familiar with really rare diseases. This is already very difficult due to the small number of experts in the field who are located at major academic medical centers across the country which tend to be located in large, metropolitan cities. Travel to these centers and insurance coverage varies, leaving many patients without adequate or proper diagnosis or treatment plans. And this is certainly exacerbated during a PHE with social distancing concerns and overwhelmed facilities. Even if a specialist is available, it is likely that they will be outside the patient's network. Receiving inadequate treatment and/or improper diagnosis can have a long-term impact on an individuals' disease management and progression.

**We have long called for a uniform mechanism for providers to qualify for accepting Medicaid payments from other state programs.** Patients with conditions best addressed by sub-specialists should be able to obtain treatment without incurring additional costs. **If providers deem appropriate, Medicaid programs would have to allow telemedicine options for specialist care management, reducing patient disruption and likely reducing costs after initial face-to-face visits enabling a treatment plan.**

State and federal efforts to implement waivers for both telehealth and reaching outside of state boundaries have proven very helpful during the PHE. While there has been a lot of attention on the need to extend or make permanent the gains made in accessing care through telehealth for rural communities, we want to emphasize the critical need for access to clinicians with very specific expertise when patients face conditions so rare that there are only a few specialists in the country.

We strongly urge these changes be made permanent as these challenges will persist for our community. They are a critical lifeline between our patients and the extremely rare disease experts that are few and far between for each condition.

Once again, we thank you for the opportunity to think critically about what is needed in this and future public health emergencies. We look forward to discussing these issues in greater detail with your staff.

Sincerely,

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