



# HAYSTACK PROJECT

## The Voices of Rare & Ultra Rare

NOVEMBER RECAP / NEWSLETTER

NOV 2022

## SPEAKER SERIES

Save the Date! Our December Dec. 8/4pm ET Speaker will be Tim Mooney, Senior Counsel a at Bolder Advocacy. Tim will discuss non-profits and advocacy/lobbying limits, what constitutes lobbying and what doesn't and how to maximize your lobbying footprint within federal limits.

The call will be Thursday, December 8, at 4p EST. [REGISTER HERE](#) to join this session.

## LEGISLATIVE

### HEART Act/AA Pathway

This work group continues to actively engage key Hill offices as we head into year-end bolus of activity!

- We have some reassurance from Hill staff that HEART Act provisions will be included in Congress' end-of-year package.
- Haystack sent a letter to Congressional leaders emphasizing importance of Heart Act to rare patient experience at FDA.
- The work group continues to reiterate support for the Sens. Kaine/Collins Accelerated Approval Council, given that it answers Haystack's education/advocacy efforts on ensuring rare reviewers learn from other review divisions about applying the pathway consistently and transparently.
- However, we oppose OOPD being named to the Council in statute. We appreciate Sen. Kaine raising this with committee staff.

Haystack Project is incredibly grateful to Senators Kaine (AA Pathway Council), Scott and Casey (HEART Act) and Rep. Tonko for their engagement and support of Haystack's FDA-related efforts this year. It has been gratifying to see that Haystack's thoughtful and measured approach to policy on behalf of rare patients can be effective.

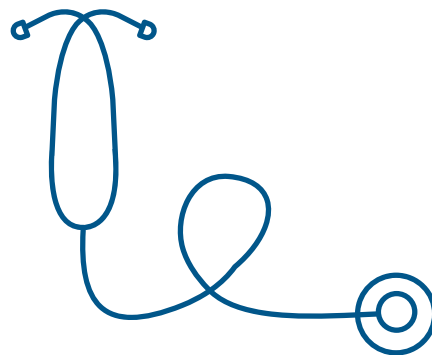
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# LEGISLATIVE CONTINUED

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## H.R.6160 WORK GROUP

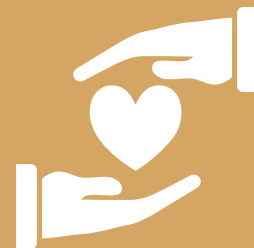


### Timely Virtual “Fly-In”

Workgroup members organized a virtual ‘Fly In’ with key Senators ahead of a new Congress. Patient groups tapped into their patients and caregivers to turn their stories into effective advocacy with Haystack’s help. Haystack will follow up on these meetings in early December and report back to the work group for next steps. We are hopeful these efforts will lead us to a Senate champion for legislation that would expand the definition of “medical necessity” for rare disease patients so that rare disease patients are on equal footing with others when it comes to insurance coverage.

Marc Yale shared that Senate staff comments suggested the ‘fly-in’ was timely given our goal of a 2023 introduction. Gillian Sapia discussed her work with their patients and other stakeholders to raise the profile of the bill and of Haystack generally. Dean Suhr proposed leveraging upcoming platforms to discuss the value of H.R. 6160.

## HP 50 WORK GROUP



The pilot envisioned by work group members officially launched in November with a webinar featuring two state lobbyists who shared their experiences and suggestions for state level advocacy. The webinar can be accessed [here](#). Brett Kopelan (DEBRA) and Michelle Davis (IFOPA) recommended a “glossary of terms” as a next step, while they identify patients and perspectives likely to resonate with state Medicaid agencies and related stakeholders. Haystack is working on engaging additional expertise to support the pilot.



# REGULATORY

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## MEDICARE ADVANTAGE

We hosted a lively discussion about ongoing/mounting policymaker concerns about the benefits and marketing practices of Medicare Advantage plans. We shared ways patient groups could educate their patients about MA plans, those likely to benefit vs. those that might want to consider traditional Medicare. We shared [the recent Senate Finance Committee report](#) calling for CMS to better regulate these plans.

## MEDICARE PROVIDER DIRECTORY

We shared and discussed a series of questions for patient group input based on our analysis of CMS' proposed National ProviderDirectory. Comments will be based on feedback to the questions and the discussion at our monthly call. Comments due December 6.

# REGULATORY CONTINUED

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## CAREGIVER SUPPORT COMMENTS

We discussed again the opportunity for input to HHS' National Caregiving Plan. Details at: <https://acl.gov/CaregiverStrategy/Comments> by November 30. We recommended groups consider commenting about their own experiences.

## ICD-10 EDUCATION

Patient groups discussed their concern that certain stakeholders continue to encourage individual ICD-10 codes for every rare disease, without regard for individual patient circumstances, nuances, and downstream consequences. Haystack resources are posted online so patient groups can confidently share them with other groups and spread the word that ICD-10 codes may not be right for every rare disease. Webinar [here](#) and memo summarizing expert speaker [here](#).



*Please pay your 2022 dues today and help us reach our  
100% participation goal!  
THANK YOU to those who have already done so!*

# HOUSEKEEPING

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Please be sure to pay your 2022 dues at [haystackproject.org/join](https://haystackproject.org/join)

Participate in our [Giving Tuesday](#) Day effort.

Join us on social media – [Linkedin](#) [Facebook](#) and [Twitter](#)

Our friends at VHL are looking for a new ED. Check out their [LinkedIn Post](#)

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## THANK YOU TO THE SPONSORS

*Please check the website for the growing list of Haystack sponsors, whose support allows us to do what we do!*



Haystack Project is grateful to all of our Alliance Partners for lending their insights and perspectives, as well as for combining their efforts with ours to better serve the rare and ultra-rare communities.

All Copays Count Coalition



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