

# HAYSTACK PROJECT

## The Voices of Rare & Ultra Rare

APRIL NEWSLETTER

APRIL 2022

## HOUSEKEEPING

### 1. Please pay 2022 dues today!

Thank you to the 100 patient groups that have already done so. Help us reach our 100% participation goal!

[Pay dues](#)

### 2. Did you see a doctor/rare disease expert across state lines w/o the usual hassles during Covid? Via telehealth? Did you pay more for at-home infusions during Covid? Ask your patients to take this survey! We will share the Rare Experience with Congress!

[Take Survey](#)

## WORKGROUPS

Workgroup Meetings start in May! Email us with your choice of workgroup and dive into a topic you care about....

[Email Us](#)

### Work Groups Kicking Off:

- **FDA & Rare** (HEART Act & AA Pathway) meets second Mondays 3-4pm ET
- **Medical Necessity & RARE** (HR 6160) meets first Wednesdays 4:30pm ET
- **HP50** (State Work) - meets third Tuesdays 3pm ET
- **"First Look"** – meets third Wednesdays at 12pm ET

### Work Groups Still in Need of Interest:

- **Testing**
- **Bundled Payments**



## LEGISLATIVE UPDATE

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Discussion this month centered around:

- 1) HEART Act Progress. Help us build support for H.R. 6888 and S. 4071!

Send [THIS LINK](#) to your patients to build grassroots support! **Let's help Sens. Casey and Scott and Reps. Tonko and McKinley** get it passed this year!

Read Politico coverage [HERE](#).

- 2) Accelerated Approval Pathway “reforms” – Haystack is actively educating Congress about what FDA can do to improve transparency, consistency, defensibility of the AA Pathway. “Reforms” should not be limited to what sponsors can do with respect to confirmatory trials. We discussed patient experiences, groups involved with Hill meetings with Haystack, and more. We also reviewed and provided comments on House bills and Senate drafts. [Read more.](#)
- 3) Access to Rare Indications Act (HR 6160) – we still need a Senate bill. Changing the definition of “medically necessary” care will help all our rare patients access treatments not on label. Please join the work group (see above) to pitch in on this effort!
- 4) Build Back Better – we discussed dynamics, progress, etc.

## CMS UPDATE

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CMS’ annual season of reimbursement proposals is upon us once again.

We discussed CMS’ INPATIENT proposal. Of note, CMS calls out an issue Haystack has been educating the agency about for 2+ years. CMS asks for comments on how bundled payments based on “averaging” patient conditions/costs do not work for rare and especially ultra-rare patients. Previous comments to CMS on this issue are on Haystack’s website.

Draft Haystack letter to CMS coming for your review in early June!

# MISCELLANEOUS



## ICER PUBLISHED A WHITE PAPER ON RARE DISEASES

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[Read Paper](#)

We discussed a number of concerns with the ICER report, including:

The paper's focus on drug development incentives and pathways fails to acknowledge the obvious: assurance of insurance coverage is a critical incentive for drug development.

The coverage/reimbursement-related recommendations are disingenuous at best, as they would most certainly be a **DISINCENTIVE** for rare and ultra-rare drug development.

FDA's lack of consistency in reviewing rare applications and use of the AA pathway continue to be a deterrent to investments in rare.

With so few of the 7,000+ rare diseases having any approved treatments, it is hard to support ICER's assertion that there is "too much" investment in rare diseases.



**Beth Roberts, Partner, Hogan Lovells**  
headlined our April Speaker Series  
on the topic of ICD 10 codes

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She reminded us of the primary purpose of ICD 10 codes: to aid in the processing of insurance claims.

An engaged and lively discussion, with lots of follow up emails and more!

**We will re-run the session on May 5 @ 11am ET if there is sufficient interest.**

There will be a discussion summary (not the recording) posted on our website after May 5th.

[Register](#)



## ADMINISTRATIVE ASSISTANT NEEDED

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For a complete list of current responsibilities, please visit the job posting below.

Please submit resumes to  
[Haystack1@HaystackProejct.org](mailto:Haystack1@HaystackProejct.org)

[Email Us](#)

THANK YOU TO OUR SPONSORS

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

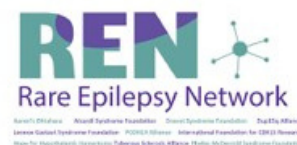


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Haystack Project is grateful to all of our Alliance Partners for lending their insights and perspectives, as well as for combining their efforts with ours to better serve the rare and ultra-rare communities.

All Copays Count Coalition



# SHOW YOUR SUPPORT!

