

HAYSTACK PROJECT

The Voices of Rare & Ultra Rare

OCTOBER RECAP / NEWSLETTER

OCT 2022

SPEAKER SERIES

In October we will have TWO speaker sessions!

On November 3, 2022, at 4 pm ET, Aimee Diaz Lyon and Brian Henderson will discuss *when* to educate state Medicaid agencies about your rare disease, *how* to engage them, *what* information to share, *what* parts of the process patients can participate in, and more. [REGISTER HERE](#) to join this session.

On November 10, 2022, at 4 pm ET, Dr. Stephen Kingsmore MD, DSc, will join us to talk about the role of genetics in rare and ultra-rare diseases. [REGISTER HERE](#) to join this session.

Who would you like to see Haystack host on our next Speaker Series? Send your suggestions [HERE!](#)

LEGISLATIVE-SPECIFIC WORK GROUPS

HEART ACT



led by Kara Berasi, CDG Cares and Dottie Caplan, Applied Therapeutics
Meets second Mondays at 3pm ET

Want to tell your Congressperson/Senator to support the Senate HEART language in the End-of-Year Legislation expected to become law?

We will send you the language and the staff person to email. Just ask us, personalize it, and hit SEND!

We are organizing Virtual Fly-In Week of Nov 14!

Are your patients tired of hassling with insurance to get 'medically necessary' care paid for? [Email Kara B.](#) for details on the virtual meetings your patients can attend.

HR6160

led by Marc Yale, IPPF
Meets first Wednesdays at 4:30pm ET



OCTOBER RECAP / NEWSLETTER

OCT 2022

WORKGROUPS

Come join a Work Group!

Remember, Work Groups are Multi-Stakeholder, so companies, physician groups, and patients are all welcome!

HP50 PILOT



led by Dean Suhr, MLD Foundation
Meets second Tuesdays @ 3pm ET

Do you have a treatment pending approval in the next 6 months?

Are you worried about Medicaid won't pay for it when it's approved?

Sign up for the pilot Haystack is kicking off to help patient groups navigate this process on behalf of your patients...[Email us](#) to learn more!

Is it getting harder to get insurance to pay for treatments?

Are you interested in the newly forming Rare Cancer Work Group?

[Email us here](#)

RARE CANCER

Now forming!



Does your condition have a 'tell tale' sign, lab value, etc. that, if only doctors noticed and understood sooner, could hasten diagnosis with some confirmatory testing?

[Email us here](#) and learn more about Haystack's project to create an incentive for doctor participation...

FIRST LOOK



Now forming!



REGULATORY

Medicare Open Enrollment

Thanks for your input on Medicaid Enrollment. Comment letter coming soon for you to consider signing on.

Medicare RFI

We discussed and approved this letter to CMS, and you received an email with the text. Should be on our website in the next two weeks.

National Provider Directory

We discussed CMS proposal to create a national directory and the implications for rare. Please look out for an opportunity to provide your input and help us capture your concerns ...

CED

We reviewed Haystack's comments to AHRQ to protect patients during a CED clinical trial; we'll review and revisit with MedCAC next, as they are also asking about clinical trial requirements. We'll submit similar comments without sign-on per our discussion, attend their Dec. 7 meeting, and report back at the next monthly Haystack meeting.

CMS Pilots and Demos

CMS recently announced 14 of their demos/pilots showed savings to the Medicare program. But did they show better patient outcomes? Before CMS looks to scale these programs nation-wide, Haystack Project will examine them for impact to rare. We'll discuss at our Nov. monthly call....

Drug Prices

The President has asked CMS to find additional ways to reduce drug prices. A report is expected in 90 days. Haystack will monitor and analyze any impact for our rare community! We'll present in January ...



REGULATORY CONTINUED

MEDICARE OPEN ENROLLMENT IS HERE...

Medicare Open Enrollment runs Oct. 15-Dec. 7

About 50% of all Medicare beneficiaries are enrolled in Medicare Advantage (MA) plans. We discussed two studies/findings about Medicare Advantage Plans:

- Seniors largely pick MA plans because of the perks, but would choose traditional Medicare if they looked at the choice in providers;
- MA plans have higher rates of inappropriate prior authorizations;

For rare disease patients, choice of doctors/a larger network of doctors and specialists is critical and prior authorization hassles are already a nightmare. Help your patients make good choices during open enrollment!

FDA

While Haystack is largely not active in FDA issues without 'reimbursement' or 'access' implications, we noted the following opportunities for patient groups to engage with FDA:

- A new [Rare Disease Endpoint Advancement Pilot Program](#) to support novel efficacy endpoint development for drugs that treat rare diseases;
- A [Real World Evidence Program](#) that seeks to improve the quality and acceptability of RWE-based approaches to labeling claims;

HOUSEKEEPING

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

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



AMERICAN
BRAIN
COALITION

