

# HAYSTACK PROJECT

## The Voices of Rare & Ultra Rare

SEPTEMBER RECAP

SEPTEMBER 2023

**DUES, DUES, DUES!** Pay your 2023 dues [here](#). Please help us keep up all the good work you've come to count on us for!

## STATE ADVOCACY

**AUGUST** was a great time for the groups to undertake a “planning session” about their need/interest in state-level advocacy, and how Haystack might support them. The ‘experiment’ started with Haystack’s “HP50” Work Group, and the planning session made clear that the appetite for more is urgent.

**OCTOBER** will bring patients and companies together to hear from Matt Salo, who recently retired from the National Association of State Medicaid Directors (NAMD). He'll discuss the gaps and opportunities in state-level advocacy in the rare community.

**[REGISTER HERE!](#)**

**NOVEMBER** will allow Haystack to consider specific goals, resource needs, and an implementation timeline to serve our patients. goals, resource needs, and an implementation timeline to serve our patients.

**SEPTEMBER 28** Haystack Project will host a call with companies to discuss rare disease patient advocacy at the state level.

**[RSVP HERE!](#)**

## REGULATORY

Haystack's September meeting focused almost entirely on the CMS draft guidance on the Medicare Prescription Payment Plan (used to be known as 'smoothing'), allowing patients to opt into a program to spread their Rx costs over a plan year.

Groups had very specific feedback that Haystack incorporated into the comment letter, which can be found [here](#). Groups appreciated the burden the program could place on plans, pharmacies, etc., but urged CMS to roll out the program in ways that would reduce confusion and enhance access to the program.

In the letter, Haystack Project asked CMS to:

- Implement an interactive online tool for patients to understand and calculate monthly costs;
- Spread costs over 12 months rather than a plan year, to reduce the likelihood of patients delaying care until the next plan year;
- Smooth unpaid amounts;
- Give advance warning of upcoming payments;
- Require uniform, simple, and easy-to-locate forms, notices, and all other communication at the pharmacy and plan level;
- Work with groups like Haystack Project to aid in developing materials, including examples that reflect the ultra-rare experiences;
- Ensure a POS option for opting in from Year 1;
- Allow same-day participation in Year 1;

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## LEGISLATION

Following up on last month's extensive discussion on the role of PBMs and the impact on patient costs and care – legislation moving through Congress includes

- **ban on spread pricing in Medicaid**
- **requirement that PBMs provide employers with detailed data on drug spending, out-of-pocket spending, formulary placement rationale and aggregate rebate information**
- **removal of gag clauses employed by PBMs**

## HAYSTACK LEGISLATION

Even as we were implementing the HEART Act, the Galactosemia Foundation alerted Haystack about the lack of engagement they were facing with the FDA. Another “poster child” for the Heart Act. Haystack worked with the Foundation's leadership and patients to help them share their experience in ways that would be most impactful with Hill offices. Haystack scheduled and participated with them in 40+ Hill meetings helped draft/edit their follow-up messages, and more. As a result, over a dozen Hill offices reached out to the FDA, making sure the FDA knows Congress is watching and is not happy about what's happening yet again with a rare disease group. Heart Act leaders are pushing the agency to course correct here! REMINDER: PLS LET US KNOW ABOUT YOUR FDA ENGAGEMENT EXPERIENCES (GOOD AND BAD....)



**PROTECT RARE ACT**  
Providing Realistic Opportunity To Equal and Comparable Treatment for Rare



### PROTECT Act (previously the Access to Rare Indications)

**Name Change!** Providing Realistic Opportunity to Equal and Comparable Treatments for Rare or PROTECT RARE is the new name for the last Access to Rare Indications Act. In this new Congress, the House bill will be introduced by Rep. Dunn (R-FL) on the Energy and Commerce Committee, along with previous leaders, Rep. Matsui (D-CA), Kelly (R-PA), and Thompson(D-CA) to introduce Haystack's bill!!!

### Patient Group “TO DO” List on PROTECT Rare focused on:

- Sign On** letter thanking Reps Dunn, Matsui, Thompson, and Kelly.
- These Representatives will list your group in their press release if you sign onto the letter in (a)...
- Bill text** to use with your own meetings with Representatives asking they cosponsor.
- Ask other coalitions you belong to sign on to the letter in (a):
- One-pager** targeting Rare Disease Week to gain cosponsors and other fly-in events
- Groups highlighted prior criticizing this bill at PAC events they are invited to attend.



**SENATE UPDATE:** A bipartisan group of Finance Committee members is awaiting CMS feedback before introduction. We've made progress in identifying the Finance

## MANAGED CARE

Haystack member groups have long discussed concerns about narrow networks, aggressive prior authorization processes and limited access to Medicare Advantage plans. Now the HHS Office of Inspector General is reporting Medicaid managed care plan prior authorization denial rates are more than double the already controversial rates in Medicare Advantage.

This is even more concerning when you consider patients cannot always choose a “traditional” fee-for-service plan in Medicaid (unlike in Medicare) and that state Medicaid agencies conduct very limited oversight of the PA denials.

Haystack’s upcoming monthly speakers include Matt Salo, formerly of NAMD, and Michael Bagel of ACHP. We look forward to raising these issues and learning more about how ultra-rare disease patients can play a productive role in these issues.

## STUDIES

### GAO

GAO recommends CMS track implications of rebates on Medicare beneficiaries

<https://www.gao.gov/assets/gao-23-105270.pdf>

(prefer here) The September 2023 study on Medicare Part D drugs revealed patients pay 4x more for their Rx than the plans who insure them! The study delved into the impact of rebates, which reduce the cost of drugs for health plans while patient's share of OOP costs is based on the “list price” that does not recognize the rebates negotiated by third parties. Worse, these rebates impact formulary placement and patient access to treatments. Haystack’s groups have previously discussed that patients often believe that some ‘learned intermediary’ is behind the decisions that land some drugs on formulary over others, require prior authorization or step therapy of some drugs versus others, etc. They are concerned their patients have no understanding that these decisions are driven by rebate calculations rather than clinical benefit and safety.

### OIG

HHS OIG will investigate Medicare Advantage (MA) and Medicaid managed care contracts, citing that over 50% of Medicare beneficiaries are enrolled in an MA plan and nearly 80% of Medicaid beneficiaries have received at least one component of their care through an MCO. The OIG is interested in ensuring payments to these managed care plans are accurate and that the plans work as intended for patients. OIG will begin its work at the initial stage of contracting, and then investigate plan design, service areas, enrollment, payments to plans and providers, quality of the services provided to patients, network adequacy, long wait times, prior authorization processes, coverage determinations, use of non-traditional benefits, and more.



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## Q4 2023 SPEAKER SERIES

Find our September speaker webinar [here](#).



On **October 17, 2023, at 1 p.m. ET**, Matt Salo will discuss gaps in state-level patient engagement and how Haystack Project and its 140+ participating patient groups can work together to effectively address them.

[REGISTER HERE!](#)



On **November 21, 2023, at 1 p.m. ET**, Michael Bagel and Nissa Shaffi will discuss Medicare Advantage and Medicaid managed care plans – their evolution and policy priorities.

[REGISTER HERE!](#)

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

## WORK GROUPS

Updates were provided on the several work groups underway, including:

**PROTECT Rare/Access to Rare Indications** – This workgroup announced the upcoming introduction of the newly named PROTECT Rare Act in the House.

**First Look Project** – This workgroup is focused on phenotypes/"tell-tale signs" of rare diseases.

**HP50** – This workgroup has a pilot underway to improve advocacy at state Medicaid departments – three states and two patient groups with recent/near approvals.

**Do you have these on your calendar?**

Please email Tiara Logan at [tiara.logan@haystackproject.org](mailto:tiara.logan@haystackproject.org).



## HOUSEKEEPING

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Do you have calendar invitations for our standing monthly calls?

**3rd Tuesdays 1-2 pm ET** - Speaker Series – Invite includes required registration link.

**3rd Wednesdays 1-2 pm ET** - Member calls with patient groups

Follow us on social media – [LinkedIn](#), [Facebook](#), and [Twitter](#).

Any questions, contact [Tiara.Logan@haystackproject.org](mailto:Tiara.Logan@haystackproject.org)

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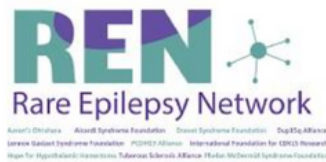
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AMERICAN  
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ALLIANCE for  
CONNECTED CARE

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.