



Haystack Advocacy Empowerment Initiative (AEI)  
Speaker Series  
February 10, 2022

**Speaker:** Sarah Shapiro, Legislative Director, Rep. Swalwell  
Precision Medicine for Kids Act

Sarah spoke at Haystack Project's February Speaker Series meeting about her Congressman's legislation on precision medicine.

**Background:** Sarah discussed The Precision Medicine for Kids Act (HR 5989). She explained the legislation is the culmination of several compromises. Initially, there were competing bills that covered some but not all kinds of tests. And bills that covered all tests were too expensive. Eventually, a compromise was reached and a new bill uniting differing interests was introduced by Rep. Swalwell.

**The bill** would:

- Direct CMS to issue guidance to states to increase frequency of coverage for genetic and genomic testing diagnostic services
  - ▶ Medicaid programs already have authority to cover and pay for genetic and genomic testing diagnostic services, including whole exome sequencing, whole genome sequencing, and gene panels, but claim that cost is prohibitive
- Require a three year HHS demonstration project
  - ▶ Up to 15 states to test and evaluate the provision of medical assistance for purposes of providing such individuals with genetic and genomic testing.
  - ▶ CMS will choose the 15 states
- Require a study on how genetic and genomics testing may:
  - ▶ improve preventative care and precision medicine;

- ▶ be used to reduce health disparities in marginalized communities;
- ▶ improve health outcomes for all pediatric populations in the US

### **Discussion:**

Sarah talked about Rep. Swalwell's interest in rare diseases, cofounding the Precision Medicine Caucus in 2019 with Rep. Emmer. His office has been working on this legislation since that time. She noted her boss' specific interest in eliminating barriers to health professionals for people with genetic & genomic diseases, something Haystack Project has focused on for quite some time. Sarah also noted that approximately 80% of rare diseases are genetic and 70% are childhood diseases.

We discussed the problem with Medicaid programs being so diverse, not only one in each of 50 states, but numerous Medicaid managed care plans *within* each state as well, all with different rule. Sarah noted there is no uniform reporting from the states to CMS in Washington, DC. Even the most basic facts about which plans in which states cover which tests is not reported. Her bill calls for even more detailed reporting to learn how such testing is helping reduce disparities and improve health outcomes.

One patient group asked about which tests would be covered under the legislation and whether it would address an issue she's seen repeatedly crop up in her state where the test comes back inconclusive and requires re-testing. Sarah explained her bill would cover all manner of testing, leaving it to the individual doctor and patient to decide what is best for them. This is, in fact, why the bill had to be narrowed initially to a three year pilot to contain costs. Another patient group jumped in to note that when tests have to be re-done, it is likely time for the patient to ask their doctor to possibly recommend a different test.

We also discussed which states would be chosen for the pilot, since it is already so difficult for rare disease patients to travel for their care. Sarah noted a 15 state pilot was not their first choice, and said she expected CMS to pick the states through a grant/application process once the bill passes. Her hope is the study will show earlier diagnosis will lead to earlier treatment and reduced health care costs. This will then let them come back and expand the pilot to more states or scale the program nationwide.

Sarah also clarified if a person lives in a state that already provides coverage, this will not disrupt that coverage.

### **2022 Congressional Calendar**

Sarah explained that although it's only February, there are not a lot of "legislative days" left in the year. Although a lot of work will continue in the various committees in Congress, the number of days for Senators and Representatives to vote on matters is limited. March and April, Sarah said, will be dedicated largely to Appropriations (the process why which Congress keeps the Federal government open and funded) and then Members typically leave for campaigning and elections by mid/late July.

### **Next Steps**

After Sarah signed off, Haystack members had a robust discussion about various nuances of different kinds of testing, the lack of a standard of care in testing, which tests are needed for kids, which tests are more appropriate for diseases that present later in life, etc. We also discussed the importance of Haystack continuing to learn and grow in the diagnostics space, the intersection with newborn screening, and finally, which conditions can be identified without screening and testing.

**Haystack Request:** Do you know of any conditions that can be identified with a simple exam at birth? i.e., the head is larger than the body, a bilateral deformity of the big toe, others?