Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
of
Subcommittee on Health Ranking Member Anna Eshoo

Health Subcommittee Hearing on "Innovation Saves Lives: Evaluating Medicare Coverage Pathways for Innovative Drugs, Medical Devices, and Technology"

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The New York Times Magazine last month declared the following: "It looks like we're in a golden age for medicine." Thanks to breakthroughs in mapping the human genome, advancing mRNA technology, and creating multicancer blood tests and other new diagnostics, we're on the cusp of seeing life-saving innovations for some of the most intractable diseases.

This potential golden age is why I worked so hard with all of the members of this Subcommittee to create the Advanced Research Projects Agency for Health (ARPA-H), which we got over the finish line last year, and that is designed to accelerate research and development to bring more cures to really the most intractable diseases, those diseases that when someone is diagnosed is essentially a death sentence.

However, the R&D pipeline doesn't end with a successful clinical trial or FDA approval. To bring cures from the benchtop to the bedside, patients need Medicare to cover new drugs and devices.

But the Medicare coverage determination process can be lengthy. According to the Stanford Byers Center for Biodesign, nationwide Medicare coverage for breakthrough medical technologies can take on average 4 to 6 years following FDA authorization.

Medicare has tried to speed up coverage decisions through a pathway called "Coverage with Evidence Development" or CED. A CED allows for Medicare to cover a new drug or device more quickly while still collecting information about whether the new drug or device is reasonable and necessary for Medicare beneficiaries.

In theory, a CED sounds like a reasonable compromise. Medicare beneficiaries get timely access to new breakthroughs, while the Medicare program receives more information about how the treatments work in the real world.

In practice, however, there has been a wide variability in the implementation of a CED. Some therapies in a CED have had no data collection mechanisms. That means no one could actually receive coverage for the treatment. So that's a bust in plain English. Other therapies have had registries to collect the patient data, but they were too costly or burdensome for the doctors, leading to inequities in coverage.

This unpredictability in CED requirements is partly why there was such a huge outcry over CMS announcing that it would require a CED for new Alzheimer's treatments. Patients weren't sure how they were going to get the care they need.

It is also unclear when a CED requirement will end. Out of the 26 treatments that have CEDs, only 4 have had their data collection requirements retired.

For the CED process to be successful, CMS needs to issue clear policy and provide more predictable timelines.

CMS will also need resources and expert staff to make coverage decisions. That's why I was really horrified to see that the House Republicans released last week a draft FY24 LHHS appropriations bill that cuts nearly $800 million from CMS. $800 million. That's a whopping amount of money that provides resources for what is necessary. These cuts are going to hurt seniors by making them face longer wait time for Medicare.

Industry can do its part by planning earlier for how to provide the evidence Medicare needs for coverage. More diverse clinical trials will help speed up CMS coverage decisions. That's why my DEPICT Act that passed last year required drug and device makers to plan to include more diverse populations in their pivotal clinical trials.

With over 65 million Americans enrolled in Medicare, every coverage decision is fraught. Medicare beneficiaries deserve access to safe, effective, and affordable treatments.

I look forward to hearing from our witnesses today, you are a panel of experts, on how Medicare can better achieve that balance that I have hopefully drawn out where the kinks are and how we can do much better for them. They are counting on us to make sure this really does take place.

Thank you and I yield back.