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Accelerating Innovation in Medicine (AIM) Act

Cutting the red tape between Medicare beneficiaries and cutting edge medical products

Background

Under the current structure for making coverage decisions, the Centers for Medicare and Medicaid Services (CMS) evaluates products approved by the Food and Drug Administration (FDA) based on clinical evidence and comparative effectiveness to other products that are already covered by CMS. Because it can be difficult to compile adequate clinical evidence at the time that the product is initially approved or cleared by the FDA, cutting edge medical technologies are often subject to limited coverage or inadequate reimbursement under Medicare. As a result, manufacturers sometimes choose not to make these products or procedures available in the United States, and instead offer these technologies in foreign countries, where regulation allows for patients to access these medical innovations. If these products are produced in the United States, self-paying beneficiaries often face discouraging bureaucracy, time delays, and uncertainty.

The Solution

The AIM Act seeks to address this problem by providing an option for medical device manufacturers to "opt-out" of the Medicare coverage determination process for at least three years. By opting out of this process, manufactures have time to obtain the necessary clinical evidence within the United States in order to support a stronger case for a future Medicare coverage decision. This change would reduce the obstacles Medicare beneficiaries currently face in trying to access these new technologies. It would also ensure that these patients are informed of the costs and allow them to self-pay before Medicare coverage is sought by the manufacturer. By allowing beneficiaries to have this option, clinical studies and data collection can take place and access to innovative technologies will be streamlined for patients in the United States.

Congressional Request

Cosponsor and pass the *Accelerating in Innovation (AIM) Act* (H.R.2597/ S.1757)
to ensure that patients have access to necessary medical products and procedures.