



H.R. 8816, *American Medical Innovation and Investment Act*

Rep. Buchanan (R-FL)

Background:

- Medicare coverage for **drugs** and **medical devices** is achieved through three distinct pathways—the National Coverage Determination (NCD) process, the more restrictive Coverage with Evidence Development (CED) pathway under the NCD process, and the more varied Local Coverage Determinations (LCD) process. Innovators applying for **Medicare coverage** seek transparency and efficiency as they navigate this process, but often are met with **opaque** and **slow bureaucracy in each of these pathways**.
 - NCD applicants often don't realize the application is incomplete or missing information until rejected, which can be months after waiting in limbo.
 - Only **four** CEDs have ever graduated to a full NCD, which means products receiving CEDs on a "class wide" basis, such as the **new drugs treating Alzheimer's disease**, have an uncertain fate for widespread coverage.
 - LCDs are not supposed to supersede an NCD or existing law, but often times are **even more restrictive**.
- New and innovative technologies are coming to market that have the potential to greatly **improve patient outcomes** and make health care more accessible and affordable, unfortunately, Medicare coverage is often delayed and unclear for patients seeking these products, including:
 - Dose delivery devices utilizing **artificial intelligence (AI)**.
 - **Prescription digital therapeutics (PDTs)**, which are FDA approved, software-based applications prescribed by a physician or other provider to treat a range of diseases.
 - Self-administered **home infusion pumps which** offer a convenient way for patients to receive certain infused therapies at home rather than at a hospital.
 - Access to medically tailored meals (MTM) that help **patients and seniors recover more quickly** from health procedures.
- Annual wellness visits in the Medicare program currently do not require a specific test for **cognitive impairment** evaluations, which can result in differing standards of care.

The American Medical Innovation and Investment Act:

- **Prohibits CEDs from lasting longer than 10 years** unless agreed upon by the applicant, guarantees a determination whether a request for a NCD is complete **within 90 days**, and **prohibits LCDs from being more restrictive** than existing NCDs.
- Requires Medicare to clarify and update coverage for AI-enabled dosing devices and PDTs.
- **Guarantees coverage of self-administered home infusion pumps.**
- Provides a **budget-neutral pilot program** for medically tailored meals for seniors.
- Requires cognitive impairment tests for Alzheimer's to be **conducted with up-to-date devices.**