



H.R. 5343, the *Ensuring Patient Access to Critical Breakthrough Products Act*

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Background:

- In 2016, the **21st Century Cures Act** created a new pathway for “*breakthrough*” medical devices to receive expedited Food and Drug Administration (FDA) approval.
- *Breakthrough* devices utilize **novel technology** to treat a condition that has no other approved alternatives or the devices’ technology provides a significant benefit above existing therapies.
- **Medicare coverage process** for these *breakthrough* devices after FDA approval remains a **barrier**.
 - Lag time between FDA approval and Medicare coverage is often called the “*valley of death*” for innovators. Devices can wait up to **5 years** for Medicare coverage determinations post FDA approval.
- In January 2021, the Trump Administration finalized the **Medicare Coverage of Innovative Technology (MCIT) rule** which created a pathway for *breakthrough* devices to receive **immediate Medicare coverage** through a transitional coverage period while awaiting a 4-year review process for permanent coverage.
 - In November 2021—just days before MCIT was set to take effect—the Biden Administration **repealed the rule** citing “operational challenges.”
 - In August 2024—**nearly 3 years later**—the Biden Administration released a lackluster replacement rule.
- *Examples of breakthrough medical devices:*
 - CytoSorbents’ DrugSorb-ATR system, which reduces bleeding complications during open heart surgeries.
 - Novocure’s Tumor Treating Fields technology, which utilizes electric fields to disrupt cancer cell division with high efficacy and minimal side effects.
 - Bluestar Genemics’s novel liquid-biopsy cancer diagnostic device, which screens newly diagnosed diabetes patients to diagnose possible pancreatic cancer.

The Ensuring Patient Access to Critical Breakthrough Products Act:

- Provides a clear pathway for immediate **4 years of transitional Medicare coverage** of breakthrough medical devices and requires CMS to make a **permanent coverage determination** by the end of the coverage period.
- This expedited coverage pathway will encourage **more innovative medical devices** to come to market and provide quicker treatments and cures for Medicare patients.