EDUCATIONAL BRIEFING

Real-world evidence, AI-enabled devices, and patient-generated data

Companion to the federal Policy Brief – written for congressional staff, with a technical appendix for federal implementers

July 31, 2026

Congressional staffer primer

Why this matters now

Your constituents already use AI-enabled health products. An app that flags an irregular heartbeat, a continuous glucose monitor that adjusts insulin, a tool that reads a scan. Unlike a pill or a pacemaker, these products change after they reach the market: software updates, AI models retrain. That creates a regulatory question the current system was not built to answer. How does the government know a product is still safe and effective six months after it gains market access?

Three terms worth knowing

- ✔ **Real-world evidence (RWE)** is proof about how a medical product performs in everyday use, drawn from real-world data (RWD). For years that data came from two places, the electronic health records your doctor keeps and the insurance claims your plan processes. Both are trusted because the federal government spent decades building the standards that make them reliable.

- ✔ **AI-enabled medical devices** are products that use software and machine learning to inform care. Their strength is that they can improve over time. Their risk is that they can also drift, meaning performance can quietly degrade or shift for certain groups of patients as the model or the population changes.
- ✔ **Patient-generated health data (PGHD)** is health data that comes from patients themselves, outside the clinic. Think wearables, home monitors, and connected apps. It is abundant, fast, and close to the patient. Today it is the least utilized of the major data sources for federal decisions, because the standards that make EHR and claims data trustworthy were never built for it. **In one FDA review of medical device decisions from 2020 to 2025, PGHD appeared in just 1 of 73 cases.**

> **The core problem**
>
> *We are regulating and paying for 21st-century products with a 20th-century evidence system.*

What the government is already doing

This is not a call to start from zero. FDA is piloting continuous, lifecycle-based oversight through programs like **TEMPO** and the **RAPID pathway**. CMS is testing payment tied to patient outcomes through the **ACCESS model** and building a **Medicare App Library**. The gap is operational. These programs need standards, infrastructure, and implementation pilots to work at scale.

Near-term federal actions recommended in the accompanying policy brief:

1. Establish national standards for trusted PGHD to create a consistent foundation for regulatory and payment decision-making.
2. Modernize PMS for software and AI-enabled medical products through proactive, lifecycle-based monitoring approaches.
3. Develop shared methods for identifying meaningful safety and performance signals to support continuous oversight of rapidly evolving technologies.
4. Build interoperable infrastructure for bidirectional PGHD exchange across clinical, regulatory, and payment systems.
5. Align measurement strategies for regulation and payment by establishing governance that supports outcomes-based reimbursement while preserving the integrity of regulatory oversight.

Why legislation is not the ask

A regulatory gap analysis found that FDA, CMS, ONC, and the CMS Innovation Center already have the authority to act. The missing pieces are coordination and resources to implement, not new law. For Congress, that makes this a rare chance to drive results through appropriations without new legislation.

What to watch for

Two risks deserve attention. First, safety monitoring that relies on manual adverse-event reporting cannot catch the slow drift of an AI model. Second, when payment gets tied to outcome measures, there is an incentive to optimize the measure rather than the patient's health. **Both are solvable with the right standards and governance, and both are addressed in the accompanying policy recommendations.**

The bottom line for your office

Supporting coordinated federal implementation of PGHD standards protects patients from AI products that degrade unnoticed, and it helps ensure taxpayers pay for health improvements rather than engagement metrics.

Appendix: The policy brief in plain terms

The policy brief uses technical language that federal agencies rely on. This section explains those terms, grouped by the five recommendations they support.

1. Standards for trusted PGHD

Provenance is the record of where a piece of data came from and how it was produced. *Metadata* is the background detail attached to a reading, such as the device, the time, and the settings. *Version tracking* records which version of a device or AI model produced a given reading. *Unique device identifiers (UDIs)* are the barcode-style IDs that make that tracking possible. *Missingness* is the gaps in a dataset, and knowing why data is missing matters as much as the data itself.

2. Modernizing post-market surveillance

Post-market surveillance (PMS) is how the government watches a product's safety after it is already on the market. *MAUDE* is FDA's current system for that, built around

people filing reports one incident at a time. *Model drift* is an AI quietly getting less accurate as the world or the patient population changes. *Federated networks* analyze data where it already lives instead of copying it into one central pile, which protects privacy.

3. Shared methods for safety signals

An *early warning signal* is a change big enough to suggest a real safety or performance problem is emerging. A *predetermined change control plan (PCCP)* is an FDA mechanism that lets a manufacturer get planned future updates approved in advance. *Subgroup performance* is how well a product works for a specific group of patients rather than the average. *Adaptive AI* is a model that keeps learning after it is deployed.

4. Interoperable infrastructure

Interoperability is different systems being able to exchange data and actually use it. *Read* and *write capabilities* are the difference between pulling data out of a record and putting data back in, and today's EHRs can read out but barely write in. *FHIR* is the common format that lets health systems share data. *TEFCA* and *USCDI+* are national frameworks that set the rules and the shared list of data elements for that exchange.

5. Aligning measurement for regulation and payment

Outcome-aligned payment (OAP) pays for whether a patient actually got better rather than for each service delivered. *Measure isolation* is keeping the numbers used to judge safety and performance of a device separate from the numbers used to decide payment for a medical service, so neither corrupts the other.