POLICY BRIEF

Building the Next Generation of Real-World Evidence

Federal policy recommendations to operationalize patient-generated health data for regulation and payment

July 31, 2026

Executive Summary

Software and AI-enabled health technologies are transforming healthcare delivery, regulation, and payment. They also expose a fundamental limitation in today's real-world data and evidence (RWD/E) infrastructure: the data sources that enabled the last generation of regulatory and payment decisions were not designed for technologies that evolve continuously or for payment models tied to patient outcomes.

Electronic health records (EHR) and claims data became foundational sources of RWD/E because federal policy invested in the standards, infrastructure, and governance needed to make them usable at scale. Patient-generated health data (PGHD) has reached a similar inflection point. It has the potential to become a foundational component of the nation's RWD/E ecosystem, but the operational infrastructure required to support its widespread use has not kept pace.

> **Patient-generated health data (PGHD)**
> PGHD is health-related data generated by or from patients outside of the clinical setting to address a health concern.

Federal agencies already possess the statutory and regulatory authority needed to address this challenge. Our analysis found that the primary barriers are operational rather than legislative. Coordinated federal action can establish the standards, infrastructure, and implementation models needed to operationalize PGHD in support of:

- Continuous FDA oversight and post-market surveillance (PMS) of software and AI-enabled medical products.
- Outcome-aligned payment (OAP) models led by CMS.
- A modern, interoperable national RWD/E infrastructure.

This brief recommends five near-term federal actions:

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.

The case for modernizing federal RWD/E infrastructure

The federal government is modernizing how healthcare is regulated and paid for

Because software and AI-enabled medical products go through rapid iterative development cycles, the FDA is steadily evaluating regulatory approaches that shift from point-in-time evaluation toward **total product lifecycle (TPLC)** management to ensure safety and effectiveness across the device's entire lifespan. The **TEMPO pilot** specifically promotes access to certain digital health devices while safeguarding patient safety using a risk-based enforcement approach driven by RWD/E.

Additionally, payers, and especially CMS, have realized that paying for health technology directly drives healthcare cost inflation and incentivizes developers to optimize software for user engagement. To improve patient outcomes, especially in people with chronic conditions, payment needs to be increasingly tied to the medical services that impact **outcomes that matter to patients** directly, a trend happening **across the industry** and most visibly championed by the **CMS ACCESS model**.

Other notable FDA and CMS initiatives that are modernizing how healthcare is regulated and paid for include the **RAPID pathway** to expedite access to certain breakthrough devices for people with Medicare, and the **CMS Health Tech Ecosystem** to modernize the nation's digital health ecosystem.

Existing RWD/E infrastructure enabled yesterday's innovation

EHR data collected in a clinical setting and claims data are trusted sources of evidence because they benefited from federal investments in standards, interoperability, governance, and implementation.

Due to the rapid iterative development cycles of software and AI-enabled medical products, they require TPLC oversight paradigms that are continuous and data-driven. Those same products increasingly support longitudinal care pathways, and we need trusted RWD/E sources that can reliably measure outcomes and inform payment decisions. The existing RWD/E sources, while well-adopted, are inherently too slow to support these use cases.

PGHD is ubiquitous; yet there are limited pathways for integrating it into clinical systems, regulatory frameworks, and federal payment models. As a result, **PGHD remains the least operationalized source of RWD/E**.

PGHD enables the next generation of RWD/E

PGHD is uniquely positioned to become a critical component of the RWD/E infrastructure, filling gaps that existing sources cannot. It is readily available and enables more timely evidence generation. As a patient-centric source of RWD/E, it supports TPLC-based monitoring of safety and performance and captures outcomes outside traditional care settings.

Achieving safe and accelerated adoption of software and AI-enabled medical products does not require new legislation or regulatory guidance. Existing FDA guidance and regulatory frameworks have largely matched the speed of innovation: FDA has updated guidances and launched new initiatives (e.g., TEMPO, RAPID), signaling an openness to TPLC oversight and use of RWD/E. Because the authority already exists, federal agencies can act now by focusing on coordinated implementation rather than new statutory mandate.

However, we lack the operational and infrastructure specifications needed to implement PGHD at scale. Its slow adoption for regulatory decision-making demonstrates this gap. FDA reports on the use of RWE in medical device regulatory decisions show minimal use of PGHD. Of the 90 RWE examples in the **2012-2019 report**, only 2 used PGHD and of the 73 examples in the **2020-2025 report**, only 1 did.

The value of PGHD is well established; the priority now is to operationalize it as a trusted component of the nation's real-world evidence infrastructure backed by shared standards, technical infrastructure, and implementation tools.

Federal policy recommendations

1. Establish national standards for trusted PGHD

- **Opportunity:** Create the technical foundation that allows PGHD to become a trusted source of RWD/E.
- **Lead agencies:** FDA + ONC
- **Specific actions:**
  - ✔ Harmonize PGHD provenance standards.
  - ✔ Define minimum metadata requirements.
  - ✔ Standardize version tracking of devices, algorithms, and AI models.
  - ✔ Improve and harmonize documentation of data quality and missingness.
- **Expected impact:** Trusted, interoperable PGHD suitable for regulatory and payment decision making.

Context that informed this recommendation

Granular version tracking should be implemented across devices, software and firmware versions, and AI models via unique device identifiers (UDIs). Currently, EHRs and other PGHD databases do not consistently track which specific version of an AI model a clinician or patient used. Without this structured version tracking, it is impossible to attribute real-world adverse events or performance drift to specific software updates.

While EHRs remain a primary source of RWD/E for regulatory use, alternative data environments are emerging for PGHD integration. Such data aggregator platforms, incentivized by the **CMS Medicare App Library** and the maturity of data exchange frameworks such as **TEFCA** or potential future extensions of **USCDI+**, increasingly enable PGHD and EHR data to be linked and analyzed outside traditional EHR systems, and help standardize how PGHD is structured, exchanged, and interpreted.

2. Modernize PMS for software and AI-enabled medical products

- **Opportunity:** Transition from predominantly passive reporting toward proactive, continuous lifecycle oversight.
- **Lead agency:** FDA
- **Specific actions:**
    - Develop implementation guidance.
    - Launch a demonstration pilot.
    - Evaluate federated and agent-enabled surveillance models.
- **Expected impact:** Earlier identification of safety and performance issues while supporting more agile innovation to shorten the path to market.

Context that informed this recommendation

Systems like MAUDE rely on manual reporting of discrete adverse events, which is fundamentally incompatible with identification of model drift or subpopulation biases, and may expose patients to unnecessary risk.

Rather than solely relying on centralized reporting and UDI-anchored surveillance infrastructure, future monitoring systems could incorporate distributed or federated data network architectures and agent-enabled oversight systems. In these models, data remain within institutional environments while standardized analytics are deployed across sites, detecting safety signals such as performance drift, subgroup degradation, or unexpected outcome patterns without centralizing the underlying data. Once a safety signal is detected, UDIs, software versions and other metadata could be used to attribute that signal to specific products, models, or updates. This approach is gaining traction because centralized surveillance models are difficult to operationalize across fragmented health data environments, especially where privacy, institutional governance, and data-sharing constraints limit the movement of raw data across sites. Examples of similar approaches from adjacent domains include FDA's **Sentinel System**, which uses a distributed data network for active safety surveillance, as well as broader distributed research networks such as **PCORnet** and **OHDSI**.

More proactive PMS could also offload certain safety and performance evaluation steps to later lifecycle phases, depending on the risk class of the device, to accelerate access to life-saving technologies as less emphasis is placed on the premarket evaluation phase.

3. Develop shared methods for identifying meaningful safety and performance signals

- **Opportunity:** Create consistent approaches for detecting clinically meaningful changes in software and AI model performance.
- **Lead agency:** FDA
- **Specific actions:**
    - Develop best practices for early warning signals.
    - Establish approaches to monitoring model drift.
    - Define methods for evaluating subgroup performance.
    - Expand lifecycle approaches for adaptive AI models.
- **Expected impact:** Greater consistency, transparency, and confidence in continuous oversight.

Context that informed this recommendation

Best practices for defining performance thresholds will enable transparent and consistent reporting. As we continue to increase our reliance on software and AI-enabled medical products to drive patient outcomes, we must develop methods that define what change in a safety or performance measure constitutes an early warning signal. This is not specific to the use of PGHD, but its strengths (ubiquitousness, large scale availability and timeliness), outweigh its weaknesses (higher degree of noise and variability introduced by data sources, collection environments, and users), especially when we consider PGHD an additional and complementary class of RWD/E.

We should not attempt to identify absolute benchmarks and thresholds for industry to comply with. Development moves too fast and it would lead to “check-the-box” evaluation processes. Instead, we need pragmatic best practices to ensure technology makes it to those patients who need it the most, as efficiently as possible while ensuring their safety.

FDA’s **Predetermined Change Control Plan** (PCCP) guidance is aligned with that reasoning. Our analysis identified that PCCPs in their current form work well for more static AI models, but require adaptation to support the newer generation of (gen)AI models.

4. Build interoperable infrastructure for bidirectional PGHD exchange

- **Opportunity:** Enable PGHD to move securely into, and be used across, clinical, regulatory, and payment systems.
- **Lead agencies:** ONC + CMS (FDA supporting)

- **Specific actions:**
    - Advance PGHD “write” capabilities.
    - Support interoperable data exchange for PGHD.
- **Expected impact:** A national RWD/E infrastructure that is “PGHD ready” and capable of supporting clinical care, regulatory oversight, and payment innovation.

Context that informed this recommendation

Unclear data ownership, inconsistent patient consent frameworks, and variability in vendor data architectures can create barriers to sharing and linking PGHD across healthcare systems, while unclear responsibilities for data stewardship and interpretation may discourage incorporation into clinical workflows.

While outbound data sharing standards have matured through **APIs**, FHIR-based data exchange, CMS-led efforts to advance a **connected healthtech ecosystem**, and national health information exchange (HIE) frameworks, EHRs still have very limited data “write” capabilities. Expecting patients to bring fragmented data to their providers via flash drives or PDFs is technically interoperable but practically useless.

To ensure PGHD does not live in a set of fragmented siloes across vendor systems, poorly integrated with clinical workflows, we must provide pathways to securely ingest it in several databases, including EHRs to drive timely clinical intervention, PMS systems for safety monitoring, and payer claims systems.

5. Align measurement strategies for regulation and payment

- **Opportunity:** Ensure outcome-based payment and regulatory oversight reinforce one another without creating unintended incentives.
- **Lead agencies:** CMS + FDA (CMS Innovation Center supporting)
- **Specific actions:**
    - Identify best practices to separate measures used for regulatory oversight from those used for payment.
    - Develop governance principles for AI-enabled outcome measurement.
- **Expected impact:** Supports trustworthy OAP models while protecting the integrity of regulatory decision making.

Context that informed this recommendation

As we continue to rely more heavily on AI to both drive and monitor patient outcomes, regulators and payers need to establish safeguards against opportunities

to “game the system”. Goodhart’s Law states “When a measure becomes a target, it ceases to be a good measure.”, i.e., when a measure is used to measure performance, we provide an incentive to manipulate the measure in order to receive the reward.

For example, conversational AI could be trained to subtly condition patient behavior to generate “better” outcome measures, or an ML model could be fine-tuned to meet payer benchmarks rather than clinical safety ones.

Good OAP models incentivize the development of digital health technologies that are outcome-based by tying reimbursement to independently validated, objective, and audited RWD/E. Bad OAP models incentivize the development of technologies that optimize for payment by directly linking it to proxy measures that could be manipulated, and encourage developers to engineer user flows and patient selection strategies that maximize payouts rather than true clinical efficacy.

Measures defined to monitor the safety and performance of a medical device should be functionally isolated from measures that are used to determine reimbursement of a medical service bundling those devices.

Roadmap for coordinated federal implementation

The existing authorities across FDA, CMS, ONC, and the CMS Innovation Center can implement our proposed specific actions by establishing technical standards, modernizing implementation infrastructure, and launching new demonstration products.

We propose the following:

Timeframe	Mechanisms to implement priority actions
Near-term (0-12 months)	Convene an interagency workshop to establish PGHD governance, shared methodologies to define early warning signals of safety and performance deterioration; initiate standards development and identify priority pilots.
Medium-term (1-3 years)	Launch demonstration projects (e.g., sandbox environments within existing federal initiatives) to validate technical standards, implement interoperable PGHD exchange, and evaluate modernized surveillance models.
Longer-term (3+ years)	Scale successful approaches nationally across regulatory oversight, PMS, and OAP programs.

Methods

This brief was informed by the following DiMe-facilitated activities:

- A **public workshop**, co-hosted with FDA, that brought together more than 2,000 stakeholders to explore how PGHD can support medical device development, regulatory decision-making, and post-market oversight.
- A gap analysis that analyzed relevant regulatory and academic literature (n = 27).
- Semi-structured interviews with subject matter experts (n = 14).
- A roundtable with representatives from FDA, CMS, and the CMS Innovation Center.

Our sincere thank you to the experts who helped inform this work.