

# Public Comment on CMS–0042–NC

---

Submitted by: Max Doppelt, Founder & CEO, Patient Data Vault

Submitted via: Regulations.gov

I'm Max Doppelt, founder of Patient Data Vault. I started this company after helping my mother navigate a late-stage cancer diagnosis. Despite having access to excellent providers, we struggled to collect her records, find accurate clinical trial matches, and coordinate care across systems. We nearly missed a promising treatment because the data her doctors needed was locked in fragmented systems and inaccessible at the moment it mattered. That experience showed me the life-and-death consequences of poor interoperability, and the urgent need for digital tools built around patients, not systems.

Patient Data Vault is now a platform helping patients assemble longitudinal records, identify evidence-based care options such as clinical trials, and share outcomes with researchers. Informed by that experience, I respectfully submit the following comments.

## 1. A unified, patient-controlled health record is now technically feasible and urgently needed (PC-2, PC-8).

Medicare beneficiaries tell us their greatest pain point is piecing together records scattered across portals, imaging CDs, and paper correspondence. When PDV ingests Blue Button 2.0 claims and reconciles them with FHIR data retrieved from multiple provider APIs, average time to confirm trial eligibility falls from weeks to hours and redundant lab tests drop by roughly 20 percent. CMS can accelerate this benefit by expanding Blue Button to include Medicare Advantage encounter data, Part D explanation-of-benefit fields, prior-authorization decisions, and durable-medical-equipment claims.

## 2. Add high-value data classes to USCDI and require them in payer and provider APIs (PC-9, TD-7).

PDV's matching engine relies on biomarker results, social determinants of health, and patient-reported outcomes—all routinely captured but rarely delivered through standards-based APIs. We recommend that USCDI v5 include structured genomic variant data (HGVS nomenclature), PRO instruments such as PROMIS-29, and housing- and transportation-related SDOH concepts.

### 3. Drive adoption through clear certification signals rather than app-by-app pre-approval (PC-5, TD-8, TD-9).

Instead of reviewing every consumer app for 'efficacy,' CMS should require that certified API endpoints return complete, computable data and that certified apps publish a machine-readable attestation covering privacy practices, secondary use limits, and continuous-penetration-test status.

### 4. Modern digital identity is a prerequisite for equity and safety (PC-14, PR-9, PA-3).

CMS should permit and ultimately encourage Login.gov or another NIST 800-63-3 IAL2/AAL2 credential as a portable patient key that payers, providers, and certified apps must accept.

### 5. Make TEFCA a backbone for patient-initiated bulk data pulls (PC-10, PR-6, TD-14).

Allowing a beneficiary to trigger a one-time TEFCA pull—specified by their Login.gov credential and routed to the destination app's FHIR bulk-export endpoint—would give patients the same efficiency that large payers enjoy.

### 6. Leverage patient-generated data for real-world evidence while protecting privacy (PC-7, VB-1).

CMS could standardize this pathway by piloting a Beneficiary Digital Evidence Program: participating apps push structured PRO and device data to a CMS endpoint, which evaluates outcome improvements and shares anonymized datasets with qualified researchers.

### 7. Align value-based-care incentives with complete, computable data exchange (VB-3, PR-7, PA-5).

CMS should tie ACO and advanced APM quality payments to demonstrated use of certified bulk-FHIR exports and receipt of structured SDOH and genomic data for at least 80 percent of attributed lives.

The policy foundation laid by CMS and ONC has enabled startups like Patient Data Vault to show what a patient-centric ecosystem can deliver. The next phase requires complete data, portable identity, and predictable certification rather than piecemeal app vetting. We stand ready to collaborate on pilots, standards refinement, and real-world-evidence collection to ensure every Medicare beneficiary—regardless of technical savvy—can benefit from

modern digital health tools.

Respectfully submitted,

Max Doppelt

Founder & CEO, Patient Data Vault

<https://www.data-vault.health>