Serif Health Response to the Departments' RFI on the Prescription Drug Machine-Readable File Requirement

Submitted in Coordination with Patient Rights Advocate Response
RE: CMS-9905-NC / RIN 0938–AU88

Introduction & Organizational Perspective

Serif Health is a healthcare technology and analytics company specializing in the structuring and enrichment of machine-readable data specifically released under the federal *Transparency in Coverage* (TiC) and *Hospital Price Transparency* regulations. We ingest, normalize, and validate commercial negotiated rate disclosures across all national and regional payers to power use cases in price benchmarking, drug affordability analytics, market access modeling, and consumer navigation for a wide range of health care organizations.

This response is intended to provide **supplemental analysis and commentary** in support of the proposed prescription drug machine-readable file (MRF) requirement. Serif Health has **helped develop and co-signed the Patient Rights Advocate (PRA) response to the RFI, as well as contributed to PRA's proposed schema for the drug file MRFs submitted with the response.** Serif Health aligns strongly with the PRA recommendations for schema improvements, enforcement priorities, and the public utility of these disclosures.

Our response below focuses specifically on:

- **Section II.A.1 (Required Data Elements)**
- **Section II.A.4 (Remuneration and Rebate Disclosure)**
- **Section II.A.7 (Benefits Structure: Medical vs. Pharmacy)**
- **Section II.B.1 (Implementation Timeline)**
- **Section II.B.2 (Operational Feedback)**
- **Section II.B.3 (Leveraging Existing Infrastructure)**

We offer **empirical evidence** using our national, combined TiC data assets with public reference data sources to assess the current availability of prescription drug price data under the current TiC framework, and demonstrate that meaningful coverage has already been achieved for physician-administered drugs, highlighting the clear feasibility of an expanded approach to drug price reporting while demonstrating remaining gaps in reporting for retail and specialty pharmacy drugs which the federal government is seeking to address.

We thank the Departments and their staff for the opportunity to comment on the RFI and welcome additional dialogue on this topic moving forward.

I. Completeness of Existing NDC Drug Price Data under TiC

Responding to RFI Sections II.A.1 and II.B.1–3

The Departments' RFI rightly asks whether plans and issuers have built the infrastructure necessary to implement prescription drug transparency (Section II.B.1), and whether the current reporting requirements align with real-world drug pricing practices (Section II.A.1). To assess this, we compared NDCs observed in Serif Health's structured TiC database to the **reference NDC universe as posted in CMS' RxDC database**, which captures manufacturer-submitted formulary drugs across plan types reported to CMS under the Consolidated Appropriations Act (CAA) of 2021.

Methodology Overview

Specifically, we completed an empirical analysis combining:

- **RxDC-reported NDCs** (2024 CY data)[1]
- **CMS ASP April 2025 NDC–HCPCS crosswalk**[2]
- **Serif's own enriched rates TIC database**, containing payer-submitted rates at the provider/pharmacy, payer, and plan network as of June 2025. For NDC code types, our database incorporates both NDC codes reported without drug-specific elements like dosing through primary payer MRFs as well as, where available, drug MRF files already posted by some payers (e.g., OptumRx).

This straightforward analysis, notwithstanding limitations, allows us to:

1. Determine the % of unique NDCs already observed in payer-submitted negotiated rate files, treating the RxDC crosswalk as a denominator;
2. Quantify the extent of reporting across unique provider organizations (as defined by federal EINs) and payers;
3. Similarly evaluate reporting of drug HCPCS reimbursement for drugs commonly billed under a medical benefit (e.g., Part B drugs);

Findings

Metric	Value
Total Unique NDCs from RxDC crosswalk	**196,626**
Unique NDCs observed in Serif TiC payer data (as of June 2025)	**93,181**
Coverage (% of RxDC NDCs)	**47.4%**
Unique EINs with negotiated rates for NDCs	**36,430**
Unique payers reporting NDCs	**22**
Total Unique Drug HCPCS from Part B ASP crosswalk	**907**
Unique HCPCS observed in Serif TiC payer data (as of June 2025)	**907**
Coverage (% of Part B Crosswalk)	**100%**
Unique EINs with negotiated rates for Drug HCPCS	**1,076,170**
Unique payers reporting Drug HCPCS	**133**

This analysis demonstrates that **a substantial share of real-world NDCs already have observed negotiated rates** in public TiC data and Serif has also observed that **these rates vary meaningfully by payer and EIN**. We note that many observed rates appear at the **pharmacy-specific** or **network-level**, providing greater granularity than what is disclosed through RxDC or other summary data. While coverage of unique NDCs across RxDC-reported drugs stands at approximately **47.4% overall**, the data are sparsely populated overall, with only **22 unique payers** and an associated **36,000 unique EINs** having any associated negotiated rate in our data.

In contrast, for drugs reimbursed under the medical benefit, **100% of Part B ASP HCPCS codes** are matched to observed rates in TiC, indicating full coverage of the current Medicare crosswalk. These rates span over **1 million EIN-level entries** from **133 unique payers**, demonstrating that medical-benefit drug price transparency is already highly complete in practice.

Together, these findings support the Departments' position that infrastructure for prescription drug price transparency is well underway, and that finalizing schema guidance is critical to enhance public visibility into drug pricing.

II. Differences in Drug Pricing Under Medical vs. Pharmacy Benefit

Responding to RFI Section II.A.7

As the Departments note in Section II.A.7 of the RFI, many high-cost drugs are reimbursed differently depending on benefit channel, often billed via **HCPCS codes** under a medical benefit (e.g., hospital outpatient infusion), or as **NDCs** via the pharmacy benefit (e.g., home delivery). Our data confirms that:

- **A significant number of HCPCS-coded drugs are directly linked to NDCs also observed in pharmacy-rate files**;
- **Rates for the same active ingredient may vary by thousands of dollars per dose** depending on site of care;
- This variation is **invisible** without integrated disclosure of both benefit channels and a **crosswalk linking NDC ↔ HCPCS**;

We recommend the Departments **require dual disclosure** for such drugs in both MRFs, with clear flags for place of service (e.g., office, HOPD, pharmacy), and encourage CMS to **publish or reference a canonical crosswalk** to link NDC and HCPCS codes.

III. Implementation Feasibility and Public Readiness

Responding to RFI Sections II.B.1–3

The Departments inquire in Section II.B whether TiC infrastructure can support prescription drug price transparency. Based on our experience structuring over **a billion rate records per month** across 600+ MRFs posted by payers under TiC, Serif Health affirms:

- **Yes**: The infrastructure is already in place and functioning for commercial medical rates and thus should be applicable to all commercial prescription drug rates;
- **Yes**: JSON-based schemas are processable at scale with standard computing infrastructure;
- **Yes**: Payers are already disclosing prescription drug rates, often voluntarily or embedded in medical files.

Remaining barriers are **not technical**; it is regulatory and compliance-based. Releasing the final schema, through formal rule making or otherwise, and strictly enforcing publication requirements will allow healthcare stakeholders throughout the US to fully leverage these data for the public benefit.

Conclusion and Recommendations

Responding to RFI Sections II.A.1, II.A.4, II.A.7, II.B.1–3

Consistent with the PRA response to the RFI which we have co-signed, Serif Health urges the Departments to:

1. Finalize and fully enforce the prescription drug MRF schema in alignment with PRA recommendations and proposed schema;
2. Remove the 20-claim suppression threshold, which disproportionately limits visibility for rare disease and specialty therapies;

3. Require dual reporting of drugs covered under both pharmacy and medical benefit, using standard coding crosswalks;
4. Clarify that public MRF data may be enriched, restructured, and reused by third parties, fueling broader development of price transparency tools and analyses;
5. Require structured fields for days supply, unit of measurement, and rebate pass-through flag to better reflect drug pricing structures.

Serif Health welcomes continued engagement with the Departments and is available to share additional technical documentation or participate in schema refinement working groups.

Footnotes

1. **CMS RxDC Data Crosswalk** (April 2025 version): https://www.cms.gov/marketplace/about/oversight/other-insurance-protections/prescription-drug-data-collection-rxdc
2. **CMS Medicare Part B ASP NDC–HCPCS Crosswalk**, April 2025 version: https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files