

# ConnectedHealthInitiative

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Philip J. Lindenmuth  
Acting Associate Chief Counsel  
Internal Revenue Service  
Department of the Treasury  
1111 Constitution Avenue, Northwest  
Washington, District of Columbia 20224

Helen H. Morrison  
Benefits Tax Counsel  
Department of the Treasury  
1500 Pennsylvania Avenue, Northwest  
Washington, District of Columbia 20220

Timothy Hauser  
Deputy Assistant Secretary for Program  
Operations  
Employee Benefits Security Administration  
Department of Labor  
200 Constitution Avenue, Northwest  
Washington, District of Columbia 20210

Robert F. Kennedy, Jr.  
Secretary  
Department of Health and Human Services  
200 Independence Ave. Southwest  
Washington, District of Columbia 20201

**RE: *Comments of the Connected Health Initiative, Request for Information Regarding the Prescription Drug Machine-Readable File Requirement in the Transparency in Coverage Final Rule [CMS-9882-NC; 90 FR 23303]***

The Connected Health Initiative (CHI) writes to provide input to the Departments of Labor, Health and Human Services (HHS), and the Treasury (the Departments) in response to a request for information (RFI) regarding the prescription drug machine-readable file disclosure requirements in the Transparency in Coverage final rules.<sup>1</sup>

CHI is the leading multistakeholder policy and legal advocacy effort dedicated to improving health outcomes while reducing costs. Our work is driven by the consensus of stakeholders from across the connected health ecosystem. CHI aims to realize an environment in which Americans can see improvements in their health through policies that allow for connected technologies to advance outcomes and reduce costs. CHI members develop and use connected health technologies across wide range of use cases. We actively advocate before Congress, numerous U.S. federal agencies, and state legislatures and agencies, where we seek to promote responsible pro-digital health policies and laws in areas including reimbursement/payment, privacy/security, effectiveness/quality assurance, U.S. Food and Drug Administration (FDA) regulation of digital health, health data interoperability, and the rising role of artificial intelligence (AI) in care delivery. For more information, see [www.connectedhi.com](http://www.connectedhi.com).

Accessible and actionable health data is foundational to CHI's mission of advancing digital health innovation and improving patient outcomes, and the Departments' focus on prescription drug

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<sup>1</sup> 90 FR 23303.

machine-readable file disclosure requirements is an important mechanism for making prescription drug pricing information more accessible to consumers, employers, and other stakeholders. CHI recognizes that when patients, providers, and purchasers have real-time access to clear and accurate prescription drug pricing data, it empowers more informed decision-making and drives competition that can help lower healthcare costs. CHI is committed to ensuring that the technical implementation of these requirements leverages modern health data standards and best practices so that the resulting data is not only available but also truly usable within digital health tools and platforms. CHI also prioritizes minimizing unnecessary administrative burdens and ensuring that compliance processes are efficient and scalable.

To support the Departments, we offer responses to various questions posed in the RFI below. In aligning with CHI's recommendations, the Departments can support both transparency and innovation, ultimately benefiting patients, providers, and the broader healthcare ecosystem.

#### **A. Required Data Elements, Including Potential Additional or Alternative Data Elements**

**1. *Improvements to disclosure requirements:* Are there existing data elements described in [26 CFR 54.9815-2715A3\(b\)\(1\)\(iii\)](#), [29 CFR 2590.715-2715A3\(b\)\(1\)\(iii\)](#), and [45 CFR 147.212\(b\)\(1\)\(iii\)](#) that would be more useful if reported in a different form or manner? Are there ways to simplify the reporting schema to streamline disclosure to relieve reporting burdens? What are the appropriate metadata elements that should be required to be associated with the public disclosure file? Are there any improvements to disclosure requirements that would be particularly useful to interested parties including consumers, employers, and other purchasers of health care?**

CHI recognizes the progress made through the data disclosure requirements set forth in 26 CFR 54.9815-2715A3(b)(1)(iii), 29 CFR 2590.715-2715A3(b)(1)(iii), and 45 CFR 147.212(b)(1)(iii), which provide a foundation for improved transparency of in-network provider rates, out-of-network allowed amounts, and negotiated rates for prescription drugs. However, through the lens of advancing digital health innovation and interoperability, CHI sees further opportunities to enhance the utility, accessibility, and impact of these disclosures.

Initially, we urge for the standardization of data formats and terminologies. Presently, the lack of uniformity across health plans and reporting entities can create confusion and limit the comparability of data. Adoption of widely accepted industry standards, such as those found in the United States Core Data for Interoperability (USCDI), would ensure that data is consistent, interoperable, and more easily integrated into digital health platforms. Ultimately, this would streamline the reporting process for health plans while empowering developers to build consumer-facing tools that translate complex pricing data into actionable insights.

CHI also suggests that the scope of relevant data elements be expanded to include additional classes of information, namely patient-generated health data (PGHD). Incorporating these elements would provide a more comprehensive picture of care and costs, aligning with the goal of a truly connected care continuum where more and more relevant information is available to support decision-making.

CHI also supports streamlining the reporting scheme itself through leveraging APIs and interoperability standards (such as HL7 FHIR and SMART App Launch Implementation Guides recommended by the Office of the National Coordinator for Health IT/Assistant Secretary for Technology Policy [ONC/ASP]) to reduce the manual burden on reporting entities and enable real-time data updates.

Finally, CHI supports making machine-readable files accessible through intuitive digital tools that can further enhance transparency. By aligning disclosure requirements with federal interoperability standards, the Departments can foster third-party innovation.

**2. *Unnecessary or irrelevant disclosures:* Are there any data elements that are currently in the public disclosure requirement with respect to prescription drugs that are not relevant or useful and could be removed in order to simplify the reporting schema while maintaining the integrity of the prescription drug pricing disclosure requirements? Should the Departments remove any data elements, and why? Are there ways to reduce the volume of redundant or duplicative data?**

CHI recognizes that current disclosure requirements may include unnecessary or duplicative data elements that can complicate reporting, increase administrative burdens, and dilute the clarity of information intended to help consumers, providers, and payers make informed decisions. As an example, granular historical pricing data or administrative fee breakdowns can add few actionable insights and may already be captured elsewhere. We encourage the Departments to, with the public, review and remove such elements to simplify the reporting schema while maintaining the integrity and utility of disclosures.

**8. *Alignment:* Are there ways the Departments should align the TiC prescription drug reporting requirements with the prescription drug data reporting requirements under the Hospital Price Transparency rule?**

CHI believes there are clear opportunities for the Departments to better align the Transparency in Coverage (TiC) prescription drug reporting requirements with those under the Hospital Price Transparency rule. CHI has consistently advocated for greater interoperability, reduced administrative burden, and more actionable transparency in healthcare data reporting.

Currently, the TiC and Hospital Price Transparency rules operate can require overlapping/duplicative data submissions, which can be confusing for stakeholders and limit the utility of the information for patients, providers, and payers. CHI believes that aligning these requirements would streamline compliance and make prescription drug pricing information more accessible and meaningful.

A key step in this alignment would be the adoption of consistent data standards and definitions across both rules. For example, leveraging widely recognized standards, such as those developed by the National Council for Prescription Drug Programs (NCPDP) and supporting technologies like real-time prescription benefit (RTPB) tools, would facilitate

more seamless data exchange and reduce the complexity of reporting for health plans and providers. This harmonization would also support the integration of prescription drug data into electronic health records and digital health platforms, improving visibility for both patients and providers at the point of care.

## **B. General Implementation Questions**

### **1. *Implementation timeline:* Have any plans or issuers begun building the infrastructure needed and if so, to what extent has that been completed?**

Numerous health plans and issuers have already taken significant steps to build the infrastructure necessary to comply with prescription drug data reporting requirements. Many have implemented new platforms or enhanced existing ones to aggregate, standardize, and securely transmit the required prescription drug pricing and utilization data. CHI defers to responses of plans and issuers to share their individual perspectives.

### **2. *Operational feedback:* Are there operational, formatting, or technical considerations that would improve and quicken the Departments' ability to begin enforcement of the required prescription drug machine-readable file while maintaining data integrity?**

CHI believes there are several operational, formatting, and technical considerations that could improve and accelerate the Departments' ability to enforce the prescription drug machine-readable file requirements, all while upholding the highest standards of data integrity.

First, CHI believes that the adoption of widely recognized interoperability standards is essential. By requiring the use of established formats such as HL7 Fast Healthcare Interoperability Resources (FHIR), the Departments can ensure that prescription drug data is not only machine-readable but also easily exchangeable across different health IT systems, facilitating more consistent enforcement by regulators.

Operationally, CHI suggests establishing a phased or pilot approach to enforcement. Allowing plans and issuers to submit test files and receive real-time feedback before full enforcement begins would help identify and resolve technical issues early, reducing the risk of widespread non-compliance. This approach would also give the Departments an opportunity to refine their own processes for reviewing and validating submissions, ensuring that enforcement is both fair and efficient.

Last, CHI encourages the Departments to foster ongoing dialogue with stakeholders, including digital health innovators, health plans, and technology vendors, through regular webinars, feedback sessions, and public comment opportunities. A collaborative approach will surface operational challenges and technical barriers in real time, allowing for swift adjustments that benefit both enforcement efforts and the broader goal of meaningful transparency.

**3. *Leveraging existing infrastructure:* Are plans and issuers able to leverage the infrastructure used to implement the in-network rates and out-of-network allowed amounts machine-readable files to comply with these requirements, and to what extent are they able to do so?**

Yes, CHI believes that many health plans and issuers are able to leverage much of the infrastructure developed for in-network rates and out-of-network allowed amounts machine-readable files to meet the new prescription drug reporting requirements. The core systems for data aggregation, secure transmission, and machine-readable file generation already in place may, in some circumstances, allow plans and issuers to efficiently adapt to the additional mandate. CHI defers to responses of plans and issuers to share their individual perspectives.

**4. *File format:* What challenges and advantages would result from requiring that machine-readable prescription drug files be delivered in JSON or CSV file formats?**

CHI observes that requiring machine-readable prescription drug files to be delivered in JSON or CSV formats brings both advantages and certain challenges for plans, issuers, and the broader connected health ecosystem.

A primary advantage is that both JSON and CSV are widely recognized, nonproprietary formats that support interoperability and ease of use. CSV has long been used in healthcare data reporting, including for state and federal prescription drug programs, and is familiar to both technical and non-technical users; JSON is increasingly favored in modern health IT environments for its compatibility with APIs and its ability to represent complex, hierarchical data structures. By standardizing on these formats, the Departments would enable more seamless data exchange, easier integration with digital health tools, and faster adoption by technology vendors.

However, there are operational and technical challenges to consider. CSV, while simple and accessible, can struggle with representing nested or highly complex data, and is sensitive to formatting errors such as misplaced commas or quotation marks. JSON addresses many of these issues but may be less familiar to some legacy systems and stakeholders who have not yet transitioned to more modern data architectures. Additionally, enforcing strict file specifications and validation rules is essential to maintain data integrity and prevent inconsistencies, especially as the volume and complexity of prescription drug data continues to grow.

CHI urges the Departments to provide clear guidance on file structure, data definitions, and validation requirements for both formats. Offering sample files, robust error-checking tools, and support resources will be critical to ensure consistent, high-quality data submissions across the industry. Ultimately, the adoption of JSON or CSV formats, when paired with strong technical support and stakeholder engagement, should advance the goals of transparency, interoperability, and innovation in prescription drug pricing data.

**5. *State approaches and innovation:* Are there state laws with requirements similar to the prescription drug machine-readable file disclosure requirements that could serve as models**

for implementing or amending the requirements under [26 CFR 54.9815-2715A3\(b\)\(1\)\(iii\)](#), [29 CFR 2590.715-2715A3\(b\)\(1\)\(iii\)](#), and [45 CFR 147.212\(b\)\(1\)\(iii\)](#)? If so, in what ways are these state laws directly comparable to [26 CFR 54.9815-2715A3\(b\)\(1\)\(iii\)](#), [29 CFR 2590.715-2715A3\(b\)\(1\)\(iii\)](#), and [45 CFR 147.212\(b\)\(1\)\(iii\)](#)? Are there other innovations that states have employed with respect to prescription drug reporting that the Departments should consider implementing?

CHI notes that a number of state laws may offer valuable experiences to learn from in implementing or refining federal prescription drug machine-readable file disclosure requirements under 26 CFR 54.9815-2715A3(b)(1)(iii), 29 CFR 2590.715-2715A3(b)(1)(iii), and 45 CFR 147.212(b)(1)(iii). As of 2025, more than twenty states have enacted drug price transparency laws, and a growing number have established prescription drug affordability boards to monitor and report on drug costs. These state-level efforts merit study and may provide practical insights that the Departments could consider as they develop or amend federal requirements.

**6. *File size optimization:* Are there steps that the Departments can take, either in regulations, technical implementation guidance, or otherwise, to minimize the size of the prescription drug machine-readable files while ensuring data therein remains useful and relevant?**

CHI believes that the Departments can take several effective steps to minimize the size of prescription drug machine-readable files while ensuring the data remains useful and relevant. Allowing and encouraging file compression formats like .zip can significantly reduce storage and bandwidth demands without compromising data integrity. Additionally, refining the file schema to focus on essential data elements and eliminate duplicative or unnecessary fields will streamline files and enhance usability. Incorporating best practices such as using average allowed amounts from electronic remittance data and excluding placeholder codes when historical data is unavailable can further reduce file size.

**7. *Compliance costs:* What actions could the Departments take to minimize the compliance costs of implementing and maintaining the prescription drug machine-readable file disclosure requirements of the TiC final rules?**

CHI believes that the Departments can minimize compliance costs for the prescription drug machine-readable file disclosure requirements by adopting widely recognized interoperability standards and implementation guides. Standardizing technical requirements enables plans and issuers to build reusable infrastructure, reducing the need for bespoke solutions and supporting innovation.

Further, by providing clear, detailed, and timely guidance (including sample files, validation tools, and FAQs) the Departments can avoid costly errors and rework. Stakeholder engagement further clarifies expectations and addresses challenges early.

CHI appreciates the Departments' consideration of our views, and welcomes the opportunity to assist further any way that we can.

Sincerely,

A handwritten signature in black ink, appearing to read 'B. Scarpelli', with a stylized flourish at the end.

Brian Scarpelli  
Executive Director

Chapin Gregor  
Policy Counsel

**Connected Health Initiative**  
1401 K St NW (Ste 501)  
Washington, DC 20005