July 2, 2025

Office of Health Plan Standards and Compliance Assistance\Employee Benefits Security Administration, Room N-5653
Department of Labor
Washington, DC 20210
Attention: 1210-AC30

Subject: Request for Information Regarding the Prescription Drug Machine-Readable File Requirement in the Transparency in Coverage Final Rule

To Whom It May Concern,

Covered California appreciates the opportunity to provide comments in response to the Request for Information on Prescription Drug Machine-Readable File Requirement in the Transparency in Coverage Final Rule (CMS-9882-NC). As the largest State-Based Marketplace under the Affordable Care Act, Covered California is dedicated to advancing affordability, transparency, and equity in healthcare for all Californians and beyond. Access to high-quality care depends on greater transparency in prescription drug pricing, rebate arrangements, and benefits processing, which also plays a critical role in improving healthcare affordability and system-wide efficiency. We welcome the opportunity to support the Departments' efforts to enhance reporting standards and address current practices and consumer costs.

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

3. *Disclosure of dosage units:* How do plans, issuers, and PBMs store and manage pricing information for dosage units of prescription drugs? Should the Departments require a standardized format for disclosing dosage units and supply periods for prescription drugs (e.g., by 7-day, 30-day, or 90-day supply, by each dosage, or some other standardized dosage unit)? Should the Departments require disclosure of the quantity of the drug on which the price is reported?

Ensuring that drug price data is interpretable by the public and comparable within a drug class is critical for usability and impact of any file. Therefore, the Departments should consider adopting a standardized format to ensure consistency and transparency. However, this is easier said than done, given some drugs are used daily for a lifetime,

while others may be used only weekly for a six-month period. Indeed, the same exact drug may have different dosing and durations of use depending on the clinical condition, which would impact the cost. One approach the Departments could consider is requiring the submission of dosage, frequency and then annualized price of the medication. This approach has been used by organizations who release drug cost reports and supports ease of interpretation for multiple stakeholders.

> **4.** *Remuneration details:* What specific data elements should the Departments require to provide meaningful disclosure of pre-rebate and post-rebate pricing? Should the Departments require plans and issuers to provide specific data pertaining to bundled payment arrangements or any alternative payment models in a manner that shows actual prices?

Drug rebates often have complex structures including funds for:

- Placement on a preferred drug list or formulary (formulary placement drug rebate)
- Quotas for a drug used in a set window of time (volume-based drug rebate)
- A sliding scale based on overall rebate agreement, market share, or patient outcomes

Given the above, we recommend that the Departments include an additional field to collect if a drug is included in a broader rebate arrangement such as formulary placement, volume-based, or other. This could be as simple as adding an additional column with header “Drug included in broader rebate arrangement” and including a “yes/no” option.

While this will not directly translate into transparency for drug-specific pricing, it will provide valuable visibility into the pervasiveness of these complex rebate structures and allow for broader learning across the healthcare ecosystem. To disentangle the impact of rebates on consumer premiums and out-of-pocket costs, additional data collection must be pursued.

> **7.** *Benefits structure:* Are there any prescription drugs that are typically processed under a plan's or coverage's medical benefits or under its pharmacy benefits depending on the setting in which the items or services are provided? To the extent that prescription drugs that are processed under a plan's or coverage's medical benefits are disclosed in the in-network or out-of-network machine-readable files, are there benefits to requiring that such drugs be disclosed in the prescription drug machine-readable file in addition to the other machine-readable files? For example, would such duplication reveal disparities in pricing of prescription drugs based on the setting in which they are administered or the vendor that processes the benefit?

There are numerous examples of prescription drugs that are processed under medical benefits or pharmacy benefits depending on the setting in which the medication is administered or dispensed. Common medications, such as albuterol nebulizer treatments, may be administered in a doctor's office or may be picked up from a pharmacy and self-administered by a patient who has an asthma diagnosis. Vitamin B12 injections or antibiotics may be administered in a doctor's office or self-administered at home by a patient who picks up these medications from a pharmacy. Even supportive therapies for patients on chemotherapy can be offered in multiple sites of care. For example, granulocyte colony-stimulating factors (G-CSF), such as neupogen, may be dispensed in an outpatient infusion center, doctor's office, or an outpatient pharmacy.

Of note, as medical and pharmacy benefits often have substantially different cost-sharing for consumers, a site of care shift may reduce the cost of drug administration for a health plan by thousands of dollars (i.e., removing hospital facility fee surcharges), but may increase the out-of-pocket cost for a member who may have a co-pay. The benefits of including prescription drugs processed under a plan's medical benefits on machine readable files would allow consumers to understand with greater transparency the impact of site of care on healthcare costs, and specifically drug costs. We believe that, while there may be duplication of drugs across these files, this has the potential to uncover disparities in drug pricing based on the setting or vendor.

B. General Implementation Questions

> **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?

There are now 25 states with 40 total laws on drug price transparency. A major lesson learned is that a requesting department requires sufficient staff, resources, and knowledge to perform data validation and quality assurance. Access to clinical staff such as pharmacists and physicians to aid in interpretation of data as well as assessing its quality is valuable. Creating a usable, public-ready report requires both the submitting and receiving organizations to be in frequent communication to trouble-shoot and resolve identified issues.

Another key takeaway is that turning data into action requires an understanding of pricing across the entire supply chain, from the manufacturer to a benefit manager to a

health plan to a pharmacy and to the point of sale for out-of-pocket consumer costs. It is critical to “follow the money” to see where there may be unwarranted inflation. While out of the scope of the current file, we would strongly encourage federal pursuit of a broader drug cost transparency effort beyond solely health plan reporting. Many states have successfully pursued this broader approach.

Thank you for the opportunity to comment.

Sincerely,

S. Monica Soni, MD
Chief Medical Officer, Covered California