APhA
American Pharmacists Association

July 2, 2025

Timothy D. Hauser
Deputy Assistant Secretary for Program Operations
Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5677
U.S. Department of Labor
200 Constitution Ave NW
Washington, DC 20210
Attention: 1210-AC30

RE: Request for Information Regarding the Prescription Drug Machine-Readable File Requirement in the Transparency in Coverage Final Rule (RIN 1210-AC30) (RIN 1545-BR51) (RIN 0938-AV64) (CMS-9882-NC)

Dear Deputy Assistant Secretary Hauser,

The American Pharmacists Association (APhA) appreciates the opportunity to provide the Department of the Treasury (DOT), Internal Revenue Service (IRS), Department of Labor (DOL), Employee Benefits Security Administration (EBSA), Department of Health and Human Services (HHS), and Centers for Medicare and Medicaid Services (CMS) (collectively "the Departments") with comments on "Request for Information Regarding the Prescription Drug Machine-Readable File Requirement in the Transparency in Coverage Final Rule." APhA and the Departments agree that "transparency in healthcare pricing is a priority."[1] APhA supports efforts that lead to greater price transparency, as increased transparency will enable patients to make more informed decisions about their health. However, APhA has concerns regarding the utilization of this information by certain entities, such as pharmacy benefit managers (PBMs), within the drug supply chain, which could manipulate the data to lower reimbursements for pharmacies at a loss when dispensing medications, which will jeopardize patient access to needed medications. Additionally, APhA notes that as patients get access to this information, they will come to the pharmacy with questions and expectations that they only have to pay the price obtained from the prescription drug machine-readable file at that pharmacy counter; thus, any education or services provided by a pharmacist represents an unfunded mandate on our

[1] Request for Information Regarding the Prescription Drug Machine-Readable File Requirement in the Transparency in Coverage Final Rule, 90 Fed. Reg. 23303, 23303 (June 2, 2025). Available at: https://www.federalregister.gov/d/2025-09858/p-20.

nation's pharmacists for these insurance benefit consultations that should be compensated by both commercial and public (Medicare and Medicaid) health plans.

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

Background

In 2020, the Departments issued the Transparency in Coverage (TiC) final rules, which "require[d] group health plans and health insurance issuers offering group or individual health insurance coverage to make available to the public, among other things, certain information relating to prescription drug expenditures."[2] Following the issuance of these final rules, the Departments deferred enforcement of these final rules related to prescription drugs.[3] This request for information provides that the Departments now "intend to implement disclosure requirements related to prescription drug expenditures and effectuate the goals of greater price transparency[,] including transparency related to prescription drug pricing."[4] The Departments' new sense of urgency to act in this area aligns with President Trump's Executive Order 14221, "Making America Health Again by Empowering Patients With Clear, Accurate, and Actionable Healthcare Pricing Information," which "prioritizes the promotion of universal access to clear and accurate healthcare prices, including by improving existing price transparency requirements, increasing enforcement of price transparency requirements, and identifying opportunities to further empower patients with meaningful price information."[5]

Pharmacies are the place where millions of Americans are first exposed to the impact of complex pharmaceutical pricing policies. As such, pharmacists are often the ones working through these complexities to ensure that patients have access to their medications. Finding appropriate medications for a patient that are covered by the patient's insurance and within the patient's budget can be a time-consuming process, which is currently not incentivized in the health care system. Accordingly, APhA supports the adoption of transparent pricing systems and procedures that will provide patients and their health care providers with an understanding of the true costs or "net" costs of their medications. In particular, when medications at pharmacies are reimbursed by "middlemen," or PBMs) at "zero" or below their acquisition costs to align with President Trump's Executive Order (EO), 14273 "Lowering Drug Prices by Once Again Putting Americans First," "Sec. 8 Reevaluating the Role of Middlemen," where "[w]ithin 90 days of the date of this order, the Assistant to the President for Domestic

[2] *Id.* Available at: https://www.federalregister.gov/d/2025-09858/p-18.
[3] *Id.* Available at: https://www.federalregister.gov/d/2025-09858/p-20.
[4] *Id.* Available at: https://www.federalregister.gov/d/2025-09858/p-20.
[5] *Id.* at 23307. Available at: https://www.federalregister.gov/d/2025-09858/p-96.

Policy, in coordination with the Secretary, the OMB Director, and the Assistant to the President for Economic Policy, shall provide recommendations to the President on how best to promote a more competitive, efficient, transparent, and resilient pharmaceutical value chain that delivers lower drug prices for Americans."[6] Greater transparency and access to the impacts of PBMs on patients' prescription drug prices and transparent pricing data will allow pharmacists to more easily navigate situations where a patient brings in a prescription for a medication that the patient's insurance does not cover or the patient cannot afford. Additionally, it will enable patients to better advocate for themselves throughout their entire health care experience, as they work with their trusted community pharmacists to determine medications based on affordability and coverage.

Prescription Drug Machine-Readable File Disclosure Requirement of the TiC Final Rules (FR 23304)

Increasing Transparency, Emphasizing Net Price

The TiC final rules provided that "non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must disclose to the public on an internet website, on a monthly basis, the negotiated rates and historical net prices for covered prescription drugs in a separate prescription drug machine-readable file that is publicly available and accessible to any person free of charge and without conditions."[7] Regarding negotiated rates, the final rules provide that the "rates must be: reflected as a dollar amount, with respect to each NDC [National Drug Code] that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser; associated with the National Provider Identifier (NPI), Tax Identification Number (TIN), and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and associated with the last date of the contract term for each provider-specific negotiated rate that applies to each NDC."[8] With respect to historical net prices, they "must be: reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser; associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and associated with the 90-day time period that begins 180 days prior to the publication date of the machine-readable file for each provider-specific historical net price that applies to each NDC (except that a group health plan or health insurance issuer must omit such data in relation to a particular NDC and provider when disclosing such data would require the plan or issuer to report payment of historical net prices calculated using fewer than 20 different claims for

[6] Lowering Drug Prices by Once Again Putting Americans First, Executive Order No. 14273, 90 Fed. Reg. 16441, 16443 (Apr. 18, 2025). Available at: https://www.federalregister.gov/d/2025-06837/p-18.
[7] Request for Information Regarding the Prescription Drug Machine-Readable File Requirement in the Transparency in Coverage Final Rule, 90 Fed. Reg. 23303, 23304-23305 (June 2, 2025). Available at: https://www.federalregister.gov/d/2025-09858/p-38.
[8] *Id.* at 23305. Available at: https://www.federalregister.gov/d/2025-09858/p-47.

payment)."[9] The TiC final rules also provide that "public disclosure of the historical net prices **takes into account rebates, discounts, dispensing fees, administrative fees, and other price concessions [emphasis added]**."[10] Additionally, the TiC final rules also allow the Secretary of HHS to require health plans to disclose "other information as determined appropriate by the Secretary."[11]

APhA appreciates the Departments' efforts within the final rule to increase drug price transparency, as greater transparency will empower patients to make more informed decisions regarding their medications and may drive down health care costs. APhA supports the disclosure of the historical net price when it accounts for rebates, discounts, dispensing fees, administrative fees, and other price concessions. By requiring health plans and PBMs to disclose the net price, the American people will better understand the true price of their medications, and those involved with drug pricing will be forced to justify any added costs or fees. APhA also notes the benefit of the final rules permitting the Secretary of HHS to require disclosure of additional datapoints that "are of similar character to the items enumerated in the statute."[12] APhA urges the Departments to ensure that the data made available can be meaningfully compared. If pricing data is separated between large chain pharmacies with hundreds of locations and single independent pharmacies or in-network pharmacies and out-of-network pharmacies, the data may not benefit the patient and could potentially harm independent pharmacies and pharmacies lacking significant buying power. For example, pricing and reimbursement centered around the national average drug acquisition cost (NADAC) saw dramatic fluctuations last year after a large chain pharmacy started participating in NADAC surveys for the first time.[13] The reporting by each location of the large chain pharmacy caused a notable drop in NADAC overall, given their significantly lower acquisition costs.[14] The large chain stopped reporting shortly after, and NADAC was appropriately rebalanced before a different chain pharmacy started reporting, causing the same trend to occur.[15] During these volatile times, reimbursements to small, independent pharmacies were lower if NADAC was a factor in their reimbursement model because they were purchasing the medication at a higher cost than NADAC reflected as the average. Accordingly, APhA recommends the Departments review the entire pharmacy reimbursement system to understand how additional transparency requirements could impact pharmacies and work to ensure that greater transparency is not

[9] *Id.* Available at: https://www.federalregister.gov/d/2025-09858/p-53.
[10] *Id.* Available at: https://www.federalregister.gov/d/2025-09858/p-60.
[11] Transparency in Coverage Final Rule, 85 Fed. Reg. 72158, 72167 (Nov. 12, 2020). Available at: https://www.federalregister.gov/d/2020-24591/p-147.
[12] *Id.* Available at: https://www.federalregister.gov/d/2020-24591/p-147
[13] Michael Murphy & Jennifer Rodis, *Shedding Light on NADAC: How Pricing Power Influences Pharmacy Reimbursement*, The Ohio State University College of Pharmacy: PolicyRx (June 26, 2025). Available at: https://pharmacy.osu.edu/news/shedding-light-nadac-how-pricing-power-influences-pharmacy-reimbursement.
[14] *Id.*
[15] *Id.*

utilized against these small business pharmacies within the system that lack significant leverage.

PBMs have a longstanding history of engaging in practices that evade transparency requirements, including structuring rebate agreements to prevent sponsors from accessing this information, utilizing complex fee structures, and offshoring specific operations to jurisdictions that do not have or comply with such regulations. For example, more PBMs are registering as "pharmacy benefit corporations" (PBCs) and exploring alternative corporate structures or naming conventions to navigate around new regulations. However, many states now require PBMs to register or obtain licenses regardless of their corporate form. For example, Maryland mandates PBM registration through its Insurance Administration, and similar requirements exist in over 40 states. Accordingly, APhA urges the Departments to promptly enforce the provisions with the PBMs or PBCs within this final rule, as price transparency is needed with these "middlemen," for patients and their pharmacies.

Increasing Access, Empowering Patients

The TiC final rules also provide that "the prescription drug machine-readable file must be made available in a form and manner specified in guidance issued by the Departments."[16] Following the issuance of the TiC final rules, "the Departments have published this technical implementation guidance on GitHub, … [but] have not issued final form-and-manner guidance implementing the prescription drug machine-readable file requirement."[17] Patient access to this data will enable them to make better health care decisions, hopefully allowing them to take a more active role in their overall health and become more involved in working with their pharmacist in clinical decision-making. By requiring this information to be released to the public, pharmacists and other health care providers will gain a deeper understanding of all that goes into setting a drug's price. This information will also likely be used by others within the health care sector, as costs of medications, services, fees, and other price concessions will be readily accessible. APhA encourages the Departments to establish a framework in these rules that will actually drive down patient costs for medications while also requiring PBMs implementing additional fees or costs in the overall process to justify them to patients and other involved parties. APhA is concerned that PBMs may be able to utilize this data to manipulate the current systems in place, decreasing product-specific reimbursements to the point where pharmacies lose money for dispensing prescriptions. As such, APhA encourages the Departments to promote mechanisms and procedures that prevent PBMs from utilizing this data to intentionally harm pharmacies or drive down reimbursements to a point at zero or below the costs of acquiring the product from wholesalers and dispensing the medications to patients.

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[16] Request for Information Regarding the Prescription Drug Machine-Readable File Requirement in the Transparency in Coverage Final Rule, 90 Fed. Reg. 23303, 23305 (June 2, 2025). Available at: https://www.federalregister.gov/d/2025-09858/p-67.

[17] *Id.* Available at: https://www.federalregister.gov/d/2025-09858/p-67.

One example of how greater access to pricing data can negatively impact pharmacies is when discount card programs partnered with insurers and PBMs to find patients the lowest price.[18] These partnerships enabled the health plans and PBMs to review the aggregate pricing data of the discount card company to determine if another PBM's network price was lower than their own. If a lower price was found within this dataset, the PBM then directed its beneficiary's prescription to be processed using the discount card in coordination with the rates and information of another PBM. When the discount card program is utilized, the pharmacy then pays a fee to the discount card company, which is then split amongst the PBM directing the patient to use the program, the PBM with the lower rate, and the discount card company. These fees, in combination with the lowest price found within this dataset, can often lead to the pharmacy taking a loss when dispensing the medication. Examples like this highlight how powerful entities within the sector could use transparency to force losses onto pharmacies. Accordingly, APhA urges the Departments to protect pharmacies from such practices. This request is especially urgent given the trend in pharmacy closures[19] due to inadequate reimbursements by PBMs, which jeopardize patient access as well as Medicare Part D plans' compliance with federal pharmacy access requirements under § 423.120.[20]

APhA also reminds the Departments that as they develop mechanisms to lower drug costs, they need to separately consider the reimbursement of the product, which is fixed for pharmacists, from the cost of dispensing and any related patient care service or performance incentive payment to provide adequate reimbursement under a sustainable business model that improves and does not disrupt our nation's pharmacy distribution system. The current framework fails to provide coverage for the true cost of the medication and any payment for pharmacies to provide the associated patient care services that come with dispensing a medication. Over $528 billion is wasted and 275,000 lives are lost each year in the United States due to non-optimized medication use.[21] Comparing this to the U.S. expenditure on prescription medications, $340 billion, **for every $1.00 spent on drug therapy, we spend an additional $1.55 to address the problems associated with non-optimized drug therapy**![22] Pharmacists can play a significant role in the solution, and the Departments, in particular, CMS, should reimburse pharmacists as health care providers to drive costs down and save lives.

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[18] *See* Luke Slindee, *How GoodRx Helped Steal $7 From My Pharmacy (Featuring Algorithmic Price Fixing)*, YouTube (Mar. 25, 2024). Available: https://www.youtube.com/watch?v=NWJ9ZqxssWw.

[19] Ruichen Xu, et al., *Mapping U.S. Pharmacy Closures January 2014 to March 2024*, University of Pittsburgh (May 14, 2024). Available at: https://storymaps.arcgis.com/stories/21620f1e07c14d7f81adc4503faaf51e.

[20] 42 CFR 423.120. Available at: https://www.ecfr.gov/current/title-42/section-423.120.

[21] Jonathan H. Watanabe, et al., *Cost of Prescription Drug-Related Morbidity and Mortality*, 52 Annals of Pharmacology 829 (2018). Available at: https://pubmed.ncbi.nlm.nih.gov/29577766/.

[22] *Prescription Drug Spending in the U.S. Health Care System*, American Academy of Actuaries (Mar. 2018). Available at: https://actuary.org/prescription-drug-spending-in-the-u-s-health-care-system/#:%7E:text=Health%20care%20spending%20in%20the,was%20spent%20on%20prescription%20drugs.

Because pharmacies are where most Americans are likely first exposed to the complexities of pharmaceutical pricing policies, APhA is concerned that patients accessing information from the prescription drug machine-readable file may come to the pharmacy expecting to pay one price and then be charged another. Using difficult-to-understand disclaimers or insufficient background information associated with a patient's estimated cost-sharing liability may result in greater patient confusion, as the regulatory framework can be complex and circumstantial. Because of this, pharmacists and pharmacy personnel will be required to explain these price discrepancies or errors in understanding to the patient, which can be difficult and argumentative, especially when a patient's price is higher than they intended and they cannot afford the actual price of the medication. Pharmacists, pharmacy technicians, student pharmacists, and other pharmacy personnel will have to undergo the time-consuming task of getting information regarding the price differential from the issuer. It also puts pharmacists in an awkward position as they will likely have limited or no information or explanation for the patient until speaking with the health plan. As such, if pharmacists are placed in this position, CMS should allow trained pharmacists to bill independently and as members of patient care teams for each 15-minute insurance consult to all issuers. Under Medicare Part D, PBMs already receive fees from plans, and plans are reimbursed by CMS for acting as agents. If pharmacists do the additional work of PBMs and plans, APhA supports efforts and mechanisms that compensate them for their time and services without requiring an unfunded mandate that will only contribute to decreasing patient access.

APhA appreciates the opportunity to provide the Departments with additional insight into how enforcing these final rules will impact pharmacies, pharmacists, and patients. APhA encourages the Departments to promptly implement disclosure requirements regarding drug pricing while being mindful of the challenges that may be present for pharmacies and pharmacists. If you have any questions or would like to meet with APhA to discuss these comments, please contact Corey Whetzel, APhA's Senior Manager, Regulatory Affairs, at cwhetzel@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Vice President, Government Affairs

cc: Philip J. Lindenmuth, Acting Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes), Internal Revenue Service, Department of the Treasury
Helen H. Morrison, Benefits Tax Counsel, Department of the Treasury
Robert F. Kennedy, Jr., Secretary, Department of Health and Human Services.