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Hon. Janet L. Yellen
Secretary of the Treasury
RIN 1545-BQ10/1545-BQ27/REG-117575-21
Department of the Treasury
1500 Pennsylvania Avenue
Washington, DC 20220

Hon. Martin J. Walsh
Secretary of Labor
RIN 1210-AC07, EBSA
Department of Labor
200 Constitution Ave. NW, N-5653
Washington, DC 20210

Hon. Xavier Becerra
Secretary of Health and Human Services
CMS-9905-IFC
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Hon. Kiran Ahuja
Director
RIN 3206-AO27
Office of Personnel Management
1900 E Street NW
Washington, DC 20415

RE: OPM/Treasury/Labor/HHS Notice of Interim Final Rules, File Code CMS-9905-IFC, and Treasury Notice of Proposed Rulemaking, REG-117575-21, Both Titled "Prescription Drug and Health Care Spending," 86 Fed. Reg. 66662 and 86 Fed. Reg. 66495 (November 23, 2021)

Dear Secretaries Yellen, Walsh, and Becerra, and Director Ahuja:

The Purchaser Business Group on Health (PBGH) appreciates the opportunity to comment on the proposed Interim Final Rules implementing Sec. 204 of the Consolidated Appropriation Act on Prescription Drug and Health Care Spending. We applaud the departments for addressing prescription drug costs and transparency. Affordability is a critical issue for consumers and employer purchasers. PBGH is a not-for-profit public benefit organization consisting of large public and private purchasers of health care. Together our members spend nearly \$100 billion each year to provide health care coverage for about twelve million Americans.

PBGH is cognizant of the potential administrative burden for reporting these data and believes that the regulations can help streamline reporting process and enhance the likelihood of providing meaningful and actionable information by setting forth data specifications applicable to all suppliers. Purchasers rely on health plans, pharmacy benefit managers and additional parties to provide comprehensive prescription drug benefits to their members. Even as purchasers work diligently to assure high quality

and affordable benefits for their members, there are many hidden rebates, administrative fees, market access fees and other remuneration that are embedded in prescription drug pricing that are not visible to purchasers.

Addressing Complex Ownership and Business Relationships

There has been recent growth in the formation of Group Purchasing Organizations and expansion of wholesale aggregators that introduce an additional layer of middlemen and costs for drug acquisition. Despite their core business focused on the US drug supply chain, many of these entities are headquartered outside of the United States, whether designed to optimize tax benefits or escape regulatory oversight. Regulations implementing Sec. 204 and similar transparency requirements should require prescription drug suppliers to disclose detailed pricing information on rebates, administrative fees any other transactional fees when the supplier relies on any third parties between the pharmaceutical manufacturer and ultimately the delivery of medications to the patient. **These transparency requirements should extend to contracted suppliers and in particular, any subsidiary corporations in which there may be a mutual or indirect ownership interest, including corporate entities headquartered outside the United States.**

Assuring Appropriate Granularity in Reporting

PBGH supports efforts to identify and describe the highest cost drugs, as required in Sec. 240. Such drugs are often medical specialty drugs that are billed through a doctor's office or hospital and paid through the medical benefit. Many of these drugs are billed through J-codes or the Healthcare Common Procedure Coding System (HCPCS) that are commonly used for billing Medicare & Medicaid patients. Purchasers are often challenged by use of generic non-specified codes such as J3490 that limit transparency into high-cost drugs and the potential for identifying opportunities to support affordability and competition through adoption of biosimilar medications. Instead, **we recommend the IFR be amended to capture National Drug Codes (NDC) for medical specialty drugs, improving our collective ability to improve value and access.**

To optimize the utility of reported data and mitigate the administrative burden of collecting drug cost information, updated regulations should specify that the top 50 drugs be counted based on the NDC, a unique 11-digit, 3-segment number. This universal product identifier provides information identifying the labeler, the product, and the commercial package size. **PBGH recommends that the top 50 drugs be defined and counted based on the first two segments, with itemized reporting on the third segment based on all packages dispensed.** Given the diverse combinations of specific strength, dosage form (i.e, capsule, tablet, liquid) and formulation of a drug for a specific labeler, the top 50 drug list could reflect only 10 branded drugs as currently defined in the IFR. Ultimately, the number of top volume drugs may need to be

increased from 50 to provide meaningful benchmarking information that is actionable by purchasers to improve value and reduce consumer out-of-pocket costs.

Temporary Enforcement Discretion for Employers Acting in Good Faith

While Sec. 204 of the CAA places responsibility for reporting on plan sponsors, much of the required information is held by third parties, which have historically limited the ability of plan sponsors to access the necessary data. In early efforts to obtain required prescription drug cost data, many employers have expressed difficulty obtaining the requisite reporting from their suppliers. **We recommend that the Administration use enforcement discretion for a transitional period to recognize best efforts that purchasers are undertaking to access required data.** Ultimately, we believe it may be necessary for the Administration to directly require third party entities to report on required data.

Thank you again for the opportunity to provide our perspective on this vital rule. Please contact Shawn Gremminger, Director of Health Policy, at sgremminger@pbgh.org, for further information.

Sincerely,

/s/

William Kramer
Executive Director, Health Policy