July 23, 2020

Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Ave., SW
Washington, D.C. 20201

Submitted via www.regulations.gov

Re: Request for Information: Reporting on Pharmacy Benefits and Prescription Drug Costs (RIN 0938-AU66)

Dear Secretary Becerra:

The Alliance of Community Health Plans (ACHP) appreciates the opportunity to provide feedback on complying with the pharmaceutical data collection requirements under the Consolidated Appropriations Act of 2021.

ACHP represents the nation's top-performing non-profit health plans improving affordability and outcomes in the health care system. ACHP member companies are provider-aligned health organizations that provide high-quality coverage and care to more than 24 million Americans across 36 states and D.C. They are leading the industry in practical, proven reforms around primary care delivery, value-based payment and data driven systems improvement.

Addressing the high cost of prescription drugs in the United States is a priority for ACHP and its members. We believe improved transparency in the biopharmaceutical marketplace is a critical component to lowering the cost of medicine for American patients. We would be remiss if we did not take this opportunity to suggest the Administration should also pursue reporting requirements for pharmaceutical manufacturers regarding the prices they set for prescription drugs, how they determine price increases, as well as other expenditures such as research, development and marketing.

Earlier this month, President Biden signed an Executive Order, instructing the Department of Health and Human Services to issue a comprehensive plan within 45 days to combat high prescription drug prices and price gouging. ACHP urges the Department to consider what reporting requirements could be imposed through administrative authorities on drug makers as part of that plan.

Regarding the reporting requirements of pharmacy benefits and prescription drug costs for health plans under the Consolidated Appropriations Act of 2021, we urge the Department

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to implement the law in a way that will not be impractical but satisfy the goals of the law. Further, we recommend the Department develop parameters that will not be overly burdensome for plans to comply but provide information on the impact drug costs have on our ability to provide quality, affordable health coverage. Increasing specificity of data will require more resources and time for plans to gather, verify and submit on a routine basis.

Below are specific recommendations and feedback in response to the Department's request for information.

Deadline to gather, prepare, and submit data

Our members urge sufficient time to collect, prepare and submit complete data. Specifically, we recommend setting an initial reporting date that is one year after the final rule and technical reporting specifications are finalized. We also recommend collecting data by calendar year and implementing at least a six-month time period before data submissions are due to allow health plans to complete their reports (e.g., if data is due on June 1 of a calendar year, the data being captured should apply to January 1 – December 31 of the prior year).

Data elements and definitions

Our members recommend identifying prescription drugs by National Drug Code (NDC) only, as other group/designations would create unnecessary burden and increase the amount of time/resources needed to compile the information. In order to account for the issue of multiple NDCs per drug, the "top 50" and "top 25" lists should require issuers to combine all formations and strengths to the parent drug level instead of mandating separate reporting requirements. For example, atorvastatin 10mg, atorvastatin 40mg, and atorvastatin 80mg would all roll up to atorvastatin. Additional categorization codes (from USP-DC or RxNORM) would also assist in the ability to roll up data, making the information more user friendly.

We recommend limiting reporting to only those drugs dispensed through an outpatient pharmacy. There should be a consistent definition for "prescription drug" across all reporting requirements that indicates the drug is a non-compounded, legend drug. We also recommend using the AFHS Therapeutic Classifications when defining "therapeutic class.". Standard PBM contracts may also provide guiding nomenclature for designations such as mail, retail and specialty.

We recommend rebates and other remuneration should be measured using the total dollar amount and not further divided into subcategories (e.g., administrative fees, data sharing fees, formulary placement fees, credits, market share incentives, etc.).

It is also worth noting there is typically a six-month lag time in terms of when the health plan obtains rebate information from its pharmacy benefit manufacturers (PBM). The Department should be cognizant of such time lapses in establishing reporting deadlines. Finally, we are concerned that health plans will be responsible for collecting information they do not have access to. For instance, our members collect information on total premiums directly from employers but do not have a means to separate the amount

contributed by employees. Accordingly, any requirement to provide a breakdown between employer and employee share of monthly premiums would be particularly problematic or impractical to comply with.

Formatting
We recommend requiring a simple CSV file for submitting required information. Our members request the Department avoid requiring the submission of fillable forms (e.g., PDFs) as the opportunity for inputting errors are much greater.

States laws and lessons learned
We are aware of similar state laws in Minnesota, Oregon, Montana, and Washington that can be informative. For example, Washington has similar reporting requirements, however, regulators in that state agreed that reporting should occur at the line-of-business level. It was determined that reporting data at the plan level is neither reasonable nor would it produce meaningful data. We urge the Department to adopt a similar approach and require issuers to only report data at the line-of-business level.

Additionally, Montana's requirement for reporting will go into effect on January 1, 2022 and mandates Pharmacy Benefit Managers (PBMs) provide the data being sought. We agree that PBMs should play a major role in collecting and furnishing the required information. Requiring PBMs to provide the data may help minimize the variations that will likely occur between plan sponsors.

Avoid duplication
Our members participating in the Federal Employees Health Benefits Program (FEHBP) are already required to report detailed information to the Office of Personnel Management (OPM) for prescription drug prices. We urge the Department to avoid expanding the reporting requirements under the FEHBP to other markets or lines-of-business, as this level of detail is not appropriate for oversight of prescription drug costs at the national level and would be impractical for our members to collect and submit.

ACHP thanks the Administration for your consideration of our view on this matter. We welcome additional opportunities to engage to combat the high cost of prescription drugs once and for all. Please contact Michael Bagel, Director of Public Policy at mbagel@achp.org or 202-897-6121 with any questions or to discuss.

Regards,

Ceci Connolly
President and CEO, ACHP