



July 23, 2021

Xavier Becerra  
Secretary, The U.S. Department of Health & Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue SW  
Washington, D.C. 20201

Janet Yellen  
Secretary, Department of the Treasury  
The Treasury Building  
1500 Pennsylvania Avenue NW  
Washington, D.C. 20220

Martin J. Walsh  
Secretary, Department of Labor  
The Department of Labor Building  
200 Constitution Avenue NW  
Washington, D.C. 20210

Kiran Ahuja  
Director, U.S. Office of Personnel Management  
Theodore Roosevelt Federal Building  
1900 E Street NW  
Washington, D.C. 20415

Charles P. Rettig  
Commissioner, Internal Revenue Service  
Internal Revenue Service Headquarters Building  
1111 Constitution Avenue NW  
Washington, D.C. 20224

Ali Khawar  
Acting Assistant Secretary, Employee Benefits Security Administration  
Frances Perkins Building  
200 Constitution Avenue NW  
Suite N-5677  
Washington, D.C. 20210

**RE: Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs**

Dear Secretary Becerra, Secretary Yellen, Secretary Walsh, Director Ahuja, Commissioner Rettig, Acting Assistant Secretary Khawar:

Consumers for Quality Care (CQC), a coalition of advocates and former policymakers working to provide a voice for patients in the health care debate, appreciates the opportunity to provide comments on the Department of Health and Human Services (HHS), Department of the Treasury, Department of Labor,

Office of Personnel Management (OPM), Internal Revenue Service (IRS), and the Employee Benefits Security Administration's (EBSA) proposed rule (file code CMS-9905-NC). These offices, organizations, and departments will be hereinafter referred to as "the agencies."

CQC is concerned that several of the provisions in this proposed rule will harm patient access to high quality, affordable health care. We are committed to ensuring patients and their right to affordable, high-quality care remain at the forefront in the development of health care policies and regulations. It is with this goal in mind that we submit the following comments (I-VI):

### **I. Manufacturer Co-pay Assistance Programs, Coupon Cards, and Copay Accumulator Programs (§B.1)**

Under §B.1 of the proposed rule, the agencies request a better understanding of the issues related to compliance with this provision, and to estimate the impact of any potential rules, both generally and in specific areas.<sup>1</sup> This includes determining how manufacturer co-pay assistance programs, coupon cards, and co-pay accumulator programs should be accounted for.

We are concerned about the impact of any rollback of co-pay assistance program and coupon card benefits on consumers, specifically co-pay accumulator programs which can be harmful to beneficiaries with chronic diseases relying on costly medicines. Preventing co-pay assistance contributions from counting towards a beneficiary's deductible and maximum out-of-pocket spending limits leaves individuals at risk for discontinuing necessary treatments. Further, insurers are expected to be "transparent" about their assistance programs in plan documents, but there is no mandatory disclosure requirement, leaving patients vulnerable. Thus, insurance companies are creating an environment that will lead to poorer health outcomes and higher costs for consumers.

### **II. Roles for Pharmacy Benefits Managers (PBMs) (§C.4)**

Under §C.4 of the proposed rule, the agencies request information on "[the] role, if any . . . Pharmacy Benefits Managers (PBMs) play in furnishing necessary information to plans and issuers, or to the Agencies and whether PBMs could obtain all the required reporting information, including general information; each state in which the plan or coverage is offered; monthly premiums paid by employers and by participants, beneficiaries, and enrollees; total spending on health care services broken down by type; and the impact on premiums of prescription drug rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers."<sup>2</sup>

We express concern in the role of PBMs acting as a go-between or middleman in the supply chain. When PBMs get involved, they can actually increase the cost that patients pay at the pharmacy counter.<sup>3</sup> A [recent study](#) published in the Journal of the American Medical Association found that intermediaries drive up the price of common generic drugs, and a streamlined payment system as employed by "Costco" could save Medicare billions of dollars a year.<sup>4</sup> Instead, policy makers have frequently adopted the PBM argument that their role cannot be regulated because they will raise premiums. This is unacceptable. Further, they are handed the keys to prescription drug benefits, which can lead to determinations on which

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<sup>1</sup> "Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs," Federal Register. OPM et al. (2021). <https://www.federalregister.gov/>

<sup>2</sup> "Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs," Federal Register. OPM et al. (2021). <https://www.federalregister.gov/>

<sup>3</sup> "The consolidation of health insurance and drug benefits is back," Axios. Bob Herman. (2019). <https://www.axios.com/>

<sup>4</sup> "Comparison of Spending on Common Generic Drugs by Medicare vs Costco Members," Erin Trish, PhD; Laura Gascue, MS; Rocio Ribero, PhD; et al. JAMA Intern Med. Published online July 6, 2021.

drugs are covered by a health insurance plan.<sup>5</sup> We cannot sit idly by while consumers are victims of “clawbacks,” or times where consumers are forced to pay higher co-pays than the cost of the drugs they need.

### **III. Measuring the Impact of Rebates on Premiums and Out-of-Pocket Costs (§D.8)**

Under §D.5 of the proposed rule, the agencies request information on the important “considerations . . . for plans and issuers in determining the 25 drugs that yielded the highest amount of rebates and other remuneration from drug manufacturers during the plan year” and ways to measure it (i.e. by total dollar amount, in comparison to total spending, or drug prices).<sup>6</sup>

Under §D.8 of the proposed rule, the agencies request information on which “considerations are important for plans and issuers in measuring the impact of drug manufacturer rebates on premiums and out-of-pocket costs.” Additionally, the agencies request detail on the “quantitative or qualitative analyses . . . plans and issuers [might] perform” and those they “currently perform.”

We do not believe that rebates, and their utilization, should have any impact on premiums or deductibles. Our research indicates that voters almost unanimously agree (92%) on the importance of ensuring that deductibles are low enough to not impede access to care.<sup>7</sup> 63% of those responding in the affirmative did so strongly, indicating widespread support for increased accountability.<sup>8</sup> Manufacturer coupons go far in helping individuals meet ever-rising deductibles, and consumers should be able to take advantage of savings in the health care system wherever they can to reduce their out-of-pocket costs. Consumers are concerned with health care costs; lower deductibles are crucial to sustainable change.

### **IV. Publicizing Analysis for the Consumer (§G.2)**

Under §G.2 of the proposed rule, the agencies request information on how generating regulatory impact analysis will benefit consumers. It is our belief that consumers can greatly benefit from publicizing the analysis due to increased transparency in health care, specifically around accumulator adjustment programs, pharmacy benefit managers’ relationships with insurers, and rebates.

We want to reiterate the need for improvement around co-pay accumulators, support for lower deductibles, and the importance of creating affordable options for consumers to address high or unexpected out-of-pocket costs. By addressing these concerns, we believe potential rules around pharmacy benefits, pharmacy benefit managers, and prescription drug costs will better assist consumers in accessing quality, affordable care.

Thank you for the opportunity to comment on the Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs as you plan your final rule.

Sincerely,  
Consumers for Quality Care

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<sup>5</sup> Ibid.

<sup>6</sup>“Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs,” Federal Register. OPM et al. (2021). <https://www.federalregister.gov/>

<sup>7</sup>“Research Winter 2021,” Consumers for Quality Care. (2021). <https://consumers4qualitycare.org/>

<sup>8</sup> Ibid.