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Submitted via [www.regulations.gov](http://www.regulations.gov)

**RE: Docket No. EBSA-2021-0005  
Request for Information Regarding Reporting on Pharmacy Benefits and  
Prescription Drug Costs**

JDRF is pleased to submit comments in response to the Departments of Health and Human Services, Labor, and the Treasury (the Departments) and the Office of Personnel management (OPM) request for information regarding implementation considerations on collecting and reporting information on pharmacy benefits and prescription drug costs.

#### **ABOUT JDRF**

JDRF is the leading global organization funding type 1 diabetes (T1D) research. Our mission is to accelerate life-changing breakthroughs to cure, prevent and treat type 1 diabetes and its complications and we collaborate with a wide spectrum of partners in the community to achieve this mission. Founded in 1970 by parents of children with type 1 diabetes, JDRF has invested over \$2.5 billion in research since its inception and employs doctorate-level scientists to manage our research portfolio.

## ABOUT TYPE 1 DIABETES

Type 1 diabetes (T1D) is an autoimmune disease that strikes children and adults suddenly and can be fatal. To stay alive until a cure is found, people with T1D require lifelong and continuous insulin therapy coupled with continuous blood glucose monitoring. Too much insulin can result in seizures, coma, or death from hypoglycemia, or low glucose levels. Too little insulin over time leads to devastating kidney, heart, nerve, and eye damage from hyperglycemia, or high glucose levels. Due to the nature of T1D, patients and their caregivers use medical products on a daily basis and in many cases around the clock, relying on them to try and help maintain glucose control to avoid both short- and long-term complications.

Type 1 diabetes is an autoimmune disease that strikes children and adults suddenly and can be fatal. According to the CDC, 1.6 million Americans are living with T1D, including 187,000 people under the age of 20. Until a cure is found and in order to stay alive, people with T1D require lifelong and continuous insulin therapy coupled with continuous blood glucose monitoring. Too much insulin can result in seizures, coma, or death from hypoglycemia, or low glucose levels. Too little insulin over time leads to devastating kidney, heart, nerve, and eye damage from hyperglycemia, or high glucose levels.

Due to the nature of T1D, patients and their caregivers use insulin daily and in many cases around the clock, relying on it to help maintain glucose control that avoids both short- and long-term complications. The unmet needs in T1D are still significant specifically as it relates to access to affordable, lifesaving insulin. Recent studies have shown that one in four patients at an urban diabetes center reported rationing their insulin resulting in poor glycemic control.<sup>1</sup> This study simply highlights the health risks associated with unaffordable costs of insulin for some living with T1D.

## COMMENTS ON REQUESTED INFORMATION

**The Departments and OPM should ensure that information required to be collected and reported be data that is the most important to consumers and patients.**

JDRF is encouraged the Departments and OPM are accepting public feedback on implementation considerations associated with collecting and reporting key prescription drug information. Millions of Americans rely on prescription drugs to maintain their health and are increasingly facing a greater financial burden at the pharmacy counter.

Insulin list prices and the subsequent out-of-pocket cost to patients who require insulin to manage their disease and survive, are increasing at a rapid pace. For example, according to a report published by the Mayo Clinic, “one vial of Humalog (insulin lispro), which used to cost \$21

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<sup>1</sup> Herkert, D., Vijayakumar, P., Luo, J., Schwartz, J. I., Rabin, T. L., DeFilippo, E., & Lipska, K. J. (2019). Cost-Related Insulin Underuse Among Patients With Diabetes. *JAMA Internal Medicine*, 179(1), 112. <https://doi.org/10.1001/jamainternmed.2018.5008>

in 1999, costs \$332 in 2019, reflecting a price increase of more than 1000%”.<sup>2</sup> These ongoing increases in insulin prices are occurring at the same time that average annual deductibles for employer-sponsored insurance plans have nearly tripled since 2008.<sup>3</sup> This aligns with increasing adoption of High-Deductible Health Plans (HDHPs) as 51% of Americans are now enrolled in a HDHP.<sup>4</sup> These cost-shifting efforts result in more Americans forgoing or rationing necessary care. For example, recent studies suggest that 1 in 4 patients have rationed their insulin due to the high cost.<sup>5</sup> This cost-shifting impacts those living with chronic conditions especially hard, as any rationing of care can lead to dangerous clinical events that further imperil health and can even result in death. Efforts by the Department and OPM to implement transparent, public reporting of drug price and benefit information is a vital step in better understanding and controlling rising drugs costs.

We encourage the Departments and OPM to prioritize data reporting of those data elements that impact consumer decision-making and patient care; specifically, transparency in out-of-pocket costs, application of utilization tools such as prior authorization, and formulary tier placement. As an organization that believes savings generated from rebates should be shared directly with those patients prescribed a rebated drug, we would also encourage the public reporting of rebates by drug class by benefit plan.

Given the impact of prescription drugs on certain consumer and patient populations, we believe it important, and of great potential value, that prescription data reporting requirements consider key chronic conditions and diseases. We encourage the Departments and OPM to consider how it may categorize reporting by key diseases and chronic conditions to ensure information is relevant to select patient populations.

As noted in Section D (1) and (2) we believe the criteria for the 50 drugs that must be reported by plans should take into consideration specific chronic conditions and diseases that represent significant costs to the plan, require prescription drugs for the survival of the patient, and align with broader public health goals. We would recommend that the Departments and OPM specifically require the reporting of drugs relevant to the treatment of certain conditions such as diabetes and this information be categorized specifically by disease.

Diabetes is a disease that 34 million Americans are currently living with; nearly 1 in 8 adults.<sup>6</sup> In 2017, estimates project that one of every 4 health care dollars spent was spent on diabetes related care.<sup>7</sup> A 2020 survey of employers found that diabetes was one of their top drivers of

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<sup>2</sup> Rajkumar, S. V. (2020). The High Cost of Insulin in the United States: An Urgent Call to Action. *Mayo Clinic Proceedings*, 95(1), 22–28. <https://doi.org/10.1016/j.mayocp.2019.11.013>

<sup>3</sup> Kaiser Family Foundation. (2020, October). *Employer Health Benefits 2020 Annual Survey*. <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>

<sup>4</sup> Price, S. (2021, February 2). *51% of U.S. Workforce Enrolled in High-Deductible Health Plans, Which May Leave Some Underinsured*. ValuePenguin. <https://www.valuepenguin.com/enrollment-changes-to-high-definition-health-insurance-plans>

<sup>5</sup> Herkert, D., Vijayakumar, P., Luo, J., Schwartz, J. I., Rabin, T. L., DeFilippo, E., & Lipska, K. J. (2019). Cost-Related Insulin Underuse Among Patients With Diabetes. *JAMA Internal Medicine*, 179(1), 112. <https://doi.org/10.1001/jamainternmed.2018.5008>

<sup>6</sup> U.S. Department of Health and Human Services Centers for Disease Control and Prevention. (2020). *National Diabetes Statistics Report 2020*. Centers for Disease Control and Prevention. <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>

<sup>7</sup> Economic Costs of Diabetes in the U.S. in 2017. (2018). *Diabetes Care*, 41(5), 917–928. <https://doi.org/10.2337/dci18-0007>

cost.<sup>8</sup> There are likely several ways to determine which drugs must be reported that would include the treatments for diabetes based on its prevalence in the population such as claims volume or price increase. However, there is value in understanding the similarities and difference between health plans by disease category as it can provide helpful insight for not only plans and regulators but also researchers, public health officials, and employers crafting benefit strategies.

In closing, given the daily importance of prescription medication for the 1.6 million Americans living with T1D, we encourage you to give consideration to implementing a program that is not only operational for the health plans but one that promotes greater transparency for patients.

Thank you for the opportunity to comment on this request for information. If you have any questions, please contact Aaron Turner-Phifer at [aturner-phifer@jdrf.org](mailto:aturner-phifer@jdrf.org).

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<sup>8</sup> *Managing Health Care Costs*. (2021, March 29). SHRM. <https://www.shrm.org/resourcesandtools/tools-and-samples/toolkits/pages/managinghealthcarecosts.aspx>