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June 6, 2019

The Honorable Richard Neal
Chairman
House Ways and Means Committee
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Kevin Brady
Ranking Member
House Ways and Means Committee
1139 Longworth House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Chairman
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Greg Walden
Ranking Member
House Energy and Commerce Committee
2322 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Neal, Chairman Pallone, Ranking Member Brady, and Ranking Member Walden:

On behalf of the more than 30 million Americans living with diabetes and the 84 million more with prediabetes, thank you for the opportunity to comment on discussion draft legislation to improve the Medicare Part D program. We appreciate your bipartisan leadership in drafting this important legislation which aims to reform and improve Medicare Part D. The American Diabetes Association (ADA) is pleased to provide comments on the discussion draft.

As you may know, Medicare Part D covers insulin that is not administered with an insulin pump. The rising cost of insulin is one of the most critical health care cost issues affecting people with diabetes. The price of insulin has drastically increased in recent years. Between 2002 and 2013, the average list price of insulin nearly tripled.[1]There is no medication that can be substituted for insulin and approximately 7.4 million Americans with diabetes use this lifesaving medication. For millions of people living with diabetes, including all individuals with type 1 diabetes, access to insulin is literally a matter of life and death.

In 2017, the ADA convened an Insulin Access and Affordability Working Group to examine the full scope of the insulin affordability issue and published their conclusions and recommendations in a white paper that was released last May. As a follow-up to the Working Group's findings, the ADA released a Public Policy Statement with an array of short- and long-term recommendations to address the rising costs of insulin.

[1] Hua X, Carvalho N, Tew M, Huang ES, Herman WH, Clarke P. Expenditures and prices of antihyperglycemic medications in the United States: 2002-2013. JAMA 2016;315:1400–1402

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One area of focus in the policy statement pertains to cost-sharing under the Medicare Part D program. Currently, there is no limit on cost-sharing for Medicare Part D beneficiaries who are not eligible for a low-income subsidy. Beneficiaries who reach the catastrophic phase of the benefit are eligible for cost-sharing under the standard benefit structure, which is 5% of a drug's cost. For drugs with a high list price, such as insulin, even 5% can be unaffordable, especially if the beneficiary reaches the catastrophic phase early in the plan year. Those who reach the catastrophic level fill twice as many prescriptions and have an average price per prescription that is more than twice as high compared to those who are not in the catastrophic phase. Further, average annual spending for those reaching the catastrophic level is $16,914 per person. This burden disproportionately impacts people with and at risk for developing diabetes. Specifically, among individuals who reach the catastrophic coverage level, gross spending on diabetes medications is the second highest of all therapeutic classes. Medicare Part D enrollees who reach the catastrophic phase are also more likely to be African American, a population with a high risk of developing diabetes when compared to the overall population of those enrolled in Part D.[2]

The draft legislation would create an out-of-pocket maximum on prescription drug costs for Medicare beneficiaries in Part D, which would be based on the current catastrophic threshold. The ADA supports this provision because it would limit out-of-pocket spending for Medicare Part D beneficiaries in the catastrophic phase. This would provide some financial protection for individuals with high annual drug costs.

In its request, the Committee asked for feedback on improvements pertaining to out-of-pocket costs for beneficiaries below the catastrophic level. Providing diabetes medications with low or no cost-sharing has been shown to increase medication adherence and result in better long-term health outcomes.[3][4] The ADA recommends that the Committee consider ways to ease the financial burden for people with diabetes by lowering or removing cost-sharing for insulin coverage under the Part D program. Covering insulin at low or no cost-sharing will reduce the financial burden for people living with diabetes who rely on this life saving drug.

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[2] Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System, June 2016, available at: http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-thehealth-care-delivery-system.pdf?sfvrsn=0. Includes spending by all parties, including Medicare, Part D plan, and enrollee.

[3] Blumenthal DM, Goldman DP, Jena AB, Outcomes-Based Pricing as a Tool to Ensure Access to Novel but Expensive Biopharmaceuticals, Annals of Internal Medicine, February 2017, available at: http://annals.org/aim/article-abstract/2592775/outcomes-based-pricing-tool-ensure-access-novel-expensivebiopharmaceuticals.

[4] Spaulding A, Fendrick AM, Herman WH, et al., A Controlled Trial of Value-Based Insurance Design - the MHealthy: Focus on Diabetes (FOD) Trial, Implementation Science, April 2009, available at: https://www.ncbi.nlm.nih.gov/pubmed/19351413.

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Thank you again for the opportunity to comment on this important legislation. If you have questions or would like to discuss further, please contact Rob Goldsmith, Director, Federal Government Affairs at rgoldsmith@diabetes.org or (703) 253-4837.

Sincerely,

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