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May 16, 2019

VIA ELECTRONIC TRANSMISSION

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Dear Administrator Verma,

We write to request information from the Centers for Medicare & Medicaid Services (CMS) regarding the cost of insulin products and their effect on both the federal government's healthcare spending, and the impact on the tens of millions of Americans its programs serve. The Centers for Disease Control and Prevention estimates that more than 30 million Americans have diabetes, equaling roughly 10 percent of the population.¹ The American Diabetes Association has estimated that 1.5 million people will receive new diagnoses each year.² For some with diabetes, particularly Type 1, patients require daily insulin injections or an insulin pump to manage blood sugar levels. However, even though insulin has been used to treat diabetes for almost 100 years, its price has continued to increase, putting stress on patients and taxpayers.

Earlier this year, we sent letters to the three primary manufacturers of insulin, and the three largest pharmaceutical benefit managers (PBM), seeking information about how their actions have contributed to rising healthcare costs for patients and taxpayers.³ As the committee charged with oversight of Medicare and Medicaid, we are concerned about the impact of rising insulin costs on patients and taxpayers. For example, one recent analysis found that from 2007 to 2017, Medicare's pre-rebate spending on insulin increased 840%, while aggregate annual out-of-pocket spending more than quadrupled.⁴

¹ Centers for Disease Control and Prevention, *New CDC report: More than 100 million Americans have diabetes or prediabetes*, (July 18, 2017). <https://www.cdc.gov/media/releases/2017/p0718-diabetes-report.html>.

² American Diabetes Association, *Statistics About Diabetes*, <http://www.diabetes.org/diabetes-basics/statistics/>.

³ Grassley, *Wyden Launch Bipartisan Investigation into Insulin Prices*, (Feb. 22, 2019), <https://www.finance.senate.gov/chairmans-news/grassley-wyden-launch-bipartisan-investigation-into-insulin-prices>; Grassley, *Wyden Question Role of Middlemen in Skyrocketing Insulin Prices*, (Apr. 2, 2019), <https://www.grassley.senate.gov/news/news-releases/grassley-wyden-question-role-middlemen-skyrocketing-insulin-prices>.

⁴ Juliette Cubanski and Tricia Neuman et al., *How much Does Medicare Spend on Insulin?*, Kaiser Family Foundation (Apr. 1, 2019). <https://www.kff.org/medicare/issue-brief/how-much-does-medicare-spend-on-insulin/>

Accordingly, we are seeking your assistance in gathering data to better understand how insulin price increases have affected costs for federal healthcare programs and the patients that use them.⁵ Please answer the following and provide the requested information no later than May 30, 2019:

1. For each of the following programs, please provide the total amount of federal spending that CMS paid in reimbursements for each insulin product with a unique National Drug Code (NDC) on an annual basis for each fiscal year from FY2010 to the present (including partial year totals for the current fiscal year), and the amount that the federal government has received in rebates, including mandatory, supplemental, and other relevant rebates:
 - a. Medicare Part D
 - b. Medicare Part B
 - c. Medicaid⁶
 - d. Children's Health Insurance Program
2. For each of the following programs, please provide the average out-of-pocket insulin costs for patients on an annual basis for each fiscal year since FY2010 to the present:
 - a. Medicare Part D (stand-alone and Medicare Advantage)
 - b. Medicaid
 - c. Children's Health Insurance Program
3. For each insulin product, please provide the total amount of insulin prescriptions (in units and aggregate dollar value) purchased when enrollees were in Part D's coverage gap and when enrollees entered the catastrophic phase. Please also provide the dollar value of manufacturer discounts for insulin prescriptions purchased in the coverage gap. In both cases, please provide this information on an annual basis for each fiscal year from FY2010 to the present.
4. Please provide the total direct and indirect remuneration (DIR) collected from the following PBMs on an annual basis for insulin drugs with a unique NDC for each year since FY2010 to the present and specify which federal programs such information is—or is not—available or collected from:⁷
 - a. Express Scripts
 - b. CVS Health⁸
 - c. OptumRx⁹

⁵ *Id.*

⁶ Please provide all federally mandated rebates including any portions related to any supplemented rebates negotiated by individual states that were provided to the federal government.

⁷ For each pharmacy benefit manager listed, please include the requested data for all entities it merged with or acquired within the specified date range. For example, in providing the requested data for Express Scripts, CMS should include the requested data for Express Scripts and Medco prior to the two companies completing their merger.

⁸ This request should be understood to include all entities that may have existed or negotiated with CMS prior to "CVS Health," including but not limited to CVS Caremark.

⁹ This request should be understood to include all entities that may have existed or negotiated with CMS prior to "OptumRx," including but not limited to Optum Health and UnitedHealth Group's Prescription Solutions division.

5. Please provide the total amount of administrative fees paid by Eli Lilly, Sanofi, and Novartis to PBMs for the purposes of managing and distributing rebates to plan sponsors since FY2010 to the present, and specify which federal programs such information is—or is not—available or collected from.
6. For each of the following programs, please provide the total amount of federal spending on diabetes-related costs beyond insulin, including spending that resulted from comorbid conditions and complications (e.g. amputations, renal disease, retinopathy), spending on equipment and supplies, and non-insulin medications. Please provide a breakdown of the spending data by reason (e.g. comorbid condition, equipment, supplies) from FY2010 to the present (including partial year or estimates for the current fiscal year) and include a description of the data source.
 - a. Medicare Part D
 - b. Medicare Part B
 - c. Medicaid
 - d. Children's Health Insurance Program
7. Please list and describe all CMS programs or initiatives—e.g., the Medicare Diabetes Prevention Program—that are designed to reduce federal spending on diabetes-related care, and improve patient outcomes. To the extent results in reducing federal spending and improving patient outcomes are available for such programs, please provide them.
8. Please provide all data and records, to include memoranda and reports, relating to CMS' examination of the impact of rising insulin costs to federal spending in Medicare, Medicaid, and the Children's Health Insurance Program, and the health outcomes of people enrolled in Medicare, Medicaid, or Children's Health Insurance Program.

We look forward to your response to better understand how insulin price increases have impacted patients and taxpayers. Should you have questions, please contact Joshua Flynn-Brown of Chairman Grassley's Committee staff and Peter Gartrell of Ranking Member Wyden's staff at 202-224-4515.

Sincerely,


Charles E. Grassley
Chairman
Senate Finance Committee


Ron Wyden
Ranking Member
Senate Finance Committee