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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

BY ELECTRONIC DELIVERY

Re: CY 2019 Medicare Advantage and Part D Advance Notice and Draft Call Letter

Dear Administrator Verma:

Celgene Corporation (Celgene) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) CY 2019 Medicare Advantage and Part D Advance Notice and Draft Call letter, released on February 1, 2018.

Celgene is a global biopharmaceutical company specializing in the discovery, development, and delivery of therapies designed to treat cancer, inflammatory, and immunological conditions. Celgene strongly believes that medical innovation can lead to better health, longer life, reduced disability, and greater prosperity for patients and our nation. To this end, we seek to deliver truly innovative and life-changing therapies for the patients we serve. There are more than 160 Celgene-sponsored clinical trials underway, examining at least 42 novel assets for more than 60 indications.

As committed as Celgene is to clinical progress, we are equally committed to patient support and access, which is a guiding principle at Celgene. We believe all who can benefit from our therapies should have the opportunity to do so. Celgene focuses on putting patients first with programs that provide information, support, and access to our innovative therapies.

The Part D program has enjoyed wide success since 2006, today providing critical prescription drug coverage to more than 40 million Americans. Celgene supports the Part D program and its robust competitive structure, which allows beneficiaries to choose a prescription drug plan that meets their clinical and financial needs.

While we applaud the program's successes, we agree that Part D must evolve to deliver the best possible outcomes to beneficiaries. We strongly support the Administration's focus on

beneficiary out of pocket (OOP) costs in Medicare, and we encourage the Administration to act to ensure that beneficiaries can afford the medications they need.¹

Beneficiaries who face substantial OOP costs are at greater risk for non-adherence to their prescription regimens and the associated risks of non-compliance: worsening of symptoms, poorer clinical outcomes, and higher total healthcare costs. For example, a 2016 study found that beneficiaries who were not eligible for the low-income subsidy (LIS) were less likely to initiate treatment for chronic myeloid leukemia (CML) than LIS-eligible beneficiaries and, among those who did initiate treatment, patients exposed to higher cost sharing took longer to start therapy.² The authors note that treatment delays are associated with lower rates of clinical response and may lower overall survival in patients with CML. Similarly, a 2017 analysis found that beneficiaries abandoned more than 40 percent of prescriptions with cost sharing above \$250 in therapeutic classes like oncology, HIV, and multiple sclerosis.³ In some classes, like antipsychotics, beneficiaries abandoned more than three out of every four prescriptions. Individuals who face high cost sharing for prescription drugs may be unable to take their medications as prescribed; a 2015 analysis found that approximately 8% of all adults do not take their medications as prescribed due to cost concerns.⁴

Beneficiaries who face high overall OOP costs are particularly likely to forego critical treatment. Sixty percent of beneficiaries with total annual spending above \$4,000 abandoned a prescription, highlighting the need to protect beneficiaries who reach catastrophic coverage from cost-related barriers to care.

Data show that reaching the catastrophic phase of the Part D benefit is far from exceptional, and that beneficiaries' cost-sharing obligations once in catastrophic coverage can be substantial. For example, the Kaiser Family Foundation recently found that one million non-LIS beneficiaries reached the catastrophic threshold in 2015, and paid approximately 40 percent of their total annual cost sharing in this phase of the benefit.⁵ Paying nearly half of total cost sharing in this benefit phase is inconsistent with the goal of "catastrophic" coverage, which is meant to limit costs for beneficiaries with particularly complex health conditions.

An annual OOP cap would provide consistent, clear, and targeted protection against high OOP costs for Part D beneficiaries, and would align Part D with other federal and commercial healthcare programs. We recommend that CMS exercise its authority to limit beneficiary cost sharing by establishing an annual OOP limit under the Part D program's non-discrimination provision.⁶

¹ Office of Management and Budget. "An American Budget: President's Budget FY 2019." February 2018.

² Doshi, JA et al. High Cost Sharing and Specialty Drug Initiation Under Medicare Part D: A Case Study in Patients With Newly Diagnosed Chronic Myeloid Leukemia." *Am J Manag Care*. 2016;22 (4 Suppl): S78-S86.

³ Amundsen Consulting. "Medicare Part D Abandonment." November 2017.

⁴ Cohen, RA et al. "Strategies Used by Adults to Reduce Their Prescription Drug Costs: United States, 2013." NCHS Data Brief No. 184. January 2015.

⁵ Kaiser Family Foundation. "No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending." November 2017.

⁶ Social Security Act § 1860D-11(e)

CMS addressed the idea of a Part D OOP limit in 2011 rulemaking, raising no legal concerns but noting that a Part D limit was not “feasible or practical” given the Part D benefit structure.⁷ Based on the data summarized in this letter, we believe that a Part D OOP limit is both feasible and necessary.

The Part D statute establishes 5% beneficiary coinsurance in the catastrophic phase. Importantly, this paragraph of the statute is labelled “Protection against high out-of-pocket expenditures,” suggesting that Congress intended for this section to guard against rising expenses rather than expose beneficiaries to ongoing and escalating costs. Further, the statute directs the Secretary not to approve Part D plans with designs that “are likely to substantially discourage enrollment by certain part D eligible individuals under the plan.”⁸ CMS relied upon very similar language to establish an OOP limit for local plans in the Medicare Advantage program, and we believe that the Part D non-discrimination provision also supports OOP protection for beneficiaries with the highest healthcare needs.

CMS could also consider other options to protect beneficiaries from high OOP costs, such as encouraging Part D plans to limit beneficiaries’ OOP exposure in catastrophic coverage through actuarially equivalent and enhanced alternative plan designs, or establishing a demonstration to evaluate the impact of eliminating catastrophic cost sharing on beneficiary outcomes.

We believe that protecting beneficiaries from high OOP costs will help to modernize the program, align Part D with current insurance offerings in other markets, and – most importantly – improve beneficiary outcomes and satisfaction with the Part D program.

Thank you for your consideration of our comments.

Sincerely,

A handwritten signature in black ink that reads "Rich Bagger". The signature is written in a cursive, flowing style.

Richard H. Bagger

⁷ Federal Register Vol. 74, No. 203.

⁸ Social Security Act § 1860D-11(e)