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October 25, 2018

Susan Edwards
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0803-N
Room 5513 Cohen Building
330 Independence Avenue SW
Washington, DC 20201

BY ELECTRONIC DELIVERY

Re: OIG-0803-N: Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP

Dear Ms. Edwards,

Celgene Corporation (Celgene) appreciates the opportunity to respond to the Department of Health and Human Services (HHS) Office of the Inspector General's (OIG) Request for Information (RFI) on potential revisions to safe harbors under the Anti-kickback Statute and beneficiary cost sharing.

Celgene is a global biopharmaceutical company specializing in the discovery, development, and delivery of therapies designed to treat cancer and 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. We are currently engaged in 160 clinical trials with 42 novel medicines across 60 indications. In 2017, we reinvested 45.5% of our revenue into research and development to discover and develop the therapies of tomorrow.[1]

As committed as Celgene is to discovering and developing new treatments, we are equally committed to patient support and access to those medical advances, which is a guiding principle for our company. We believe all who can benefit from our discoveries 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.

[1] Celgene 2017 Annual Report. Available at: http://files.shareholder.com/downloads/AMDA-262QUJ/6204845187x0x978672/138C3639-1839-499D-8191-34F9E08A0CBD/Celgene_AR_complete_PDF_041718.pdf.

Celgene strongly supports the Administration's focus on enabling value-based arrangements for prescription drugs, and we appreciate HHS' ongoing dialogue with stakeholders on this topic. We continue to believe that targeted changes to legal safe harbors, combined with updates to government pricing rules, could facilitate the evolution of these arrangements in the market. Building on our prior comments on value-based arrangements for prescription drugs,[2] we offer below our specific and detailed feedback in response to the questions posed by OIG.

We also applaud HHS' interest in addressing beneficiary cost sharing, particularly in public programs like Medicare Part D. The link between high cost sharing and medication non-adherence, or medication abandonment, is well documented – as is the relationship between non-adherence and poor health outcomes for patients. We encourage HHS to work with biopharmaceutical companies and Part D plans to explore novel approaches to make cost sharing more predictable and more affordable for patients based on stakeholder feedback provided in response to Section 2 of the RFI. Specifically, we believe that allowing biopharmaceutical companies to offer cost-sharing support to Part D enrollees, subject to certain conditions, could achieve HHS's goal of reducing patient out-of-pocket (OOP) costs with minimal if any increased risk of fraud, abuse, and other potential unintended consequences of lower beneficiary cost sharing.

Our detailed comments, grouped by RFI section, follow.

Promoting Care Coordination and Value-Based Care

Need for Revisions to Existing Safe Harbors

Celgene appreciates this opportunity to provide feedback on potential changes to the safe harbors to the anti-kickback statute. We echo other commenters in noting that the ambiguity surrounding how the anti-kickback statute and its attendant safe harbors applies to value-based contracting arrangements has chilled the development and implementation of these types of contracts. For example, many such contracts require data collection and analysis – or at least data collection and transmission – by the health care provider, but the discount safe harbor and Department of Justice (DOJ) activities call into question whether those activities can be included in the contract, or whether such terms would open the biopharmaceutical company to risk of enforcement action.[3] Therefore, we encourage the OIG to update the safe harbors as described below to provide greater clarity, remove uncertainty in the market, and facilitate the adoption of innovative contracts.

As you know, the statutory provisions of the Anti-Kickback Statute permit the annual solicitation of safe harbor proposals. However, the discount safe harbor was last substantively revised in 1999, and no safe harbor exists for value-based arrangements, despite repeated requests from many stakeholders seeking a modernization of these provisions. In particular, the discount safe harbor still focuses on the

[2] Celgene comments on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, submitted June 27, 2018 and Celgene comments on Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model (CMS-1695-P), submitted September 24, 2018.

[3] *See, e.g.,* 42 CFR § 1001.952(h)(5)(vi); United States ex rel. Banigan v. Organon USA Inc., No. 07-12153 (D. Mass) (Stat. of Interest on Behalf of the U.S., Dkt. No. 144).

quantitative components of a transaction, rather than the holistic treatment regimen. More and more, treatment extends beyond the provision of an injection or a pill to include interrelated supportive care across settings. Treatment may begin in a clinic or physician office but require observation or follow-up to monitor for adverse events or help ensure adherence. Such patient support can often be conducted more effectively – and more affordably – in the patient's home, rather than in the clinic or office setting. Yet, the safe harbor looks solely at the drug purchase and administration in the office – not at the other activities that may be needed to help ensure the efficacy of the treatment.

Similarly, just as the discount safe harbor focuses on one element of a course of treatment, the safe harbor does not recognize that, for many therapies – including new gene and cell therapies – the relevant outcome may not be realized for many years. Specifically, the safe harbor requires that a cost-reporting buyer claim the benefit of a discount within a maximum of two years.[4] To the extent a therapy's outcome is determined outside of this window, biopharmaceutical companies and other stakeholders may be reluctant to enter these types of agreements, for fear that a price concession provided five or more years into the future may be viewed as a kickback.

Further complicating the issue, particularly for value-based arrangements that include elements of care coordination, recently unsealed *qui tam* complaints have called into question the level of support biopharmaceutical companies may be able to provide to support therapeutic choices made by health care practitioners. In its 2003 guidance[5], the OIG noted that "[s]tanding alone, services that have no substantial independent value to the purchaser may not implicate the antikickback statute,"[6] and specifically cites tailored billing assistance, reimbursement consultation, and "other programs specifically tied to support the purchased product."[7] However, notwithstanding this guidance, *qui tam* plaintiffs are challenging reimbursement and other support services, raising additional ambiguity and concern as to the scope of safe harbor protection.

We ask that the OIG provide clear direction, either through an update to current safe harbors, or through a new safe harbor designed for value-based arrangements. Additionally, we ask the OIG to restate and clarify its 2003 guidance document to allow for greater clarity and understanding by all stakeholders as to which activities are and are not considered appropriate activities for contracting and support. We also support the analysis and comments submitted separately by the Pharmaceutical Researchers and Manufacturers of America (PhRMA) and highlight a few specific items below.

Eligible Value-based Arrangements

Like PhRMA, we believe that arrangements falling within a properly structured value-based agreement safe harbor should improve patient health outcomes, improve patient access and choice of therapies, increase competition, curb Federal health care program spending, and present minimal risk of fraudulent or abusive practices of concern to the OIG (such as interference with clinical decision-making and overutilization). As explained below, the agreements that would fall within an appropriately

[4] 42 C.F.R. § 1001.952(h)(1)(ii)(B).
[5] 68 Fed. Reg. 23731 (May 5, 2003).
[6] *Id.* at 23735.
[7] *Id.*

structured safe harbor conform well with the prudential factors that are commonly examined by the OIG and listed in 42 U.S.C. §1320a-7d(a)(2).

First, these arrangements should not interfere with clinical decision-making or encourage overutilization. The purpose of a value-based arrangement is to encourage the most effective treatment, rather than additional unnecessary treatments. In a regime where a practitioner is reimbursed based on a successful outcome and a biopharmaceutical company faces greater financial exposure for less successful outcomes, inappropriate or excessive utilization of services is discouraged rather than rewarded. Instead, payment – for the service and the product – is structured to incent the most efficacious treatment for the specific beneficiary. We respectfully direct you to PhRMA's comments for additional discussion.

Second, value-based agreements should improve the quality of patient care, rather than creating concerns regarding patient safety. For example, with indication-based agreements, payors would be better able to structure guidelines for treatment – and have payment match those decisions – based on the disease states for which a therapy is most effective. As we described in our response to the American Patients First Blue Print, innovative medicines can bring different value to different patient populations based on a variety of factors, including improvement relative to other treatment options. In some cases, several indications may have similar value to patients; in others, one indication's value may be higher than another's. Indication-based payment models can ensure that a product's pricing reflects this dynamic by linking the price for each product indication to its value to the specific patient population it serves. Sophisticated payers, providers, and biopharmaceutical companies have the data and expertise necessary to negotiate indication-based payments.[8]

Additionally, outcomes-based agreements, by their nature, would incent providers to choose the most effective therapy to meet quality incentives, and biopharmaceutical companies would be further incented to not only ensure that their products work safely and effectively, but to identify the specific patient populations (e.g., through retrospective data analysis or companion diagnostics) for which a medicine does and does not work well. Armed with additional data about when a medicine is mostly likely to be effective, providers and patients are likely to use that medicine when it would most improve quality of care.

Third, these arrangements would expand patients' access to medicines by helping reduce payor costs when a treatment does not perform as expected permitting payers to expand access to new therapies with the potential to save lives or deliver better outcomes. Today, payers are increasingly excluding or limiting coverage of newer therapies; providing for outcomes-based contracts could enable less restricted access to novel treatments. Indication-based agreements would similarly promote patient access to medicines and increase their choice of therapies. For example, permitting a health plan to negotiate appropriate payment for each of a medicine's indications may expand patients' choices and spur competition in the relevant therapeutic areas.

Finally, these arrangements are unlikely to inappropriately increase costs, but rather are more likely to ultimately produce overall cost savings, including savings for Federal health care programs. For

[8] We recognize that indication-based agreements also require adjustments to current price calculation and reporting structures and would need guidance from the Centers for Medicare & Medicaid Services to fully implement these agreements.

example, biopharmaceutical companies generally negotiate and enter into value-based agreements for medicines that treat serious health conditions that could have costly consequences (such as hospitalizations) if treatment is ineffective or suboptimal. Therefore, if patients achieve the agreed-upon outcomes, payers would realize the value they hoped for (e.g., in the form of lower hospitalizations). This could save Federal health care programs money that would otherwise have to be spent on managing expensive diseases, and thus ultimately reduce overall healthcare spending.

Safe Harbor Structure and Safeguards

For these reasons, we respectfully recommend that OIG develop a safe harbor for the types of value-based arrangements for medicines described in this letter. We believe that any such safe harbor should include the following key features:

1. Any value-based agreement safe harbor should protect appropriately structured agreements between biopharmaceutical companies and purchasers (i.e., direct or indirect purchasers or a party that arranges for the purchase of products, such as health plans, payers, PBMs, or providers) that provide for warranties or value-based price adjustments based on measurable clinical or cost outcomes. The types of outcomes to be included should capture the types of arrangements described in this letter, including direct clinical outcomes, measures that reliably predict clinical benefits, or measures that involve the cost of caring for patients treated by the product.[9]

2. The safe harbor should also explicitly protect contract performance activities that are central to the ability to administer or implement many value-based agreements. For example, an organization may pay for or perform a function related to measuring outcomes under the agreement (e.g., hire a third party to collect data and calculate the metrics underlying a rebate agreement), to auditing and resolving disputes regarding outcomes achieved, or to facilitating patients' adherence to their providers' prescribed treatment regimen.

3. In terms of safeguards to deter fraud and abuse and to help identify arrangements qualifying for safe harbor protection, a safe harbor should require that value-based arrangements specifically identify any value-based price adjustment, warranty, or contract performance activities included in the arrangement. It should also require that the written value-based agreement set out all material terms of the arrangement (e.g., the method for computing the value-based price adjustment or warranty and the key roles and responsibilities of each party). OIG could also require that purchasers fully comply with any applicable Federal health care program requirement to report the price, price adjustment, or warranty for the product.

4. A safe harbor could also include patient protections around contract performance activities, such as requiring the biopharmaceutical company to disclose its role, if any, in adherence support communications, as well as safeguards to protect the physician-patient relationship and maintain the independence of health care provider decision-making (including, for example, provider decisions to change to a different drug or treatment regimen, to discontinue a drug or treatment regimen, or to extend a drug or treatment regimen). Further, the safe harbor could require that any communications to patients be submitted to the FDA to help ensure the

[9] A clinical or cost outcome should include whether the product is used as monotherapy or used with additional therapies, as measured under the agreement itself or in a previous study.

messaging contains the necessary fair balance and safety messaging, which could help address some of the concerns raised by recent investigations and complaints regarding biopharmaceutical company engagement of third-parties to interact with patients.

5. Finally, the safe harbor could include safeguards addressing the use and distribution or patient data, for example, requiring that any data collected to administer a value-based agreement must be used in compliance with applicable privacy laws.

Patient Cost-Sharing Obligations

Reduced patient cost sharing could be an important component of value-based arrangements. Furthermore, we also encourage HHS to develop a specific safe harbor that would allow for lower OOP costs in public programs. In particular, we believe that financial assistance provided by biopharmaceutical companies could play an important and appropriate role in lowering Part D enrollees' OOP costs.

Financial assistance plays a critical role in helping patients with commercial insurance afford their medications; hundreds of thousands of patients receive financial support each year for a variety of complex and life-altering illnesses. Importantly, many medications with commercial assistance programs have no lower-cost alternative; a recent analysis of the top 200 branded medicines found that half of the drugs with assistance programs had no generic equivalents.[10]

Part D patients, as described below, face cost sharing that is as high or higher than patients with commercial insurance. Foundations provide an essential source of support to Medicare patients, but cannot support every patient who needs assistance. Part D patients, especially those with OOP costs above the catastrophic threshold, require additional support to afford their medications. We describe below key considerations and limitations that would maximize the benefit of biopharmaceutical company-provided assistance and minimize the risk of unintended consequences.

High Cost Sharing Poses an Ongoing Challenge for Part D Enrollees

OIG seeks input about how relieving or eliminating beneficiary cost-sharing obligations might improve care delivery, enhance value-based arrangements, and promote quality of care, and asks for specific examples in which high cost sharing is particularly problematic for patients.

Tiered or graduated cost sharing is intended to guide patient behavior and create an incentive for patients to use lower-cost alternatives when available. However, many patients – and in particular patients in the Part D program – encounter formulary designs that place all specialty medications on high cost-sharing tiers, with limited or no options on lower tiers. Rather than create an incentive for "appropriate" medication use, these formulary designs effectively discriminate against patients who require specialty medications to treat their diseases.

Data show that Part D patients struggle with high cost sharing. For example, patients in one study abandoned more than 60% of prescriptions for antipsychotics, multiple sclerosis agents, and medicines to treat Alzheimer's Disease when cost sharing exceeded $250 per prescription.[11] In some cases,

[10] Van Nuys K, Joyce G, Ribero R, and Goldman DP. "A Perspective on Prescription Drug Copayment Coupons." February 2018.
[11] Amundsen Consulting. "Medicare Part D Abandonment." November 2017.

patients with life-threatening illnesses may forego their medicines at even lower levels of cost sharing. For example, in another study, patients abandoned 10% of oncology medications when cost sharing exceeded $100 per prescription.[12] As cost sharing for individual prescriptions adds up throughout the year, patients with significant healthcare needs face difficult choices about their care. For example, nearly two thirds of patients facing total cost sharing between $4,000 and $4,999 abandoned at least one prescription during the year.[13]

A recent *Health Affairs* article summarized the consequences of high cost sharing as follows:

> A series of recent studies, including several published by our team, have found that higher out-of-pocket costs under current Medicare Part D policies are associated with markedly higher rates of abandonment of new specialty drug prescriptions; reductions and delays in treatment initiation following a new diagnosis or disease progression; delays between refills or treatment interruptions; and earlier discontinuation of treatment. These patterns are consistent across each of the disease areas we have examined, including multiple sclerosis, rheumatoid arthritis, psoriasis, and a variety of cancers such as chronic myeloid leukemia and metastatic renal cell carcinoma.[14]

These challenges are particularly acute for beneficiaries who reach Part D's catastrophic phase. The number of beneficiaries who reach catastrophic coverage has increased every year since 2011. In 2015, more than 1 million beneficiaries who were not eligible for the low-income subsidy had OOP costs above the catastrophic threshold.[15] Importantly, while these 1 million beneficiaries represented approximately 2 percent of all Part D enrollees in 2015, they accounted for 20 percent of total Part D OOP spending in that year.

Celgene supports policy solutions that would reduce patient OOP costs in Part D; first and foremost, we strongly support the creation of an OOP cap in the Part D program. We also encourage HHS to develop additional, targeted solutions for this high-need patient population – for example, allowing biopharmaceutical companies to provide financial assistance to a subset of Part D enrollees, subject to conditions established by HHS. We believe that permitting assistance under well-defined circumstances would both achieve HHS' overarching goal of lowering cost sharing for patients and minimize or eliminate any potential concerns related to fraud, abuse, and increased demand.

Impact of Reduced Cost Sharing on Providers, Beneficiaries, and HHS

OIG asks commenters to identify any concerns associated with reduced cost sharing in federal programs, including any risks to beneficiaries and to the government. We believe that reducing cost sharing for Part D enrollees in the catastrophic phase of the benefit would provide a direct benefit to patients without increased risk to beneficiaries, providers, or the federal government.

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[12] Streeter, S. et al. Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions. Journal of Oncology Practice. (2011). 7(3S).

[13] Amundsen Consulting. "Medicare Part D Abandonment." November 2017.

[14] Doshi JA, Pettit AR, and Pengxiang L. "Addressing Out-Of-Pocket Specialty Drug Costs In Medicare Part D: The Good, The Bad, The Ugly, And The Ignored." *Health Affairs*. July 2018.

[15] 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.

Part D enrollees who qualified for financial assistance would experience a meaningful reduction in their OOP costs, positioning them for better treatment adherence and improved outcomes. Because prescribers do not collect cost sharing in Part D, a policy solution targeted to high-need Part D beneficiaries would have no impact on providers – except to alleviate financial burden on their patients.

Some stakeholders may argue that financial assistance provided by biopharmaceutical companies encourages unnecessary utilization. We appreciate that reduced cost sharing could raise the risk of inappropriate utilization in some cases. However, we strongly believe that the risk of increased demand varies greatly by therapeutic area, service type, availability of therapeutic alternatives, and many other factors, and that HHS should consider the specific risk of increased demand presented by different policy scenarios.

High-need Part D patients taking medications for life-threatening or life-altering illnesses are highly unlikely to respond to lower cost sharing with unnecessary utilization – in contrast, the available evidence suggests that these patients are foregoing needed care because cost sharing is too high. Further, the premise of increasing demand through lower cost sharing is inapplicable in certain disease areas. For example, patients take oncology medications because they must; these medicines save or prolong patients' lives. We believe that focusing assistance on patients for whom the possibility of inducing unnecessary demand is already low, combined with selected guardrails, could substantially mitigate any risk to the Part D program.

Guardrails to Maximize Benefit to Patients and Minimize Risk to HHS

A limited number of guardrails could maximize the benefit and reduce or eliminate the risk of biopharmaceutical company-provided financial assistance to Part D enrollees. Specifically, we believe that HHS could materially reduce or eliminate concerns about potential increased demand or fraud and abuse by permitting biopharmaceutical companies to cover or contribute to beneficiary cost sharing when:

- the medicine in question treats a serious medical condition;
- no lower-cost generic or biosimilar option is available to patients;
- beneficiaries have already contributed substantially to the cost of the medicine through cost sharing; and
- the relevant biopharmaceutical company agrees to materially reduce patient cost sharing.

Focusing on medicines that treat complex, acute, or life-threatening illnesses would both target financial assistance to the patients who are most likely to experience high cost sharing and reduce the risk of changes in utilization due to lower cost sharing. Permitting assistance only when beneficiaries have no lower-cost alternative, in the form of a generic or interchangeable biologic, would further lower this risk, as there would be no opportunity to discourage patients from using a lower-cost therapeutic option.

High-need Part D beneficiaries would particularly benefit from financial assistance. Focusing on this group of patients would also reduce the risk of any unintended consequences of lower cost sharing. For example, HHS could permit assistance only in the catastrophic phase of the benefit. Limiting assistance to the catastrophic phase of the benefit, after patients have already paid significant cost-sharing amounts, further emphasizes that these medicines are clinically appropriate.

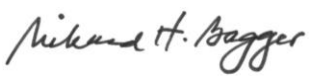
We recognize that to benefit patients and achieve HHS's goal of lowering OOP costs, any financial assistance provided by biopharmaceutical companies must meaningfully reduce patients' cost-sharing obligations. HHS could establish a required contribution percentage that strikes an appropriate balance between lowering patients' financial burdens and minimizing the risk of higher utilization.

Conclusion

Celgene shares the Administration's goal of ensuring that all Americans, irrespective of their source of coverage, have affordable access to the medicines they need. We are proud of the value that prescription medicines bring to our healthcare system and believe that innovation in payment models must keep pace with innovations in science. We hope to help advance the Administration's work in this important area, and we would welcome the opportunity to discuss our comments and any of these issues in further detail.

Thank you for your consideration of our comments.

Sincerely,



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