



HEALTH POLICY
GOVERNMENT AFFAIRS & POLICY
1350 EYE STREET, N.W.
WASHINGTON, D.C. 20005-3305

TEL. (202) 589-1000
FAX. (202) 589-1001

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Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Re: Comments on CMS-4192-P, Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program

SUBMITTED ELECTRONICALLY VIA ***Regulations.gov***

On Behalf of Johnson & Johnson's Operating Companies, I am pleased to provide comments regarding CMS-4192-P, Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program.

Johnson & Johnson (J&J) is the world's most comprehensive and broadly-based manufacturer of health care products for the consumer, pharmaceutical and medical devices and diagnostics markets. For more than 125 years, J&J Companies have supplied the health system with a broad range of products and has led the way in innovation, beginning with the first antiseptic bandages and sutures.

J&J is a member of the Pharmaceutical Research and Manufacturers' Association (PhRMA) and the Biotechnology Innovation Organization (BIO), and we support and endorse their comments on CMS-4192-P.

Below, we provide our comments on the proposal to treat biosimilars as generics for the purpose of determining cost sharing in certain instances and our response to CMS's request for information related to passing rebates through to Part D patients at the point of sale.

Treatment of Biosimilars as Generic Drugs for Non-LIS Catastrophic and LIS Cost Sharing

J&J fully supports efforts to implement regulatory standards for the review and approval of biosimilars in which patient well-being is the first priority. Patients deserve safe and effective treatments that are backed by robust data sufficient to scientifically justify their use in each disease in which they are approved. We believe biosimilar adoption will increase as new biosimilars become available, as manufacturers become increasingly competitive on price, and as physicians continue to gain experience with new biosimilar agents.

While we recognize CMS's interest in supporting the use of lower-cost alternatives wherever possible, we do not believe that CMS has cited its authority or presented sufficient justification for the proposed change to treat biosimilars as generics in determining non-LIS catastrophic and LIS cost-sharing.

First, the Social Security Act (SSA) § 1860D-14(a)(1)(D), defines the maximum LIS copay for the lowest-income-dual eligibles and § 1860D-2(b)(4) sets the maximum copay for non-LIS patients in catastrophic coverage. These

sections refer to “generic” and “multiple source” drugs when setting these maximum copays. These terms have specific definitions in statute, and these definitions do not encompass biosimilars.

Second, the difference between biosimilars and generics is underscored by the FDA’s approach to regulating in this area. Janet Woodcock, the Director of the Center for Drug Evaluation at the FDA highlighted this point in testimony to the Senate HELP Committee on September 7, 2015. and to the House Committee on Energy and Commerce on February 4, 2016. She said

“Biological products consist of large, complex molecules that are difficult to define and produce. This is in contrast to “small molecule” drugs that generally are produced through chemical processes, and can be replicated as “generic” drugs that are essentially exact copies. Unlike generic drugs, biosimilars must be highly similar to, not the same as, the reference product to which they are compared. A biosimilar can have certain allowable differences because it is made from living organisms, but it must demonstrate no clinically meaningful differences in terms of safety, purity and potency from its reference product. The complexity of biological products generally makes it more challenging to demonstrate biosimilarity, as compared to demonstrating sameness for a generic drug.”

In addition, the FDA flatly states on its [website](#) that “biosimilars are not generics”.

While we appreciate that advocates and stakeholders have argued that CMS should treat biosimilars as generics for the purpose of determining these cost sharing amounts, such advocacy does not change the plain statutory definitions.

Furthermore, we share CMS’s concerns that classifying biosimilars as generics could cause confusion because it would be inappropriate to treat biosimilars as generics for purposes of other Part D policies that hinge on whether a drug is a “generic.” The majority of generic drugs approved by FDA are AB-rated generic drugs, which FDA approves as therapeutically equivalent and are widely understood to be able to be substituted for one another without differences in safety or efficacy. Classifying biosimilars as generics could lead to the incorrect assumption that they are interchangeable with the innovator product and each other when this is not the case. The incentive introduced by the proposed change, along with the confusion created about the difference between generic and biosimilar products, would likely lead to an erosion in the quality of care as patients who are stable on their branded therapy are switched to biosimilar products without appreciating the lack of FDA-validated interchangeability. We believe that the appropriate way to avoid such confusion in relation to provisions related to transition policies or formulary change is to refrain from treating biosimilars as generics in all Part D circumstances.

Therefore, we recommend CMS not proceed with the proposed definition change but instead continue to seek other ways to reduce patient cost sharing and incentivize efficiency.

Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

We applaud CMS for issuing this Request for Information (RFI) on sharing savings from negotiated rebates directly with patients at the point-of-sale. We support the agency’s efforts to ensure that patients using Part D drugs directly benefit from the aggressive rebate negotiations that underpin the Part D program.

While we support CMS’s intention to ensure that the rebates that plans currently negotiate with manufacturers benefit patients who are actually using Part D drugs, we are concerned that the suggested approach would have

unintended consequences and recommend that CMS reconsider this approach. In particular, determining rebate pass-through amounts at the therapeutic category or class level would result in cross subsidization among manufacturers, which could lessen the incentive for manufacturers to compete aggressively. We recommend careful consideration of the design of any pass-through approach to ensure that the significant rebates that manufacturers already provide are used to reduce patient cost sharing burdens to the maximum extent possible.

We encourage CMS to continue working with all stakeholders to craft a workable solution that will ensure that patients benefit from manufacturer rebates at the point of sale, and we recommend consideration of benefit design alternatives (e.g., eliminating coinsurance) that could address concerns about point of sale patient cost sharing.

In addition to the issues discussed above, we recommend that CMS issue regulations to incorporate Part D data into alternative payment model programs.

This problem has been illustrated in multiple specialty areas, especially rheumatology and gastroenterology where both Part D and Part B drugs have indications for treatment of the same condition. This is of particular concern when a patient receives a Part B drug for reasons of clinical efficacy, adherence and safety. Specifically, quality of care concerns over “non-medical switching” of therapeutic interventions are well-documented, particularly for biologics. Section 1848(q)(2)(B)(ii) of the Act recommends accounting for the costs of Part D drugs as appropriate and feasible under the resource use performance category of MACRA.

CMS has indicated its concern that including Part D data would incorrectly indicate higher costs for beneficiaries with Part D coverage relative to otherwise comparable beneficiaries without such coverage and for whom prescription drug costs cannot be measured directly by CMS. To address this issue, CMS could create benchmarks for resource use for beneficiaries enrolled in Parts A, B & D separately from those enrolled in Part A & B. This approach would facilitate comparisons across practices with different proportions of patients with Part D coverage. We have also submitted comments suggesting approach for estimating final Part D drug prices.

J&J greatly appreciates the opportunity to submit these comments and recommendations to CMS. We welcome the opportunity to further discuss as you deem appropriate.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert Donnelly". The signature is fluid and cursive, with a large, stylized initial "R".

Robert Donnelly
Senior Director, Health Policy
Johnson & Johnson Worldwide Government Affairs and Policy