Mallinckrodt Pharmaceuticals

Via Electronic Submission – www.regulations.gov

January 16, 2018

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4182–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: 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 [CMS-4182-P]

Dear Administrator Verma:

Mallinckrodt Pharmaceuticals (Mallinckrodt or the Company) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS' or the Agency's) Proposed Rule regarding Medicare Advantage and Medicare Part D benefits and policies for contract year 2019.[1]

Mallinckrodt is a global business that develops, manufactures, markets and distributes specialty pharmaceutical products and therapies. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; and non-opioid analgesics. The company's core strengths include the acquisition and management of highly regulated raw materials and specialized chemistry, formulation and manufacturing capabilities. The company's Specialty Brands segment includes branded medicines and its Specialty Generics segment includes specialty generic drugs, active pharmaceutical ingredients and external manufacturing.

As a company with deep and growing experience in bringing therapies to market that may treat the most vulnerable patients, we appreciate the opportunity to provide comments on the Medicare Advantage and Part D Proposed Rule (the Proposed Rule). Based on this experience, we submit the following comments on selected portions of the Proposed Rule.

- **Manufacturer Rebates and Pharmacy Price Concessions to Point of Sale.** We applaud the Agency's steps to collect information on this issue and explore potential policy options that may help reduce patients' out-of-pocket and point-of-sale costs. We believe that, in considering whether to implement a policy applying manufacturer rebates and pharmacy price concessions to the price of a drug at the point of sale, CMS must carefully assess potential outcomes and possible unintended consequences, as well as potential operational challenges. We note that the Medicare Payment Advisory

[1] 82 Fed. Reg. 56,336 (Nov. 28, 2017).

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Commission (MedPAC) likewise has expressed concerns about potential operational challenges, confidentiality concerns, and other considerations in response to this Request for Information in the Proposed Rule.[2] We encourage CMS to continue seeking and assessing stakeholder feedback on this topic. We also recommend further study, such as by MedPAC, to analyze possible policy options and the potential effects, focusing on whether patient costs would actually be expected to be reduced and whether adherence would be expected to improve.

- **Mid-Year Changes to Formularies.** Current protections against mid-year formulary changes, particularly mid-year *removals* of drugs from a formulary under Medicare Part D, are extremely important to patients. We urge CMS not to finalize proposed policies that would expand plans' ability to remove drugs from a formulary mid-year. We are concerned that such changes would be detrimental and unfair to patients, including disruptions to continuity of care as well as having negative effects on adherence. We also note that improved adherence can lead to lower health care costs in other segments of the system. Accordingly, to protect beneficiary access, promote adherence and continuity of care, and support beneficiary and provider choice, we urge CMS to continue to allow drugs to be added to a formulary in the middle of a plan year, but not removed except in very limited circumstances (which should not be expanded).

- **Medicare Advantage (MA) Uniformity Requirements and Segment Benefits.** While we appreciate proposals designed to improve plan flexibility and meet the needs of particular patient populations, we have concerns about potential unintended consequences from these proposals, as discussed further below. Because the potential unintended consequences are unclear, we urge CMS and/or MedPAC to further study these potential implications and to consider the findings of such studies prior to pursuing policy changes in this area.

I. Manufacturer Rebates and Pharmacy Price Concessions to Point of Sale

Regarding the Proposed Rule's Request for Information soliciting comments on potential policy approaches for applying some manufacturer rebates and all pharmacy price concessions to the price of a drug at the point of sale, we support efforts to reduce beneficiary costs at the point of sale. We applaud the Agency's steps to collect information on this issue and note that, in considering whether to implement such a program, CMS must carefully assess potential outcomes and potential unintended consequences. To the extent that certain policy options may be viewed as potential ways to reduce beneficiary costs at the point of sale, we believe those are promising options worth exploring further through specific proposals subject to a new notice and comment period.

We note that reducing a beneficiary's cost at the pharmacy also may improve medication adherence, thereby improving patient health and reducing other health care expenditures. A

[2] MedPAC, Comments to 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, pp. 14-16 (Jan. 3, 2018).

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recent Association for Accessible Medicines (AAM) report, for example, found that adherence problems are responsible each year for approximately 125,000 deaths, at least 10% of hospitalizations, and a substantial increase in morbidity and mortality.[3] In addition, a recent study of Medicaid patients with diabetes demonstrated that controlling blood pressure, total cholesterol, and HbA1C (a key blood sugar metric) significantly reduced the onset of several chronic conditions for patients with diabetes and could save more than $4 billion based on Medicaid health care spending in 2016.[4] These findings underscore the importance of reducing beneficiary costs and improving adherence in order to achieve critical public health goals.

While we support CMS' efforts to reduce beneficiary out-of-pocket costs, we have questions regarding how such a policy would operate in practice, particularly for beneficiaries with very significant out-of-pocket costs for prescription drugs. Because of the potential unintended consequences for Medicare beneficiaries, Part D sponsors, pharmacies, manufacturers, and other stakeholders, we urge CMS to carefully evaluate stakeholder comments received on this topic, and to provide additional opportunities for stakeholder input.

In addition, we strongly encourage CMS to seek further study of this topic and the potential implications and impact of any contemplated policy options, such as through a MedPAC study and report. We note that MedPAC has already submitted comments to CMS, in response to the Proposed Rule, that express concerns about operational challenges and confidentiality concerns that may be raised in connection with potential policies that would apply manufacturer rebates or pharmacy price concessions to the price of a drug at the point of sale. Specifically, MedPAC stated in its comments that "we are concerned that CMS's proposed approach would be complex to implement, administratively burdensome and, for drug classes with few competing therapies, would risk disclosure of confidential rebate information."[5]

Following further study and review of initial public comments to the Request for Information, we encourage CMS to issue any future specific proposals using separate notice and comment rulemaking. We believe such an approach would help CMS and stakeholders to assess the potential impact of these ideas and help mitigate any negative unintended consequences that could result if a policy were pursued without sufficient study and consideration.

For example, policies affecting beneficiaries' costs could impact the rate at which at least some beneficiaries may move toward and through the Medicare Part D donut hole. For beneficiaries with chronic conditions who may be taking numerous drugs or certain specialty drugs that lead to significant out-of-pocket costs for Part D medications, it is not clear whether or to what extent a policy of passing through rebates may or may not help them, particularly if the pass-through amounts were not counted toward a beneficiary's true out-of-pocket costs (TrOOP) for purposes of advancing through the coverage gap. Accordingly, if CMS does in the future pursue a pass-through policy for Part D rebates, we encourage the Agency to consider including rebates amounts passed through to the patient as part of the beneficiary's TrOOP. By

[3] AAM, Generic Drug Access & Savings in the U.S., *available at* https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf.
[4] IHS Markit Blog, "Better diabetes treatment can save Medicaid over $4 billion per year," (Nov. 9, 2017) *available at* http://blog.ihs.com/better-diabetes-treatment-can-save-medicaid-over-4-billion-per-year.
[5] MedPAC, Comments to 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, pp. 14-16 (Jan. 3, 2018).

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doing so, the policy would help ensure that even patients with very high levels of prescription drug out-of-pocket spending could see a reduction in annual costs. That, in turn, could also lead to potential improvements in adherence and resulting outcomes.

We also urge CMS to consider potential implications of policy options that could be viewed as reducing the rebate amounts received by pharmacy benefit managers (PBMs). We are concerned that plans or PBMs potentially could respond in the wake of such policies by imposing costs in other areas such as higher premiums or deductibles. To protect against potential increases to patient costs in other areas of the benefit, we encourage CMS to consider prohibiting plans and PBMs from taking into account any rebate pass-through amounts when setting premiums, deductible amounts, or other cost-sharing policies. While we appreciate the difficulties inherent in enforcing policy options along those lines, we believe such ideas are important to explore in order to evaluate potential policy options and the possible implications of those options – both intended and unintended.

In addition, these types of policies could affect rebate practices and, in particular, potentially could reduce the value to Part D sponsors of obtaining a rebate or price concession. That, in turn, potentially could lead to reduced use of rebates and concessions and resulting effects and implications for healthcare stakeholders and the system overall. Certain pass-through policies also could have a potential unintended effect of reducing rebates overall if the rebates were aggregated within each therapeutic class. This appears to be one option that CMS may be considering. As the Pharmaceutical Research and Manufacturers of America (PhRMA) has stated, under such a policy, manufacturers may be disincentivized to offer significant rebates if some of that rebate would go to competitor drugs. We support PhRMA's position that, if rebates are passed through, it should be done at the individual drug level and not aggregated within a therapeutic class.

We also believe that it is critical that CMS continue to protect the confidentiality of manufacturer negotiations with pharmacy benefit managers and the resulting rebate amounts. In connection with any potential policy that the Agency may consider or pursue, CMS should ensure that the provision of rebate data and the sharing of such data with plan sponsors remains confidential.

As indicated above, to help determine the potential effects of policy options that CMS may implement, and to help evaluate the potential intended and unintended consequences, we recommend a study, perhaps by MedPAC, to analyze possible options and their potential effects, focusing on whether patient costs would actually be expected to be reduced and whether adherence would be expected to improve.

Finally, we appreciate CMS' initial Request for Information on this topic and urge the Agency to provide a separate and additional public comment period on any specific proposals the Agency may formally consider going forward. An opportunity for public review and feedback on the details of any such proposals, if and when CMS considers them, will be important to ensure that stakeholder perspectives are appropriately addressed and that potential unintended consequences can be identified and considered prior to pursuing or finalizing any new policies.

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II. Mid-Year Changes to Formularies

Current protections against mid-year formulary changes under Medicare Part D are extremely important to patients. Beneficiaries choose plans based on formularies, and access to particular medications is a critical need and driving aspect of beneficiary choice. Permitting plan sponsors to change a formulary mid-way through the plan year as proposed would limit beneficiaries' ability to choose the best plan for their needs and would lead to disruptions in care that can be harmful to patients. Continuity of care is critical for patients with serious and chronic conditions. In addition, for a number of patients, differences in the inactive ingredients used in drugs can have significant effects, such that changing from a brand-name to a generic drug or from one generic to another could have harmful consequences or lead to negative outcomes.[6] Moreover, it is fundamentally unfair to change a beneficiary's coverage options in the middle of a plan year when the beneficiary has enrolled in a particular plan based on different information. We urge CMS to continue to allow drugs to be added to a formulary in the middle of a plan year, but not permit drugs to be removed during a plan year, except in very limited circumstances (such as a product being recalled or withdrawn).

As CMS states in the Proposed Rule, the Agency has "recognized that both current and prospective enrollees of a prescription drug plan need to have the most current formulary information by the time of the annual election period described in § 423.38(b) in order to enroll in the Part D plan that best suits their particular needs." In addition, "MedPAC observed that the continuity of a plan's formulary is very important to all beneficiaries in order to maintain access to the medications that were offered by the plan at the time the beneficiaries enrolled." Despite these statements, CMS sought "to balance formulary continuity with requests from Part D sponsors to provide greater flexibility to make midyear changes to formularies."

For these reasons, we urge CMS not to finalize policies that would expand plans' ability to make mid-year changes that remove drugs from formularies. We are concerned that such changes would be detrimental and unfair to patients. In addition, they could lead to increased costs if patient access to care is interrupted and patient adherence is subsequently negatively impacted. Improved adherence can lead to lower health care costs in other segments of the

[6] For example, some patients may be allergic to, or may have medical conditions (such as certain autoimmune diseases, diabetes, or other disorders) that are triggered and/or exacerbated by, certain inactive ingredients that may vary between brand and generic versions of products. *See, e.g.*, Allison R. King, et al., *Special Feature: Gluten Content of the Top 200 Medications: Follow-Up to the Influence of Gluten on a Patients Medication Choices*, Hospital Pharmacy 48(9): 736-743 (2013), p. 736–37 (discussing adverse effects that often result for patients with celiac disease, an autoimmune disorder, if the inactive ingredients in a patient's medication include gluten); L. Kathleen Mahan, et al., *Krause's Food & the Nutrition Care Process ed. 13* (Elsevier 2011) (discussing adverse effects that can result for patients with various types of conditions if a medication includes certain types of excipients or inactive ingredients, including, for example, side effects for a lactose intolerant person if a medication contains lactose, or for a person who has a wheat allergy or celiac disease if a medication contains wheat, or for a person with diabetes or insulin resistance if they ingest a medication that contains glucose or other sugars, or for other patients who may have severe—even life-threatening—reactions to sulfites, certain dyes, or vegetable oils containing peanuts, if such substances are used in medications as fillers, coloring agents, or other types of inactive ingredients in medications); National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), "Handout on Health: Systemic Lupus Erythematosus," http://www.niams.nih.gov/HEALTH_INFO/LUPUS/DEFAULT.ASP#Lupus_6 (May 2013) (noting that, for patients with the autoimmune disease lupus, a treatment plan must be based on the patient's specific symptoms and characteristics, and "tailored to the individual's needs").

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system. Indeed, the Congressional Budget Office (CBO) has found that access to medications under Medicare Part D can lead to reduced expenditures in other areas of healthcare costs.[7] Finally, we are concerned about the potential to negatively impact provider and patient choice if a drug prescribed by a provider were removed from a formulary mid-year. Accordingly, we urge CMS not to finalize the proposed policies under the Proposed Rule relating to mid-year formulary changes.

III. Medicare Advantage (MA) Uniformity Requirements and Segment Benefits

Currently, CMS requires MA plans to offer all enrollees access to the same benefits at the same level of cost sharing. In the Proposed Rule, CMS states that the Agency has determined that it has the authority to permit MA organizations to change cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer differing deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees (i.e., all enrollees who meet the identified criteria) are treated the same. CMS also proposes to provide for additional flexibility relating to MA plan segment benefits.

While we appreciate proposals designed to improve plan flexibility and meet the needs of particular patient populations, we have concerns about potential unintended consequences from these proposals. These potential unintended consequences could include, for example, patient access problems or inadvertent discriminatory effects if benefits or cost-sharing structure start to be designed on the basis of a beneficiary's health conditions or health status. While the Proposed Rule discusses the possibility of adding benefits for certain populations through this contemplated increased flexibility, such as adding foot exams for diabetic enrollees, we fear that the proposal affecting uniformity requirements and suggesting possible "segment benefits" potentially could be used, even if inadvertently, to create benefit disparities and/or reductions for certain populations, creating concerns about discrimination and/or unfair and inadequate access. Because these potential unintended consequences are unknown, we urge CMS to further study the potential implications on clinical care, continuity of care, patient access and adherence, and patient protections against discrimination. Alternatively or in addition, we recommend that CMS ask MedPAC or another third-party organization to study this issue, including a process to seek input in connection with the study from providers and patients.

[7] *See* CBO, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (Nov. 2012), *available at* https://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-medicalOffsets-11-29-12.pdf (reporting CBO's conclusion that drug spending in Medicare Part D has an "offsetting" effect that reduces spending in other areas of medical care, and explaining that, as a result, CBO scoring will account for this offset by "estimat[ing] that a 1 percent increase in the number of prescriptions filled by beneficiaries would cause Medicare's spending on [non-drug] medical services to fall by roughly one-fifth of 1 percent").

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Mallinckrodt appreciates the opportunity to comment on this Proposed Rule. We look forward to continuing to work with CMS on these important issues.

Sincerely,

Mark Tyndall
Vice President
Government Affairs, Policy and Patient Advocacy

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