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Seema Verma, M.P.H., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-4182-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

Dear Administrator Verma:

Sunovion Pharmaceuticals Inc. (Sunovion) thanks you for the opportunity to comment on the proposed 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; RIN 0938-AT08), 82 Fed. Reg. 56336 (November 28, 2017) and particularly on the Medicare Prescription Drug Benefit (or Part D) proposals in the rulemaking. The Proposed Rule includes numerous proposals affecting beneficiary access to medications under the program, many of which implicate prescription drug manufacturers like Sunovion. We thus appreciate the opportunity to share our comments with the Agency in the hopes of improving and refining the proposed rule changes.

Sunovion is a global biopharmaceutical company focused on the innovative application of science and medicine to help people with serious medical conditions. With patients at the center of everything we do, Sunovion has charted new paths to life-transforming treatments that reflect ongoing investments in research and development and an unwavering commitment to support people with psychiatric, neurological and respiratory conditions.

Our comments are focused on five aspects of the proposed rule:

(1) We oppose the proposal to permit Prescription Drug Plans (PDPs) to substitute generic medications mid-plan year with minimum notice to beneficiaries;

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(2) We request clarification of the Agency's proposal regarding the process of defining "frequently abused drugs" that would be subject to Medicare Part D access restrictions in the context of Comprehensive Addiction and Recovery Act (CARA) implementation;

(3) We support the proposal to permit Medicare Advantage Plans to specialize in particular disease states; and

(4) We support the Agency's pursuit of policies that would require pharmacy benefit managers (PBMs) and PDPs to pass through rebates, discounts and other Direct and Indirect Remuneration (DIR) fees to beneficiaries at the point of sale.

Our specific comments appear below.

1. Expedited Substitution of Generics – Mid-Year Formulary Changes

CMS proposes to permit immediate mid-plan year substitution of a generic for a branded medication that was on the Plan formulary and elimination of coverage for the brand with no notice to the beneficiary other than a general advance notice that such substitutions might occur during the plan year. Sunovion objects to this proposal and urges the Agency not to adopt it. The proposal removes basic patient protections that are needed for the proper functioning of the Part D program. Beneficiaries require advanced notice of formulary changes, even if branded to generic medications, to ensure they have sufficient time to: (1) discuss the anticipated changes with their health care professional; (2) prepare for prescriptions that may have a different name, different appearance, and different payment (including co-payment) process; and (3) ensure they are not surprised at the pharmacy counter when a different medication is dispensed. Medication adherence is already a well-documented challenge, and rates of non-adherence are particularly acute for patients with serious mental illness. We are concerned that enacting this policy change would serve to exacerbate this problem.

Sunovion appreciates that CMS proposes to require Plans to *generally* notify beneficiaries in the Explanation of Coverage (EOC) that the plan may switch medications mid-year, and that under the proposal PDPs will not be able to undertake this switch if the generic medication was available prior to the beginning of the Plan year. However, in our experience the EOC notice is insufficient to protect beneficiaries. If the Agency finalizes its proposal, the Agency would be open to critique for permitting a classic "bait and switch," where a beneficiary, believing they are enrolling in a Plan to secure access to a specific medication, learns mid-plan year without notice that their medication is no longer covered and they are required to substitute a "new" generic. This will harm beneficiary confidence in the Part D program, and undermine beneficiary confidence in their PDP.

Part D Plans already have a plethora of utilization controls, including step therapy and prior authorization, that they can immediately deploy to steer beneficiaries to new generics that are added on formulary mid-plan year. We believe that the existing tools are more than adequate to

ensure that patients in appropriate circumstances utilize generics. For these reasons, Sunovion asks that the proposed regulation be withdrawn.

2. Defining and Limiting Access to "Frequently Abused Drugs"

Sunovion supports the Agency's role in implementing provisions of the Comprehensive Addiction and Recovery Act of 2015 (CARA), and is grateful that the Agency is prioritizing this new regulatory initiative as part of the Proposed Rule. As the Agency acknowledges, the threat to our country as a result of prescription drug abuse is significant, and there is a real need for a comprehensive effort to curb opioid abuse.

Sunovion offers one comment on the proposed rules implementing CARA: a drug will be defined as "frequently abused" based upon (1) the US Drug Enforcement Agency (DEA) scheduling status, (2) professional guidelines, and (3) an analysis of Medicare and scientific data. We note that there are a myriad of drugs used for indications other than pain (and that are not opioids) that will be scheduled by the DEA, including attention deficit disorder medications, sleep agents, and others with important therapeutic benefits that could inadvertently fall within the broad definition. Although certain medications are scheduled and subject to professional guidelines, they may not be subject to frequent abuse and should not be restricted under CARA controls.

For that reason, Sunovion recommends that any classification of a medication as "frequently abused" be subject to expedited notice and comment rulemaking (in the same manner in which CMS is soliciting comments on including all opioids as frequently abused), rather than be subject to the informal comment process of the Call Letter, so that a full public review of the clinical considerations beyond DEA scheduling can be considered. In the alternative, if CMS does not choose to change its proposed rule, we ask CMS in its preamble to the Final Rule to clarify that DEA scheduling alone will not presumptively classify a medication as a "frequently abused drug" and that the Agency will exercise caution in labelling medications (other than opioids) as "frequently abused," in order to minimize the risk of stigmatizing medically necessary medications and reducing access for patients in need.

3. Medicare Advantage Plans and Disease Specialization

The Agency has also proposed to provide Medicare Advantage (MA) Plans new flexibility to offer cost-sharing reductions and targeted supplemental benefits for health care services that are medically related to specific disease conditions. Sunovion agrees that providing MA Plans the ability to specialize in particular disease states could help with overall health management of chronically ill beneficiaries, and may have the potential to improve medication management and compliance as well. While we appreciate the role of "special needs plans" (or SNPs) to assist with these goals, MA Plans should be empowered to specialize in more focused ways to cover particular disease states. In that regard, we appreciate the Agency referencing the possibility of specific MA programs for chronic obstructive pulmonary disease (COPD), a condition for which patients remain in need of specialized and coordinated care management.

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In general, we urge CMS to require that any specialized Plan offerings be structured to meet existing and current consensus based treatment guidelines. For example, for COPD, CMS should require MA plans offering specialized COPD programs to consult the 2017 Global Initiative for Chronic Obstructive Lung Disease ("GOLD") report[1] which offers consensus recommendations on the effective management of COPD, emphasizing the importance of individualized treatment for patients. In addition, CMS should consider requiring such COPD Plans to consider the National Action Plan for COPD recently published by the National Institutes of Health (NIH), which includes recommendations to increase coordination across the continuum of care. We commend the Agency for its initiative in permitting more specialized care through the MA program, provided that the agency continues to adhere to policies to discourage discrimination in its implementation.

4. Requiring PBMs to Pass Through Rebates, Discounts and other DIR Fees to Beneficiaries at the Point of Sale

Sunovion appreciates the Agency's request for information on the variety of proposals to address how PBMs are handling manufacturer rebates, and endorses the concept that a portion of manufacturer rebates should be passed through to the beneficiary at the point-of-sale in a manner that protects the confidentiality of the actual rebate agreement amount. For far too long, PBMs have been retaining, rather than passing through, rebate dollars, which prevents beneficiary access to lower drug costs and which increases the government's share of costs in the Part D program. Although Sunovion will not provide specific comments on the different proposals advanced by CMS, Sunovion does endorse and incorporate by reference the comments of its trade association, PhRMA, on the issue, and urges the Agency to propose a specific rule as soon as possible in response to the information the Agency collects in this rulemaking proceeding.

We thank you for consideration of these comments, and welcome any questions or follow up that you may have. Please feel free to contact me at (866) 556-8818 or eric.rasmussen@sunovion.com if we can provide any additional information.

Sincerely,

Eric Rasmussen
Executive Director, Government Affairs and Policy

[1] 2017 Global Initiative for Chronic Obstructive Lung Disease ("GOLD") report. http://goldcopd.org/gold-2017-global-strategy-diagnosis-management-prevention-copd/