The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-4180-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses Proposed Rule

Dear Administrator Verma:

The Society for Immunotherapy of Cancer (SITC) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS') Modernizing Part D and Medicare Advantage (MA) to Lower Drug Prices and Reduce FY20 Proposed Rule. With nearly 2,500 members representing 17 medical specialties, SITC is the world's leading member-driven organization specifically dedicated to improving cancer patient outcomes by advancing the science and application of cancer immunotherapy. SITC aims to increase the standard of care applications of cancer immunotherapy, and thus supports efforts to ensure maximal patient access to these life-saving therapies.

SITC would like to comment on both the **Medicare Advantage Step Therapy Policy for Part B drugs and the proposed changes to the Medicare Part D protected classes of drugs.**

We understand that the intent of the proposed rule is to implement better drug utilization management processes and prior authorization programs for managing drug costs. We support CMS' efforts to lower patients' out of pocket costs and prevent the misuse or abuse of drugs that are not medically necessary. However, these policies, as currently proposed, could be detrimental for patients or beneficiaries living with chronic or life-threatening conditions.

Medicare Advantage:
As currently written, the proposed rule could negatively impact the clinical treatment of cancer patients. While we are pleased that CMS will not allow MA plans to disrupt a beneficiary's current treatment plan, the rule does permit future treatment to be dictated according to the plan's step therapy policy. In cancer care, the first treatment decision is the most important decision. By subjecting a cancer patient to step therapy, a plan could be delaying access to the most appropriate treatment option. The rule does provide for a review process by which a physician can present the reasons necessary to bypass the step therapy plan. However, even with an expedited process, this takes up precious time that cancer patients often cannot afford to spare. Further, patients could actually experience higher out of pocket costs if they are forced to try numerous costly products that may not actually work before getting on the right treatment.

We also appreciate CMS' acknowledgement and efforts to reduce the administrative burden. However, it would be more efficient for CMS or the Pharmacy & Therapeutic Committee to pre-determine a list of exempted patients or beneficiaries from step therapy when the beneficiaries' healthcare provider's assessment of medical necessity indicates that alternative treatment or preferred drugs are not clinically appropriate and efficient. We also suggest that such pre-determined list be reviewed not only in instances where the policy requires stepping across B and D drugs but also when the drug may be

subject to a step therapy requirement. To make gathering this information easier for beneficiaries, we support the inclusion of such a list in the Medicare Plan Finder. We also believe the list should be updated at least on an annual basis to avoid unnecessary prior authorization processes and should allow patients in critical conditions to receive the right drug at the right time.

To better understand the science of patient heterogeneity, which is an important factor as it relates to utilization management, you may refer to SITC's TimIOs project[1] to address this particular issue. The TimIOs team is a group of early career scientists aiming to build a platform that will help identify fundamental differences between patients' response cohort. Full details are provided in section III of "Sparkathon project TimIOs" published in the Journal of Immunotherapy of Cancer (JITC).[2]

Part D:
For the first time since the implementation of the Medicare Part D program, CMS is taking steps to allow Part D drug plan sponsors to impose formularies on the six protected classes of drugs. While the rule does not eliminate the protected classes, SITC has concerns about the proposed changes, or "exceptions", which would be permissible if CMS finalizes the proposed rule.

First, the proposed rule would allow Part D sponsors to use prior authorization and step therapy for protected class drugs, including to determine use for protected class indications**.** A prior authorization for patients with chronic or life-threatening conditions may delay the benefit of a protected therapy under Part D if they are required to try alternative and/or inefficient low-cost therapies. We cannot limit patients' access to novel therapies when their lives are at risk and physicians know for fact than preferred or low-cost drugs won't be effective. A prior authorization should not be applicable to everyone. Additional exceptions to this rule should be considered, especially in the oncology field. For these reasons, SITC opposes this proposed policy.

Second, recent data from an Avalere study[3] shows that the use of generics among the protected classes is at an all-time high – with 91 percent of prescriptions filled in 2016 being for generic products. This trend is evident in the dispensing of chemotherapy and other antineoplastics, as well, with 75 percent of generic drugs being covered. The Avalere study also finds that the average Part D plan already places drugs in the protected classes onto higher tiers. We believe this data is evidence that Part D plans are already doing a sufficient job in managing out-of-pocket spending in the Part D program and question whether additional management tools are truly necessary.

Again, we appreciate the opportunity to submit our comments on the proposed policy. We respectfully offer our society's leadership and expertise in future considerations impacting the field of cancer immunotherapy.

Should you have any questions, please do not hesitate to contact SITC Executive Director, Tara Withington, at twithington@sitcancer.org.

Sincerely,

Tara Withington

Tara Withington, CAE,
Executive Director, Society for Immunotherapy of Cancer

[1] https://www.sitcancer.org/education/sparkathon/2017-class/projects/timios
[2] https://jitc.biomedcentral.com/articles/10.1186/s40425-018-0453-4
[3] http://www.partdpartnership.org/uploads/8/4/2/1/8421729/partnership_for_part_d_report_2018.pdf