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January 25, 2019

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-4180-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Modernizing Part D and Medicare Advantage to Lower Drug
Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P)

Dear Administrator Verma:

On behalf of the over 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) proposed rule, *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses*, published in the *Federal Register* on November 30, 2018.

The ACS is a scientific and educational association of surgeons founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Since a large portion of surgical care is paid for under Medicare Advantage (MA) and Medicare Part D, the College has an interest in these programs and CMS' efforts to reduce costs for beneficiaries, and we believe that we can offer insight to the Agency's modifications to such policies. Our comments below are presented in the order in which they appear in the rule.

PROVISIONS OF THE PROPOSED REGULATIONS

Providing Plan Flexibility to Manage Protected Classes

Broader Use of Prior Authorization for Protected Class Drugs

Section 860D-4(b)(3)(G)(i)(II) of the Social Security Act grants CMS authority to allow Part D plans to exclude from their formularies, or otherwise limit access through prior authorization (PA) or other utilization management tools, a particular Part D drug that is otherwise required to be



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on the formulary because it is in one of six protected drug classes (i.e., anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants). CMS states in this proposed rule that, although Part D plans can currently employ some utilization management within the protected drug classes, the Agency does not believe that plans' ability to do so is comparable with neither the commercial market nor what is already permitted for non-protected medications. CMS therefore proposes to expand the use of PA within the protected classes to align with what is currently allowed for all other drug categories, including implementing step therapy for protected class drugs, determining use for protected class indications, or both.

While the ACS understands CMS' focus on curtailing rising drug costs, we do not support the imposition of step therapy on protected class drugs—specifically, immunosuppressants—available to Part D enrollees. **The College has grave concerns that such coverage restrictions have the potential to disrupt care, impede patient access to medically-appropriate treatments, and threaten the safety of beneficiaries who are prescribed immunosuppressants for the purposes of preventing organ rejection following a transplant procedure.** The Agency's proposal would enable Part D plans to exclude certain immunosuppressants from their formularies altogether based wholly on increases in the price of these medications, which would substantially limit the availability of immunosuppressants both for new starts and for patients who are already on an effective drug regimen. We believe that it is highly inappropriate for CMS to authorize plans to require transplant recipients to stop a stable and life-sustaining immunosuppressant therapy in order to switch to a less expensive alternative, which could thereby jeopardize the viability of the transplant and in turn result in significantly increased costs for Medicare.

CMS' sole rationale for its step therapy proposal is that, under current policy, the profitability of products not subject to normal formulary inclusion negotiations because of their protected class status is a strong incentive for overutilization (particularly off-label overutilization) of these drugs. **We wish to remind CMS that physicians prescribe drugs based on clinical judgement, patient needs, and evidence-based medicine—not on profit incentives.** The Agency indicates that, by permitting Part D plans to perform more stringent utilization management within protected drug classes, such plans would be able to increase their leverage in negotiating drug prices with manufacturers since they would no longer be required to include all protected class medications in their formularies.

The ACS believes that whatever negotiating power plans may gain by

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expanding utilization management is far outweighed by the potential harm both to patients and the Medicare program should changes to coverage for immunosuppressants lead to unnecessary hospitalizations, organ rejection, or other serious health consequences. We therefore urge CMS to revoke its proposal to broaden the use of PA and step therapy for protected class drugs under Part D.

E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards

Proposed Adoption of a Real-Time Benefit Tool

CMS currently requires providers, dispensers, and Part D plan sponsors to convey and/or utilize the National Council for Prescription Drug Programs (NCPDP) SCRIPT and Formulary and Benefit (F&B) standards for the purposes of communicating prescription-related information for certain electronic transactions made under the Part D program. The Agency notes that, while the existing SCRIPT standard enables providers to electronically prescribe drugs, and that the F&B standard allows providers to access Part D plans' formularies, neither can transmit patient-specific, real-time cost or coverage data to a provider at the point of prescribing.

In an effort to offer a more complete view of a patient's prescription benefit information, CMS proposes to require Part D plans to develop and make available to providers one or more real-time benefit tool (RTBT), which would serve as an adjunct to the SCRIPT and F&B standards, by January 1, 2020. The Agency states that all RTBTs should be capable of integrating with at least one provider's electronic prescribing (eRx) and electronic health record (EHR) systems, and that each RTBT program response must show: (1) how a given prescription claim would be adjudicated given the information submitted and the patient's claims history with their Part D plan—including relevant indications that could impact coverage—at the time the provider query is made; (2) real-time values for a patient's cost-sharing information and additional formulary alternatives; and (3) any utilization management requirements, step therapy, prior authorization, quantity limits, and indication-based restrictions for all formulary alternatives.

The ACS thanks CMS for its efforts to make beneficiary-specific drug coverage and cost information more available to prescribers at the point-of-care, and we support the Agency's proposal to require Part D

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plans to implement interoperable RTBTs. We provide our input below on CMS' requests for feedback on the following RTBT issues:

- **Feasibility.** The Agency solicits comments regarding the feasibility of its proposal for Part D Plans to meet the January 1, 2020 RTBT deadline. While the ACS does not think that this deadline is unreasonable, we are concerned that baseline compliance with CMS' RTBT instructions is unlikely to attain measureable reductions in patient or total drug costs. The College believes that a feedback policy that documents the specifics of RTBT-generated information, implementation details, and the outcomes of RTBT use could contribute to achieving more cost-effective prescribing and lowering beneficiaries' out-of-pocket spending. Because of the complexity of changing prescriber behavior and gaining actual savings using drug cost decision support mechanisms at the point of care, it is essential that CMS include such a feedback policy so that the Agency can (1) assess the impact of RTBT use on drug costs, (2) identify the best, most effective practices that achieve CMS' intended objectives, and (3) promote or mandate these best practices. **As such, we urge CMS to require Part D plans to incorporate a feedback policy into their RTBTs, as this information would highlight best practices that can be used by the Agency to examine drug pricing and to refine its Part D rules over time.** We also encourage CMS to share the data gathered from the RTBT feedback loop with clinicians to assist them in making informed prescribing decisions.
- **Existing Standards.** CMS solicits comments regarding standards (if any) currently under development that may be suitable to meet the intended purpose of the RTBT requirement. We wish to highlight that, while the NCPDP has hosted a workgroup on real-time benefit checks for several years, political and financial challenges have impeded a single meaningful standard from emerging from the group due to conflicting interests between its members. **We encourage the Agency to take a leadership position in the development of RTBT standards, and to work with organizations already experienced in this area (e.g., Surescripts, Gemini Health) to obtain additional guidance.**
- **Standardization of RTBTs.** CMS solicits comments regarding ways the Agency can standardize RTBTs. **The ACS believes that the Agency should establish baseline utilization requirements that include a feedback policy (as described above).**

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- **Overall Impact.** CMS solicits comments regarding the effect of its proposal on Part D plans and providers, including the impact on interoperability and medical record systems. **We believe that drug cost information should be available within basic EHR workflows, and that prescribers can play an essential role in the delivery of cost-effective care and medications that support patient access. The Agency's RTBT proposal has the potential to play a role in advancing interoperability, as it provides a pathway for real-time integration of medical record systems and pharmacy benefit manager claims systems.**

The ACS appreciates the opportunity to provide feedback on this proposed rule and looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Vinita Ollapally, Regulatory Affairs Manager, at vollapally@facs.org.

Sincerely,

David B. Hoyt, MD, FACS
Executive Director

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