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January 25, 2019

Seema Verma
Administrator - Centers for Medicare and Medicaid Services
Centers for Medicare & Medicaid Services,
Department of Health and Human 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,

The American College of Cardiology (ACC) appreciates the opportunity to provide input on the CMS Proposed Rule: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P).

The ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned JACC journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions.

ACC's Policy Principles on Patient Access to Prescription Drugs

The College has advocated that access to healthcare is not merely about availability of care. Cost plays a significant role in access and must be treated as such. To that end, the ACC supports affordable access for all patients, regardless of insurance coverage or lack thereof, to all approved prescription drugs with scientific evidence of net clinical benefit or as articulated in clinical practice guidelines.

Recognizing the increasing role that pharmaceuticals play in conversations on health care access and affordability, the College approved policy principles on patient access to prescription drugs in 2018. ACC is pleased to share these principles (below) with CMS as part of the larger nationwide discussions on drug pricing, access, and patient affordability. If CMS has any questions regarding these policy principles, ACC would appreciate the opportunity to discuss this work further with CMS.

Policy Principles for Patient Access to Prescription Drugs
Patient Access: The ACC advocates for affordable access for all patients, regardless of insurance coverage or lack thereof, to all approved prescription drugs with scientific evidence of net clinical benefit or as articulated in clinical practice guidelines.

Barriers: Excessive out-of-pocket expense represents an insurmountable hurdle for many patients. It is essential to diminish any financial barriers including co-pays, co-insurance and deductibles. In addition, the ACC calls for the reduction of administratively burdensome processes that hamper patient access to evidence-based, approved therapies.

Transparency: The ACC urges transparency toward price determination throughout the distribution chain. Accurate information on drug prices, plan benefits, formulary changes, and discounts must be made readily available so clinicians and patients can be better informed about expected cost-sharing when discussing treatment plans.

Value-Based Pricing: Pricing decisions should be made with an emphasis on value, as assessed through scientific evidence and analysis of both comparative effectiveness and cost-effectiveness. Any movement toward value-based pricing must prioritize the impact on patient outcomes and not consider cost as the sole criterion.

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

Cost plays a significant role in access to care. The College supports CMS's efforts to reduce the costs of prescription drugs and thanks CMS for acting to address the rising cost of drugs through increased transparency efforts. The ACC encourages continued action by CMS to ensure patients have access to affordable prescription drugs.

Ensuring clinicians and patients have access to the most up to date information on drug prices, plan benefits, formulary changes, and discounts is essential to the medical decision-making process and supports efforts to ensure this information is easily accessible in a transparent manner. Specifically, the ACC thanks CMS for proposing real-time benefit tools (RTBTs) as a mechanism for providing the most up to date drug information to clinicians and patients. **RTBT development showing each drug's full negotiated price, in addition to the beneficiary's out-of-pocket cost information, integrated into an electronic health record (EHR) is a promising step that aims to provide necessary pricing transparency.**

While the ACC is a longtime opponent of overly burdensome prior authorization requirements, the College supports CMS' proposed requirement that the RTBT needs to present real-time values for the patient's cost-sharing information and additional formulary alternatives, including the formulary status of clinically appropriate formulary alternatives, any utilization management requirements, such as step therapy, quantity limits and prior authorization, and indications-based restrictions, for each specific alternative presented. This is necessary to provide clinicians and patients with the necessary coverage requirements and cost information for informed-decision making during the drug selection process. This requirement also would help to remove patient concern and uncertainty prior to the pharmacy visit and provide clinicians with the clear tasks for obtaining their patients' medications. Administrative tasks like prior authorization are constantly a major source of dissatisfaction for physicians. They take time away from direct patient care, contribute to clinician burnout, and should serve as a lesson for how not to implement RTBT.

CMS encourages Part D plans use RTBTs to promote full drug cost transparency by showing each drug's full negotiated price, in addition to the beneficiary's out-of-pocket cost information. The College supports this use of RTBTs. If plans do not promote full drug cost transparency through RTBTs by publishing a drug's full negotiated price, the ACC encourages CMS to strengthen RTBTs by requiring each drug's full negotiated price in addition to the beneficiary's out-of-pocket cost information in the tool to ensure full price transparency

While supportive of a RTBT system that provides long due transparency to drug pricing and potential administrative relief, the ACC has several concerns related to RTBT interoperability with existing EHRs, increased administrative burdens, as well as the RTBT implementation timeline and process.

<u>Interoperability</u>
As currently proposed, "each Part D plan sponsor [would be] required to implement an RTBT capable of integrating with at least one of prescribers' electronic prescribing (eRx) and EHR systems." While CMS writes RTBT intent is "to provide the prescriber with complete, accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information at the point of eRx" for all clinicians, the ACC is concerned plan sponsors may create a system which integrates only with the largest EHR vendors.

The ACC believes interoperability requires more than the ability of two or more health information systems or components to exchange clinical and other information; it also requires that information be exchanged using common data standards to facilitate coordinated care and improved outcomes. By saying a RTBT needs to integrate with at least one eRx and EHR system, CMS may inadvertently limit RTBT availability and interoperability. **For an RTBT to truly provide necessary drug pricing transparency and provide sufficient data to the largest number of patients and clinicians, the College asks CMS to clarify this language and ensure plan sponsors develop tools capable of integrating with all prescribers eRx and EHR systems which use a widely accepted industry data standard.**

CMS intends to move forward without an industry-wide standard readily available for development. Without a standard, RTBTs will have limited utility and EHR integration will be poor, as CMS acknowledges. **The decision to implement a tool capable of integrating with eRx and EHR systems without a common data standard will repeat the failures of the Meaningful Use program, leading to network segmentation throughout the medical community and dominance by a select few vendors.** As recent interoperability successes following the development of common standards such as FHIR (Fast Healthcare Interoperability Resources specification) have shown, industry wide cooperation and development with participation from federal agencies such as the Office of the National Coordinator for Health Technology (ONC) is essential to overcome technological barriers that prevent true interoperability's realization.

Instead of rapidly implementing a tool before an industry-wide standard which promotes collaboration and interoperability across industry partners is ready, CMS should delay implementation while an accredited standard setting body develops a suitable RTBT standard. In the interim, CMS and organizations that have implemented RTBT systems should study their impact and work to fine tune policies that encourage drug price transparency. CMS should make these findings public and use them to help with standards development and organizational system implementation. The ACC supports the intent behind RTBT system development and encourages CMS to continue to work with industry partners by providing technical assistance to these standard setting bodies to ensure appropriate system implementation.

Administrative Burden

Under the 21st Century Cures Act, Congress asked ONC to reevaluate the reporting criteria for the EHR reporting program, including certification standards and reporting criteria for several categories including interoperability and incorporation of user-reported data. The ACC and many other stakeholders provided input on how ONC can work to improve EHRs, including steps to reduce the administrative burden placed on clinicians by poorly designed user-interfaces and increased click counts. The College encourages CMS to take this same approach and apply input gathered from stakeholders when crafting the policies governing RTBT systems.

When designing RTBT systems, it is important for plan sponsors and EHR vendors to consider usability and user-centered design to ensure any administrative burden reductions gained through real-time access to drug information are not erased by poorly designed user-interfaces. CMS should work with vendors to incorporate human-computer interface evaluation methods into RTBT development processes to ensure the systems fully and neatly integrate with eRx and EHR systems. **RTBT integration into existing and future eRx and EHR systems should complement, not hamper, clinician workflow and should not interfere with the clinician-patient relationship.**

Implementation

The ACC agrees action to promote drug price transparency, increase access to drugs, and reduce drug prices is necessary. However, the implementation date of January 1, 2020 appears to be premature. As previously mentioned, without a widely accepted industry standard available, interoperability between

RTBTs, eRx, and EHR systems will be severely hindered, limiting the effectiveness of the tool for widespread utilization. As CMS concedes, the standards development process is currently underway and CMS should provide these organizations with the necessary time to develop a stable and viable industry-wide standard. It is essential that CMS learn from previous programs such as EHR Meaningful Use and use real-time input from early innovators and accredited standard setting bodies to help inform policy making.

As CMS develops the RTBT program, it is also important to work with federal partners in other agencies to ensure patients and clinicians in rural or underprivileged communities have equal access to these tools through increased access to broadband services or development of alternative methods of accessing RTBT information if access to an eRx or EHR system is unavailable. CMS should ensure that price transparency information is accessible to all patients regardless of circumstance. **Some of the most vulnerable populations would benefit most from access to real-time drug pricing information and it is important that CMS ensure tools grant all patients access to information contained in RTBT systems.**

Finally, it is important that CMS work with colleagues at ONC and the Office of the Inspector General (OIG) to make sure data is freely accessible without special effort through RTBT systems by applying and enforcing information-blocking prohibitions to this and other transparency tools made available to patients and clinicians.

Conclusion

The ACC is committed to working with CMS and providers to ensure access to affordable drugs for all patients. The College looks forward to ongoing discussion and collaboration with CMS on drug pricing and transparency initiatives.

If you have any questions or would like additional information regarding any recommendations in this letter, please contact Joseph Cody, Associate Director, Research and Innovation Policy, at (202) 375-6251 or jcody@acc.org.

Sincerely,

C. Michael Valentine, MD, FACC
President