ENDOCRINE SOCIETY
Hormone Science to Health

January 25, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Baltimore, MD 21244

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 Endocrine Society, I offer the following comments on the Proposed Rule on Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. The Society is the world's oldest and largest organization of scientists devoted to hormone research and physicians who care for people with hormone-related conditions. Drug pricing reform is critical to us and the patients our members treat. Our member endocrinologists have difficult conversations every day with their patients who cannot afford the drugs needed to keep them alive or avoid complications.

Insulin is an important example of why drug pricing reform is needed. The cost of insulin has nearly tripled in the past fifteen years, making it difficult for many people to afford this medication and effectively manage their disease. This has put patient safety in jeopardy as rationing insulin may lead to unnecessary complications or death and should not be an option that people with diabetes are forced to choose. The Endocrine Society supports policy changes that provide physicians and patients with transparent information on the out-of-pocket cost of medications and lower-cost alternatives or reduces the amount that a patient must pay out-of-pocket without raising health insurance premiums.

E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards
If finalized, the Rule would require that Part D sponsors implement a real-time benefit tool (RTBT) to convey patient-specific real-time cost or coverage data to the prescriber at the point of prescribing. **The Society strongly supports this requirement as our members consistently share their frustrations with the lack of patient-specific information available to them during a patient visit.** Without this patient-specific information, physicians are unable to have informed conversations with their patients that consider cost of medication, patient cost-sharing, formulary restrictions, and lower-cost alternatives. This often means that a patient will visit the pharmacy to fill the prescription and only then learn that their share of the cost is more than they are able to afford. In these cases, the patient often must return to the physician's office to obtain a new prescription or the physician must take time away from patient care to address the issue with the pharmacy. Access to a RTBT

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would reduce the burden on patient and physician to figure out the cost of a drug and allow for informed conversations during the prescribing process.

Although there are numerous RTBTs available, most physicians either do not have access to these tools or even know of their existence. A requirement by the Federal Government would expand awareness of and access to RTBTs and likely increase their use in non-Part D plans as well. As mentioned in the Proposed Rule, no industry standard exists for integration of RTBTs into electronic medical records (EMRs), which complicates efforts to ensure that all prescribers have access to these tools. **While CMS is not requiring that an industry standard for RTBTs be developed, we urge the agency to take steps within its authority to advance the development of such a standard.** Only when RTBTs can be easily integrated into all EMRs will the benefits for price transparency and reduced prescription drug costs be realized.

Part D Explanation of Benefits

Part D sponsors are required to provide beneficiaries with an explanation of benefits (EOB) in every month in which the enrollee utilized their prescription drug benefit. CMS proposes to require Part D sponsors to include information about negotiated price changes and lower-cost therapeutic alternatives in the monthly EOB with a goal of increasing transparency and lowering drug spending. **The Society supports efforts to increase transparency in drug pricing and provide patients with information needed to make informed decisions about the best medication based on their own circumstances.**

However, until prescribers have access to RTBTs, it is important that the information provided in the EOB also be shared with them. The Proposed Rule indicates that it is CMS' hope that patients will use the information in their EOB to have a conversation with their physician about potential alternatives that have lower negotiated prices or patient cost-sharing. Patients may not be proactive in sharing this information, thereby limiting the impact that it could have on drug spending. Sending a monthly EOB to a physician whose practice included 500 Medicare patients would result in 6000 notifications each year. This would create another administrative burden on the practice, negating the benefit it would offer. **As such, providing prescription information through a monthly EOB report will not have the desired impact, which further supports the importance of implementing RTBT.**

Pharmacy Price Concessions in the Negotiated Price

CMS requests comments on whether the current definition of "negotiated price" should be deleted and instead defined as "the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D sponsor or the sponsor's intermediary." Under the current definition, the Part D sponsor must only include concessions that can be reasonably determined at the point of sale. This means that performance-based pharmacy payment adjustments, the second largest category of direct or indirect renumeration received by sponsors

and pharmacy benefits managers, are excluded from the negotiated price on the grounds that they cannot be reasonably determined at the point of sale. Although beneficiaries may benefit from these price concessions through lower premiums, they do nothing to impact the patient's out-of-pocket costs for their medications. Furthermore, the higher negotiated price results in a more rapid movement of a beneficiary through the Part D benefit phases, shifting more of the total amount spent on medications into the catastrophic phase.

The Society has identified several potential policy solutions that could impact the rising cost of insulin, including sharing more of the price concessions (rebates) with the patient at point of sale. However, lower out-of-pocket costs for medications should not come at the expense of higher insurance premiums or allow plan sponsors to force patients from higher-cost medications (for which plans currently receive higher rebates) to lower-cost alternatives that may not be as effective in treating their disease.

Thank you for considering our comments. The Endocrine Society supports policy changes that increase transparency in how drugs are priced and lower out-of-pocket costs for patients. If we can provide any additional information, please contact Stephanie Kutler, Director, Advocacy & Policy at skutler@endocrine.org.

Sincerely,

Susan Mandel, MD
President, Endocrine Society