

January 25, 2019

Seema Verma
Administrator,
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Contract Year (CY) 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS-4180-P)

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments regarding the Centers for Medicare and Medicaid Services' (CMS) Contract Year (CY) 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS-4180-P) released November 26, 2018. ASN represents more than 20,000 physicians, scientists, nurses, and other health professionals dedicated to treating and studying kidney diseases to improve the lives of people with kidney diseases. ASN is a not-for-profit organization dedicated to promoting excellence in kidney care. Foremost among the society's concerns is the preservation of equitable patient access to optimal quality kidney disease care and the integrity of the patient-physician relationship.

ASN appreciates CMS' efforts to lower the out-of-pocket costs of prescription drugs for Medicare beneficiaries. The society specifically supports provisions of the proposed rule that prohibit "gag clauses" in pharmacy contracts by restricting Part D sponsors from prohibiting or penalizing a pharmacy from disclosing a lower cash price to an enrollee. However, the removal of protections from the "six protected classes of drugs" raises serious concerns about patient safety and access to essential care. ASN has concerns about proposals to:

- Implement broader use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indications; and
- Exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period.

When Congress designed the Medicare Part D program, it ensured that the full range of six classes of critically important drugs - antidepressants, immunosuppressants, antipsychotics, antiretrovirals, anticonvulsants and antineoplastics - would be guaranteed for all patients who desperately need them. Due to the complex range of conditions treated by these different drugs – and the equally variable reactions of patients to these drugs – physician discretion to prescribe the most appropriate

medicines for their patients from these classes is an indispensable pillar of caring for patients with some of the most serious diseases.

Among the 725,000 people in the US who have kidney failure, nearly 250,000 have a kidney transplant and approximately 114,000 Americans are waiting for an organ transplant annually. Considering the needs of this large and vulnerable patient population, ASN focuses on protecting access to the critical, protected drug class of immunosuppressants. The society expresses concerns that the proposed changes to Medicare Part D protected classes will make it more difficult for some transplant recipients to access the vital range of drugs used to prevent organ rejection.

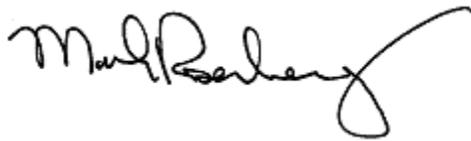
Transplant recipients need immunosuppressive medications to support long-term graft survival. Without access to the proper immunosuppressive pharmaceuticals, patients can lose the transplanted organ – an event nothing short of tragic for the patient and the entire healthcare system. A patient who loses their transplanted kidney will return to dialysis. Some patients will seek re-transplantation after organ rejection, but this poses challenges in the context of the organ shortage. Moreover, receiving a second organ transplant implies denying another person a similar opportunity. Organ rejection causes a medically dangerous event for a transplant recipient, associated with higher mortality than any other phase of ESRD care. Providing more effective, although possibly costlier, medications for transplant patients may save lives and money as a result.

Immunosuppression medications are not interchangeable and limiting options for immunosuppression will likely negatively impact patient outcomes. Not all patients tolerate immunosuppressive drugs, even if listed within the same class, in the same way. Their therapeutic benefits and adverse effects can vary significantly from patient to patient. Physicians often must adjust therapeutic regimens to address their patient-to-patient variability. For some patients, especially children who are unable to take tablets or capsules, liquid formulations of immunosuppressive drugs must be prescribed. Limiting immunosuppressive options can also negatively impact transplant recipients doing well on a particular immunosuppressive regime. Altering their drugs as a result of the proposed rule could result in reduced efficacy or intolerable side effects and result in allograft rejection.

Therefore, to guarantee optimal treatment and preserve the gift of life for kidney transplant patients, physicians need to have all FDA approved immunosuppressive drugs at their disposal. The society strongly believes that decisions about this complicated drug regimen should be left to a physician and their patient, and not limited or constrained by payment policies. The proposed policy could result in the lack of availability of certain drugs because of pricing issues, step therapy delays, and prior authorization requirements. In the case of transplantation, “failing” a less expensive agent may equate with rejection, a costly and dangerous complication. These events could erode the physician’s ability to find the most effective regimen for their kidney transplant patients, and run counter to the vital priority of maximizing the long-term function of each transplant.

Again, ASN supports CMS' commitment to lowering out-of-pocket drug costs for Medicare beneficiaries and providing them with pricing transparency through the prohibition of "gag clauses." However, the society strongly objects to proposals that undermine the patient-physician relationship and the latitude to individualize care, thereby, jeopardizing access to the most beneficial medicines for such severely ill and complex patients. If you would like to discuss the contents of this letter, please feel free to contact ASN Director of Policy and Government Affairs, Rachel N. Meyer, at 202-640-4659 or rmeyer@asn-online.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark E. Rosenberg". The signature is fluid and cursive, with a long, sweeping tail that loops back under the name.

Mark E. Rosenberg, MD, FASN
President