



January 23, 2019

Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-4180-P
P.O. Box 8016
Baltimore, MD 21244-8013

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

Dear Administrator Verma:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease. We are writing with regard to the potential impact of the 2020 Medicare Advantage and Part D Drug Pricing Rule on the availability of immunosuppressive drugs for ESRD beneficiaries with kidney disease.

The focus of RPA's concerns centers on the proposed additional exceptions related to the protected classes of drugs, including immunosuppressive drugs, that would allow Part D sponsors to: (1) implement broader use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indications; (2) exclude a protected class drug from a formulary if the drug is a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market; and (3) 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.

RPA believes that these additional exceptions if implemented would create barriers to the availability of immunosuppressive drugs to end-stage renal disease (ESRD) beneficiaries with kidney transplants. As senior CMS leadership knows, kidney transplants are safe, cost-effective procedures that can extend and significantly improve the lives of patients with ESRD, allowing them the freedom to forgo time-consuming and costly dialysis treatments three to four times per week. However, the unfettered availability of immunosuppressive drugs is critically important to the success of the transplanted organ. As such, RPA would posit that any policy revision that could serve as a barrier to transplant patients receiving immunosuppressive drugs should be rescinded.

Further, we would urge the agency to consider the potential long-term health policy ramifications of the proposal as it specifically applies to ESRD care and the Agency's goal to promote value over volume in Medicare. Immunosuppressive drugs not only facilitate the long-term viability of transplanted kidneys, but they also help avoid costly dialysis treatments and reduce the likelihood that the expense originally incurred by Medicare in transplanting the kidney to a patient that would otherwise require dialysis is not squandered. RPA is sensitive to CMS' fiduciary responsibilities, and we understand the rationale for the Agency's efforts to provide plan flexibility in order to manage the protected classes of drugs. However, RPA also believes that the additional exceptions have the potential to both unnecessarily threaten the health outcomes of kidney transplant patients and heighten the possibility that Medicare will incur the additional expense of a kidney patient returning to dialysis. This proposed policy is neither in the best interest of patient-centered quality kidney care nor the financial viability of the Medicare program.

RPA believes that any action that complicates the ability of patients to acquire these medications increases the potential for transplant failure, with the inability to pay for these medications being a frequent cause of such failure. Given that CMS has invested considerably in the initial transplant, RPA urges CMS to rescind the proposal to create additional exceptions related to the protected classes of drugs.

As always, RPA welcomes the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation's kidney patients, and we stand ready as a resource to CMS in its future endeavors. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael D. Shapiro". The signature is fluid and cursive, with the first name "Michael" being the most prominent part.

Michael D. Shapiro, MD, MBA, FACP, CPE
RPA President