

March 5, 2014

Hon. Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs: CMS-4159-P

Dear Administrator Tavenner:

As America's largest patient-led organization representing 26,000 dialysis patients and family members, Dialysis Patient Citizens (DPC) strives to improve the quality of life for all dialysis patients through education and advocacy. Thank you for the opportunity to comment on behalf of end-stage renal disease patients regarding proposed changes to the Part D program.

We are writing to express our opposition to the proposal to end the protected status of immunosuppressive drugs. We cannot imagine any set of circumstances under which it makes sense to subject immunosuppressive drugs to formularies in Part D.

Immunosuppressive drugs prevent a patient's immune system from attacking a transplanted organ. For end-stage renal disease (ESRD) patients who receive a kidney transplant while covered by Medicare, immunosuppressive drugs are paid for through Part B. Some patients retain private group coverage while and after receiving a transplant and become entitled to Medicare upon reaching their 65th birthday. These patients may receive their immunosuppressive drugs through Medicare Part D. We recognize that a relatively small number of patients may be impacted by the change at a given time, but the implications for these individuals are tremendous.

Drug formularies play an important role in the Part D program by permitting Prescription Drug Plans (PDPs) to negotiate lower prices from manufacturers in return for favorable placement on their formulary. The mechanism by which the system operates is a financial incentive for patients to request that their physicians first prescribe generic or other medications that the PDP places on lower-cost tiers. This system will work relatively well for patients with common conditions, such as high blood pressure or high cholesterol, for which there are numerous drugs available. We recognize that this system has broken down in certain circumstances, such as where the low-income subsidy insulates beneficiaries from higher co-payments, allowing physicians to prescribe higher-cost brand drugs without drawing patient push-back.

However, we are not aware of any such abuses in the prescribing of immunosuppressive drugs, nor do we believe that formulary restrictions for immunosuppressive drugs could lower costs in any meaningful way. We believe the experience of Mr. A, a member of Dialysis Patient Citizens, illustrates the circumstances in which these drugs are prescribed. After Mr. A received a kidney transplant, his physician prescribed generic versions of Cellcept and Tacrolimus. (Our review of the medical literature indicates widespread efforts to start out transplant patients on generic drugs.)

Within a year, however, Mr. A's doctors at Mayo Clinic substituted Azathioprine for Cellcept due to a reaction to a co-morbidity, short bowel syndrome. Within another year, Rapamune and Prednisone had to be substituted for Azathioprine due to it contributing to multiple occurrences of skin cancer.

Another member of Dialysis Patient Citizens, Mr. B., also suffered from side effects from first-line therapies. It was determined that his transplanted kidney was being damaged by Tacrolimus. Several different immunosuppressant drugs, including generic versions of brand drugs, were tried before his renal transplant would function. He now takes Rapamune and Myfortic.

As we understand the proposed rules change, if Mr. A and Mr. B had received their transplants while covered by private insurance, upon turning 65 and entering Medicare, they would be encouraged to undergo "step therapy" for a second time, or to substitute drugs on the PDP formulary without regard to their earlier experiences with those drugs. This strikes us as an absurd policy outcome.

We would further note that physicians will soon have their resource use monitored by episode groupers through the Physician Value-Based Payment Modifier. Under this program, physicians who unnecessarily prescribe expensive brand drugs can be penalized with payment reductions. This program should deliver the Rx drug savings CMS desires by deterring "outlier" physicians from expensive prescribing without burdening Medicare beneficiaries.

Immunosuppressive drugs were extended protected treatment because they are different from other medications. For commonly prescribed drugs, such as blood pressure drugs and statins, not only are there multiple treatment options, but the underlying condition can often be treated without the use of drugs at all, as by making lifestyle changes. Immunosuppressive drugs *must* be taken to prevent rejection of a transplant, and are *not* interchangeable.

We understand that lifting the protections extended to immunosuppressive drugs is one of the few potential cost containment tools that CMS possesses at this time, and it must be tempting to use it. But the mere fact that this avenue is available through rulemaking while superior reforms aren't is not a sound basis for making policy. The Congressional Budget Office has expressed doubts about savings from expanding drug substitution, noting it would be "medically inappropriate in many cases," which "would reduce the actual savings that could be obtained."

“Even among drugs approved to treat the same condition, important differences can exist. Some drugs in a class may be more effective than others, at least for some members of a population. Certain subpopulations—for example, those with liver or kidney disease—may need a specific brand-name drug in a class. In addition, some drugs in a class may have harmful side effects for different patients... Also, physicians and their patients may be reluctant to switch to a therapeutic alternative once a condition has been stabilized using a brand-name drug. Finally, physicians’ clinical experience with their patients may lead them to conclude that certain patients respond better to a particular drug from a given class.”¹

In closing, we note our disappointment that the CMS proposal manifests the same penny-wise and pound-foolish mindset of the Medicare statute in ending coverage for immunosuppressive drugs 36 months after a transplant. Like the statute, this proposal fails to recognize the considerable taxpayer investment in procuring a donor organ and transplanting it into a patient; as well as the high costs of a failed kidney transplant, which results in the return to an expensive dialysis regimen. To ask transplant patients to engage in the same back-and-forth with doctors and insurers over prescribing that is expected of patients with high blood pressure reflects a gross underestimation of the stakes for both the patient and the public.

Thank you for your consideration of our views. If you have any questions or comments, please contact me or our Director of Government Affairs, Jackson Williams, who can be reached at 866-877-4242 or jwilliams@dialysispatients.org.

Yours very truly,



Hrant Jamgochian
Executive Director

¹ Congressional Budget Office, Effects of Using Generic Drugs on Medicare's Prescription Drug Spending (September 15, 2010).