



NATCO objects to the proposal published by the Centers for Medicare and Medicaid Services (CMS) on Monday, January 6, 2014, to remove immunosuppressants from the list of six protected classes of drugs under Medicare Part D, effective in 2015 (the “Proposed Rule”).

Current policy ensures that transplant recipients have access to the most appropriate immunosuppressants by prohibiting Part D plans from restricting access through formularies. The Proposed Rule would enable Part D sponsors to impose formulary restrictions on these critical drugs, resulting in substantial risk of rejection, serious side effects, and other adverse drug reactions for Medicare Part D beneficiaries who are transplant recipients.

Restrictive formularies limit the ability to prescribe the right combination of medications to protect the recipient from organ rejection and other serious side effects. This delicate balance was recognized in the original decision to include these medications under protected status.

Transplant professionals devote a significant portion of their training to learning the nuances of recipient-centered immunosuppression. One of the largest areas of transplant research is directed toward comparison of different immunosuppressive drugs and regimens. All of these efforts are based on the need to prolong transplant graft survival and to decrease the multitude of life-threatening side effects caused by immunosuppressive agents. Each patient has a unique risk for rejection and for untold effects of immunosuppressive drugs. Access to all available drugs permits choice of a regimen that minimizes side effects such as renal failure, diabetes, hypertension, hyperlipidemia, neurotoxicity, bone marrow suppression, gastrointestinal toxicity, and others. It is precisely such access to a growing number of immunosuppressive agents and attention to individualizing regimens for each patient that has been a major contributor to improved transplant organ and patient survival. Any barrier to nuanced immunosuppression will likely lead to worse patient outcomes.

NATCO strongly urges CMS to refrain from finalizing the Proposed Rule and to retain immunosuppressants as one of the protected classes of drugs under Medicare Part D.