ASTS
American Society of Transplant Surgeons

December 21, 2015

Re: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017; Federal Register / Vol. 80, No. 231 / Wednesday, December 2, 2015 / Proposed Rules

Dear Secretary Burwell:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have this opportunity to comment on the *HHS Notice of Benefit and Payment Parameters for 2017* (the "Proposed Rule"). ASTS is a medical specialty society representing approximately 1,800 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through leadership, advocacy, education, and training.

These comments focus on the patient cost sharing requirements that would be applicable to immunosuppressants under the "standardized options" set forth in the Proposed Rule. These comments supplement ASTS' comments on the network adequacy provisions of the Proposed Rule as they pertain to Transplant Centers, which are being filed under separate cover.

We understand that, to simplify the consumer plan selection process, HHS is proposing to establish ''standardized options'' for Qualified Health Plans (QHPs) included in the individual market Federally Facilitied Exchanges (FFEs). Under this proposal, all QHPs in the individual market FFEs would impose standardized cost sharing requirements for a key set of Essential Health Benefits (including outpatient pharmaceuticals, such as immunosuppressants). While issuers would retain the flexibility to offer non-standardized plans, FFE-certified standardized options would have certain marketing advantages over other plans, and may be entitled to advantages in the future.

We are extremely concerned that transplant recipients are currently bearing an extraordinary cost burden for the immunosuppressants necessary to prevent organ rejection. A study conducted by Avalere on behalf of the National Kidney Foundation (NKF) on drug coverage in 2015 healthcare exchange plans found that some plans are currently charging high cost-sharing for immunosuppressant medications. The Medicare program currently provides coverage for immunusuppressants for only 36 months post-transplant, and the NKF study suggests that patient cost-sharing requirements imposed by some QHPs after Medicare coverage expires are so high that patients have difficulty paying for their medications. For example, the average patient cost-sharing across all Silver exchange plans is 36% of the cost of (generic and non-generic) immunosuppressive medications.

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This problem is likely to be exacerbated in the future, since recent data (.ppt) shared by the Organ Procurement and Transplant Network (OPTN) Advisory Committee suggests an increase in transplants among younger adults from December 2014 to June 2015. To the extent this trend continues, the cost sharing burden for transplant recipients will grow, since younger recipients bear the cost burden of paying for immunosuppressants for longer periods before becoming eligible for Medicare.

We urge HHS to consider the impact of the proposed standardized options on this problem. Table 9 of the Proposed Rule summarizes the standardized drug benefits for QHPs offered on the FFE as follows:

Drug class	Bronze	Silver	Silver 73% actuarial value	Silver 87% actuarial value	Silver 94% actuarial value	Gold
Generic Drugs	$35 (*)	$10 (*)	$10 (*).	$5 (*)	$3 (*)	$10 (*).
Preferred Brand Drugs	50%	$50 (*)	$50 (*)	$25 (*)	$5 (*)	$30 (*).
Non-Preferred Brand Drugs	50%	$100 (*)	$100 (*)	$50 (*)	$10 (*)	$75 (*).
Specialty Drugs	50%	40% (*) .	40% (*)	30% (*)	25% (*)	30% (*).

*Not subject to the deductible

The NKF study suggests that an estimated 60% of plans impose copayment (as opposed to coinsurance) requirements for immunosuppressants, and the current national average copayment ($38) is roughly consistent with the copayment that would be applicable to Bronze Plans ($35) under the Proposed Rule. On average, under the proposed standardized options, Silver and Gold plan transplant recipients whose immunosuppressants are covered under the Generic Drug Tier could pay less for their immunosuppressants than they currently pay, since the standardized copayment for both Silver and Gold plans for generics is $10. Unfortunately, however, the NKF study identified some plans that arbitrarily place immunosuppressive drugs, including generics, into the Specialty Drug Tier, which, under the standardized options set forth in the Proposed Rule, would trigger coinsurance requirements of up to 50%.

Moreover, we are concerned that, under the Proposed Rule's standardized options, the cost sharing burden for name brand immunosuppressants is likely to be prohibitive—especially for Bronze Plan enrollees who are least likely to be able to afford these critical medications. Under the Bronze Plan standardized option, these medications would be subject to a deductible exceeding $6000 and, after that, to a 50% copayment requirement. Even Silver and Gold plan enrollees, whose name brand immunosuppressants would not be subject to the deductible, would be subject to high cost sharing requirements (up to $100 per prescription (non-preferred Brand Drug Tier) or 40% copayment (Specialty Drug Tier)). ASTS opposes such high financial barriers to access to name brand immunosuppressants, which are critical for some transplant recipients for whom generics are clinically inappropriate or ineffective.

Based on these considerations, ASTS recommends that:

- Deductible requirements be made inapplicable to all immunosuppressants for transplant recipients;
- Criteria should be established for the placement of drugs on a specialty tier and all generics should be made ineligible for specialty tier classification;
- Drug-related cost-sharing across all tiers should be capped at a reasonable amount.

We strongly urge HHS to keep in mind the extent of the potential cost burden of all immunosuppressants for transplant recipients and the critical need for transplant recipients to have access to these critical medications without the extraordinary financial barriers that they face today.

Sincerely yours,

Charles Miller, MD
President
American Society of Transplant Surgeons