



American Society of Transplant Surgeons

Saving and improving lives with transplantation.

September 7, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue S.W., Room 445-G
Washington, DC 20201

Re: 42 CFR Parts 416 and 419; [CMS-1678-P] RIN: 0938-AT03; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (HOPPS Proposed Rule)

Dear Administrator Verma:

On behalf of the American Society of Transplant Surgeons, I am pleased to have the opportunity to submit these comments on the HOPPS 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.

We understand that CMS is proposing to increase Medicare payment for hospital outpatient services overall by 1.75 percent. We have concerns that a number of provisions have the potential to impact Medicare payment rates for services rendered to hospital outpatients who need immunotherapy. For the first three years post-transplant, immunotherapy to prevent rejection and loss of a transplanted organ is covered under Medicare Part B. These critical therapies are often provided in hospital outpatient departments or off-site hospital clinics. Accordingly, the proposals included in the HOPPS Proposed Rule that impact Medicare payment for drugs furnished in these settings have the potential to adversely impact our patients access to these medications. In fact, first time prescriptions for outpatient immunosuppressive drugs are often filled at a hospital outpatient pharmacy, and some patients continue to use hospital outpatient pharmacies to continue to fill their prescriptions. In addition, special therapies to desensitize and treat antibody-mediated rejection (plasmapheresis, IVIG, rituximab) are often performed on an outpatient basis.

I. Proposed Payment Reductions for 340B Drugs

Many large teaching hospitals serve a disproportionate share of uninsured or underinsured patients, and therefore, qualify for participation in the 340B drug pricing program. For CY 2018, CMS is proposing to pay for certain drugs

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purchased at a discount through the 340B drug pricing program at the average sales price (ASP) minus 22.5 percent rather than ASP plus 6 percent. ASP minus 22.5 percent was the Medicare Payment Advisory Commission's (MedPAC's) estimate of the average minimum discount eligible hospitals received for drugs acquired under the 340B program. This proposal, if adopted, has the potential to substantially adversely impact Medicare payment for drugs (including separately payable immunotherapy) provided by Transplant Centers to our patients.

Adequate immunosuppression is critical to the success of transplantation, and a large proportion of renal transplants are covered by Medicare. The United States Renal Data System (USRDS) 2015 Report^[1] notes that total Medicare expenditures per person/per year for hemodialysis patients is \$84,550; for those on peritoneal dialysis, \$69,919; and for renal transplantation, \$29,920¹ (approximately \$34,795/year including estimated Part D expenses). The average expected duration of the benefit of therapy after renal transplantation is twice that of hemodialysis.^[2] Average life expectancy for transplantation is over twice as long for transplantation as for hemodialysis. Therefore, we believe that significantly reducing Medicare payment for immunosuppressive drugs provided pursuant to the 340B program is imprudent considering the huge benefit and cost savings that renal transplantation provides over dialysis.

Recommendation: We recommend that CMS exempt immunosuppressive drugs from any payment reduction adopted under the final rule that is applicable to 340B drugs furnished by hospital outpatient departments and provider-based clinics.

II. Packaging of Payment for Drugs Costing \$100 or Less

We also note that CMS is proposing to eliminate separate payment for the administration of drugs costing \$100 or less. It is unclear to us whether this proposal would impact immunosuppressives administered orally and dispensed by a hospital outpatient laboratory, or would apply solely to drugs that are infused. We would appreciate CMS' clarifying whether and how oral medication that is not dispensed in conjunction with any professional service would be impacted by this proposal. We are concerned that the packaging of drugs into the underlying payment rates for associated infusion services has the potential to negatively impact access to immunosuppressive drugs, especially if the \$100 packaging threshold is increased over time.

Recommendation: We recommend that CMS refrain from packaging low cost drugs into APC rates and that any drugs furnished by hospital outpatient departments, infusion clinics, and other provider-based entities continue to be paid on the basis of the statutory formula (Average Sales Price +6%).

III. New Off-Campus Hospital Facilities

Under proposed CMS policy, as set forth in the Physician Fee Schedule Proposed Rule for 2018, services provided by new off-campus clinics, infusion centers, and other provider-based facilities would be paid for their services at 25% of the otherwise applicable HOPPS rates. This represents a 50 percent

^[1] USRDS 2015 Annual Report <https://www.usrds.org/2015/view/Default.aspx>, accessed March 2016.

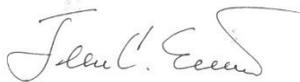
^[2] *Id.*

reduction of the current payment rates for these facilities. This change is very likely to reduce Medicare payment below actual costs for many services, including immunosuppression and other services provided to transplant recipients. Such a payment reduction is especially problematic if CMS finalizes its proposal to “package” the costs of drugs into the APC rates for infusion services. We are concerned that this combination of proposals, if finalized, has the potential to impede our patients’ access to needed immunosuppressives in outlying infusion centers and other clinics that may be needed to serve patient populations who do not reside close to Transplant Centers.

***Recommendation:** We recommend that CMS refrain from adopting the proposed Medicare payment reduction for new off-campus hospital clinics, infusion centers, and other provider-based facilities.*

We appreciate the opportunity to comment on the HOPPS Proposed Rule. If you have any questions or if we can provide any additional information regarding these comments, please do not hesitate to contact ASTS Executive Director Kim Gifford at kim.gifford@asts.org or 703-414-7870.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jean C. Emond".

Jean C. Emond
President