



*Saving and improving lives with transplantation.*

**American Society of Transplant Surgeons®**

Via electronic submission

September 24, 2018

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

Re: File code CMS-1695-P; Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for Potential CMS Innovation (Proposed Rule); RIN: 0938-AT30

Dear Administrator Verma:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to comment on the 2019 Hospital Outpatient Prospective Payment System Proposed Rule (the “HOPPS Proposed Rule”). ASTS represents 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.

Our comments address those provisions of the HOPPS Proposed Rule that relate to Medicare payment for clinic visits performed by off-campus outpatient facilities and those provisions that relate to Medicare payment for 340B drugs furnished at these facilities.

It is our understanding that, if the provisions of the HOPPS Proposed Rule were adopted without change, Medicare payment for clinic visits provided in off-campus hospital outpatient facilities would be paid at 40% of the otherwise applicable HOPPS rates. We understand that CMS is proposing this

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change due to the shift in site of service for clinic visits from physicians' office to hospital outpatient settings, and the perception that this shift is solely or primarily the result of physician practice acquisitions intended to take advantage of the current Medicare payment differential between payment for physicians' office visits under the Physician Fee Schedule and payment for clinic visits under HOPPS.

While we understand CMS' concern over the potential impact of this shift on Medicare program outlays, we are very concerned about the potential impact of this proposed change on access to transplant evaluations and pre- and post-transplant clinic visits. The clinical literature establishes that there is a clear relationship between a patient's zip code and access to transplantation. Rural areas far away from transplant centers are disadvantaged in terms of access to transplantation, and satellite clinics play a critical role in facilitating access for rural populations.<sup>1</sup> These satellite clinics serve a vital role in their communities, and the proposed payment clinic visit payment reductions have the potential to jeopardize the financial viability of these satellite clinics. For this reason, we urge CMS to reconsider its proposed payment reductions.

We are also concerned about CMS' proposal to extend to satellite facilities Medicare payment reductions for 340B drugs. It is our understanding that, last year, CMS finalized a policy to pay for covered outpatient drugs and biologics acquired by hospitals under the 340B Program at a rate of average sales price (ASP) minus 22.5 percent, rather than ASP plus 6 percent that is typical under the payment system. While this cut did not initially apply to off-campus hospital-based facilities, the HOPPS Proposed Rule would reverse this policy.

Immunosuppressive drugs are covered under Medicare Part B for three years post-transplant, and access to these drugs is vital to ensure that transplanted organs are not rejected. We are concerned that this greatly reduced Medicare payment for immunosuppressive drugs and other drugs needed for the

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<sup>1</sup> Goldberg DS, French B, Forde KA, et al. Association of Distance From a Transplant Center With Access to Waitlist Placement, Receipt of Liver Transplantation, and Survival Among US Veterans. *JAMA*. 2014;311(12):1234-1243. doi:10.1001/jama.2014.2520.

Buccini L, Goldfarb D, Poggio E, Flechner S, Schold J. The Association of Life Expectancy by Resident Zip Code and Kidney Transplant Outcomes – What Is True Baseline Risk? [abstract]. *Am J Transplant*. 2016; 16 (suppl 3).

*American Journal of Transplantation* 2008; 8: 647–657. doi: 10.1111/j.1600-6143.2007.02130.x The Geography of Kidney Transplantation in the United States B. L. Kasiske,\*, J. J. Snyder, M. A. Skeans, A. V. Tuomari, J. R. Maclean and A. K. Israni

Rates of Solid-Organ Wait-listing, Transplantation, and Survival Among Residents of Rural and Urban Areas. David A. Axelrod, MD, MBA; Mary K. Guidinger, MS; Samuel Finlayson, MD; et al Douglas E. Schaubel, PhD; David C. Goodman, MD; Michael Chobanian, MD; Robert M. Merion, MD. *JAMA*. 2008;299(2):202-207. doi:10.1001/jama.2007.50

patient populations we serve and may dissuade satellite clinics from making these drugs available to our patients. For this reason, we request that CMS refrain from finalizing the proposed policy and continue to provide Medicare payment for these drugs based on the same formula used when the same products are furnished by non-hospital providers.

We appreciate the opportunity to comment on the 2019 HOPPS Proposed Rule. If you have any questions about our comments, please do not hesitate to contact Kim Gifford at [kim.gifford@asts.org](mailto:kim.gifford@asts.org).

Sincerely yours,

A handwritten signature in black ink, appearing to read "Dixon Kaufman". The signature is fluid and cursive, with the first name "Dixon" and last name "Kaufman" clearly legible.

Dixon B. Kaufman, MD, PhD

President

American Society of Transplant Surgeons