December 1, 2017

The Honorable Jason Smith
US House of Representatives
1118 Longworth House Office Building
Washington, DC 20515

The Honorable Tony Cárdenas
US House of Representatives
1510 Longworth House Office Building
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
US House of Representatives
1314 Longworth House Office Building
Washington, DC 20515

The Honorable Earl Blumenauer
US House of Representatives
1111 Longworth House Office Building
Washington, DC 20515

Dear Representatives Smith, McMorris Rodgers, Cárdenas, and Blumenauer:

On behalf of the leading national transplant organizations, we write to you as original sponsors of the "Dialysis PATIENTS Demonstration Act of 2017" (H.R. 4143) to express our significant concerns about the potential impact of this legislation on Medicare beneficiaries' continued access to kidney transplantation.

When we commented on the predecessor version of this legislation (H.R. 5942/114th Congress), ASTS, AST, and AAKP applauded you for seeking to incentivize "innovation and efficiency and improving quality of care for patients receiving kidney dialysis." However, we also expressed strong concerns that the legislation had the potential to have "serious, unintended consequences for potential transplant patients."

ASTS, AST, and AAKP also noted in these comments that we have been working on an alternative approach to the care of ESRD patients that is designed to improve the accessibility of transplantation as a treatment option. Our approach would involve a broader community of relevant stakeholders including transplant centers, dialysis facilities, organ procurement organizations (OPOs), community hospitals, and nephrologists. We are therefore disappointed to learn that your latest version of the legislation actually exacerbates the disincentive for demonstration participants to make transplantation accessible to ESRD patients.

Kidney transplantation clearly is often the best treatment option for Medicare patients with End Stage Renal Disease (ESRD). Moreover, kidney transplantation has been widely demonstrated to be the most cost-effective long-term treatment for such patients, resulting in marked savings when compared to a lifetime of dialysis treatment. Yet, if enacted, it appears that the PATIENTS Act would create a new major financial incentive that would sharply curtail the access to this potentially life-saving treatment option for Medicare beneficiaries with ESRD.

As we understand it, while the PATIENTS Act is characterized as a voluntary demonstration[1] bill, under this legislation, it appears that essentially all Medicare-eligible ESRD patients residing in the service area of an ESRD Integrated Care Organization (Organization) would be automatically "assigned" to the Organization for the provision of virtually all Medicare-covered services, including transplantation.[2] Specifically, this version of the PATIENTS Act—unlike the version introduced last year—appears to include transplantation within the scope of services to be provided by an Organization: each Organization is required to provide all Part A and Part B services to all eligible ESRD patients assigned to it, and a patient does not become ineligible for assignment to the Organization until after a transplant procedure has been determined to be "successful." In addition, the payment provisions of the bill indicate that an Organization is to be paid on the basis of the same capitated payment formula as Medicare Advantage plans, and that formula takes into account virtually[3] all transplantation-related costs. Therefore, both the benefits and the payment provisions of the bill suggest that Organizations will be responsible for the provision (and cost) of medically necessary transplantation procedures for the ESRD patients assigned to it.

However, Organizations will have an extremely strong financial incentive NOT to make transplantation accessible or attractive. Because successfully transplanted Medicare beneficiaries are not eligible for participation in an Organization, an Organization that makes transplantation available will incur the (not insubstantial) cost of the transplantation, but will reap none of the economic benefits. To the contrary, the newly transplanted patient will become ineligible for further participation in the Organization, and the capitated payments associated with the assignment of the patient to the Organization will cease.

Moreover, this bill appears to place complete control over transplantation—one of the most highly complex of surgical procedures—in the hands of Organizations that have no expertise in the field; that do not include transplant centers as "participating providers"; that are evaluated based on quality measures that do not track access to transplantation; and that are owned and operated by renal dialysis facilities that provide a clinical alternative to transplantation.

Finally, we believe that this bill is duplicative of a number of other efforts focused on improving the care provided to ESRD patients. The CMS Innovation Center (CMMI) has already instituted a demonstration program (the Comprehensive ESRD Care (CEC) Model) which tests a number of the same concepts that are the basis for the proposed bill. In addition, the 21st Century Cures legislation, which will make ESRD patients eligible for enrollment in Medicare Advantage programs for the first time in 2021, will test the practicability of capitated rates (the same payment methodology proposed in the bill) for the ESRD patient population. In light of these changes, we do not believe that the time is right to further modify care models for this vulnerable patient population.

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[1] The bill does not limit the number of Organizations that could be established, but even if the number were initially limited, this new and untried system could be expanded nationally without the need for additional legislation. Under these circumstances, we believe that the potential impact of the bill is far more extensive than its characterization as a "demonstration" would suggest.

[2] While beneficiaries are theoretically entitled to "opt out," they are subject to unrestricted marketing by the providers upon which they are dependent for care.

[3] Capitated payments made to both Organizations and Medicare Advantage plans would exclude "organ acquisition costs," which would continue to be paid on a cost pass-through basis directly by Medicare.

For these reasons, we must strongly oppose the PATIENTS Act in its present form. We strenuously urge you to engage with the transplant community to ensure that this well-intended legislation does not inadvertently curtail access to a procedure that often offers the best prospect of hope and health for Medicare beneficiaries suffering from ESRD.

Sincerely yours,

American Society of Transplant Surgeons
ASTS National Office
2461 S. Clark Street, Suite 640
Arlington, VA 22202
PH: 571-447-5447
Email: jennifer.nelson-dowdy@asts.org
Website: www.asts.org

American Association of Kidney Patients
AAKP National Office
14440 Bruce B. Downs Boulevard
Tampa, FL 33613
PH: 813-636-8100
Website: www.aakp.org

American Society of Transplantation
AST National Office
1120 Route 73, Suite 200
Mt. Laurel, NJ 08054
PH: 856-316-0924
Email: scovington@myAST.org
Website: www.myAST.org

Association of Organ Procurement Organizations
AOPO National Office
8500 Leesburg Pike, Suite 300
Vienna, VA 22182
PH: 703-556-4242 Ext. 204
Email: eeidbo@aopo.org
Website: www.aopo.org