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## United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

JOSHUA SHEINKMAN, STAFF DIRECTOR  
GREGG RICHARD, REPUBLICAN STAFF DIRECTOR

June 6, 2024

### VIA ELECTRONIC TRANSMISSION

Ms. Dianne LaPointe Rudow  
President  
OPTN Board of Directors  
700 North 4th Street  
Richmond, VA 23219

Dear Ms. Lapointe Rudow:

The Senate Committee on Finance recently became aware of concerns you and your colleagues raised about the Health Resources and Services Administration's (HRSA) implementation of the Securing the U.S. Organ Procurement and Transplantation Network Act (Act), our bipartisan legislation which became law last year.<sup>1</sup> In your May 22, 2024, letter to HRSA, and May 28, 2024, open letter to the U.S. transplant community, you and your colleagues raised several concerns, including the legal basis for HRSA's intention to restructure the operation of the OPTN and how this restructuring relates to the Organ Procurement and Transplant Network (OPTN) Board of Directors.<sup>2</sup>

As co-authors and original co-sponsors of the Act, we would like to take this opportunity to remind you of the law's intent and what the new statutory language requires. It is important we address fundamental misunderstandings of two key issues in your letters: 1) the status of the OPTN and the Department of Health and Human Services' (HHS) designation of an entity to serve as the OPTN Board of Directors, and 2) the representation of the OPTN as independent.

First, your May 22, 2024, letter states that, "[t]he independent entity must be the OPTN and not the OPTN Board of Directors," implying that the independent 501(c)(3) HRSA has established for the Board of Directors must encompass all OPTN functions as defined in statute.<sup>3</sup>

<sup>1</sup> U.S. Organ Procurement and Transplantation Network Act, Pub. L. No. 118-14, 137 Stat. 69 (2023).  
<https://www.govinfo.gov/content/pkg/PLAW-118publ14/pdf/PLAW-118publ14.pdf>.

<sup>2</sup> Exhibits 1 and 2.

<sup>3</sup> Exhibit 1; *see also* 42 U.S.C 274.

<https://uscode.house.gov/view.xhtml?jsessionid=9944B131A542277BEF4220B39A788E9A?req=granuleid%3AUSC-prelim-title42-chapter6A-subchapter2-partH&saved=%7CKHRpdGxIOjQyIHNIY3Rpb246Mjc0ZSBIZGI0aW9uOnByZWxpbSk%3D%7C%7C%7C0%7Cfalse>

However, combining the Board of Directors with the OPTN is not consistent with the congressional intent. Historically, the organization that was awarded the OPTN contract was designated to serve as the OPTN and the OPTN Board, maintaining responsibility for all OPTN functions. However, the Act specifically struck a previous statutory requirement that the OPTN be a single “private nonprofit entity that has an expertise in organ procurement and transplantation.”<sup>4</sup> The statute therefore now requires that the OPTN shall “be operated through awards to public or private entities made by the Secretary that are distinct from the awards made to support the organization tasked with supporting the board of directors.”<sup>5</sup> The Act further clarified that these awards could take the form of “grants, contracts, or cooperative agreements, as the Secretary determines appropriate, for purposes of carrying out this section.”<sup>6</sup>

These changes make clear that the HHS Secretary has the authority to 1) facilitate the operation of the OPTN across *multiple* entities, and 2) that the OPTN functions are to be carried out solely through grants, contracts, or cooperative agreements awarded by HHS *as the Secretary determines appropriate*. This discretion allows HHS to separate the Board of Directors from the OPTN functions, aligning with congressional intent.

Second, you state in your May 28, 2024, open letter to the transplant community that the OPTN Board must be, “fully independent of the contractors and the government.”<sup>7</sup> This is again inconsistent with the new statutory requirements. As noted above the Act requires that the OPTN shall “be operated through awards to public or private entities made by the Secretary that are **distinct from the awards made to support the organization tasked with supporting the board of directors**” (emphasis added).<sup>8</sup> This requires the OPTN Board be independent from entities to which HHS has made awards to carry out functions other than support of the OPTN Board. The statute in no way implies the OPTN Board is to be independent of the government. In fact, the statute makes clear that all OPTN functions are directly within the purview of HHS as they are carried out under the auspices of awards made by and overseen by HHS.

On May 2, 2024, bipartisan members of the Senate Finance Committee asserted these expectations in a letter to HRSA in which we made explicitly clear that HHS oversight of the OPTN is not only accomplished through oversight of contract awards made by HHS, but also through regulatory oversight of the OPTN Board by HHS.<sup>9</sup> The letter specifically states the OPTN Board, “will not be independent from regulatory oversight, and that this regulatory oversight, along with HRSA’s oversight of the contractors supporting the OPTN Board and carrying out other OPTN functions, is intended to ensure all OPTN activity is consistent with legal and regulatory requirements.”<sup>10</sup> We also emphasized that the OPTN Board’s responsibilities in relation to the OPTN contracts are to be defined by HHS and “stem solely

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<sup>4</sup> *Supra* note 1.

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> Exhibit 2.

<sup>8</sup> *Supra* note 1.

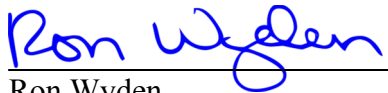
<sup>9</sup> Exhibit 3.

<sup>10</sup> *Id.*

from the designation provided by HHS.”<sup>11</sup> Of course, none of this limits congressional oversight of all matters relating to the new law.

The statutory requirements are clear, and we expect that HHS will carry out the implementation of the new structure for the OPTN consistent with congressional intent.

Sincerely,



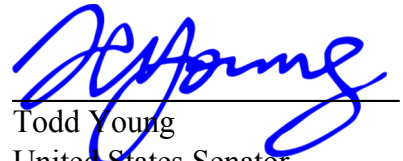
Ron Wyden  
United States Senator  
Chairman, Committee on  
Finance



Charles E. Grassley  
United States Senator  
Member, Committee on  
Finance



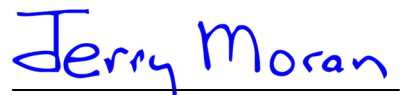
Benjamin L. Cardin  
United States Senator



Todd Young  
United States Senator



Elizabeth Warren  
United States Senator



Jerry Moran  
United States Senator

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<sup>11</sup> *Id.*