

# Policy At A Glance:

## Securing the U.S. Organ Procurement and Transplantation Network Act (H.R. 2544)

*As the number of organ transplants continues to increase, a modernized and improved system for organ procurement is necessary to expedite and secure the transplant process for clinicians and patients. This brief explores the current Organ Procurement and Transplantation Network and the efforts to improve it through the Securing the U.S. Organ Procurement and Transplantation Network Act (H.R. 2544).*

## Introduction

On July 27, 2023, the U.S. Senate passed H.R. 2544, Securing the U.S. Organ Procurement and Transplantation Network Act, which will allow competitive bidding for federal contracts under the Organ Procurement and Transplantation network (OPTN).<sup>1,2</sup> This bill will expand the pool of entities that can contract with the OPTN and modernize the system to further protect and expedite the organ transplantation process.<sup>3</sup>

The number of organ transplants performed in the United States continues to increase annually with more than 42,870 organ transplants performed in the U.S. in 2022. Additionally, a record-breaking 25,000 kidney transplants, 9,528 liver transplants, 4,111 heart transplants, and 2,692 lung transplants were performed in 2022.<sup>4</sup>

This brief will provide an overview of the Organ Procurement and Transplantation Network, the United Network for Organ Sharing, and the initiatives set forth by H.R. 2544 to improve and strengthen the operation of the organ procurement network.

## U.S. Organ Donation Statistics

- 103,361** Individuals are waiting for lifesaving organ transplants<sup>5</sup>
- 14,903** Individuals became deceased organ donors in 2022<sup>4</sup>
- 6,466** People became living organ donors in 2022<sup>4</sup>
- 6,000** People died in the U.S. while on the transplant waiting list in 2021<sup>6</sup>
- 17** People die each day while waiting for an organ transplant<sup>6</sup>

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## Background on the Organ Procurement and Transplantation Network

Regulation of organ procurement and transplants began when Congress passed the National Organ Transplant Act (NOTA) of 1984 to address the organ donation shortage and improve the organ matching process.<sup>2,7</sup> NOTA authorized the establishment of the Organ Procurement and Transplantation Network (OPTN) for the purposes of coordinating and operating the nation's organ procurement, allocation, and transplantation with the goal of increasing access to donor organ for patients with end-stage organ failure.<sup>2,8</sup>

Specifically, the OPTN is tasked with developing policies for and implementing an equitable system of organ allocation, maintaining the wait list of potential recipients, and compiling data from U.S. transplant centers.<sup>2,8</sup> Furthermore, organ procurement organizations and transplant centers certified for participation in Medicare are required to participate in the OPTN.<sup>8</sup> The OPTN is required to operate a national wait list of individuals needing organ transplants to be matched with organs from living and deceased donors.<sup>2,8</sup>

NOTA also specifies that the OPTN would be operated by a private, non-profit organization under federal contract.<sup>8</sup> The United Network for Organ Sharing (UNOS) is a non-profit organization that manages the OPTN for the Health Resources and Services Administration.<sup>2,7,8</sup> UNOS was awarded the initial OPTN contract in 1986 to develop the requirements for the operation of OPTN and has served as the sole administrator since.<sup>2</sup>

## Advance Health Care Directives (A.B. 3211)

On January 1, 2019, the Advance Health Care Directives (A.B. 3211) went into effect in California to increase the number of organ donors in the state.<sup>9,10</sup> A.B. 3211 simplified the choice to donate organs and tissues by making the choice the default option.<sup>10</sup> If a person wishes not to donate, then they must opt out. Specifically, it states that "upon death, organs, tissues, and parts can be donated for transplantation, therapy, research, and education."<sup>9,10</sup> However, individuals can specify exceptions or opt out of any of the choices in the general donation clause.<sup>10</sup> Since its implementation, research has shown that over 1 million individuals have registered as organ donors, roughly equating to a 41% increase in donations.<sup>11</sup>



## Improving the U.S. Organ Procurement and Transplantation Network

In 2020, the Senate Finance Committee began a bipartisan investigation into UNOS's failures as the sole contractor for the OPTN. Results from the investigation exposed "underperforming organ procurement organizations (OPO), mismanagement and the lack of oversight by UNOS, antiquated information technology, patient and safety risk, and the improper use of Medicare funds."<sup>12</sup> Additionally, the investigation also revealed that NOTA has been interpreted to prevent the Department of Health and Human Services (HHS) from soliciting multiple bids from public and private entities that can manage and operate the OPTN contract.<sup>12</sup>

President Biden's anticipated signature will provide the federal government the authority to break up the monopoly contract that currently manages the nation's organ donation system. The current OPTN contract with UNOS is set to expire on September 30, 2023, and will be up for renewal.<sup>13</sup>

### Organ Procurement and Transplantation Network Modernization Initiative

In March 2023, the Health Resources and Services Administration (HRSA) announced a modernization initiative to strengthen accountability and transparency in the OPTN, which focuses on five key areas: technology; data transparency and analytics; governance; operations; and quality improvement and innovation.<sup>2,14,15</sup>

### Securing the U.S. Organ Procurement and Transplantation Network Act

Securing the U.S. Organ Procurement and Transplantation Network Act (H.R. 2544) modifies how the Health Resources and Services Administration (HRSA) funds and manages the OPTN.<sup>1,16</sup> Specifically, it is the first legislative step to give the Department of Health and Human Services Secretary the authority to grant various contracts to various public and private entities to perform OPTN functions and ends UNOS' role as the sole OPTN contractor.<sup>1,2</sup>

Specifically, H.R. 2544 would:<sup>12</sup>

- Make technical amendments to NOTA.
- Remove barriers in OPTN contracting to broaden eligibility types and awards HRSA can make to ensure the entire OPTN does not have to be operated by one entity.
- Improve HHS management of OPTN contracts by providing flexibility on structure and funding of OPTN contracts via removing the \$6 million funding cap.
- Require the Government Accountability Office to report on user fees to give Congress insight on how the OPTN is current financed.
- Provide HRSA the flexibility to conduct an open competition process for the OPTN contract for the first time since the OPTN was established in 1986.<sup>7</sup>

## Conclusion

As the number of organ transplants performed annually increases across the nation, it is imperative that the Organ Procurement Transplantation Network (OPTN) is operating at its full potential. A report released by the Senate Finance Committee found that between 2010-2020, 70 deaths were due to system failures within OPTN.<sup>17</sup> By expanding the pool of entities that can contract with the U.S. OPTN and modernizing the system to protect and expedite the organ transplantation process, it will better serve patients across the country and save lives.



### Did you know?

Every ten minutes, another person is added to the national transplant waiting list and one organ donor can save up to eight lives.<sup>18</sup>

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