



October 2020

# ORGAN TRANSPLANTS

## Changes in Allocation Policies for Donated Livers and Lungs

# GAO Highlights

Highlights of [GAO-21-70](#), a report to congressional requesters

## Why GAO Did This Study

Organ transplantation is the leading form of treatment for patients with severe organ failure. OPTN, a nonprofit entity that was established in 1984 under the National Organ Transplant Act, manages the nation's organ allocation system. In 2019, 32,322 organs were transplanted from deceased donors in the United States. Nevertheless, as of July 2020, close to 110,000 individuals remained on waiting lists for donor organs. Previously, donated livers and lungs were generally offered first to the sickest candidates in donation service areas. However, livers and lungs are now generally offered first to the sickest candidates based on distance.

GAO was asked to review the changes to the liver and lung allocation policies. This report describes (1) changes to the liver allocation policy, and (2) similarities and differences in the processes OPTN used to change the liver and lung allocation policies, and federal oversight of these processes, among other things.

GAO reviewed documents, including those related to the current liver and lung allocation policies, and the 2017 liver allocation policy; interviewed HHS officials and OPTN members; reviewed the National Organ Transplant Act and its implementing regulations; and conducted a literature review of studies published from January 2017 through April 2020 in peer-reviewed and other publications.

HHS and the United Network for Organ Sharing (the contractor serving as OPTN) provided technical comments on a draft of this report, which GAO incorporated as appropriate.

View [GAO-21-70](#). For more information, contact James Cosgrove at (202) 512-7114 or [cosgrovej@gao.gov](mailto:cosgrovej@gao.gov).

October 2020

## ORGAN TRANSPLANTS

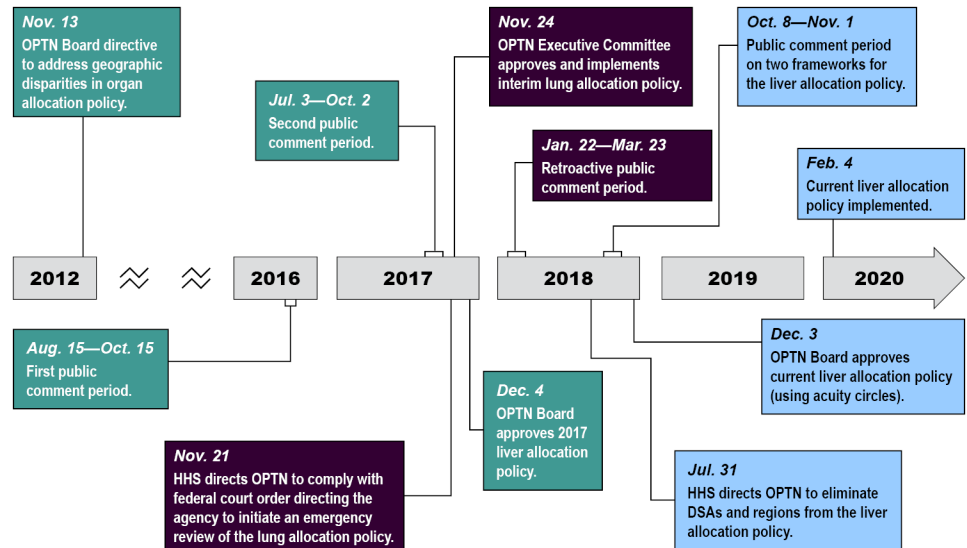
# Changes in Allocation Policies for Donated Livers and Lungs

## What GAO Found

The Organ Procurement and Transplantation Network (OPTN) develops allocation policies in the United States to determine which transplant candidates receive offers for organs, such as livers or lungs, that are donated from deceased donors. In July 2018, the Department of Health and Human Services (HHS), which oversees OPTN, directed it to change the liver allocation policy to be more consistent with federal regulations. The liver allocation policy changed in February 2020 from a system that, in general, offered donated livers first to the sickest candidates within the fixed boundaries of a donation service area or region to a system based on a candidate's level of illness and distance from the donor hospital. The current liver allocation policy offers livers first to the sickest candidates within 500 nautical miles of the donor hospital using a series of distance-based concentric circles, called acuity circles.

The processes used to develop the liver and lung allocation policies had various similarities and differences. For example, while the current liver allocation policy, the 2017 liver allocation policy, and the current lung allocation policy each had public comment periods, the length of these comment periods varied—25 days for the current liver allocation policy; two separate 62-day and 64-day periods for the 2017 liver allocation policy; and 61 days (retroactive) for the current lung allocation policy. In addition, the current lung allocation policy resulted in part from a federal district court order directing HHS to initiate emergency review of the policy. However, the 2017 liver allocation policy—that was approved but never implemented—resulted from a 2012 OPTN Board directive to reduce geographic disparities in organ allocation. HHS oversight of OPTN's processes were similar for all three allocation policies and included reviewing the proposed changes to the policies to ensure compliance with federal regulations, according to HHS officials.

Timeline of Selected Events Related to Three Organ Allocation Policies



Legend: DSA=donation service area; HHS=Department of Health and Human Services; OPTN=Organ Procurement and Transplantation Network.

■ 2017 liver allocation policy ■ Current lung allocation policy ■ Current liver allocation policy

Source: GAO. | GAO-21-70

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## **Abbreviations**

DSA donation service area  
HHS Department of Health and Human Services  
HRSA Health Resources and Services Administration  
MELD Model for End-Stage Liver Disease  
OPTN Organ Procurement and Transplantation Network

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October 16, 2020

The Honorable Roy Blunt  
Chairman  
Subcommittee on Labor, Health and Human Services, Education, and  
Related Agencies  
Committee on Appropriations  
United States Senate

The Honorable Jerry Moran  
Chairman  
Subcommittee on Commerce, Justice, Science, and Related Agencies  
Committee on Appropriations  
United States Senate

Organ transplantation is the leading form of treatment for patients with severe organ failure. In 2019, individuals received 32,322 organ transplants from deceased donors across the United States. However, as of July 2020, close to 110,000 individuals remained on a waiting list to receive an organ. On average, more than 20 people die each day waiting for an organ transplant.

Within the Department of Health and Human Services (HHS), the Health Resources and Services Administration (HRSA) oversees the Organ Procurement and Transplantation Network (OPTN), a nonprofit entity that was established in 1984 under the National Organ Transplant Act to manage the nation's organ allocation system.<sup>1</sup> OPTN develops national allocation policies that determine which patients receive organs from deceased donors, maintains the waiting lists of individuals seeking organ transplants, and tracks data on individuals awaiting and receiving donated organs in the United States, among other things.

OPTN implemented the current liver allocation policy in February 2020 and the current lung allocation policy in November 2017. Livers and lungs that are donated for transplants are now generally offered first to the sickest candidates based on distance from the donor hospital. Previously, donated livers were generally offered first to the sickest candidates within the fixed boundaries of donation service areas (DSA) and then within the

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<sup>1</sup>Pub. L. No. 98-507, § 201, 98 Stat. 2339, 2344 (1984) (codified, as amended, at 42 U.S.C. § 274(b)).

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boundaries of OPTN regions before being offered nationally. Donated lungs were generally offered first to the sickest candidates within the DSA and then in increasing increments of 500 nautical mile circles outside the donor hospital's DSA. You asked us to report on these changes, as well as federal oversight of OPTN's processes to change allocation policies and the effects of the changes to the lung allocation policy. Specifically, this report describes

1. how the liver allocation policy changed and the rationale for the changes;
2. similarities and differences in the processes OPTN used to change the liver and lung allocation policies, and HRSA's oversight of these processes; and
3. what is known about changes to outcomes and spending following the lung allocation policy changes made in 2017.

To examine how the liver allocation policy changed and the rationale for the changes, we reviewed OPTN and United Network for Organ Sharing documents, such as a December 2018 briefing paper from the OPTN Liver and Intestine Transplantation Committee (OPTN Liver Committee) that included proposals to revise the liver allocation policy.<sup>2</sup> We also reviewed federal agency documents, including a July 2018 letter from HRSA directing OPTN to review the liver allocation policy; and reports and analyses from the Scientific Registry of Transplant Recipients, including the modeling conducted to assess the potential effects of the proposals to revise the liver allocation policy.<sup>3</sup> In addition, we reviewed the National Organ Transplant Act, which established the framework for the U.S organ transplant system, and the OPTN Final Rule, which established the regulatory framework for the structure and operations of OPTN.<sup>4</sup> We also interviewed HRSA and United Network for Organ Sharing officials and OPTN members, including OPTN Liver Committee

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<sup>2</sup>The United Network for Organ Sharing—a private, nonprofit organization—serves as the OPTN through a contract with HRSA.

<sup>3</sup>The Scientific Registry of Transplant Recipients conducts analyses of data on organ donors, and transplant candidates and recipients, as well as modeling for proposed organ allocation policies. The Chronic Disease Research Group, a division of the Hennepin Healthcare Research Institute in Minneapolis, Minnesota, has a contract with HRSA to administer the Scientific Registry of Transplant Recipients.

<sup>4</sup>Pub. L. No. 98-507, 98 Stat. 2339 (1984) (codified, as amended, at 42 U.S.C. § 273 et seq.); and 63 Fed. Reg. 16,296 (Apr. 2, 1998).

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members, to obtain information on the changes to the liver allocation policy.

To examine the similarities and differences in the processes OPTN used to change the liver and lung allocation policies, and HRSA's oversight of these processes, we reviewed information related to the current liver allocation policy and two other policies: a 2017 liver allocation policy approved by the OPTN board but never implemented (2017 liver allocation policy), and the current lung allocation policy, which was implemented in November 2017. Specifically, we reviewed Scientific Registry of Transplant Recipients reports and analyses, including the modeling conducted for the proposals to revise the liver allocation policy. We also reviewed the National Organ Transplant Act and the OPTN Final Rule. We examined federal agency documents pertaining to organ allocation, to the liver and lung allocation policies, and to HRSA's oversight of these policies, including a November 2017 letter from HRSA directing OPTN to comply with a court order to initiate an emergency review of the lung allocation policy. We also reviewed OPTN bylaws, policies, and other documents, including documents on the processes used to make changes to organ allocation policies and on HRSA's oversight processes, such as OPTN meeting notes and briefing papers. We also interviewed HRSA and United Network for Organ Sharing officials and OPTN members to obtain information on changes to the liver and lung allocation policies and HRSA's oversight of these changes.

To examine what is known about changes to outcomes and spending following the lung allocation policy changes made in 2017, we conducted a literature review of peer-reviewed and trade publications since January 2017, examined OPTN monitoring reports, and interviewed federal officials and other stakeholders:

- **Literature review.** We identified peer-reviewed studies, and government, legislative, and trade articles published from January 2017 through April 2020 through a search of bibliographic databases, including ProQuest, Scopus, DIALOG, and EBSCO, using terms such as "organ," "transplant," "allocation," "liver," and "lung." Of the 242 citations we identified, we obtained 89 full studies and articles for further review. Of those, we determined that one study included relevant information. We examined this study for information related to the effects of changes in the lung allocation policy on outcomes, such as the level of illness of lung transplant recipients, and spending. We also reviewed the methodology of the relevant study to confirm our understanding of the data and analyses.



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- **OPTN monitoring reports.** We reviewed data from OPTN's monitoring reports on changes to the lung allocation policy, including outcomes, such as the number of lung transplants, the distance to recover donor lungs for transplants, and 6-month post-transplant patient survival for lung transplant recipients before and after the lung allocation policy change in 2017.<sup>5</sup> We focused on the 2-year monitoring report that contains data from the 2-year period before the current lung allocation policy was implemented and the 2-year period after the policy was implemented.<sup>6</sup> We analyzed these data and obtained additional data from the United Network for Organ Sharing that was not included in the 2-year monitoring report, including data on lung transplant recipients by OPTN region.<sup>7</sup>
  - **Federal agency and stakeholder interviews.** We interviewed federal agency officials from HRSA and the Centers for Medicare & Medicaid Services, and relevant stakeholders, including OPTN members, officials from the United Network for Organ Sharing, and officials from the Association of Organ Procurement Organizations, to identify available information related to the effect of the lung allocation policy changes on outcomes and spending.<sup>8</sup>

We conducted this performance audit from October 2019 to October 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain

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<sup>5</sup>OPTN's monitoring reports were completed by the United Network for Organ Sharing's Research Department for the OPTN Lung Transplantation Committee, which is responsible for developing national lung allocation policies, among other things. The OPTN Lung Transplantation Committee was called the OPTN Thoracic Transplantation Committee prior to July 1, 2020. We refer to both the current OPTN Lung Transplantation Committee and the OPTN Thoracic Transplantation Committee as the OPTN Lung Committee in this report. We defined outcomes to include data on lung transplants and lung transplant recipients.

<sup>6</sup>OPTN Thoracic Transplantation Committee, *Monitoring of the Lung Allocation Change, 2 Year Report: Removal of DSA as a Unit Of Allocation*, accessed June 18, 2020, [https://optn.transplant.hrsa.gov/media/3661/item\\_25\\_thoracic\\_committee\\_20200212.pdf](https://optn.transplant.hrsa.gov/media/3661/item_25_thoracic_committee_20200212.pdf). OPTN has issued six monitoring reports since the current lung allocation policy was implemented in November 2017.

<sup>7</sup>We reviewed the methodology of OPTN's 2-year monitoring report, compared the additional data we received with figures in the report, and interviewed United Network for Organ Sharing officials to confirm our understanding of the data and analyses.

<sup>8</sup>The Association of Organ Procurement Organizations is a national nonprofit organization that represents the 58 organ procurement organizations in the United States, which are the nonprofit organizations responsible for recovering organs from deceased donors for transplantation and transporting these organs to those awaiting transplantation.

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sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

The National Organ Transplant Act, enacted in 1984, established the framework for the U.S organ transplant system; and the OPTN Final Rule, issued in April 1998 and implemented in March 2000, established the regulatory framework for the structure and operations of OPTN.<sup>9</sup> The OPTN Final Rule requires OPTN to develop policies for the equitable allocation of organs to candidates who need transplants.<sup>10</sup> Such allocation policies must, among other things,

- be based on sound medical judgment;
- seek to achieve the best use of donated organs;
- be designed to promote the efficient management of organ placement;
- not be based on the candidate's place of residence or place of listing (i.e., where the candidate does not necessarily reside), except as otherwise required; and
- include appropriate procedures to promote and review compliance.<sup>11</sup>

As part of its responsibilities to oversee OPTN, HRSA awarded the United Network for Organ Sharing the initial contract to manage OPTN in 1986. The United Network for Organ Sharing has rebid on and been awarded the contract to continue to manage the national transplant network through eight terms of operation since that date.

The Scientific Registry of Transplant Recipients is an organization that conducts modeling for allocation policy proposals, including for livers and lungs, to inform OPTN's organ allocation policymaking. In addition, as called for by the National Organ Transplant Act, the Scientific Registry of Transplant Recipients analyzes data collected from OPTN on organ

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<sup>9</sup>Pub. L. No. 98-507, 98 Stat. 2339 (1984) (codified, as amended, at 42 U.S.C. § 273 et seq.); and 63 Fed. Reg. 16,296 (Apr. 2, 1998).

<sup>10</sup>OPTN is responsible for developing equitable allocation policy for organs from deceased donors. In addition to organs donated by deceased donors, some organs are donated by living donors. The OPTN policies discussed in our report are for organs from deceased donors.

<sup>11</sup>See 42 C.F.R. § 121.8(a) (2019).

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donors, and transplant candidates and recipients. The Chronic Disease Research Group, a division of the Hennepin Healthcare Research Institute, has a contract with HRSA to administer the Scientific Registry of Transplant Recipients.

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## OPTN's Role and Responsibilities

Through its members, board of directors, and committees, OPTN develops and implements the policies that govern the distribution of organs from deceased donors and other issues related to transplantation.<sup>12</sup> OPTN's functions include:

- maintaining a list of patients (candidates) waiting for transplants;
- operating a system for matching donated organs with candidates on the list;
- establishing a national system for allocating organs in accordance with medical criteria;
- collecting and analyzing data on organs donated and transplanted, including monitoring reports on the implementation of policy changes; and
- conducting work, such as promoting knowledge of effective donation practices, to increase the supply of donated organs.<sup>13</sup>

The OPTN Liver Committee and the OPTN Lung Committee are responsible for developing evidence-based policies aimed at reducing the burden of liver, and heart and lung disease, respectively, in transplant

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<sup>12</sup>OPTN's members include transplant hospitals participating in Medicare or Medicaid and all organ procurement organizations in the country. Members may also include other organizations, institutions, and individuals interested in organ donation or transplantation, such as organ donors, recipients, and their families. Membership generally means that their institution meets OPTN requirements and that they play an active role in forming the policies that govern the transplant community.

<sup>13</sup>See 42 U.S.C. § 274(b)(2). Monitoring reports compare certain outcomes before implementation of changes to an organ allocation policy to those same outcomes after implementation of the revised policy. Outcomes include the number of candidates on the waiting list and number of transplants, and patient survival probabilities.

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patients, among other responsibilities.<sup>14</sup> OPTN's processes for making changes to organ allocation policies include an impetus for policy change, evidence gathering and proposal development, public comment periods, review and revision of proposals, OPTN Board approvals, and implementation.

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## Organ Allocation

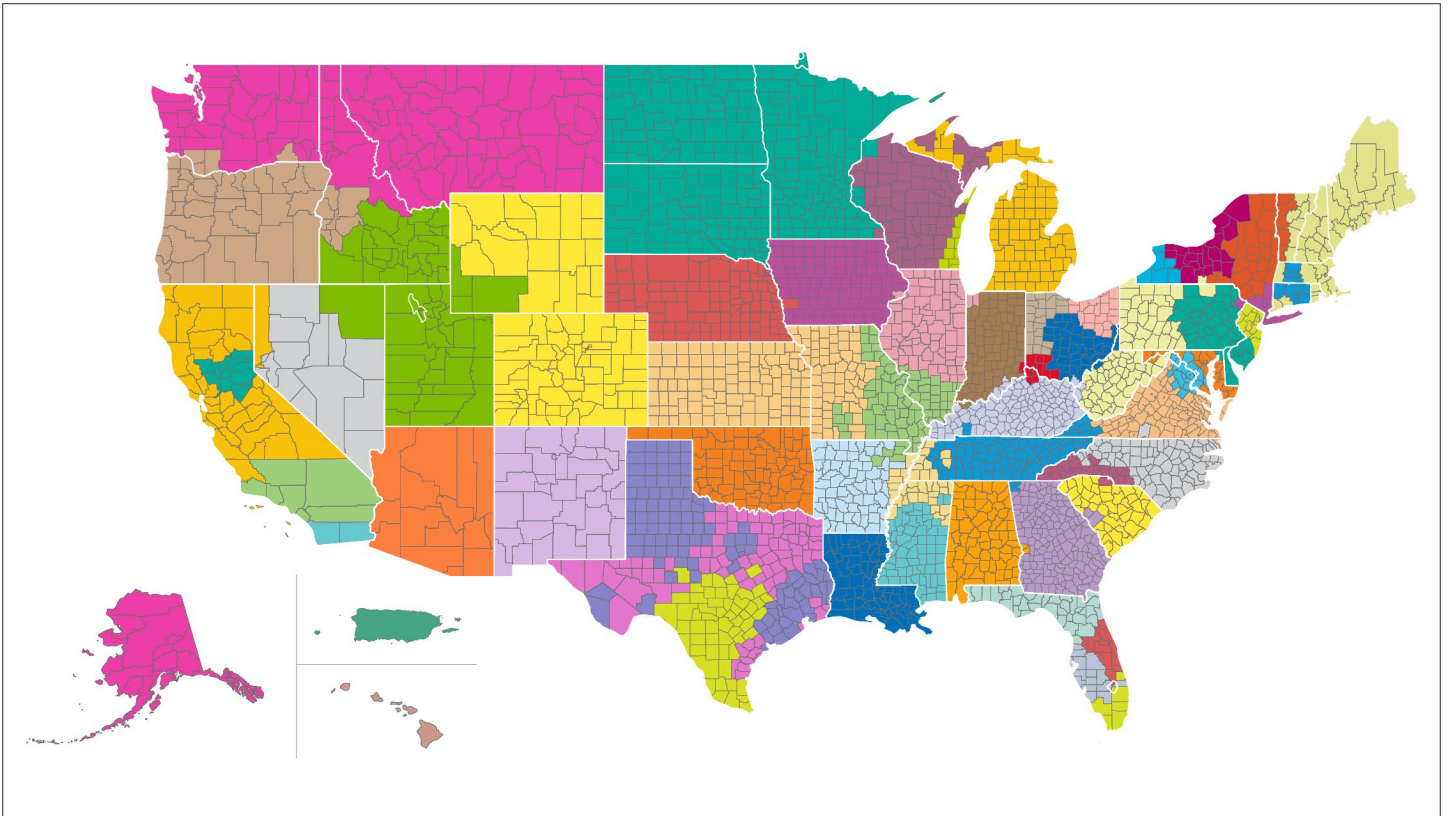
Historically, OPTN's policies allocated organs to candidates based on 58 local DSAs and 11 OPTN regions. While these administrative boundaries are no longer used for allocating donated livers and lungs, they continue to serve other purposes. For example, DSAs continue to define the boundaries of organ procurement organizations that conduct other activities, including activities to promote organ donation, and OPTN regions are used to coordinate regional activities for the transplant community.

- **DSAs.** DSAs are geographic areas established by the Centers for Medicare & Medicaid Services, which are served by one designated organ procurement organization, one or more transplant programs, and one or more donor hospitals. DSAs, which differ in size, define the boundaries in which organ procurement organizations recover organs from eligible donors. (See fig. 1.)

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<sup>14</sup>Goals of the work of the OPTN Liver and Lung Committees also include increasing liver and thoracic organ utilization, improving access to liver and thoracic transplantation, and improving the health outcomes of liver and thoracic transplant recipients. In addition to the organ-specific OPTN committees, the OPTN Board of Directors' Executive Committee continues the work of the board between meetings of the full board, including addressing emergency actions for allocation policies and approving the committees' allocation policy proposals for public comment distribution. OPTN also forms ad hoc committees for specific purposes, such as the Ad Hoc Geography Committee that was formed to develop principles for the appropriate consideration of geography in organ allocation policies.

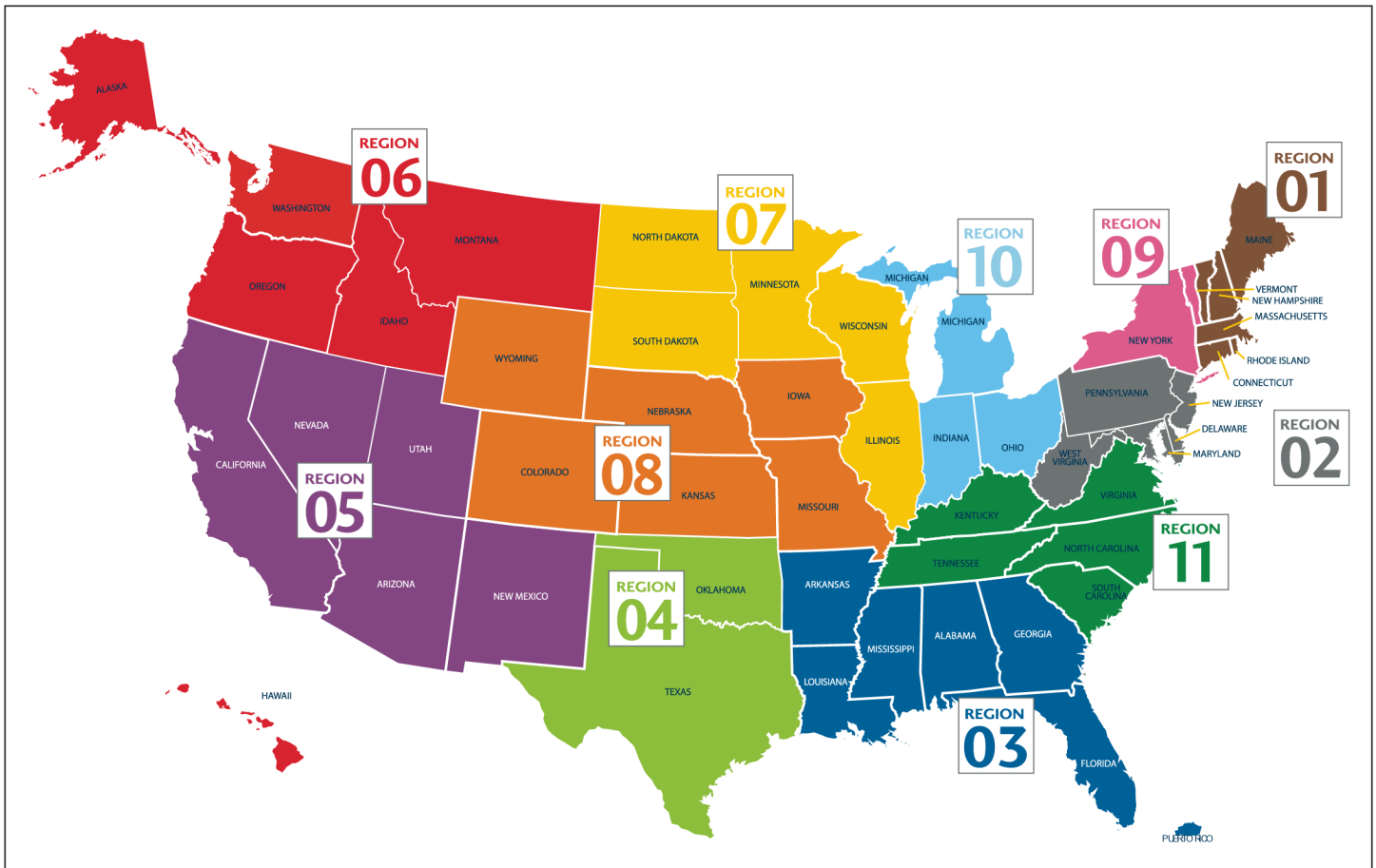
**Figure 1: United States Map of the 58 Donation Service Areas, as of August 2020**



Source: United Network for Organ Sharing. | GAO-21-70

- **OPTN regions.** OPTN regions are administrative boundaries used to facilitate OPTN governance activities, such as collecting public comments and establishing board and committee representation. Each of the 11 OPTN regions is a collection of states. (See fig. 2.)

Figure 2: United States Map of the 11 Organ Procurement and Transplantation Network (OPTN) Regions, as of August 2020



Source: United Network for Organ Sharing. | GAO-21-70

Many factors, including a candidate's compatibility with the donor organ, are used to allocate organs to transplant candidates. Specifically, once an organ becomes available, those transplant candidates who are incompatible with the donor because of certain factors, such as blood type, height, and weight, are automatically screened out. For the remaining candidates on the waiting list for that type of organ, OPTN uses a computer program that determines the order in which candidates will be offered the organ, according to the national organ allocation policies. Factors that weigh into the computer program's ordering include

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geography, proper organ size, and organ-specific factors.<sup>15</sup> Candidates waiting for a liver or lung transplant are given a score—for example, a Model for End-Stage Liver Disease (MELD) score for livers and a Lung Allocation Score for lungs. The higher the score, the greater the medical need and urgency for a transplant.

- **MELD scores** range from 6 (less ill) to 40 (severely ill) and are used for liver transplant candidates age 12 and older.<sup>16</sup> Each candidate for a liver receives a MELD score based on how urgently a liver transplant is needed within the next 3 months. Those liver candidates who have acute (sudden and severe onset) liver failure and a life expectancy of hours to a few days without a transplant, called status 1A, are given higher priority than the candidates with the highest MELD score. Similarly, very sick, chronically ill candidates (registered on the waiting list and younger than 18 years old), called status 1B, also have higher priority. Status 1A and 1B candidates together represent less than 1 percent of liver transplant candidates.
- **Lung Allocation Scores** range from 0 (less ill) to 100 (severely ill) and are used for lung transplant candidates age 12 and older.<sup>17</sup> Lung Allocation Scores are used, along with other factors, to determine priority for receiving a lung transplant when a donor lung becomes available. Pediatric lung candidates younger than 12 years old are classified as Priority 1 or Priority 2, based on their medical condition.

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<sup>15</sup>The amount of time an organ spends being preserved after recovery from the donor, referred to as cold ischemic time, can affect transplant outcomes. In organ allocation policies, cold ischemic time is a factor when considering the optimal distance between the donor hospital and transplant hospital.

<sup>16</sup>The MELD score is calculated by a formula using three routine lab test results: 1) bilirubin, which measures how effectively the liver excretes bile; 2) INR (prothrombin time), which measures the liver's ability to make blood clotting factors; and 3) creatinine, which measures kidney function (impaired kidney function is often associated with severe liver disease). Pediatric liver candidates are prioritized according to the Pediatric End-Stage Liver Disease scoring system based on lab values, growth failure, and whether the child is less than 1 year old. The liver allocation policy uses this scoring system for candidates younger than age 12.

<sup>17</sup>Each candidate for a lung receives a Lung Allocation Score based on lab values, such as creatinine (high creatinine levels reflect impaired kidney function, sometimes associated with severe lung disease); test results, including pulmonary artery pressure (the pressure the heart generates to pump blood through the lungs, which may be high in some people with serious lung disease); and disease diagnosis (success following a lung transplant varies among people with different lung diseases).

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Those that meet criteria reflecting a more urgent status are listed as Priority 1; all other candidates in this age range are Priority 2.

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## Liver Allocation Policy Changed to Include Distance after HHS Directed OPTN to Create a Policy Consistent with Federal Regulations

The liver allocation policy changed from a system that, in general, offered deceased donor livers first to the candidates with the highest level of illness within the deceased donor's DSA and OPTN region before offering them outside the region, to a system that allocates livers based on a candidate's level of illness and distance from the donor hospital.<sup>18</sup> OPTN made this change after it developed but did not implement the 2017 liver allocation policy, and after HHS, in July 2018, further directed OPTN to develop a policy that was consistent with the OPTN Final Rule.<sup>19</sup>

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## Liver Allocation Policy from June 2013 – February 2020

Under the previous liver allocation policy, which was in effect from 2013 to 2020 (2013-2020 liver allocation policy), generally, the sickest transplant candidates within a liver donor's DSA and OPTN region, were offered a liver first. Specifically, status 1A candidates (those with acute liver failure) within the deceased donor's DSA and OPTN region were offered the liver first, followed by status 1B candidates (very sick, chronically ill candidates 18 years and younger) within the same areas. Livers were then generally offered to candidates with a MELD score greater than or equal to 35 within the DSA and then OPTN region, and then to candidates within the DSA and OPTN region with MELD scores from 15 to 34, before being offered nationally.<sup>20</sup> (See fig. 3.)

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<sup>18</sup>While we are describing the allocation procedures for liver allocation policies at a general level, there may be some variances based on particular donor characteristics, such as by age groups.

<sup>19</sup>See app. I for a timeline of selected events related to organ allocation policies, including the liver and lung allocation policies.

<sup>20</sup>For candidates with MELD scores from 40 (the highest MELD score) to 35, candidates within a DSA ranked above regional candidates at each MELD score. For example, candidates with a MELD score of 40 within the DSA and then OPTN region were offered the liver followed by candidates with a MELD score of 39 within the DSA and then OPTN region.



**Figure 3: Sequence of Offers for Livers from Deceased Donors under Previous Liver Allocation Policy, June 2013 – February 2020**

**PREVIOUS LIVER ALLOCATION POLICY**

<i>Order in which livers are offered:</i>	<i>Illness category<sup>a</sup></i>	<i>Geographic unit of allocation</i> <i>Organs donated to candidates in descending order of illness in the:</i>
1	Status 1A	DSA and OPTN region
2	Status 1B	
3	≥ 35 MELD score	DSA and OPTN region (DSA candidates ranked above regional candidates at each MELD score)
4	29-34 MELD score	DSA
5	Liver-intestine candidates <sup>b</sup>	Nation
6	15-28 MELD score	DSA
7	15-34 MELD score	OPTN region
8	Status 1A	Nation
9	Status 1B	
10	≥15 MELD score	
11	<15 MELD score	DSA
12	<15 MELD score	OPTN region
13	<15 MELD score	Nation

Legend: DSA=donation service area; MELD=Model for End-Stage Liver Disease; OPTN=Organ Procurement and Transplantation Network

Source: GAO. | GAO-21-70

Note: We are describing the previous liver allocation policy at a general level for adult deceased donors, and there may be some variances based on particular donor characteristics, such as by age groups.

<sup>a</sup>The illness category is the assigned status or score assignment for a liver transplant candidate that reflects the probability of death within a 3-month period, including assignments of MELD scores, and status 1A, status 1B, or liver-intestine candidates. MELD scores range from 6 (less ill) to 40 (severely ill) and are used for liver transplant candidates age 12 and older. The higher the score, the greater the medical need and urgency for a transplant. Status 1A liver candidates are those who have acute (sudden and severe onset) liver failure and a life expectancy of hours to a few days without a transplant. Status 1B candidates are very sick, chronically ill candidates age 18 and younger. In addition to MELD scores, the previous liver allocation policy used the Pediatric End-Stage Liver Disease scoring system for pediatric liver candidates (younger than age 12), which prioritizes pediatric candidates based on lab values, growth failure, and whether the child is less than 1 year old.

<sup>b</sup>Liver-intestine candidates are adult and pediatric liver candidates who are also registered and active on the waiting list for an intestine transplant.

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## 2017 Liver Allocation Policy

On December 1, 2017, HHS received a critical comment from a liver transplant candidate, asking HHS to require that livers from deceased donors be allocated to candidates based on medical priority and not on “arbitrary geographical boundaries” (i.e., DSAs and OPTN regions).<sup>21</sup> The comment stated that the liver allocation policy in effect at that time offered an available liver to candidates within the local DSA first, even if there were candidates with a higher medical priority (i.e., a higher MELD score) within a closer distance of the donor but in a different DSA or OPTN region. Also, in December 2017, the OPTN Board approved the 2017 liver allocation policy, which expanded the first unit of distribution to include candidates within the same OPTN region as a liver donor and those within 150 nautical miles of the donor hospital, but in a different OPTN region.<sup>22</sup> OPTN planned to implement the 2017 liver allocation policy in December 2018, but this policy was never put into effect.

On May 30, 2018, HHS received a second critical comment from a group of liver transplant candidates regarding the use of DSAs and OPTN regions in the 2013-2020 liver allocation policy, as well as in the 2017 liver allocation policy. Following the second critical comment, in June 2018, HRSA requested OPTN’s views on whether aspects of the 2017 liver allocation policy, including the use of DSAs and OPTN regions as units of allocation, alone or in combination with a nautical mile circle distance from donor hospitals, were consistent with the requirements of the National Organ Transplant Act and the OPTN Final Rule.

In its June 2018 response to HRSA, OPTN stated that the 2017 liver allocation policy did not include an over-reliance on DSAs as the primary unit of liver distribution, but also stated that DSAs and OPTN regions were not good proxies for geographic distance between donors and transplant candidates. Specifically, OPTN stated that the most medically urgent patients under the 2017 liver allocation policy would be prioritized regardless of whether they were located within or outside of the DSA of the donor. However, OPTN also stated that the disparate sizes, shapes, and populations of DSAs and OPTN regions resulted in an inconsistent

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<sup>21</sup>Any interested individual or entity may submit to the Secretary of Health and Human Services critical comments related to the manner in which OPTN is carrying out its duties. See 42 U.S.C. § 274(c) and 42 C.F.R. § 121.4(d) (2019).

<sup>22</sup>OPTN uses nautical miles, as opposed to statutory miles, because if an organ had to travel over any significant distance, it would be flown, which requires use of the units for aviation (i.e., nautical miles), according to United Network for Organ Sharing officials. A nautical mile is approximately 1.15 statutory miles.

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application for all candidates and committed to adopt a liver allocation policy without DSAs or OPTN regions by December 2018.

On July 31, 2018, HRSA stated that OPTN had not justified and could not justify the use of DSAs and OPTN regions in the 2013-2020 liver allocation policy and the 2017 liver allocation policy, under the OPTN Final Rule.<sup>23</sup> HRSA directed OPTN to approve another liver allocation policy by December 2018 that eliminated DSAs and OPTN regions, and was consistent with the OPTN Final Rule. The July 2018 letter directed OPTN to revise the liver allocation policy to eliminate the use of DSAs and OPTN regions, without “directing any particular policy outcome or allocation scheme.” HRSA officials told us the agency left it to OPTN to determine how to eliminate the use of DSAs and OPTN regions.

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## Liver Allocation Policy Options

Following HRSA’s July 2018 directive to develop a liver allocation policy that eliminated the use of DSAs and OPTN regions, the OPTN Liver Committee subsequently developed and distributed for public comment two options: one called the broader 2-circle framework and another called the acuity circles framework. Each framework eliminated the use of DSAs and OPTN regions, but each allocated livers based on different distances from the donor hospital, and based on different ways to group transplant recipients’ severity of illness.



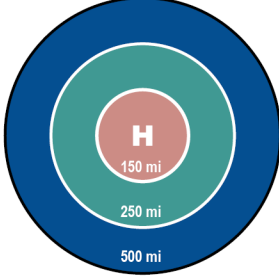


- The broader 2-circle framework would allocate livers first to candidates with the highest medical urgency within 500 nautical miles of the donor hospital, then to candidates with a MELD score of 29 or higher within 250 nautical miles of donor hospitals, and then to candidates with a MELD score of 15 to 28 within 150, 250, or 500 nautical miles of donor hospitals before offering them nationally to candidates with the highest medical urgency.
- The acuity circles framework would also allocate livers first to candidates with the highest medical urgency within 500 nautical miles of the donor hospital, then to candidates in a series of concentric circles of different distances (150, 250, and 500 nautical miles) from the donor hospital in bands of MELD scores that got progressively lower (i.e., 37 and higher, 33-36, 29-32, 15-28), before offering the livers nationally to candidates with the highest medical urgency.

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<sup>23</sup>HRSA also found that the use of DSAs and OPTN regions in all other organ allocation policies had not been, and could not be, justified under the OPTN Final Rule.

Figure 4 illustrates how the broader 2-circle framework would offer donated livers to transplant candidates, and figure 5 illustrates how the acuity circles framework would offer donated livers to transplant candidates.

**Figure 4: Sequence of Offers for Livers from Deceased Donors under Broader 2-Circle Liver Allocation Framework**

<b>BROADER 2-CIRCLE LIVER FRAMEWORK</b>		
<i>Order in which livers are offered:</i>	<i>Illness category<sup>a</sup></i>	<i>Mile<sup>b</sup> distance of eligible candidates from donor hospital</i>
1 2	Status 1A Status 1B	 500 mile radius from donor hospital
3	≥ 29 MELD score	 250 mile radius from donor hospital
4 5 6	15-28 MELD score	 Within this MELD category, the liver is offered to eligible candidates in a series of concentric circles: 1. First within 150 mile radius 2. Then within 250 mile radius 3. Then within 500 mile radius
7 8 9	Status 1A Status 1B ≥ 15 MELD score	 National allocation
10 11 12 13	6-14 MELD score	 Concentric circles and national allocation

Source: GAO. | GAO-21-70

Note: We are describing the broader 2-circle liver framework at a general level for adult deceased donors, and there may be some variances based on particular donor characteristics, such as by age groups.


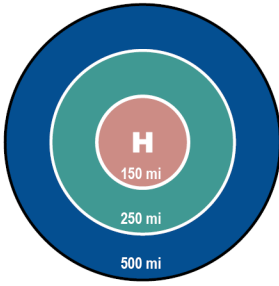
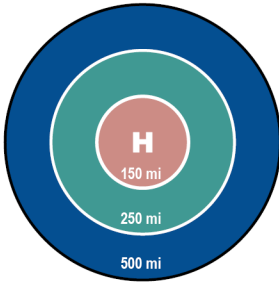
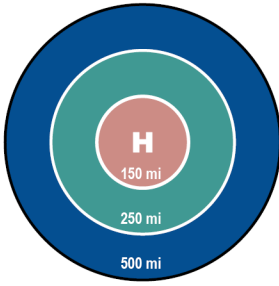


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<sup>a</sup>The illness category is the assigned status or score assignment for a liver transplant candidate that reflects the probability of death within a 3-month period, including assignments of Model for End-Stage Liver Disease (MELD) scores, and status 1A, status 1B, or liver-intestine candidates. MELD scores range from 6 (less ill) to 40 (severely ill) and are used for liver transplant candidates age 12 and older. The higher the score, the greater the medical need and urgency for a transplant. Status 1A liver candidates are those who have acute (sudden and severe onset) liver failure and a life expectancy of hours to a few days without a transplant. Status 1B candidates are highly urgent candidates age 18 and younger. In addition to MELD scores, the broader 2-circle liver framework used the Pediatric End-Stage Liver Disease scoring system for pediatric liver candidates (younger than age 12), which prioritizes pediatric candidates based on lab values, growth failure, and whether the child is less than 1 year old.

<sup>b</sup>Mile refers to nautical mile, which the Organ Procurement and Transplantation Network uses because if an organ had to travel over any significant distance, it would be flown, requiring the use of the units for aviation (i.e., nautical miles), according to United Network for Organ Sharing officials. A nautical mile is approximately 1.15 statutory miles.

**Figure 5: Sequence of Offers for Livers from Deceased Donors under Acuity Circles Liver Allocation Framework**

**ACUITY CIRCLES LIVER FRAMEWORK**

	<i>Order in which livers are offered:</i>	<i>Illness category<sup>a</sup></i>	<i>Mile<sup>b</sup> distance of eligible candidates from donor hospital</i>
SEVERITY OF ILLNESS ↑ Less to more severe	1	Status 1A	 500 mile radius from donor hospital
	2	Status 1B	
	3	≥ 37 MELD score	 Within this MELD category, the liver is offered to eligible candidates in a series of concentric circles: 1. First within 150 mile radius 2. Then within 250 mile radius 3. Then within 500 mile radius
	4		
	5		
	6		
	7		
	8		
	9		
	10	29-32 MELD score	 Within this MELD category, the liver is offered to eligible candidates in a series of concentric circles: 1. First within 150 mile radius 2. Then within 250 mile radius 3. Then within 500 mile radius
	11		
	12		
	13		
	14	15-28 MELD score	 Within this MELD category, the liver is offered to eligible candidates in a series of concentric circles: 1. First within 150 mile radius 2. Then within 250 mile radius 3. Then within 500 mile radius
15			
16			
SEVERITY OF ILLNESS ↑ Less to more severe	17	15-40 MELD score	 National allocation
	18	6-14 MELD score	 Concentric circles and national allocation
	19		
	20		
	21		

Source: GAO. | GAO-21-70

Note: We are describing the acuity circles liver framework at a general level for adult deceased donors, and there may be some variances based on particular donor characteristics, such as by age groups.

<sup>a</sup>The illness category is the assigned status or score assignment for a liver transplant candidate that reflects the probability of death within a 3-month period, including assignments of Model for End-Stage Liver Disease (MELD) scores, and status 1A, status 1B, or liver-intestine candidates. MELD scores range from 6 (less ill) to 40 (severely ill) and are used for liver transplant candidates age 12 and older. The higher the score, the greater the medical need and urgency for a transplant. Status 1A liver candidates are those who have acute (sudden and severe onset) liver failure and a life expectancy of hours to a few days without a transplant. Status 1B candidates are highly urgent candidates age 18 and younger. In addition to MELD scores, the acuity circles liver framework used the Pediatric End-Stage Liver Disease scoring system for pediatric liver candidates (younger than age

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12), which prioritizes pediatric candidates based on lab values, growth failure, and whether the child is less than 1 year old.

<sup>b</sup>Mile refers to nautical mile, which the Organ Procurement and Transplantation Network uses because if an organ had to travel over any significant distance, it would be flown, requiring the use of the units for aviation (i.e., nautical miles), according to United Network for Organ Sharing officials. A nautical mile is approximately 1.15 statutory miles.

The Scientific Registry of Transplant Recipients conducted modeling for the OPTN Liver Committee of which candidates would receive transplants under the two liver allocation policy options. It found that both frameworks reduced the variance in the median MELD scores for transplant recipients at the time of the transplant across DSAs—that is, they both prioritized candidates based on MELD scores with less regard for their geographic location, which would result in improving equity in access to transplants. However, the modeling for the acuity circles framework showed greater reductions in the variance in the median MELD scores than the broader 2-circles framework, and therefore showed greater prioritization of more medically urgent candidates.<sup>24</sup> In addition, both frameworks showed greater distances to recover livers than the 2013-2020 liver allocation policy, but the acuity circles framework showed transport metrics (e.g., number of flights to recover livers and transport time) that were higher than the broader 2-circle framework. Specifically, the acuity circles framework showed that 71.4 percent to 74 percent of livers would be flown, and 58.4 percent to 60.8 percent would be flown using the broader 2-circle framework.

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<sup>24</sup>The median MELD score is calculated from transplant recipients' MELD scores at the time of the transplant from all liver transplant programs within a DSA. There was variance in the median MELD scores across the 58 DSAs, which resulted in candidates having to achieve higher MELD scores in order to receive an offer in some DSAs than candidates with lower MELD scores in other DSAs.

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### Examples of Sequence of Liver Offers with Broader 2-Circle and Acuity Circles Frameworks

Examples of the order in which livers from deceased donors would be offered to transplant candidates for the two policy options for three hypothetical liver transplant candidates are shown below. These examples of sequences are for liver donations that did not occur after cardiac death and donors that are younger than 70 years old.

Candidate A – Status 1A (highest medical urgency); 550 nautical miles from donor hospital

Candidate B – MELD score = 38 (less ill than candidate A, but severely ill); 300 nautical miles from donor hospital

Candidate C – MELD score = 30 (less ill than candidates A and B); 100 nautical miles from donor hospital

#### How the broader 2-circle framework and acuity circles framework would affect these three candidates:

- Among the three candidates, Candidate C is closest to the donor, but has the least severe illness. Under the broader 2-circle framework, Candidate C would be offered the liver first, because this framework prioritizes patients within 250 nautical miles if they have a MELD score of 29 or higher.
- Candidate B is farther from the donor than Candidate C, but has a more severe illness. Under the acuity circles framework, Candidate B would be offered the liver first, because this framework prioritizes patients with a MELD score of 37 or greater if they are within 150, 250, or 500 miles of the donor.
- Candidate A is the farthest from the donor, but has the most severe illness. Candidate A would not be offered the liver first under either of the frameworks, due to the combination of the other candidates' distance from the donor and severity of illness. Both frameworks give top priority to status 1A candidates if they are within 500 miles of the donor, but Candidate A is outside of this range.

Source: GAO. | GAO-21-70

In November 2018, the OPTN Liver Committee voted to recommend the broader 2-circle framework to the OPTN Board for approval, with 11 members in favor of the broader 2-circle framework and 9 members in favor of the acuity circles framework. Based on the modeling for both frameworks, the majority of the committee determined the broader 2-circle framework had the optimal balance of broader distribution and distance to meet the requirements of the OPTN Final Rule, according to an OPTN Liver Committee report.<sup>25</sup>

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## Current Liver Allocation Policy

After reviewing both frameworks, at its December 2018 board meeting the OPTN Board voted 24 in favor and 14 in opposition on an amendment to adopt the acuity circles framework, rather than the broader 2-circle framework recommended by the OPTN Liver Committee. The acuity circles framework allocates livers first to the sickest candidates within 500 nautical miles of the donor hospital and then in a series of concentric circles of different distances (150, 250, and 500 nautical miles) from the donor hospital. The OPTN Board stated that it selected the acuity circles

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<sup>25</sup>OPTN Liver and Intestine Transplantation Committee, *Liver and Intestine Distribution Using Distance from Donor Hospital*, accessed June 18, 2020, [https://optn.transplant.hrsa.gov/media/2766/liver\\_boardreport\\_201812.pdf](https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf).



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framework for the liver allocation policy because this framework allocated livers to candidates with the greatest need (i.e., sicker patients) while distributing livers as broadly as possible, according to a report by the OPTN Board.<sup>26</sup>

The current liver allocation policy (using acuity circles) was briefly implemented for a little over a week in May 2019, but HRSA directed OPTN to revert back to the 2013-2020 liver allocation policy in response to a federal district court order imposing a stay on implementation of the liver allocation policy.<sup>27</sup> OPTN ultimately implemented the current liver allocation policy on February 4, 2020. For a timeline of selected events related to organ allocation policies, including the liver and lung allocation policies, see appendix I.

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## Processes for Changing Liver and Lung Allocation Policies Had Similarities and Differences; HRSA's Oversight Processes Were Similar

OPTN used similar processes to develop three organ allocation policies that we reviewed—the current liver allocation policy, the 2017 liver allocation policy that was never implemented, and the current lung allocation policy, which was implemented in November 2017. There were also differences, including the impetus for making changes to the policies and the public comment periods, among other things. In addition, HRSA officials told us that the agency's oversight of OPTN's processes to make changes to organ allocation policies is the same for all policies and includes reviewing organ allocation policy proposals to ensure compliance with the National Organ Transplant Act and the OPTN Final Rule. Table 1 provides an overview of OPTN's policy development process steps for the three policies.

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<sup>26</sup>OPTN, *Executive Summary of OPTN Approval of Policies to Eliminate the Use of DSAs and Regions in Liver Allocation*, accessed June 18, 2020, [https://optn.transplant.hrsa.gov/MEDIA/2779/BOARD\\_EXECUTIVESUMMARY\\_LIVER\\_201812.PDF](https://optn.transplant.hrsa.gov/MEDIA/2779/BOARD_EXECUTIVESUMMARY_LIVER_201812.PDF).

<sup>27</sup>This order was issued during the course of an April 2019 lawsuit filed in the U.S. District Court for the Northern District of Georgia, in which four liver transplant candidates and 14 transplant centers alleged, among other things, that HHS failed to follow legally required procedures in developing the current liver allocation policy (using acuity circles) and instead deferred authority to the United Network for Organ Sharing. *Callahan v. Azar*, No. 19-cv-01783 (N.D. Ga. Apr. 22, 2019). As of July 2020, this litigation was still ongoing.

**Table 1: Organ Procurement and Transplantation Network’s (OPTN) Policy Development Process Steps for Three Organ Allocation Policies**

<b>OPTN policy process step</b>	<b>Current liver allocation policy</b>	<b>2017 liver allocation policy (not implemented)</b>	<b>Current lung allocation policy</b>
Impetus	HHS directive following receipt of critical comment <sup>a</sup>	OPTN Board directive to address geographic disparities	Federal district court order and HHS directive following receipt of critical comment <sup>b</sup>
Evidence gathering and proposal development	OPTN Liver Committee reviewed Scientific Registry of Transplant Recipients models and evidence collected and modeled in prior policy discussions	OPTN Liver Committee conducted a survey, held two public forums, and reviewed Scientific Registry of Transplant Recipients models	OPTN Lung Committee reviewed existing OPTN data and literature
Public comment	One 25-day public comment period (10/8/18 - 11/1/18)	Two public comment periods, one 62 days (8/15/16 - 10/15/16) and the next 64 days (7/31/17 - 10/2/17)	Retroactive 61-day public comment period after the policy became effective (1/22/18 - 3/23/18)
Review/revision of proposals	OPTN Liver Committee met 20 times over a 6-month period after receiving HHS directive	OPTN Liver Committee reviewed and revised the proposal over several years after considering the findings of public forums and the first public comment period	OPTN Executive Committee reviewed and revised the proposal over 4 days because this was an emergency action
Board approval	Proposal approved on 12/3/2018	Proposal approved on 12/4/2017	Interim policy adopted by the OPTN Executive Committee on 11/24/17 and approved by the OPTN Board as permanent policy on 6/12/18
Implementation	Implemented on 5/14/19, reverted back to previous policy on 5/23/19 in response to a federal district court order, and implemented again on 2/4/20 <sup>c</sup>	Never implemented	Implemented on 11/24/17

Source: GAO. | GAO-21-70

<sup>a</sup>Any interested individual or entity may submit to the Secretary of Health and Human Services critical comments related to the manner in which OPTN is carrying out its duties. See 42 U.S.C. § 274(c) and 42 C.F.R. § 121.4(d) (2019).

<sup>b</sup>This order was issued during the course of a November 2017 lawsuit filed in the U.S. District Court for the Southern District of New York, in which a lung transplant candidate requested the court require the Department of Health and Human Services (HHS) to allocate donor lungs based on medical priority, rather than donation service areas. *Holman v. Hargan*, No. 17-cv-09041 (S.D.N.Y. Nov. 19, 2017).

<sup>c</sup>This order was issued during the course of an April 2019 lawsuit filed in the U.S. District Court for the Northern District of Georgia, in which four liver transplant candidates and 14 transplant centers alleged, among other things, that HHS failed to follow legally required procedures in developing the current liver allocation policy (using acuity circles) and instead deferred authority to the United Network for Organ Sharing. *Callahan v. Azar*, No. 19-cv-01783 (N.D. Ga. Apr. 22, 2019).

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The following are descriptions of the similarities and differences in OPTN's standard policy approval processes used to develop the current liver allocation policy, the 2017 liver allocation policy, and the current lung allocation policy.<sup>28</sup>

- **Impetus for the policy change.** The impetus for the changes resulting in each allocation policy varied. Specifically, the impetus for the changes resulting in the current liver allocation policy was an HHS directive following the agency's receipt of a critical comment regarding the use of DSAs and OPTN Regions in the 2013-2020 liver allocation policy and the 2017 liver allocation policy. The impetus for the changes resulting in the current lung allocation policy was two-fold. First, a federal district court ordered HHS to initiate an emergency review of the lung allocation policy.<sup>29</sup> Second, HRSA directed OPTN to initiate an emergency review of the lung allocation policy in accordance with the court order and as a first step in responding to a critical comment asking HHS to require OPTN to set aside portions of the lung allocation policy that utilize DSAs. The impetus for the changes that resulted in the 2017 liver allocation policy was a November 2012 OPTN Board directive to address geographic disparities.<sup>30</sup>
- **Evidence gathering and proposal development.** The evidence reviewed to develop each of these organ allocation policies varied. For example, the OPTN Liver Committee reviewed Scientific Registry of Transplant Recipients modeling of allocation policy proposals for the development of both the current liver allocation policy and the

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<sup>28</sup>OPTN's bylaws outline a policy approval process for developing organ allocation policies, which includes the main steps of 1) identifying issues (impetus), 2) creating a policy proposal (evidence gathering and proposal development), 3) distributing the proposal to the public for review and comment (public comment periods), 4) responding to comments and developing a final policy proposal (review and revision of proposals), 5) sending the final proposal to the OPTN Board for a vote (Board approval), 6) providing notice to the transplant community of the approved changes to OPTN policy and taking the necessary steps to implement the changes (implementation), and 7) periodically evaluating the policy's impact and effectiveness (oversight).

<sup>29</sup>This order was issued during the course of a November 2017 lawsuit filed in the U.S. District Court for the Southern District of New York, in which a lung transplant candidate requested the court require HHS to allocate donor lungs based on medical priority, rather than DSAs. *Holman v. Hargan*, No. 17-cv-09041 (S.D.N.Y. Nov. 19, 2017).

<sup>30</sup>OPTN Liver and Intestinal Organ Transplantation Committee, *Redesigning Liver Distribution to Reduce Variation in Access to Liver Transplantation*, accessed February 3, 2020, [https://optn.transplant.hrsa.gov/MEDIA/1269/LIVER\\_CONCEPTS\\_2014.PDF](https://optn.transplant.hrsa.gov/MEDIA/1269/LIVER_CONCEPTS_2014.PDF).

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2017 liver allocation policy prior to submitting these policies to the OPTN Board for approval. In addition, OPTN Liver Committee members presented 32 webinars over a 5-month period to the transplant community as part of the proposal development for the current liver allocation policy, according to OPTN members.<sup>31</sup> For the 2017 liver allocation policy, the OPTN Liver Committee also conducted a survey and held two public forums to gather input regarding drawing new boundaries for liver allocation. For the current lung allocation policy, the OPTN Lung Committee reviewed existing OPTN data and literature prior to OPTN Executive Committee approval of an interim lung allocation policy and reviewed Scientific Registry of Transplant Recipients modeling after the interim policy was implemented in November 2017. According to HRSA officials, the evidence gathering and proposal development process was different for the current lung allocation policy because the process was part of an emergency review.

- **Public comment periods.** The timing of the public comment periods differed for each of the policy proposals prior to OPTN Board approval. There was a public comment period for the current liver allocation policy over 25 days from October 8, 2018, through November 1, 2018, whereas the 2017 liver allocation policy had two public comment periods, each 62 days or more (August 15, 2016 to October 15, 2016, and July 31, 2017 to October 2, 2017), prior to OPTN Board approval. The comment period for the current lung allocation policy differed in that it occurred after the policy was implemented in November 2017, which is permissible under an emergency action.<sup>32</sup> OPTN provided for a 61-day retroactive comment period on the current lung allocation policy from January 22, 2018, to March 23, 2018, after the policy became effective in November 2017.
- **Review and revision of proposals.** The time frames for reviews and revisions of policy proposals differed across the three allocation policies. For the current liver allocation policy, the full OPTN Liver Committee met 20 times over a 6-month period to revise the policy

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<sup>31</sup>While developing the current liver allocation policy, the OPTN Liver Committee was able to utilize and build on modeling and analyses performed for the 2017 liver allocation policy.

<sup>32</sup>OPTN's bylaws designate policy proposals that meet at least one of the following criteria as emergency actions that may be adopted by the OPTN Board prior to public comment: 1) a proposal that is necessitated by a pending statutory or regulatory change; 2) a proposal that is required due to an emergent public health issue or patient safety factors; or 3) a proposal that is necessitated by a new medical device or technology that affects organ allocation. Such policy proposals must be distributed for public comment no more than six months after OPTN Board approval.

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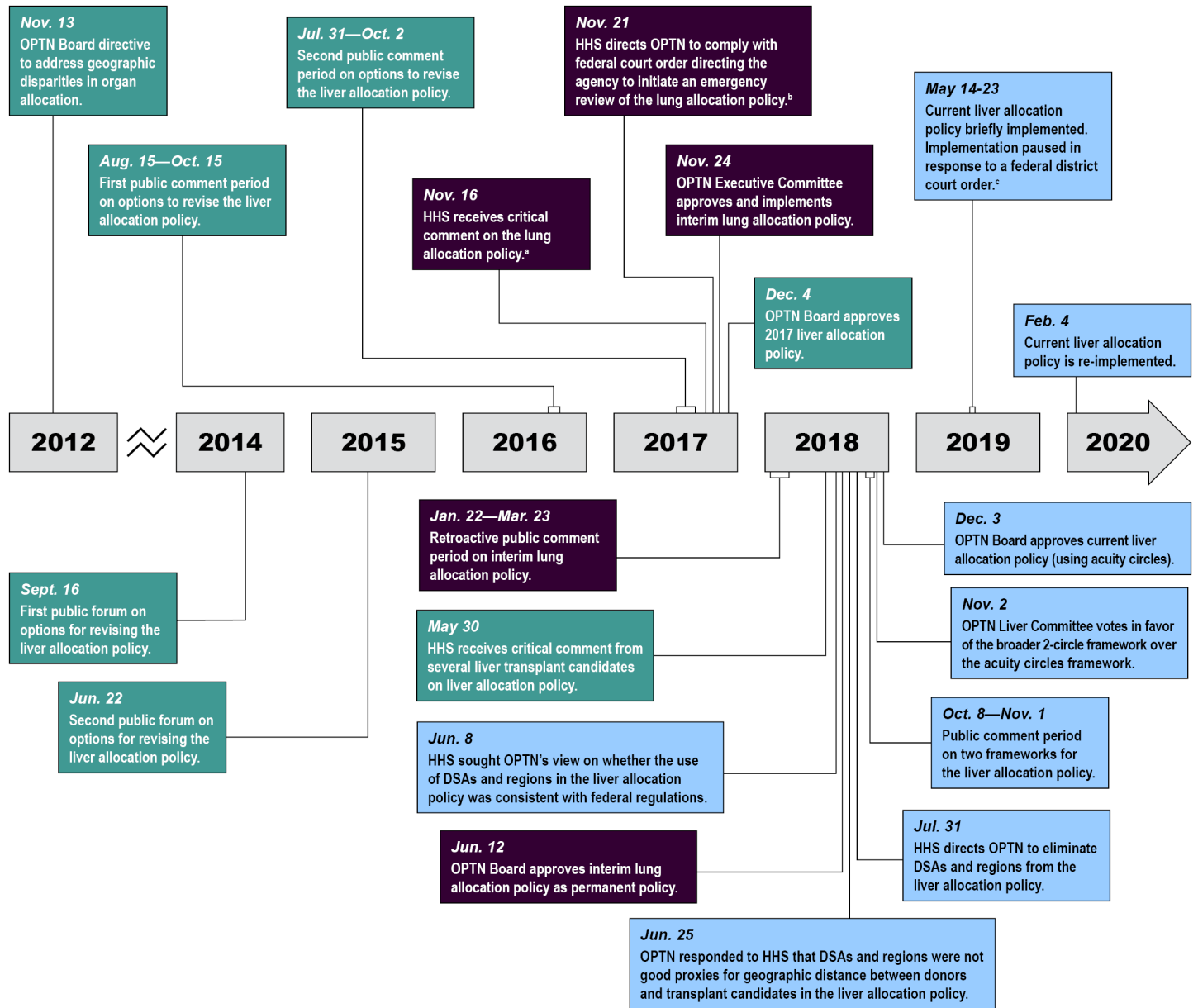
proposal. For the 2017 liver allocation policy, the OPTN Liver Committee reviewed and revised the proposal over a 5-year time frame after considering the findings of two public forums in September 2014 and June 2015 and following the first of two public comment periods described earlier. OPTN members told us that the committee held the public forums to solicit feedback from experts and revised the proposal for the 2017 liver allocation policy by incorporating ideas from these forums. For the current lung allocation policy, the OPTN Executive Committee reviewed and revised the proposal over 4 days.

- **OPTN Board approvals.** The current liver allocation policy and 2017 liver allocation policy approvals were similar in that the OPTN Board approved both as permanent policy. The OPTN Executive Committee approved the current lung allocation policy in November 2017 on an interim basis and then, after a public comment period from January 22, 2018, to March 23, 2018, the OPTN Board approved it as permanent policy in June 2018.
- **Implementation.** Implementation differed across the three policies. For example, the current liver allocation policy was initially implemented in May 2019, but reverted back to the 2013-2020 liver allocation policy 9 days later in response to a federal district court order imposing a stay on implementation. The current liver allocation policy was implemented again in February 2020. Conversely, the 2017 liver allocation policy was approved by the OPTN Board but was never implemented. The current lung allocation policy was implemented immediately after it was approved.

HRSA's oversight of OPTN's processes to make changes to organ allocation policies is the same for all allocation policies, according to HRSA officials and OPTN members. As ex officio, nonvoting members of the OPTN Board and all OPTN committees, HRSA officials participate in OPTN committee meetings. This participation entails reviewing organ allocation policy proposals to ensure compliance with the National Organ Transplant Act and the OPTN Final Rule, OPTN briefing papers on policy proposals, summaries of committee meetings, and modeling results, according to HRSA officials and OPTN members. OPTN members also told us that OPTN has frequent, collaborative interactions with HRSA officials (e.g., meetings and phone calls) regarding OPTN's changes to organ allocation policies, as well as other activities.

Figure 6 shows a timeline of selected events related to the current liver allocation policy, the current lung allocation policy, and the 2017 liver allocation policy, including public comment periods for the three policies.

**Figure 6: Timeline of Selected Events Related to the Current Liver Allocation Policy, Current Lung Allocation Policy, and 2017 Liver Allocation Policy**



Legend: DSA=donation service area; HHS=Department of Health and Human Services; OPTN=Organ Procurement and Transplantation Network.

Teal box: 2017 liver allocation policy    Purple box: Current lung allocation policy    Light blue box: Current liver allocation policy

Source: GAO. | GAO-21-70

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## OPTN Reported that Lung Transplants to Sicker Patients and Distance Increased after Changes in Allocation Policy; Little Is Known about Changes in Spending

<sup>a</sup>Any interested individual or entity may submit to the Secretary of Health and Human Services critical comments related to the manner in which OPTN is carrying out its duties. See 42 U.S.C. § 274(c) and 42 C.F.R. § 121.4(d) (2019).

<sup>b</sup>This order was issued during the course of a November 2017 lawsuit filed in the U.S. District Court for the Southern District of New York, in which a lung transplant candidate requested the court require HHS to allocate donor lungs based on medical priority, rather than DSAs. *Holman v. Hargan*, No. 17-cv-09041 (S.D.N.Y. Nov. 19, 2017).

<sup>c</sup>This order was issued during the course of an April 2019 lawsuit filed in the U.S. District Court for the Northern District of Georgia, in which four liver transplant candidates and 14 transplant centers alleged, among other things, that HHS failed to follow legally required procedures in developing the current liver allocation policy (using acuity circles) and instead deferred authority to the United Network for Organ Sharing. *Callahan v. Azar*, No. 19-cv-01783 (N.D. Ga. Apr. 22, 2019).

OPTN's 2-year monitoring report following changes to the lung allocation policy found an increase nationally in sicker patients receiving lung transplants and an increase in the distance between recovering a lung from the donor hospital and the transplant center, among other selected outcomes; however, the report did not examine changes in spending.<sup>33</sup>

HRSA officials said that the lung allocation policy was changed to provide more equitable allocation of lungs, specifically to provide transplants to sicker candidates and to provide greater access across the country through a broader distribution of available lungs. HRSA officials told us they therefore believe the current policy has met these goals based on the data from the 2-year monitoring report.

Specifically, the monitoring report found that the average Lung Allocation Score—which measures the severity of illness—for lung transplant recipients increased nationally from 47.25 in the two years preceding implementation of the current lung allocation policy to 49.79 in the two years following implementation of the current policy, a statistically significant increase.<sup>34</sup> However, this varied by the 11 OPTN regions. For example, the monitoring report found that nine of the regions had an

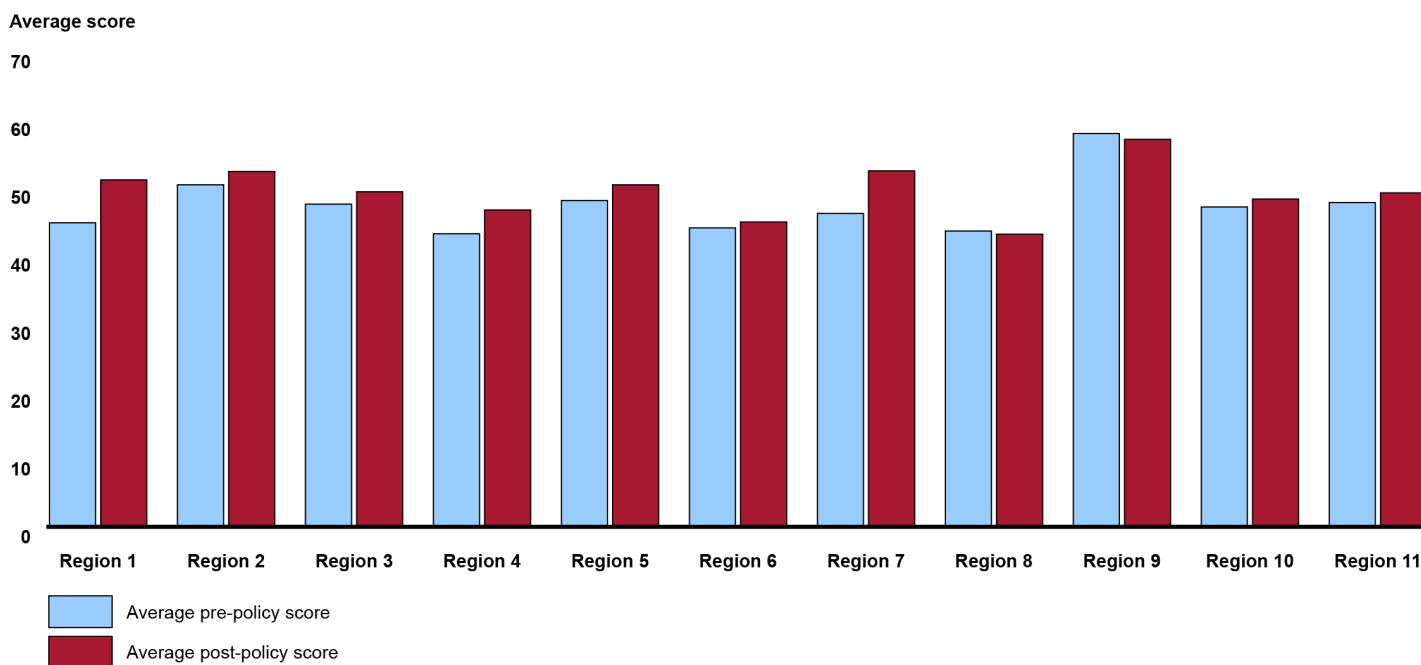
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<sup>33</sup>See app. II for additional data from OPTN's 2-year monitoring report following changes in the lung allocation policy.

<sup>34</sup>Lung Allocation Scores are a measure of the level of illness of a lung transplant candidate or recipient. These scores range from 0 to 100, and a higher score represents a clinically sicker transplant candidate or recipient. The current lung allocation policy went into effect on November 24, 2017, at 8 p.m. Eastern Time. The 2 years preceding implementation of the current lung allocation policy for these analyses was November 26, 2015 through November 24, 2017. The 2 years following implementation of the current lung allocation policy was November 25, 2017 through November 24, 2019.

increase in the average Lung Allocation Score for transplant recipients while two regions had a decrease.<sup>35</sup> (See fig. 7.)

**Figure 7: Average Lung Allocation Scores for Lung Transplant Recipients by OPTN Regions Pre- and Post-Policy Changes**



Source: Organ Procurement and Transplantation Network (OPTN). | GAO-21-70

Notes: The current lung allocation policy went into effect on November 24, 2017, at 8 p.m. Eastern Time. The pre-policy score refers to the average Lung Allocation Score for lung transplant recipients in the 2 years preceding implementation of the current lung allocation policy, which was November 26, 2015, through November 24, 2017. The post-policy score refers to the average Lung Allocation Score for lung transplant recipients in the 2 years following implementation of the current lung allocation policy, which was November 25, 2017, through November 24, 2019. Lung allocation scores are a measure of the level of illness of a lung transplant recipient. These scores range from 0 to 100, and a higher score represents a clinically sicker transplant recipient.

In addition, the monitoring report showed increases in the distance to recover donor lungs from the donor hospital to the transplant center. Nationally, the median distance between the donor hospital and transplant center had a statistically significant increase, from 109 nautical

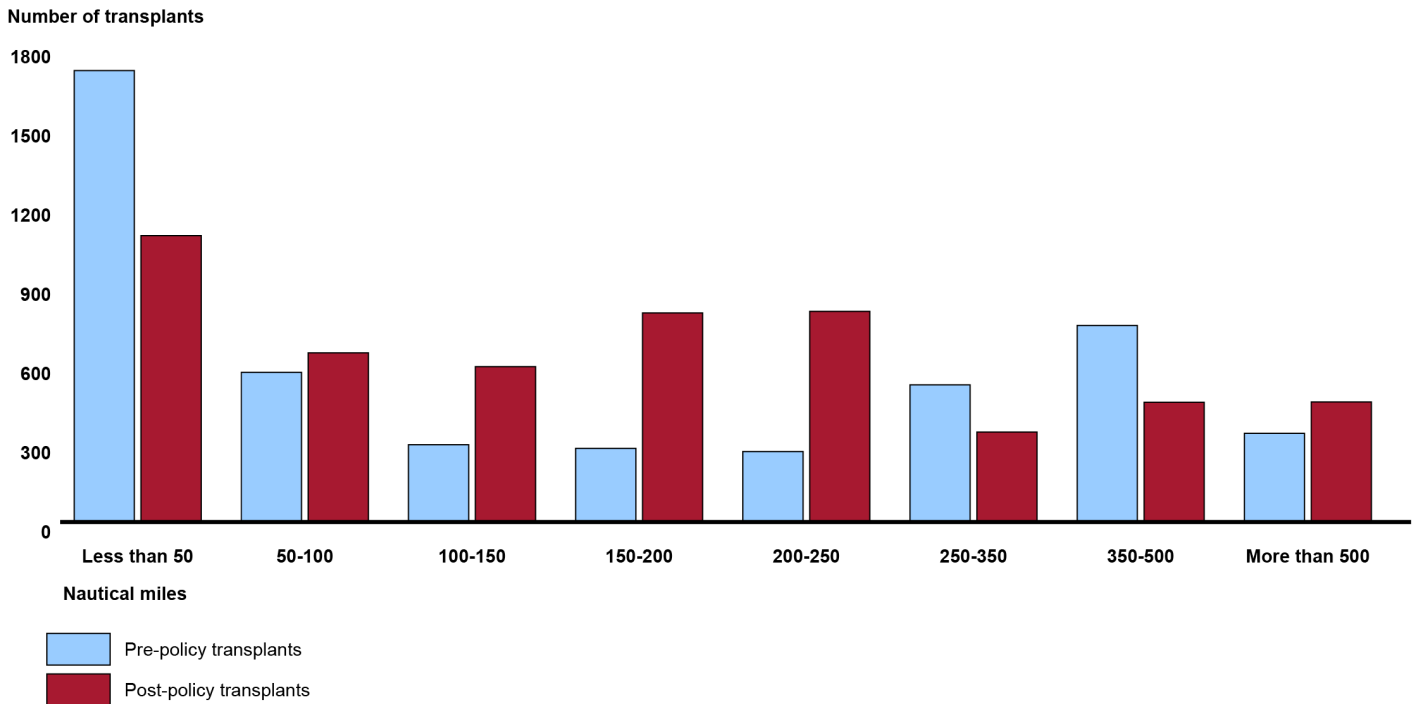
<sup>35</sup>It is not known whether any of the changes in the average lung allocation scores by OPTN region are statistically significant because comparisons of each of the 11 OPTN regions for the 2-year periods before and after the changes to the lung allocation policy were not performed or requested for the monitoring report, according to officials from the United Network for Organ Sharing.



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miles in the 2 years preceding implementation of the current lung allocation policy to 166 nautical miles in the 2 years following implementation of the current policy. Consistent with this change, the number of transplants within 50 nautical miles decreased. According to the monitoring report, the number of transplants varied for other distance groups (e.g., 50-100 nautical mile group and 200-250 nautical mile group). Figure 8 shows that the number of lung transplants increased nationally in the distance groups from 50 nautical miles to 250 nautical miles and over 500 nautical miles pre- and post-policy changes, but decreased in the other distance groups. Officials from the United Network for Organ Sharing told us that because DSAs (many of which are smaller than 250 nautical miles) were removed as units of allocation from the lung allocation policy and the first geographic unit of distribution was changed to 250 nautical miles, lungs were more uniformly distributed within 250 nautical miles of the donor hospital in the 2-year period following implementation of the current lung allocation policy. They added that a large number of lung transplants between 0-50 nautical miles is expected due in part to the fact that a lung may be donated at the same hospital, or a hospital very close to, where it is transplanted, based on the general distribution of organ recovery and transplant hospitals across the country.

**Figure 8: Number of Lung Transplants Nationally Pre- and Post-Policy Changes, by Distance Groups from Donor Hospital to Transplant Recipients in Nautical Miles**



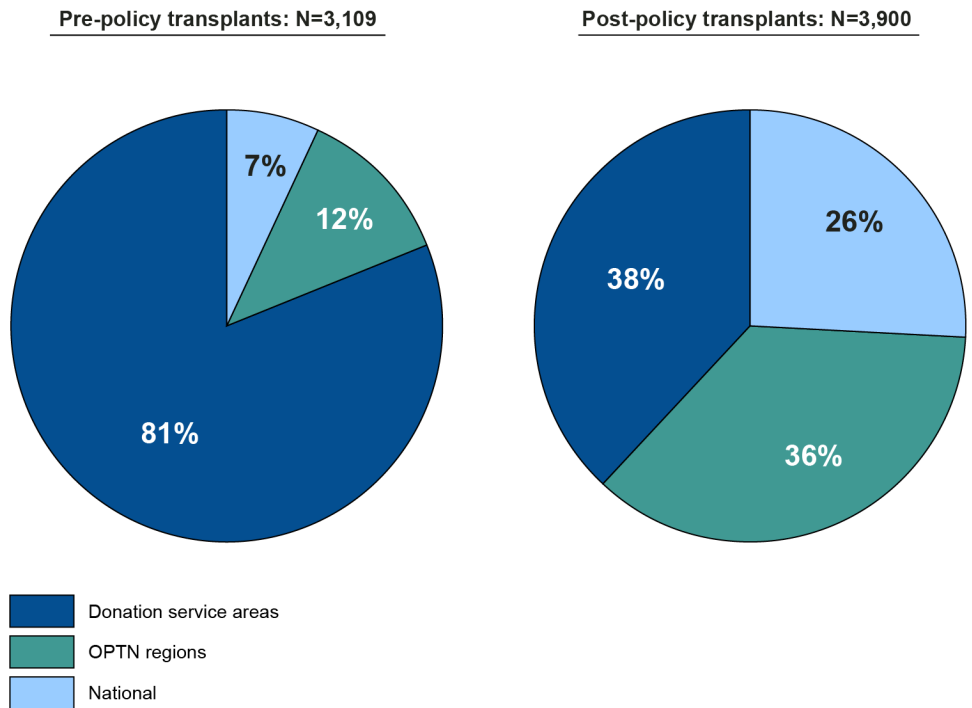
Source: Organ Procurement and Transplantation Network (OPTN). | GAO-21-70

Notes: The current lung allocation policy went into effect on November 24, 2017, at 8 p.m. Eastern Time. Pre-policy transplants refer to the number of lung transplants in the 2 years preceding implementation of the current lung allocation policy, which was November 26, 2015, through November 24, 2017. Post-policy transplants refer to the number of lung transplants in the 2 years following implementation of the current lung allocation policy, which was November 25, 2017, through November 24, 2019.

Each of the distance groups includes their upper limit but not their lower limit (unless the lower limit is 0), according to the United Network for Organ Sharing, which conducted these analyses for OPTN. For example, a distance of exactly 50 nautical miles would be in the 0-50 nautical mile group, a distance of 50.1 would be in the 50-100 nautical mile group, and a distance of 100 nautical miles would be included in the 50-100 nautical mile group.

The monitoring report also showed that for lung transplants performed within 250 nautical miles of the donor hospital (the first unit of allocation in the current lung allocation policy), the percentage of lungs transplanted outside of the DSA where the lung was recovered increased from a total of 19 percent before the policy change to a total of 62 percent after the policy change. The percentage of lungs transplanted nationally increased from 7 percent to 26 percent. (See fig. 9.)

**Figure 9: Percentage Distribution of Lung Transplants within 250 Nautical Miles Pre- and Post-Policy November 2017 Changes**



Source: Organ Procurement and Transplantation Network (OPTN). | GAO-21-70

Notes: The current lung allocation policy went into effect on November 24, 2017, at 8 p.m. Eastern Time. Pre-policy transplants refer to the percentages of lung transplants within 250 nautical miles of the donor hospital (the first unit of allocation in the current lung allocation policy) in the 2 years preceding implementation of the current lung allocation policy, which was November 26, 2015, through November 24, 2017. Post-policy transplants refer to the percentages of lung transplants within 250 nautical miles of the donor hospital in the 2 years following implementation of the current lung allocation policy, which was November 25, 2017, through November 24, 2019.

Other selected outcomes from the monitoring report showed that the number of lung transplants nationally increased from 4,709 in the 2 years preceding implementation of the current lung allocation policy to 5,147 in the 2 years following implementation of the current policy. In addition, the utilization rate (the rate at which lungs are transplanted from all deceased donors) was consistent, with little change before and after the policy changes at just over 22 percent. Further, the discard rate (the number of lungs that were discarded out of the total number of lungs recovered for the purpose of transplant) increased nationally from 5.5 percent before the policy changes to 6.5 percent after the changes. However, when excluding lung transplants using certain types of lungs with unclear or

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initially insufficient function—perfused lungs and lungs from donations after circulatory death—the discard rate remained stable.<sup>36</sup>

The monitoring report also examined outcomes for 6-month post-transplant survival nationally for recipients of lung-alone transplants and found that there was not a statistically significant difference in the 6-month survival for lung transplant recipients before and after the lung allocation policy changes.<sup>37</sup> Lung transplant recipients had a 93.5 percent 6-month patient survival estimate in the 2-year period preceding implementation of the current lung allocation policy and 93.2 percent in the period following implementation of the current policy.

Little is known about changes in spending following the change to the current lung allocation policy.<sup>38</sup> Of the 89 studies and other publications we reviewed, we identified one 2019 peer-reviewed personal viewpoint article that reported data on costs from January 1, 2017, to June 4, 2018, from one lung transplant program. This article compared information on the costs to recover donor lungs for 77 lung transplants prior to the implementation of the current lung allocation policy in November 2017 with the costs for 50 transplants in the first 6 months after implementation.<sup>39</sup> This article reported that the median cost to recover a lung for transplantation increased from \$34,000 to \$70,203 for this

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<sup>36</sup>Perfused lungs and lungs from donations after circulatory death are defined as lungs with unclear or initially insufficient function, and are sometimes referred to as marginal lungs. Lung transplants using perfused lungs and lungs from donations after circulatory death have increased in utilization since the lung allocation policy change, according to OPTN's 2-year monitoring report.

<sup>37</sup>Lung-alone transplants are transplants that are not in combination with another organ, such as a heart. The current lung allocation policy went into effect on November 24, 2017, at 8 p.m. Eastern Time. The 2-year period preceding implementation of the current lung allocation policy included recipients (age 12 and older) that received a lung-alone transplant from November 26, 2015, through November 24, 2017, and the period following implementation of the current lung allocation policy included recipients from November 25, 2017, through January 1, 2019. For this analysis, the period following implementation of the current lung allocation policy was limited to lung transplant recipients before January 1, 2019, to allow sufficient time to complete follow up, according to the OPTN 2-year monitoring report.

<sup>38</sup>We conducted a literature review of studies published from January 2017 through April 2020 in peer-reviewed journals and other publications.

<sup>39</sup>Organ costs included the organ acquisition charge from the organ procurement organization, cost of transportation by land or air, and administrative overhead charge by the local organ procurement organization when it had to coordinate organ import for organs procured from a distant organ procurement organization located in a different DSA. These costs do not include costs for lung transplants.

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transplant program. According to the article, this increase was to be expected given the decline in local lung transplants and higher transportation costs to procure lungs from greater distances. However, this information from one lung transplant program cannot be generalized to all lung transplant programs.

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## Agency and Third Party Comments

We provided a draft of this report to HHS for review and comment. HHS provided technical comments, which we incorporated as appropriate. In addition, we provided a draft report to the United Network for Organ Sharing for review and comment, and incorporated its technical comments, as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Secretary of Health and Human Services, appropriate congressional committees, and other interested parties. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or [cosgrovej@gao.gov](mailto:cosgrovej@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs are on the last page of this report. GAO staff who made major contributions to this report are listed in appendix III.



James Cosgrove  
Director, Health Care

# Appendix I: Timeline of Selected Actions Related to Organ Allocation Policies

This appendix presents information on selected actions related to organ allocation policies, including actions specific to changes in organ allocation policies for livers and lungs. The actions in table 2 are in chronological order and range from October 19, 1984, to February 4, 2020.

**Table 2: Timeline of Selected Actions Related to Organ Allocation Policies**

Action date	Action
10/19/84	The National Organ Transplant Act (NOTA) was enacted, which <ul style="list-style-type: none"> <li>prohibited the selling of human organs;</li> <li>established the Organ Procurement and Transplantation Network (OPTN) to ensure fair and equitable allocation of donated organs;</li> <li>established the Scientific Registry of Transplant Recipients to conduct an ongoing evaluation of the scientific and clinical status of organ transplantation; and</li> <li>provided for grants for the establishment, initial operation, and expansion of organ procurement organizations.</li> </ul>
9/30/86	The U.S. Department of Health and Human Services (HHS) awarded the first contract for the establishment and operation of OPTN to the United Network for Organ Sharing.
4/2/98	HHS issued the OPTN Final Rule, which established the regulatory framework for the structure and operations of OPTN.
3/16/00	HHS implemented the OPTN Final Rule, which requires OPTN to develop policies for the equitable allocation of organs. Such allocation policies must, among other things, <ul style="list-style-type: none"> <li>be based on sound medical judgment;</li> <li>seek to achieve the best use of donated organs;</li> <li>be designed to promote the efficient management of organ placement;</li> <li>not be based on the candidate's place of residence or place of listing, except as otherwise required; and</li> <li>include appropriate procedures to promote and review compliance.</li> </ul>
11/13/12	The OPTN Board of Directors (OPTN Board) approved a resolution stating that the existing geographic disparity in allocation of organs for transplant was unacceptably high, and directed the organ-specific committees to define the measurement of fairness and any constraints for each organ system by 6/30/13.
6/18/13	The OPTN Board implemented a revised liver allocation policy to broaden regional and national access for highly urgent liver candidates with a Model for End-Stage Liver Disease (MELD) score of 35 or higher, but allocation continued to be based primarily on donation service areas (DSA) and OPTN regions.
6/5/17-6/6/17	The OPTN Board approved the establishment of a National Liver Review Board to replace individual review boards in each of the 11 OPTN regions. The National Liver Review Board is a body established to promote consistency in assigning exception points to allocation scores of liver transplant candidates with special medical conditions.
7/31/17-10/2/17	The OPTN Liver Committee sought public comments on a proposed change to the liver allocation policy, which would enhance liver distribution.
10/10/17	The OPTN Liver Committee reviewed public comments collected from 7/31/17-10/2/17 on its proposal to revise the liver allocation policy and voted to advance a modified proposal to the OPTN Board.
11/16/17	HHS received a critical comment from a lung transplant candidate asking HHS to require OPTN to set aside the portions of the lung allocation policy that utilize DSAs.

**Appendix I: Timeline of Selected Actions  
Related to Organ Allocation Policies**

<b>Action date</b>	<b>Action</b>
11/19/17	The lung transplant candidate who submitted a critical comment to HHS on 11/16/17 filed a lawsuit in the U.S. District Court for the Southern District of New York, requesting the court require HHS to allocate donor lungs based on medical priority rather than DSAs. (Holman v. Hargan)
11/20/17	The district court ordered HHS to initiate an emergency review of the lung allocation policy and submit a report by 11/28/17 to address “whether and to what extent the policy will be changed and a timetable for the implementation of any change(s).” (Holman v. Hargan)
11/21/17	HHS’ Health Resources and Services Administration (HRSA) sent a letter to the OPTN President directing OPTN to comply with the court order to initiate an emergency review of the lung allocation policy and as a first step in responding to the 11/16/17 critical comment.
11/24/17	The OPTN Executive Committee reported to HRSA its conclusion that the lung allocation policy could be modified to replace DSAs as the first level of distribution with a 250 nautical mile circle around the donor hospital in order to be consistent with the OPTN Final Rule.
11/24/17	OPTN implemented and adopted the interim lung allocation policy changes effective at 8 p.m. Eastern Time on 11/24/17, with an expiration date of 11/24/18.
12/1/17	HHS received a critical comment from a liver transplant candidate asking HHS to require that livers from deceased donors be allocated to candidates based on medical priority and not on arbitrary geographical boundaries.
12/4/17-12/5/17	The OPTN Board approved a revised liver allocation policy (2017 liver allocation policy) that included DSAs and OPTN regions, but expanded the first unit of distribution to include candidates within the same DSA as a liver donor and those within 150 nautical miles of the donor hospital but in a different DSA. This liver allocation policy was never implemented.
12/4/17-12/5/17	OPTN announced the formation of the Ad Hoc Geography Committee to develop principles for the appropriate consideration of geography in organ allocation policies.
1/22/18-3/23/18	The interim lung allocation policy approved by the OPTN Executive Committee and adopted nationwide on 11/24/17 was distributed for public comment after the policy became effective.
5/30/18	HHS received a second critical comment from several liver transplant candidates, asserting that the use of DSAs and OPTN Regions in liver allocation policies was inconsistent with the OPTN Final Rule.
6/8/18	HRSA sent OPTN a letter seeking its views on the 5/30/18 critical comment challenging the liver allocation policy and whether the 2017 liver allocation policy was consistent with the National Organ Transplant Act and the OPTN Final Rule.
6/12/18	The OPTN Board approved the interim lung allocation policy, which was implemented on 11/24/17, as permanent policy.
6/13/18-11/15/18	Following the critical comment HHS received on 5/30/18 and HRSA’s 6/8/18 letter to OPTN to review the 2017 liver allocation policy, the full OPTN Liver Committee held 20 meetings from 6/13/18-11/15/18 to consider whether the use of DSAs and OPTN regions in the liver allocation policy was consistent with the National Organ Transplant Act and the OPTN Final Rule, and subsequently developed a proposal for a revised liver allocation policy that eliminated the use of DSAs and OPTN regions.
6/25/18	OPTN submitted to HRSA its opinion that DSAs are not a good proxy for geographic distance between donors and transplant candidates because of the disparate sizes and shapes of the DSAs, and OPTN noted similar problems with OPTN Regions. OPTN committed to adopting a revised liver allocation policy that eliminated DSAs and OPTN regions by December 2018.
7/13/18	The liver transplant candidates who submitted a critical comment to HHS on 5/30/18 filed a lawsuit in the U.S. District Court for the Southern District of New York, challenging the use of DSAs and OPTN regions as units of allocation in the liver allocation policy and contending that the then-current liver allocation policy and the 2017 liver allocation policy were inconsistent with the OPTN Final Rule. (Cruz v. Azar)

**Appendix I: Timeline of Selected Actions  
Related to Organ Allocation Policies**

<b>Action date</b>	<b>Action</b>
7/31/18	To address the 5/30/18 critical comment on the liver allocation policy and respond to OPTN's 6/25/18 opinion that DSAs are not a good proxy for geographic distance between donors and transplant candidates, HRSA sent a letter to OPTN directing it to adopt a liver allocation policy that eliminated the use of DSAs and OPTN Regions and was compliant with the OPTN Final Rule. HRSA also directed OPTN to submit a report outlining OPTN's plans to eliminate DSAs and OPTN regions from all other organ allocation policies.
8/13/18	OPTN responded to HRSA's 7/31/18 letter with its proposed plans to eliminate DSAs and OPTN regions from all organ-specific allocation policies.
10/8/18-11/1/18	OPTN circulated a liver allocation policy proposal for public comment that solicited input on the acuity circles and broader 2-circle frameworks. All comments were posted to the OPTN website and available to the public throughout the public comment period from 10/8/18-11/1/18. During this period, officials from the United Network for Organ Sharing, a government contractor that serves as OPTN, and OPTN Liver Committee leadership periodically shared updates with OPTN Liver Committee members on participation and themes observed from the comments submitted up to that date.
11/2/18	The OPTN Liver Committee met to discuss public comments collected from 10/8/18-11/1/18 and voted to recommend the broader 2-circle framework rather than the acuity circles framework as part of a revised liver policy with 11 members in favor of the broader 2-circle framework and 9 members in favor of the acuity circles framework.
12/3/18-12/4/18	The OPTN Board approved the revised liver allocation policy with the acuity circles framework, instead of the broader 2-circle framework that was presented earlier in the meeting by the OPTN Liver Committee. The OPTN Board voted 24 in favor and 14 in opposition of an amendment adopting the acuity circles framework. The OPTN Board voted on a few more amendments, and then voted on the policy package as a whole once all amendments were considered and voted upon. The final vote on the policy package as a whole (which included the acuity circles framework) was 30 in favor, 7 opposed, and 2 abstain.
12/3/18-12/4/18	The OPTN Board adopted the continuous distribution allocation framework as best suited for future policies for the geographic distribution of organs. The continuous distribution allocation framework distributes organs to candidates using a statistical formula that combines important clinical factors with proximity to the donor location so that candidates receive organs based on their relative distribution score. There is no absolute geographic boundary in this allocation framework.
2/13/19	HHS received a new critical comment from 10 liver transplant centers, asking that HHS set aside the revised liver allocation policy (using acuity circles) and work to expeditiously develop a new liver allocation policy.
3/14/19	HRSA requested that OPTN provide its views on issues raised in the 2/13/19 critical comment.
3/18/19-4/8/20	The OPTN Liver Committee's Acuity Circles Subcommittee held 7 meetings from 3/18/19-4/8/20 that focused on issues related to the revised liver allocation policy (using acuity circles) approved by the OPTN Board in Dec. 2018, including challenges associated with implementation, MELD at transplant calculations, local organ recovery guidance, and conducting a local organ recovery survey.
3/26/19	OPTN responded to HRSA's 3/14/19 letter concerning the 2/13/19 critical comment and found that the revised liver allocation policy (using acuity circles) adopted on 12/3/18 complied with the OPTN Final Rule.
4/22/19	Four liver transplant candidates and 14 transplant centers filed a lawsuit in the U.S. District Court for the Northern District of Georgia, alleging that HHS failed to follow legally required procedures in developing the revised liver allocation policy (using acuity circles) and instead deferred authority to the United Network for Organ Sharing. (Callahan v. Azar)
4/22/19	The plaintiffs filed a request for a temporary restraining order of the revised liver allocation policy (using acuity circles). (Callahan v. Azar)
4/23/19	HRSA responded to the 2/13/19 critical comment explaining that after careful review and correspondence about the revised liver allocation policy (using acuity circles), it determined that no further HHS actions were warranted.
5/13/19	The district court denied the plaintiffs' request for a temporary restraining order. (Callahan v. Azar)



**Appendix I: Timeline of Selected Actions  
Related to Organ Allocation Policies**

<b>Action date</b>	<b>Action</b>
5/14/19	The revised liver allocation policy (using acuity circles) was briefly implemented following the district court's denial of plaintiff's request for a temporary restraining order. (Callahan v. Azar)
5/14/19	The plaintiffs filed an appeal to the U.S. Court of Appeals for the 11th Circuit, requesting review of the district court's denial of the plaintiffs' request for a temporary restraining order. (Callahan v. Azar)
5/15/19	The district court imposed a stay on implementation of the revised liver allocation policy (using acuity circles) pending the appeal to the 11th Circuit. (Callahan v. Azar)
5/23/19	The previous liver allocation policy (using DSAs) was reinstated and went into effect pending the 11th Circuit's review of the plaintiffs' appeal. (Callahan v. Azar)
8/16/19	The parties agreed to delay implementation of the revised liver allocation policy (using acuity circles) until at least 14 days after the earliest of (1) the district court issuing an order lifting its 5/15/19 stay, (2) the 11th Circuit issuing a mandate in the appeal, or (3) the 11th Circuit issuing an order dissolving the stay pending the appeal. (Callahan v. Azar)
9/25/19	The 11th Circuit affirmed in part and remanded in part the district court's denial of plaintiffs' request for a temporary restraining order. (Callahan v. Azar)
12/3/19	The parties agreed to delay implementation of the revised liver allocation policy (using acuity circles). (Callahan v. Azar)
12/11/19	The plaintiffs renewed their request for a temporary restraining order of the revised liver allocation policy (using acuity circles). (Callahan v. Azar)
1/16/20	The district court denied plaintiffs' renewed request for a temporary restraining order. (Callahan v. Azar)
2/4/20	The revised liver allocation policy (using acuity circles) was reimplemented.

Source: GAO. | GAO-21-70

Note: Any interested individual or entity may submit to the Secretary of Health and Human Services critical comments related to the manner in which OPTN is carrying out its duties. See 42 U.S.C. § 274(c) and 42 C.F.R. § 121.4(d) (2019).

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# Appendix II: Data on Outcomes from 2-Year Monitoring Report following Changes to Lung Allocation Policy

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This appendix presents data from the Organ Procurement and Transplantation Network's (OPTN) monitoring report following the changes in the current lung allocation policy that went into effect on November 24, 2017, at 8 p.m. Eastern Time. This monitoring report examined changes in health outcomes in the 2-year period before the policy changes and the 2-year period after the policy changes.<sup>1</sup> Table 3 shows outcomes related to candidates on the waiting list, transplant recipients, and the percent of donor lungs used for transplants before and after the policy changes, by OPTN region.<sup>2</sup> Table 4 shows the number of lung transplant recipients nationally by groups of Lung Allocation Scores before and after the policy changes.<sup>3</sup>

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<sup>1</sup>OPTN Thoracic Transplantation Committee, *Monitoring of the Lung Allocation Change, 2 Year Report: Removal of DSA as a Unit Of Allocation*, accessed June 18, 2020, [https://optn.transplant.hrsa.gov/media/3661/item\\_25\\_thoracic\\_committee\\_20200212.pdf](https://optn.transplant.hrsa.gov/media/3661/item_25_thoracic_committee_20200212.pdf).

<sup>2</sup>There are 11 OPTN regions in the United States; each region includes two or more states.

<sup>3</sup>Lung Allocation Scores are a measure of the level of illness of a lung transplant candidate or recipient. These scores range from 0 to 100, and a higher score represents a clinically sicker transplant candidate or recipient.

**Appendix II: Data on Outcomes from 2-Year  
Monitoring Report following Changes to Lung  
Allocation Policy**

**Table 3: Outcomes following Changes to the Lung Allocation Policy by OPTN Region**

Pre-policy changes period: 11/26/15 - 11/24/17

Post-policy changes period: 11/25/17 - 11/24/19

Outcomes	OPTN region		Candidates on the waiting list			Transplant recipients		Use of deceased donor lungs for transplants		
			Number of candidates added	Average Lung Allocation Score at listing for candidates added <sup>a</sup>	Median Lung Allocation Score at listing for candidates added	Number of transplants	Average Lung Allocation Score at time of transplant	Median Lung Allocation Score at time of transplant	Utilization rate <sup>b</sup> (%)	Discard rate <sup>c</sup> (%)
1	Pre		202	41.50	36.86	208	44.78	38.77	22.93	2.75
	Post		195	43.46	36.55	164	51.10	43.71	18.48	6.64
2	Pre		995	44.01	37.90	746	50.38	42.19	20.57	14.59
	Post		1,061	45.50	38.30	862	52.33	43.41	22.62	14.76
3	Pre		566	43.45	37.66	479	47.53	40.12	19.70	6.11
	Post		606	44.77	37.86	522	49.35	40.42	20.55	6.64
4	Pre		665	41.60	37.72	588	43.17	38.82	25.34	2.53
	Post		658	44.04	38.40	554	46.65	40.07	24.34	3.72
5	Pre		928	43.15	38.34	770	48.06	42.14	24.66	2.47
	Post		1,028	44.77	38.88	808	50.38	42.87	22.62	2.84
6	Pre		113	39.22	35.95	106	44.03	40.42	16.24	1.59
	Post		152	39.69	35.58	109	44.89	39.31	16.50	2.30
7	Pre		454	42.97	37.24	376	46.14	38.58	24.63	5.51
	Post		480	45.56	40.06	367	52.43	44.80	21.94	6.86
8	Pre		327	20.73	32.24	276	43.56	37.25	25.09	1.82
	Post		351	34.37	34.96	333	43.08	37.22	24.48	5.13
9	Pre		206	45.97	41.86	139	57.92	48.55	13.06	8.68
	Post		449	46.33	41.33	294	57.06	50.66	16.92	4.66
10	Pre		706	43.89	36.50	596	47.11	39.0	24.22	4.55
	Post		781	44.24	37.57	634	48.27	40.02	26.22	7.77
11	Pre		462	44.17	39.38	425	47.76	42.27	23.72	6.32
	Post		563	44.95	39.90	500	49.19	42.61	23.74	5.97

Source: Organ Procurement and Transplantation Network (OPTN). | GAO-21-70

Notes: The current lung allocation policy went into effect on November 24, 2017, at 8 p.m. Eastern Time. There are 11 OPTN regions in the United States, which include two or more states.

<sup>a</sup>Lung Allocation Scores indicate the level of illness for a lung transplant candidate or recipient, and range from 0 to 100. A higher score represents a clinically sicker candidate or recipient.

<sup>b</sup>The utilization rate is the rate at which lungs are transplanted from all deceased donors.

**Appendix II: Data on Outcomes from 2-Year  
Monitoring Report following Changes to Lung  
Allocation Policy**

°The discard rate is the number of lungs that were discarded out of the total number of lungs recovered for the purpose of transplant.

**Table 4: Number of Lung Transplants by Lung Allocation Score Groups, Nationally**

Pre-policy changes period: 11/26/15 - 11/24/17

Post-policy changes period: 11/25/17 - 11/24/19

Policy period	Total number of lung transplants <sup>a</sup>	Lung Allocation Score groups <sup>b</sup>							
		<20	20 - 30	30 - 35	35 - 40	40 - 50	50 - 60	60 - 70	70 and higher
Pre	4,709	3	2	1,186	1,136	1,122	409	157	694
Post	5,147	0	2	1,124	1,111	1,208	500	273	929

Source: Organ Procurement and Transplantation Network. | GAO-21-70

Notes: The current lung allocation policy went into effect on November 24, 2017, at 8 p.m. Eastern Time.

<sup>a</sup>These numbers represent lung transplant recipients who did not receive a lung transplant in combination with another organ, such as a heart.

<sup>b</sup>Lung Allocation Scores indicate the level of illness for a lung transplant candidate or recipient, and range from 0 to 100. A higher score represents a clinically sicker candidate or recipient.

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# Appendix III: GAO Contact and Staff Acknowledgments

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## GAO Contact

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## Staff Acknowledgments

In addition to the contact above, Kim Yamane (Assistant Director), Lisa A. Lusk (Analyst-in-Charge), Sam Amrhein, Sonia Chakrabarty, Kaitlin Farquharson, Sarah Gilliland, and Fatima Sharif made key contributions to this report.

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## Strategic Planning and External Liaison

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