

# The Donation and Transplant Community Perspective: Let Our Voice be Heard

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**CUTTING EDGE** OF TRANSPLANTATION

**TRANSPLANT SUMMIT 2020**  
BALANCING EQUITY AND UTILITY IN THE FACE OF AN ORGAN SHORTAGE

# Disclosures

- I was assigned this specific topic for the debate
- My goal is to have a system that works
- Vested interest in transplant on a personal level
  - College roommate
  - Best friend's daughter
- I am a transplant hepatologist
  - I have biases and potential conflicts of interest like everyone else
  - My guiding principle is to minimize biases to achieve the best solution
  - Goal for our system should be minimize biases as much as possible
- Funded by NIDDK R01: DK120561; Using Ethics, Epidemiology and High-Quality Data to Optimize the Allocation of Livers for Transplantation
- Previously funded by NIDDK K08: DK098272; A Population-Based Cohort to Study Outcomes in End-Stage Liver Disease Patients
- Other research support (unrelated to topic): Gilead, Merck, AbbVie



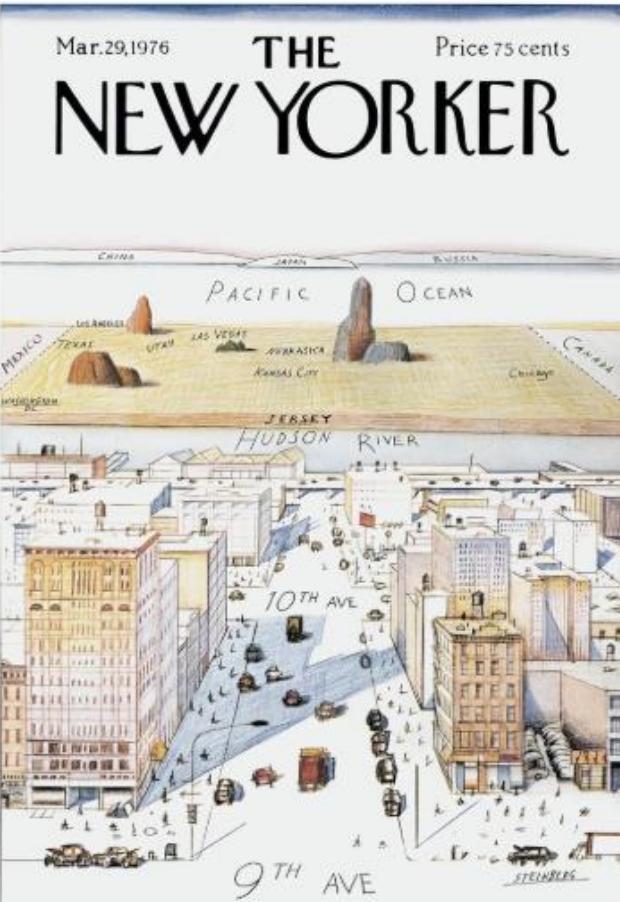
# What is the OPTN

- Public-private partnership that links all professionals involved in the U.S. donation and transplantation system
- Goals are to
  - Increase the number of and access to transplants
  - Improve survival rates after transplantation
  - Promote patient safety and efficient management of the system

The screenshot shows the official website of the Organ Procurement and Transplantation Network (OPTN). The top navigation bar includes links for Home, Governance, Members, Learn, Data, News, Resources, and Contact Us. The main content area is titled "About the OPTN". It features a brief introduction, a "Policy Initiatives" section with links to Strategic Plan, Policies, and Policy Notices, and a "Public Comment" section. A sidebar on the right provides information about the OPTN's history, its role as a public-private partnership, and its relationship with the U.S. Department of Health and Human Services (HHS). The sidebar also lists the OPTN's contractors: United Network for Organ Sharing (UNOS) and the Scientific Registry for Transplant Recipients (SRTR).



Is there a pr



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- Taking a 20,00

in a bad situation

# Is there a problem that needs to be fixed?



Sections

The Washington Post  
*Democracy Dies in Darkness*

Health

## Federal judge allows new liver transplant policy to take effect



VIDEO

LIVE

SHOWS

2020 ELECTIONS



## Some hospitals wary as new liver transplant rules begin

*Long-delayed rules that will more broadly share scarce donated livers go into effect Tuesday*

By LAURAN NEERGAARD AP Medical Writer

February 3, 2020, 5:30 PM • 4 min read



ON

# Is there a problem that needs to be fixed?

Monday, February 10, 2020 | Today's Paper

The Philadelphia Inquirer

Unlimited Access Log In



ALL SECTIONS



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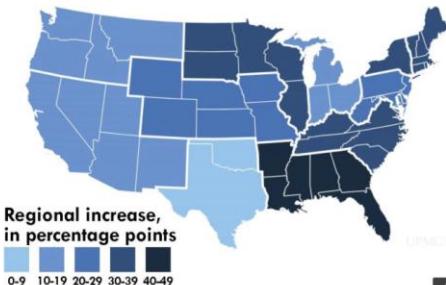
StarTribune

NEWS SPORTS BUSINESS OPINION POLITICS ENTERTAINMENT LIFE FOOD HEALTH REAL ESTATE OBITUARIES JOBS

**Heart-transplant rules meant to save more children haven't worked as hoped, study finds**

by Tom Avril, Updated: September 30, 2019

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LOCAL

**Deaths increase under new heart donor system, University of Minnesota-led research team finds**

New guidelines aimed to rush hearts to sickest patients and reduce wait times.

By Jeremy Olson Star Tribune | NOVEMBER 21, 2019 — 4:19PM

AST | AMERICAN SOCIETY OF TRANSPLANTATION



CUTTING EDGE of TRANSPLANTATION

# Recent missteps in policy development: KAS

- Kidney Allocation System (KAS)
  - Goal: Change allocation to prioritize disadvantaged groups and focus on utility for ‘best’ kidneys
- Successes:
  - Improved equity for some (e.g., minorities)
  - Improved access for sensitized patients
  - Better donor-recipient longevity matches
- Missteps
  - Increased discards according to UNOS analysis<sup>1</sup>
  - Decreased access to pediatric kidneys among pediatric recipients: “**This represents the flawed application of an adult donor metric to pediatric donors, for whom the KDPI was neither derived nor tested**”<sup>2</sup>
- Could this have been avoided under a different policymaking process?
  - My answer: Possibly

1-Stewart D, Klassen D. CJASN 2017; 12(12): 2063-2065; 2-Nazarian S, et al. AJT 2018; 18: 574-579

# Recent missteps in policy development: Lung

- 2017: Change from DSA-first to sharing by circles (response to lawsuit)
- Problem 1: National discard rate increased (OPTN thoracic committee)<sup>1</sup>
- Problems 2-4: Single-center/OPO data (Wash U)<sup>2</sup>
  - Decreased local utilization
  - Increased ischemic time
  - Doubling costs donor organs
- Could this have been avoided under a different policymaking process?
  - My answer: Yes

1-OPTN Thoracic Transplantation Committee. Monitoring of the Lung Allocation Change, 1 Year Report. 2-Puri V, et al. AJT 2019; 19(8): 2164-2167



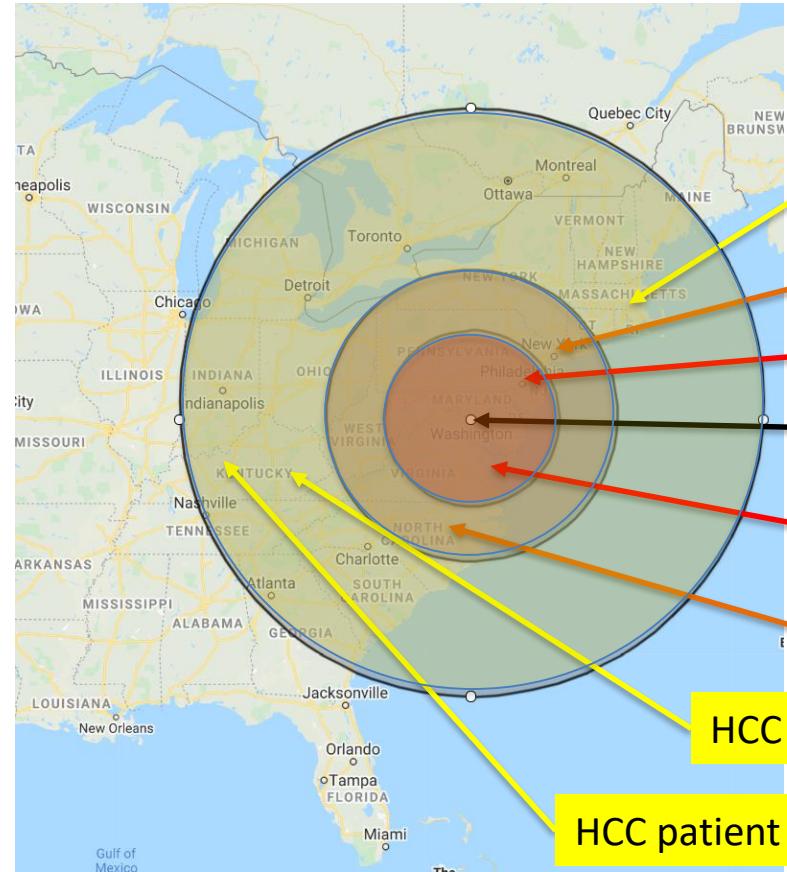
# Recent missteps in policy development: Heart

- Change distribution and allocation in 2018
  - Distribution: Changed geographic units of sharing
    - DSA->circles
  - Allocation: Changes in waitlist prioritization
    - Super-sickest receive the highest priority (e.g., ECMO)
- Problems
  - Increased cold ischemic time<sup>1</sup>
  - Plummeting post-transplant outcomes: 6-month survival decreased from **93.4%->77.9%**<sup>1</sup>
- Could this have been avoided under a different policymaking process?
  - My answer: Yes

1-Cogswell R, et al. Journal Heart Lung Transplant 2020; 39(1): 1-4

# Recent missteps in policy development: Liver

- Acuity Circles began 2/4/2020
- Allocation circles based on distance from donor hospital: 150, 250, and 500 nautical miles
- MELD thresholds: 37-40, 33-36, 29-32, 15-28, <15
- Exception points based on MMAT-3 from transplant hospital



HCC patient in Boston: 28 MELD exception points

HCC patient in NYC: 28 MELD exception points

HCC patient in Philadelphia: 27 MELD exception points

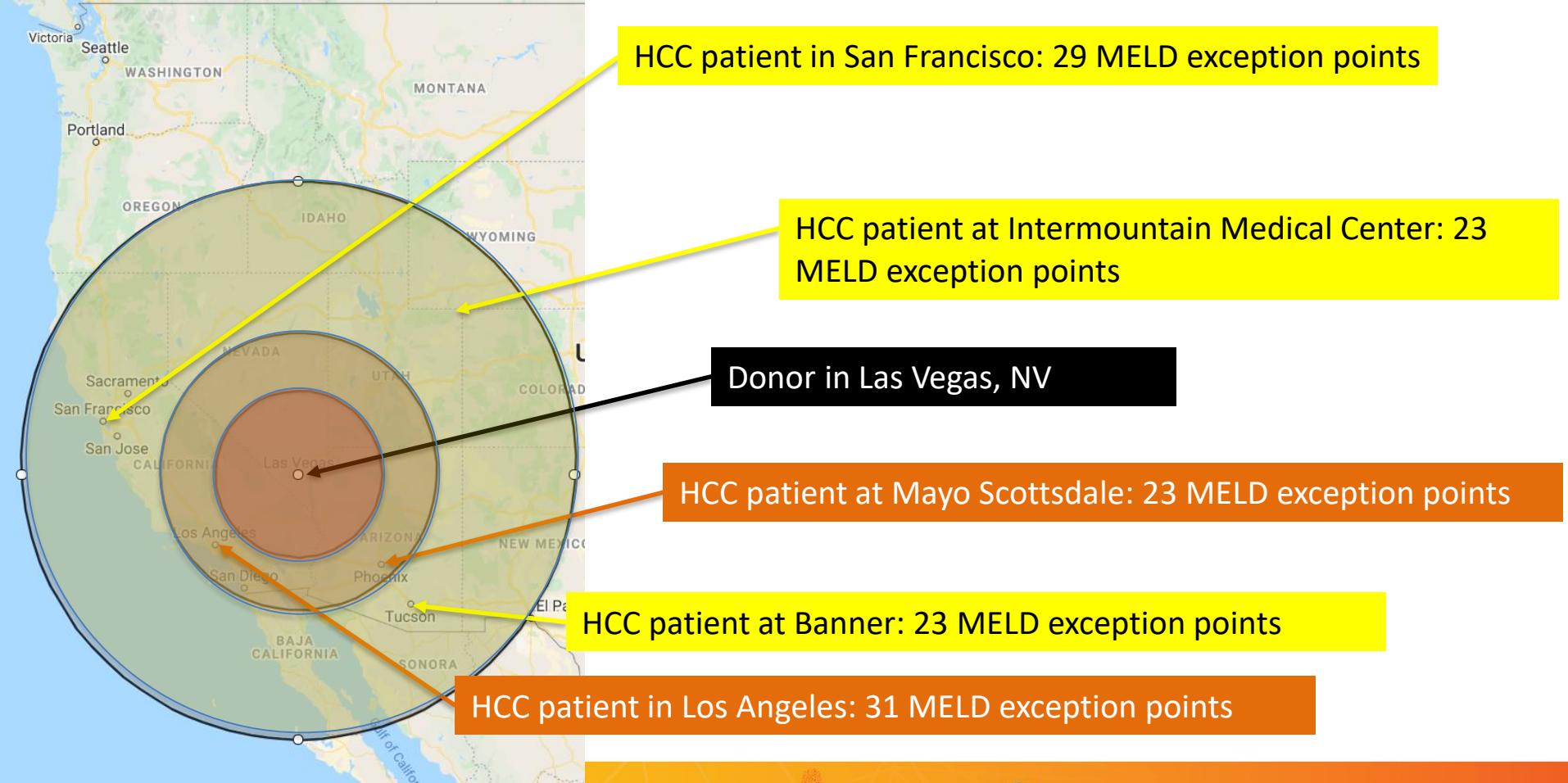
Donor in Washington, DC

HCC patient at UVA: 25 MELD exception points

HCC patient at Duke: 25 MELD exception points

HCC patient in Lexington, KY: 24 MELD exception points

HCC patient in Lexington, KY: 25 MELD exception points



# Starting point—some rules we cannot change

- Designing a new system of policy making has some constraints
- NOTA and Final Rule
  - Established regulatory framework for operations of OPTN
    - Have a Board of Directors
      - Representatives of OPOs, transplant centers, voluntary health associations, and the general public
      - Not less than 34 nor more than 412 members
      - Have an executive committee and other committees
- HRSA/HHS Oversight

# Starting point—where flexibility is allowed

- Process of choosing committee members
- Process of choosing committee leadership
- Impact of public comment and regional votes
- Transparency of process

# Possible roots of the problem

- Lack of transparency
- Committee selection and composition
- Will of the people ignored: Public comments and regional meetings
- Insufficient independent external input
- Process slow to adapt (moving forward or going back)
- Governmental overreach
- Caveat
  - Cannot prove that my proposed process would avoid missteps
  - At very least would increase transparency
  - System fails if we can't maintain public trust

# OPTN/UNOS Policy Development Process

1. Committees analyze the problem as well as any potential solutions to identify the best solutions for the problems facing the transplant community
2. Committee proposal released to the community through public comment
  - OPTN holds regional, in-person meetings throughout the country during this time
    - Allows community to convene, discuss, and comment on proposals
    - Feedback is utilized by the Board and committees to refine proposed solutions to best address the problems facing the transplant community.
3. Once the committees agree upon their proposed solutions, they are reviewed and approved by Policy Oversight Committee
4. Finally reviewed and voted upon by the OPTN Board of Directors



# Documented issues with transparency and behind the scenes decision making

- Conclusion of Judge Amy Totenberg, 11<sup>th</sup> Federal District Court
  - “But this is a difficult and wrenching case. As the Court has recognized from the outset, **there are extraordinarily complex and compelling issues raised by the conflicts at the heart of organ transplant litigation**. Unfortunately, the **manner in which the liver transplant policy change was driven in this case made the capacity of the affected institutions to effectively and preemptively address these complexities and policy tensions together all the more difficult**. Acrimony boiled over under these circumstances.”<sup>1</sup>

Opinion, Judge Amy Totenberg, US District Judge, 1/16/2020

# OPTN bylaws for standing committee assignments

- Standing committee membership (some exclusions)
  - Step 1: Regional councilor receives nominations
  - Step 2: UNOS Vice President appoints committee members from list of nominees
  - Committee Chair and Vice-Chair: Selected by UNOS Vice-President
  - Vice President can appoint person to >1 standing committee
- Policy oversight committee
  - Vice Chairs of each Committees or representative of each Committee
  - Chair and Vice Chair appointed by vice president
  - Current representation among 21 voting members: Region 1 (6), Region 4 (4), Region 2, 7, 9, 10 (1 total)
- Nominating committee
  - Appointed by the president
  - No more than 12 voting members
  - Includes: President, Immediate Past president, Past president directly preceding the Immediate Past president, Vice president

# Public involvement in policymaking

- Committee proposal released to the community through public comment
  - Usually 2-month period of public comment
- OPTN holds regional meetings throughout the country during this time
  - Allows community to convene, discuss, and comment on proposals
  - Feedback is utilized by the Board and committees to refine proposed solutions to best address the problems facing the transplant community.

# Limited role of public feedback in policymaking: Liver distribution a case study

- Optimal disparity rule majority at 2014 OPTN
- Regional meetings
  - Acuity circles: 4 regions
  - B2C: 7 regions (2)
  - OPTN/UNOS Pre-emptive rule “They’re not binning us”
- Liver Committee votes
- Limited time to review policy changes Totenberg, 1/16/2020

11/1/2018 11:10 p.m.	UNOS policy analyst, circulates a spreadsheet with 1,200 public comments, which Plaintiffs have fairly characterized as “virtually unreadable.”	HHS_oooo01544, HHS_oooo01146
11/2/2018 8:30 a.m.	Liver and Intestine Committee meeting votes on policy, less than 24 hours after close of public comment period.  Seventeen comments from major institutions submitted through the public comment email were not provided to committee members.  Liver and Intestine Committee recommends that the OPTN Board support committee’s	HHS_oooo01542  HHS_oooo08952

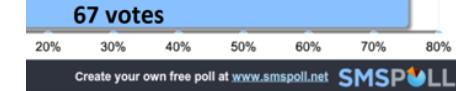
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Case 1:19-cv-01783-AT Document 261 Filed 01/16/20 Page 14 of 100

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D score at transplant.  
ill is currently stopped

94 votes



recommendation for the Broader 2 Circle policy (B2C) as opposed to Acuity Circles policy (AC).

# Independent external input: Role of the SRTR

- Scientific Registry of Transplant Recipients (SRTR)
  - PHS Act requires the operation of SRTR to support ongoing evaluation of the scientific and clinical status of solid organ transplantation
  - Mission: To provide advanced statistical and epidemiological analyses related to solid organ allocation and transplantation in support of the Department of Health and Human Services and its agents in their oversight of the national organ transplantation system.
- SRTR Senior Staff
  - Liver transplant surgeon
  - 2 transplant hepatologists
  - 2 transplant nephrologists
  - Transplant cardiologist
  - Transplant pulmonologist
- Policy oversight committee: 3 members of SRTR staff

# Process of adapting to problems or responding to unintended consequences of policies

- OPTN bylaws for “Ongoing Policy Review”

The screenshot shows a news article from NBC News. The top navigation bar includes categories: NEW HAMPSHIRE PRIMARY, IMPEACHMENT, CORONAVIRUS, U.S. NEWS, OPINION, BUSINESS, WORLD, HEALTH, and SPORTS. Below the navigation is a headline in bold white text: "Lost luggage: How lifesaving organs for transplant go missing in transit". A subtext below the headline reads: "Scores of organs – mostly kidneys – are trashed each year and many more become critically delayed while being shipped on commercial airliners." The overall background is dark blue.

HEALTH NEWS

## Lost luggage: How lifesaving organs for transplant go missing in transit

Scores of organs – mostly kidneys – are trashed each year and many more become critically delayed while being shipped on commercial airliners.

- UNOS began tracking transportation errors in 2016 for organs



# Governmental overreach

- 12/2017: OPTN/UNOS Board of Directors approves new liver distribution policy that was DSA + 150 miles

12/3/2018	OPTN/UNOS Board meeting. HRSA representatives attending the meeting reiterate to the Board HHS's position that DSAs and Regions do not meet the requirements of the Final Rule.	HHS_00009374
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# How to let the donation and transplant community's voices be heard

- Improve transparency
- Change process of committee assignments
- Increase weighing of public input into policymaking
- Get independent external input
- Be able to rapidly response to change/adapt
- Limit governmental over-reach



# Change #1: New process of policy making

- Goals
  - Improve transparency
  - Increase weighting of public input
  - Ensure independent external input
- Step 1: Developing and moving a policy through an organ-specific committee (OPTN House of Representatives)
  - Committee member can develop idea for a policy
  - Policy idea gets discussed in subcommittee
  - Subcommittee refines and discusses merits of a bill
  - Subcommittee releases policy idea to committee
  - Committee discusses policy, amends, and votes (majority)

# Change #1: New process of policy making

- Step 2: Policy moves to committee of councilors (OPTN Senate)
  - 11 Regional Councilors
  - OPO Representative(s)
  - General public representatives
  - Other representatives
  - Policy discussed, debated, and amended in collaboration with organ-specific committee (requires majority vote)
- Step 3: Policy sent out for Public Comment and Regional Meetings
  - Must obtain >50% of the ‘popular’ vote
  - Must be approved by ≥6 OPTN regions
- Step 4: Policy reviewed by independent external body
- Step 5: Policy presented to Board of Directors
  - Policy approved by simple majority



# Change #2: Revise process of committee membership and leadership

- Need broader representation and transparency in process
- Committee assignments chosen democratically at regional meetings
- Self-nominations or nominations by others
  - Nominees briefly state case for their position at regional meeting
  - 1 center-1 vote
  - Liver committee: Each liver center in region has 1 vote for who should be committee
- Committee chairs and vice chairs: Voted on by committee
- Other committees (e.g., OPO)
  - Chosen by organization (AOPO)
  - Other patient groups
- Policy oversight committee: Equal representation for every region
- Guiding principle (adapted from Chief Justice Roberts): "We do not have Region 1 Committee Members or Region 3 Committee Members, Region 9 Committee Members or Region 11 Committee Members. What we should have is an extraordinary group of dedicated committee members doing their level best to do equal right to those appearing before them."



# Change #3: Develop independent external oversight committee of experts

- Government Accountability Office (GAO)
  - Independent, nonpartisan agency that works for Congress to examine how taxpayer dollars are spent and provides objective, reliable information to help the government save money and work more efficiently
- Congressional Budget Office (CBO)
  - Produce independent analyses of budgetary and economic issues to support the Congressional budget process; strictly nonpartisan

# Change #3: Develop independent external oversight committee of experts

- OABO (Oversight and Accountability Board)
  - Independence
    - Non-clinician
    - Non-financial
  - Inclusion
    - Clinicians
    - Researchers
    - Patients
    - Payors
    - Other stakeholders
  - Limitations
    - Not to exceed 10 members
    - Not to exceed 10 meetings per year
    - Not to exceed 10 days per year
    - Not to exceed \$100,000 per year
- Chaired by non-clinician and expert not involved in clinical care



# How will we judge if my system is working

- John Lydgate, “You can please some of the people all of the time, you can please all of the people some of the time, but you can’t please all of the people all of the time.”
- Goals of the OPTN
  - Increase the number of and access to transplants
  - Improve survival rates after transplantation
  - Promote patient safety and efficient management of the system

# How will we judge if my system is working

- Feedback from stakeholders: Do they feel included? Do they feel voice matters?
- Process review: Is policy process being followed? Is public feedback being heard?
- Committee structure: Is there appropriate representation? Are new voices given opportunity to participate in process?
- How are policies working?
  - Do predicted outcomes match observed outcomes
  - Are we ensuring no policy
    - Limits the number of transplants
    - Limits access
    - Increases discards
    - Decreases utility
    - Increases inefficiency without other gains

# Phoenix Address

- These missteps in OPTN policy development shall not have occurred in vain—that this OPTN, under HHS, shall have a new birth of freedom—and that OPTN of the donation and transplantation community, by the donation and transplantation community, for the donation and transplantation community, shall not perish from the current structure of transplant policymaking in the US.