



# The MTN Minute

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**February 2021**

## **A Message from the Editor**

Hello, readers, and happy new year,

January represents the beginning of a new year, a new legislative session and the upcoming implementation of new regulations governing organ procurement organization (OPO) performance outcomes. While there is much to look forward to in 2021, this newsletter provides a summary of an exciting yet challenging 2020.

I am happy to share that Midwest Transplant Network's (MTN's) legislative and lobbying activities have continued to thrive in a virtual format, despite the pandemic. President/Chief Executive Officer Jan Finn and I have scheduled and attended 10 virtual meetings with federal senators, representatives and their staffers who serve western Missouri and Kansas since summer 2020. I have also engaged with countless Kansas and Missouri lawmakers and key governmental affairs contacts via phone and email at regular intervals throughout the fall session. During video meetings with federal legislators and their staffers, we discussed the importance of Centers for Medicare & Medicaid Services (CMS) implementing standardized, reliable OPO performance metrics and emphasized the construction of MTN's Donor Care and Surgical Recovery Unit.

Specifically, we informed legislators about the importance of removing archaic language from existing regulations that acts as a financial disincentive to transplant programs that would otherwise welcome the opportunity to free up hospital beds and operating room schedules by transferring donors for organ recovery in MTN's forthcoming Donor Care and Surgical Recovery Unit. In

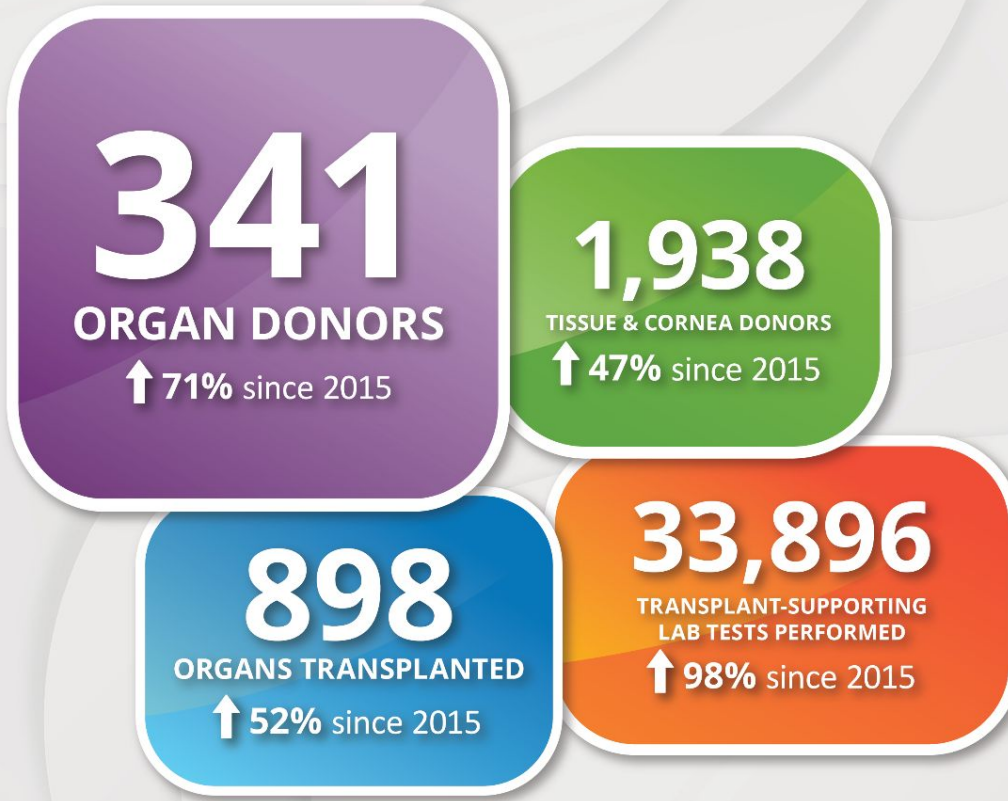
December 2020, MTN and many OPOs nationwide heavily lobbied senators to have a legislative fix to this issue incorporated into the end-of-the-year spending bill, and while this project was ultimately unsuccessful, the Appropriations Committee included language in its Explanatory Statement strongly urging “CMS to remove the disincentive for Medicare Certified Transplant Centers to transfer their braindead patients to organ recovery centers operated by organ procurement organizations without a financial penalty.”[\[1\]](#) We will continue renewed efforts to achieve a legislative fix in 2021. We look forward to cultivating MTN’s productive relationships with current legislators and establishing ties with newly elected senators and representatives in 2021.

I would be remiss not to highlight a record-breaking year for donation nationally, despite the challenges and tragedies of 2020. Across the country, organ donation experienced a 6% increase, and organ transplants from deceased donors also increased by an impressive 3%; even more exciting, 5,725 living donor transplants occurred in 2020, even though many transplant programs temporarily deferred living donor transplantation in areas particularly affected by COVID-19 outbreaks to avoid unnecessarily exposing potential living donors and recipients to possible infection.[\[2\]](#)

MTN’s excellent performance in 2020 directly contributed to the remarkable nationwide statistics. In fact, MTN broke records of its own in 2020 in almost every sector of its operations. MTN recovered 341 organ donors in 2020, the highest number ever — and an increase of 21% from 2019 — and these donors enabled 898 lifesaving transplants. MTN recovered tissues and corneas from 1,938 donors, another record number. Finally, MTN’s laboratory integrated new technology into its operations, began COVID-19 testing on donors and outpaced its previous records by performing 33,896 tests in 2020. These achievements were only possible because of the hard work of MTN’s dedicated staff members and partners. See the graphic below for a historical snapshot of how far MTN has come since 2015.

# THE IMPACT OF ORGAN, EYE & TISSUE DONORS

From the MTN Service Area in 2020\*



\* Based on MTN data as of Jan. 11, 2021. Data subject to change based on future data submission or correction.

MTN continues with an eye forward to breaking more records in 2021 and eagerly awaits the completion its Donor Care and Surgical Recovery Unit in the summer of 2022.

[1] Senate Appropriations Committee. Explanatory Statement for Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, retrieved Jan. 2, 2021, from <https://www.appropriations.senate.gov/imo/media/doc/LHHSRept.pdf> p. 141.

[2] OPTN. Annual record trend continues for deceased organ donation, deceased donor transplants. *Optn.transplant.hrsa.gov*. Retrieved Jan. 13, 2021, from <https://optn.transplant.hrsa.gov/news/annual-record-trend-continues-for-deceased-organ-donation-deceased-donor-transplants/>



## MTN Staff Members Receive Vaccinations

Initially, obtaining vaccinations for MTN's front-line clinical staff posed a daunting task, because the Centers for Disease Control and Prevention's (CDC's) COVID-19 Provider Enrollment and Provider Profile Form did not include an OPO option to select as a Phase I approved provider. Further, approved providers would have a minimum order requirement of 975 vaccines — far beyond the amount necessary for MTN, a 200+ employee organization. Unsurprisingly, many OPOs across the country faced similar hurdles in obtaining vaccinations for front-line staff and began reaching out to state health departments and hospital organizations to request assistance in obtaining vaccinations. The Association of Organ Procurement Organizations (AOPO) organized lobbying efforts directed at state health departments and officials by crafting a letter that OPO CEOs and lobbyists could send to their state and hospital contacts.

Luckily, lobbying efforts were unnecessary to obtain initial vaccinations for MTN's front-line staff due to the incredible relationships established by MTN's leadership and Hospital Services staff members. Happily, about 90% of MTN's front-line staff have elected to receive their initial COVID-19 vaccination. Wyandotte and Sedgwick county health departments in Kansas graciously shared vaccines with MTN in thanks for the services MTN provides to their county residents and hospitals. In addition, MTN staff members were able to receive vaccinations from MTN hospital partners, including University of Missouri Health Care and Boone Hospital Center in Columbia, Missouri; Saint Luke's Hospital in Kansas City, Missouri; and Freeman Health System in Joplin, Missouri. Eligible non-clinical staff members are also opting to receive

vaccinations as they are available to them in Jackson, Johnson and Wyandotte counties.

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## **New CMS Outcome Measures**

On Nov. 20, 2020, after a lengthy notice and comment period and ensuing nationwide debate, CMS issued a revised final rule that updates the Conditions for Coverage that OPOs must meet to receive Medicare and Medicaid funding. Key revisions to the rule:

### ***Donation Rate Measure***

This calculates the number of organs an OPO has procured from eligible donors in the geographical area served by that OPO. CMS changed the donation rate measure to the number of organs in an OPO's donor service area (DSA) as a percentage of inpatient deaths among patients 75 years old or younger with a primary cause of death that is consistent with donation. CMS will use death certificates to calculate this donor pool, or "donor potential." Another key change impacting donation rate is the fact that "donor" is now defined as a deceased individual from whom at least one vascularized organ is transplanted, not just procured for transplant. This measure was revised to encourage OPOs to pursue all potential donors, even donors who may only be able to give one organ.

### ***Transplantation Rate Measure***

The second measure revised by CMS calculates the number of organs transplanted from donors in each DSA as a percentage of the donor potential. By CMS' estimates, if every OPO were to meet or exceed this measure, the number of annual transplants in the United States would increase from approximately 33,000 to 41,000 by 2026.

### ***Performance Benchmarks***

CMS has established rates that OPOs will be encouraged to meet for donation and transplantation based on the lowest rates of the top 25% of OPOs from the previous 12-month period. All OPOs below the top 25% will be required to take action to improve their rates using a CMS-supervised quality assurance and performance improvement program. These rankings will be publicly available. Based on the rankings currently available to the public, when compared to the other 57 federally designated OPOs operating in the U.S. from 2011 – 2018, MTN consistently ranked in the top six OPOs nationwide based on organ

donation rates.[3] In 2017, 2018 and 2019, MTN ranked first in the nation based on its organ donation rates.[4] Even more exemplary of MTN's commitment to excellence is the fact that CMS has never found MTN to be out of compliance with any CMS performance measure.

### **Review Periods**

Throughout each four-year recertification cycle, CMS will review OPO performance every 12 months to ensure OPOs are operating efficiently and avoiding organ waste. This more frequent review will also allow CMS to more rapidly identify opportunities for improvement and more easily assess an OPO's improvement efforts.

### **Implementation**

Because OPOs are in the midst of a recertification cycle that ends on July 31, 2022, CMS will evaluate their performance according to the current outcome measures for this cycle. CMS will implement the new measures on Aug. 1, 2022, and will review OPOs accordingly throughout the survey cycle. They will hold OPOs accountable for the new measures for recertification purposes in 2026.

In an email, Michael Baker of the U.S. Department of Health and Human Services (HHS) stated that the new rule ensures quality, patient-centered care by “supporting higher donation rates, reducing discarded but viable organs, and modernizing organ recovery and transplantation. The new measures are backed up by changes that require underperforming OPOs to improve outcomes and compete for their organizational contracts — which are necessary for them to function as OPOs — while the worst performers will be unable to renew their contracts. This rule shortens waiting lists and saves lives by incentivizing OPOs to increase the number of safe, timely transplants. OPOs are a key part of the organ donation system, and ensuring quality is incredibly important to putting patients first.”

On Feb. 2, 2021, the Biden Administration, as part of their review of regulations promulgated at the end of the Trump administration, posted [notice](#) of a 60-day delay in the implementation of the OPO final rule. Initially set to take effect on Feb. 1, 2021, the OPO rule is now delayed until March 30. The notice also opens an additional 30-day public comment period that concludes on March 4, 2021.

[3] Niroomand, Elaheh & Mantero, Alejandro & Narasimman, Manasa & Delgado, Cindy & Goldberg, David. (2020). Rapid Improvement in OPO Performance: Potential for Change and Impact of New Leadership. *American Journal of Transplantation*, 11-12. 10.1111/ajt.16085.

[View the final rule \(CMS-3380-F\)](#)

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## Suspension of Kidney Allocation Policy

On Dec. 14, 2020, HHS directed UNOS to suspend the impending implementation of the new kidney allocation policy until Feb. 13, 2021, due to concerns expressed by multiple parties, including a critical comment letter from Jones Day law firm and letters from eight OPO CEOs concerned about kidney discards amid pandemic-related transportation realities. UNOS planned to implement changes to the kidney allocation policy that would remove DSA and regional boundaries historically used for kidney allocation and instead allocate using a 500 nautical mile (NM) circle around the donor hospital. The new policy was developed and adopted by the Organ Procurement and Transplantation Network (OPTN) Board of Directors in October 2020 with a proposed implementation date of Dec. 15, 2020.

Under the new, fixed circle policy, points would be assigned based on how close the candidate's transplant hospital is to the hospital where the organ donation takes place to prevent a kidney from being transported farther away when there is a candidate of similar priority closer to the donor hospital. The kidney would first be allocated to all eligible candidates inside the 500 nautical mile circle, and if the organ is not accepted by those candidates, it would then be offered to other eligible candidates. UNOS advocates for the fixed circle policy, stating, "Location should not hinder access to transplant. The goal of this proposal is to provide consistent distribution units and promote patient access to transplant. The proposed change would also increase priority for pediatric patients and for prior living donors who now need a transplant. Aside from these changes, kidneys will still be matched with patients according to current criteria."[\[5\]](#)

However, the Jones Day letter and OPO CEOs outlined the following points in support of the continued suspension of the fixed circle policy due to the COVID-19 pandemic:

1. **The policy change requires resources and attention that should be reserved for the pandemic.**
  - a. The new policy will result in a broader allocation of organs, meaning hospitals will be working with transplant programs and OPOs with

whom they have not previously worked, which may require hospitals to adjust their operations or engage in administrative relationship building to ensure recoveries proceed smoothly. However, hospitals are currently stretched to the max in order to respond to the pandemic, which should be the focus rather than “forging new relationships with OPOs and needing to adjust longstanding operations in response to an entirely new process,” according to the Jones Day letter.

**2. Effects of the policy change cannot be properly evaluated during a pandemic.**

- a. The final rule requires that changes to allocation policies include relevant metrics and data to demonstrate how well the policy achieves its goals and the amount of anticipated improvement expected, and the OPTN is required to provide the Secretary of the HHS data to evaluate the impact of allocation policies on a diverse mix of transplant centers. Jones Day argues that because COVID-19 has impacted all aspects of the transplant system and impacted certain geographic regions disproportionately, clear, reliable and meaningful data regarding transplant rates at a mix of centers cannot be obtained or assessed during the public health crisis.

**3. The impact of the pandemic on the policy has not been considered.**

- a. Kidneys are distributed across the United States on commercial flights due to the organs’ abilities to withstand longer cold ischemic times on a kidney pump without negatively impacting outcomes. OPTN has not adequately considered the fact that the pandemic has significantly changed commercial flight schedules, creating a decrease in direct flights and an increase in flight cancellations and last-minute flight changes. This is significant because a donated kidney scheduled to travel could end up spending many additional hours at the airport due to flight delays or cancellations and accrue unnecessary cold ischemic time, likely worsening posttransplant outcomes.

**4. The fixed circle policy will harm patients.**

- a. *Increased discards* — More kidneys will be discarded due to flight delays and cancellations, resulting in long cold ischemic times that make transplanting the kidney an unattractive option to surgeons.
- b. *Reduction in transplants* — More kidney discards will lead to a reduction in overall kidney transplants and an increase in time patients spend on the waitlist. Additionally, patients and the federal



government will spend more money on intermediary treatments like dialysis.

- c. *Failure to mitigate disparities* — Socioeconomic inequities in kidney transplantation are measured using cumulative community risk scores that assess the impact of a policy change on low socioeconomic status candidates who often experience a variety of hurdles in obtaining waitlist access. OPTN claims that the policy will increase access for low income candidates due to an overall increase in the recipient pool due to broader geographic allocation that would include more Medicaid recipients in Medicaid expansion states. However, Jones Day argues that OPTN has neglected to use the proper metric and notes that modeling the impact of the new policy using data provided by the Scientific Registry of Transplant Recipients shows a decrease in kidney transplants for candidates in ZIP codes with median incomes of \$35K to \$70K.

Various transplant centers, hospitals and OPOs will continue to advocate for the suspension of the fixed circle policy and even total abandonment of the policy as Feb. 13 draws nearer, but it is unclear how OPTN will resolve its stated commitment to broader allocation with the realities of an overtaxed hospital system in the midst of a pandemic.

[5] OPTN. Eliminate the use of DSA and Region in kidney allocation policy. *Optn.transplant.hrsa.gov*. Retrieved Jan. 17, 2021, from <https://optn.transplant.hrsa.gov/governance/public-comment/eliminate-the-use-of-dsa-and-region-in-kidney-allocation-policy/>

## Bill Tracker for 2021

- **Missouri HB 131 — Modifies provisions relating to autopsies**  
HB 131 was pre-filed by Ian Mackey, a St. Louis Representative, on Dec. 1, 2020. Generally, the bill appears to have the goals of increasing regulatory requirements for individuals and entities who may handle deceased bodies, organs or tissues and increasing transparency requirements for coroners and medical examiners. However, additional proposed revisions to the statute require administrative oversight over OPOs, like MTN, that previously did not exist. For example, the statute proposes new licensing requirements for “any person who is a representative of a procurement organization who accepts an anatomical gift on behalf

of the organization or who is a representative of a procurement organization who is involved in an autopsy in his or her role as the representative of the procurement organization.” **58.790. 1.**

MTN has concerns regarding the ambiguous language in the bill pertaining to OPOs, as well as the possibility that the proposed revisions to the statute may require members of MTN’s clinical staff to obtain and renew a state license every two years that the state may refuse to reissue for a variety of reasons as outlined in the section. MTN is working with Mid-America Transplant’s lobbyist and Rep. Mackey to provide education and hopefully revise the bill so that Rep. Mackey’s goals are accomplished without creating unnecessary administrative hurdles for MTN’s operations. HB 131 was introduced in the House and read for the first time on Jan. 6, 2021, and read for the second time the following day. MTN will continue tracking the bill’s progress and working with Rep. Mackey’s office as necessary.

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## Upcoming Projects and Initiatives

### Hope for the Heart Virtual Event

Thursday, Feb. 11, 2021 | 6 p.m.

Please join MTN staff and donor families from all over the country as we honor our loved ones through Hope for the Heart. The event will include a presentation from tissue recipient and MTN Quality Assurance Coordinator Lisa Cummins, a group craft project creating origami hearts and a rose ceremony featuring KU Medical Center acapella group, Doctors’ Notes. Those who have registered for Hope for the Heart will receive video presentation details via email. To register for this event, please visit [mwtm.org/events](https://mwtm.org/events).

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### Songs from the Heart

Friday, Feb. 12, 2021 | 7 a.m. – 7 p.m.

In celebration of National Donor Day, hear from people whose lives have been transformed by



organ, eye and tissue donation. Don't miss this full day of love songs and inspiring stories about the gift of life. Tune in to 90.9 FM or listen online at [bridge909.org](https://bridge909.org).

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## Celebration of Heroes Virtual Event

**Wednesday, March 31, 2021 | 6 p.m.**

MTN holds this event each year to honor organ, eye, and tissue donors and their families. This year's virtual celebration will include a presentation from an organ recipient, a sand ceremony and a video tribute.

To have your loved one's pictures included in the video tribute, please email to [photos@mwtm.org](mailto:photos@mwtm.org) by March 15. Those who have registered for Celebration of Heroes will receive video presentation details via email.

To register for this event, please visit [mwtm.org/events](https://mwtm.org/events).

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## Donate Life Legacy Walk

**Saturday, June 5, 2021**

Midwest Transplant Network invites you to join us virtually or in person for our fifth annual Donate Life Legacy Walk on Saturday, June 5. The 2021 walk will feature a virtual celebration for participants from all over the country to honor and celebrate the gift of life given through organ, eye and tissue donation. A live event adhering to local safety guidelines, including social distancing, is planned at the National WWI Museum and Memorial from 7 – 9 p.m. Check [mwtm.org](https://mwtm.org) in the coming weeks for more information.



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