

Stealing Organs?

Benjamin J. McMichael*

ABSTRACT

Every nine minutes, a new person joins a waitlist for an organ transplant, and every day, seventeen people die waiting for an organ that will never come. Because the need for organ transplants far outstrips the number of available organs, the policies and rules governing organ allocation in the United States are critically important and highly contentious. Recently, proponents of a new allocation system—one focused more on sharing organs across the nation instead of allocating organs primarily to local transplant candidates—have gained ground. Bolstered by two separate lawsuits in the past five years, advocates of greater national sharing have succeeded in changing the allocation rules for lungs and livers, with policies for other organs in development.

This Article engages with the debate over whether national or local patients should receive priority under organ allocation systems. Focusing specifically on liver allocation, it provides an innovative empirical analysis of the primary arguments and evidence that those in favor of national allocation policies have used to support their preferred policies—that the sickest patients should receive donated organs first, regardless of their location. While this argument is both ethically and intuitively appealing, those opposed to greater national organ sharing have argued that measures of “sickest patients” are both flawed and subject to manipulation. Greater national organ sharing can also exacerbate existing inequities in the organ transplant system as wealthy urban areas generally import organs from poorer and more rural parts of the country.

Analyzing a dataset of *every* patient waitlisted for a liver between 2002 and 2017, this Article reveals, for the first time, a deeply troubling reality. The results of the analysis suggest that transplant professionals have routinely manipulated the waitlist priority of their patients. Moreover, this manipulation occurs more often in areas of the country that argue most vehemently in favor of national allocation policies. This Article argues that these recent policy changes favoring greater national organ sharing are extensions of the manipulative tactics revealed by the empirical analysis. Given the results of the empirical analysis, the Article argues that the time has come to formalize local priority in organ allocation policy by amending the National Organ Transplant Act. This amendment would roll back recent changes to promote greater national organ sharing that have been justified with manipulated evidence and prevent organs from moving from poorer to wealthier areas of the country. This rollback represents an important first step in combating inequities in the transplant system.

* Assistant Professor of Law, University of Alabama School of Law. Steffie Rosene, Sean Beadore, and Alicia Gilbert provided outstanding research assistance in connection with this Article. This Article employs gender-neutral language throughout, using “they,” “them,” and “their” as third-person singular gender-neutral pronouns.

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INTRODUCTION

Few people regularly make life or death decisions. Healthcare providers, however, routinely face such decisions, and within the healthcare community, those specializing in organ transplantation must make them more often than most. Indeed, the decision of whether to assign a donated organ to a transplant candidate may be better characterized as a life *and* death decision, rather than a life *or* death decision. Because the need for transplants far exceeds the number of organs available, the decision to allocate an organ to a particular patient often results in the death of a different patient who also needs that organ.¹

As of December 2020, 108,438 people required a lifesaving organ transplant in the United States. Of those individuals, 66,745 were actively listed by the Organ Procurement and Transplantation Network (OPTN)—the organization responsible for managing organ allocation in the United States—for an organ transplant.² Unfortunately, many of those waitlisted for an organ will die before one becomes available.³ Given the high stakes involved, the rules governing organ allocation attract significant attention and generate heated debates.⁴ And “[m]ore than any other issue, the role of geography in allocation has been central in debates over the appropriate goals of organ allocation rules.”⁵

That debate recently came to a head when the OPTN announced changes to the policies governing the allocation of livers.⁶ Because Congress has banned the sale of human organs in the United States,⁷ OPTN policies play critical roles in who receives organs. The new allocation policy moved towards greater national allocation of donated livers, eliminating the waitlist priority that patients in the same locality as the donated liver previously enjoyed.⁸

A legal battle over this policy unfolded first in the regulatory arena before moving to the Eleventh Circuit.⁹ Some patients and transplant centers¹⁰—primarily from the Northeast and West Coast—argued that the new rules should have

¹ Bruce Vladeck et al., *Rationing Livers: The Persistence of Geographic Inequity in Organ Allocation*, 14 AM. MED. ASS’N J. OF ETHICS 245, 247 (2012).

² *Transplant Trends*, UNITED NETWORK FOR ORGAN SHARING, <https://unos.org/data/transplant-trends/> (last visited December 20, 2020).

³ Meredith M. Havekost, Note, *The Waiting Game: How States Can Solve the Organ-Donation Crisis*, 72 VAND. L. REV. 691, 693 (2019) (“Every day in the United States, twenty people on the organ-transplant list have their stories cut short while waiting for an available organ.”).

⁴ See, e.g., Alexandra K. Glazier, *The Lung Lawsuit: A Case Study in Organ Allocation Policy and Administrative Law*, 15 J. HEALTH & BIOMEDICAL L. 139, 144 (2018) (“This policy has been the subject of an ugly, prolonged debate within the transplant community regarding proposed changes to liver allocation and distribution policy.”).

⁵ DAVID L. WEIMER, MEDICAL GOVERNANCE: VALUES, EXPERTISE, AND INTERESTS IN ORGAN TRANSPLANTATION 75 (2010) (discussing the private rulemaking functions of UNOS).

⁶ OPTN/UNOS BOARD APPROVES UPDATED LIVER DISTRIBUTION SYSTEM, <https://optn.transplant.hrsa.gov/news/optnunos-board-approves-updated-liver-distribution-system/> (last visited Feb. 17, 2021).

⁷ 42 U.S.C. § 274e.

⁸ See *infra* Part I.C.2 (discussing the specifics of this new rule).

⁹ See *Callahan v. United States Dep’t of Health & Human Servs.* Through Azar, 434 F. Supp. 3d 1319, 1327–35 (N.D. Ga. 2020) (discussing the early stages of the legal battle).

¹⁰ Transplant centers include the hospitals and associated programs responsible for performing organ transplant surgeries.

diminished the role of geography more than they did in favor of a truly national allocation system.¹¹ Other patients and transplant centers—primarily from the Southeast and Midwest—vigorously supported the old, locally-focused, allocation rules.¹² Eventually, the OPTN was compelled to enact a new set of allocation rules that moved even closer to a national allocation system that it had originally envisioned.¹³ More important than leading to a specific new allocation policy for livers, this legal battle has highlighted the critically important debate over local versus national organ allocation generally. This debate extends to the allocation of other organs, including hearts and lungs, which have been subject to their own legal battles.¹⁴

Proponents of greater national organ sharing, which include 84 members of Congress,¹⁵ argue that systems with a local focus fail to prioritize the sickest patients first, as required by federal law.¹⁶ They contend that “[t]he burden of end stage organ failure across the country is not evenly distributed (demand) and neither is donor potential (supply).”¹⁷ Accordingly, organ allocation policy must require that areas of the country with greater access to organs export them to areas with less access or a greater need for organs.¹⁸ This sickest first approach fits well with the ethical maxim that those most in need should receive a scarce lifesaving resource,¹⁹ and it finds support in both existing federal law and among medical experts.²⁰

¹¹ See *Callahan v. United States Dep't of Health & Human Servs. through Alex Azar II*, 939 F.3d 1251, 1255 (11th Cir. 2019) (discussing these arguments).

¹² *Id.*

¹³ *Id.* (“[I]n July 2018, the Secretary [of the Department of Health and Human Services] instructed United Network’s Board to scrap the December 2017 policy and adopt a new one that eliminated the use of [geography] altogether.”).

¹⁴ See *Holman v. Secretary of HHS*, Civ. Action No. 17-cv-09041, S.D.N.Y. (filed November 19, 2017) (discussing the legal battle over lung allocation policy); Letter from George Sigounas, Adm’r, Health Res. & Servs. Admin., to Yolanda Becker, President, Organ Procurement & Transplantation Network (Nov. 21, 2017), https://optn.transplant.hrsa.gov/media/2397/hrsa_letter_to_optn_20171121.pdf (directing the OPTN to conduct an emergency review of lung allocation policy in response to an order from the district court). See also Emmanuel Akintoye et al., *State-Level Variation in Waitlist Mortality and Transplant Outcomes Among Patients Listed for Heart Transplantation in the US From 2011 to 2016*, 3 JAMA NETWORK OPEN 1, 7 (2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2773824?utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_source=articlePDF&utm_content=jamanetworkopen.2020.28856 (explaining that “[g]eographic variation in organ matching has been cited as one of the factors associated with changes made to the US heart allocation system in October 2018”).

¹⁵ Letter from Eliot L. Engel, Member of Congress, to Alex Azar, Secretary, U.S. Dep’t of Health & Human Servs. (Mar. 6, 2019), <https://static1.squarespace.com/static/5c6d6cfeebfc7f40bba3fb32/t/5c8141d5c83025d966ecbefd/1551974889506/Final+House+Letter+Regarding+Liver+Allocation+3.6.19.pdf> (“We write to voice our support for the new liver allocation policy, [which moves toward more national sharing] that was recently passed.”).

¹⁶ Glazier, *supra* note 4, at 139–143. See also Lara C. Pullen, *Lawsuits Drive Transplant Community Debate Over Liver Allocation*, 19 AM. J. OF TRANSPLANTATION 1251, 1251–54 (2019) (summarizing arguments in favor of greater national organ sharing).

¹⁷ Glazier, *supra* note 4, at 143.

¹⁸ *Id.*

¹⁹ See, e.g., Robert D. Truog et al., *The Toughest Triage—Allocating Ventilators in a Pandemic*, 382 NEW ENG. J. MED. 1973, 1973–75 (2020) (discussing the medical principles of triage, which involves providing access to lifesaving treatments to those most in need and those who can benefit the most).

²⁰ See 42 C.F.R. § 121.8 (mandating that organs be distributed “over as broad a geographic area as feasible”); Eitan Neidich et al., *Consumerist Responses to Scarcity of Organs for Transplant*, 15 AM. MED. ASS’N

Proponents of maintaining a local focus in organ allocation, which include 37 senators,²¹ have offered several arguments in response. First, they argue that the current metrics fail to capture which patients are sickest and that the metrics bias organ allocation decisions.²² Second, proponents of local sharing have argued that national rules require economically disadvantaged areas to export organs to wealthy, urban areas.²³ Advocates of locally-focused sharing do not reject all national sharing; rather, they argue that most locally donated organs should go to local patients and envision a more limited role for national sharing. Third, these proponents argue that national sharing will blunt incentives to promote local organ donation, which will reduce the supply of organs overall.²⁴ These arguments, like those on the other side of the debate, find support in federal law and among medical experts.²⁵

Perhaps no aspect of the local versus national debate is more polarizing than the argument that certain transplant centers have manipulated organ waitlists to their benefit. Those in favor of local sharing argue that some transplant centers have manipulated various metrics to make their patients appear sicker and thereby acquire more organs for transplant.²⁶ While such tactics would obviously undermine the arguments of national proponents that the “sickest” patients should receive organs first, local advocates argue that the stakes are even higher. They contend that those in favor of national allocation policies are using manipulated data not only to exploit existing organ allocation rules but also to make broad-based sickest first arguments in support of policies that require exporting organs to transplant centers in areas that fail to encourage organ donation and recover as many organs for transplant as possible.²⁷ To put it bluntly, the concern is one of “stealing” organs by (1) manipulating waitlists and (2) instituting new allocation policies that mandate organ exportation to areas that

J. OF ETHICS 966, 969 (2013) (“Ultimately, the most equitable solution will require a comprehensive policy that expands the boundaries over which organs are allocated.”)

²¹ Letter from Charles E. Grassley, Chairman, Senate Finance Comm., to Alex Azar, Secretary, U.S. Dep’t of Health & Human Servs. (Jan. 22, 2019), <https://www.finance.senate.gov/imo/media/doc/CEG%20Liver%20Letter%20Signed%20FINAL.pdf> (expressing concern that the move toward more national sharing “ignored the impact of socio-economic factors and local organ procurement efforts that help ensure successful liver transplants”).

²² Pullen, *supra* note 16, at 1255.

²³ *Id.* at 1254 (“Data models from SRTR indicate that transplant candidates with lower socioeconomic status in higher risk communities will suffer under [national organ sharing policies].”).

²⁴ See Pullen, *supra* note 16, at 1255 (“Organ procurement organizations (OPOs) supply the organs. . . . Not surprisingly, regions with better-performing OPOs tend to resent sending organs to regions with OPOs that perform poorly, as it is difficult to accept policies that allocate a scarce resource without taking into consideration variations in OPO performance.”).

²⁵ See 42 C.F.R. § 121.4 (directing the development of allocation “[p]olicies that reduce inequities resulting from socioeconomic status”); Keren Ladin et al., *Geographic Disparities in Liver Availability: Accidents of Geography, or Consequences of Poor Social Policy?*, 17 AM. J. TRANSPLANTATION 2277, 2282 (2017) (“While the proposed policy may improve aggregate efficiency by preventing some waitlist deaths, it may do so at the expense of vulnerable, identifiable populations, thereby favoring too heavily efficiency over equity.”).

²⁶ See Allan B. Massie et al., *MELD Exceptions and Rates of Waiting List Outcomes*, 11 AM. J. OF TRANSPLANTATION 2362, 2369–70 (2011) (explaining evidence that transplant clinicians appear to be making their patients appear sicker). See generally UNOS, MANIPULATION OF THE ORGAN ALLOCATION SYSTEM WAITLIST PRIORITY THROUGH THE ESCALATION OF MEDICAL THERAPIES (2018), https://optn.transplant.hrsa.gov/media/2500/ethics_whitepaper_201806.pdf (discussing ways transplant clinicians may manipulate organ waitlists by making their patients appear sicker).

²⁷ See Pullen, *supra* note 16, at 1254–55.

fail to maintain a robust local supply (and thereby obviate the need for continued waitlist manipulation).²⁸

Despite its importance to the local-versus-national debate, “[n]o studies have assessed the prevalence of waitlist manipulation.”²⁹ This Article addresses this critical gap in the existing evidence, contributing important new information to the debate over organ allocation policy. While the evidence and arguments developed here are relevant to the organ allocation debate generally, the analysis concentrates on the rules governing liver allocation for three reasons.

First, the debate over liver allocation has proved more contentious than most and is the most recent point of contact between those favoring national organ sharing and those favoring local sharing. Second, the Byzantine policies of the American organ allocation system vary with the type of organ being allocated. Focusing on livers allows the Article to concentrate on the relevant arguments and evidence without constantly switching between different policies for different organs. Third, liver allocation policy is well suited to an analysis of manipulation because transplant priority is determined by a specific score—the Median End Stage Liver Disease (MELD) score. Patients receive two scores: (1) a laboratory MELD score based entirely on the results of a blood test and (2) an allocation MELD score that can be increased through actions taken by transplant centers. The allocation MELD score ultimately determines whether a patient will receive a donated liver. By examining changes in the difference between laboratory MELD scores (which are exceedingly difficult to manipulate because they are based on the results of a blood test) and allocation MELD scores (which can be manipulated by strategic choices and actions), it is possible to uncover evidence of manipulation.³⁰

In general, the evidence revealed by the empirical analysis of liver allocation is consistent with waitlist manipulation. Specifically, this Article yields two distinct strands of evidence consistent with manipulation. First, in response to a policy change in 2013 that candidates over a certain MELD score could more easily receive a liver outside their local area, the number of patients exceeding this threshold immediately spiked. Additionally, the scores of patients at transplant centers facing more

²⁸ Brian Martin, Comment to *Liver and Intestine Distribution Using Distance from Donor Hospital*, Organ Procurement and Transplantation Network (Oct. 31, 2018), <https://optn.transplant.hrsa.gov/governance/public-comment/liver-and-intestine-distribution-using-distance-from-donor-hospital/>.

²⁹ UNOS, *supra* note 26, at 3.

³⁰ While kidneys are the most transplanted organ, uncovering evidence of manipulation would be difficult because time on the relevant waitlist plays an exceedingly large role in kidney allocation, with no single score capturing a kidney transplant candidate’s relative sickness. *See* KIDNEY ALLOCATION SYSTEM, <https://optn.transplant.hrsa.gov/learn/professional-education/kidney-allocation-system/> (last visited Dec. 21, 2020) (describing kidney allocation policies). The allocation priority for hearts and lungs, like livers, is based on patient sickness, but there is no objective score determining sickness. Instead, transplant candidates are placed into tiers based on the level of medical intervention they require. *See* ADULT HEART ALLOCATION, <https://optn.transplant.hrsa.gov/learn/professional-education/adult-heart-allocation/> (last visited Dec. 21, 2020) (describing heart allocation policies); MODIFICATIONS TO THE DISTRIBUTION OF DECEASED DONOR LUNGS, <https://optn.transplant.hrsa.gov/governance/public-comment/modifications-to-the-distribution-of-deceased-donor-lungs/> (last visited Dec. 21, 2020) (describing lung allocation policies). Without an external difficult-to-manipulate measure of sickness, examining manipulation in heart and lung transplantation would be difficult.

competition for livers were more likely to spike above the threshold than the scores of patients at transplant centers facing less competition.

Second, prior research has demonstrated that deaths in connection with the opioid crisis have become an important source of donated livers³¹ and, separately, that the enactment of cannabis access laws can reduce opioid-related deaths.³² Using these facts, the empirical analysis in this Article examines how the MELD scores of waitlisted patients change as neighboring areas (where most imported livers originate) become increasingly subject to cannabis access laws, which should restrict the supply of available livers. The results demonstrate a statistically significant increase in the average allocation MELD score but no such increase in the difficult-to-manipulate laboratory MELD score when cannabis access laws come into effect in neighboring areas. This pattern of effects suggests that transplant centers manipulate how sick their patients appear to be in order to maintain access to livers recovered in neighboring areas.

The evidence developed here, while incapable of directly proving stakeholders' intentions, strongly supports the existence of pervasive strategic manipulation. Equally relevant, the results of the analysis undermine the arguments made by those in favor of greater national organ sharing, which rely heavily on current measures of medical urgency like MELD scores. And they cast doubt on the entire evidence base used to justify a move from regionally focused allocation to national allocation policies. In other words, the results support both sets of concerns raised by those in favor of locally focused allocation—i.e., that waitlist manipulation occurs and that moving policies toward national allocation has been justified using unreliable evidence. Importantly, while a recent technocratic solution has superficially addressed the mechanisms of manipulation identified in this Article,³³ the evidence of manipulation developed here runs deeper. It vitiates the core arguments and evidence in favor of greater national organ sharing at the expense of local patients.

Based on the evidence reported here, the Article argues that recent movements toward greater national organ sharing should be reversed. Recognizing that these

³¹ Opioid-related deaths, which have increased significantly in recent years, tend to occur among patients who are well suited to organ donation. Scott G. Weiner et al., *The Opioid Crisis and Its Consequences*, 101 *TRANSPLANTATION* 678, 679 (2017) (“According to the Organ Procurement and Transplantation Network, the total number of organ donors increased from 8203 to 15 070 during the last 20 years (an 84% increase). During the same period, the number of donors who died from drug overdoses increased from 29 to 848 (a staggering 2924% increase). . . . Moreover, donors who die from drug overdose typically have no medical comorbidities that would preclude donation, thus making them good candidates for donation.”).

³² Marcus A. Bachhuber et al. *Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999–2010*, 174 *JAMA INTERNAL MED.* 1668, 1668 (2014); David Powell, *Do medical marijuana laws reduce addictions and deaths related to pain killers?*, 58 *J. HEALTH ECON.* 29, 36 (2018). *See also* Benjamin J. McMichael, R. Lawrence Van Horn & W. Kip Viscusi, *The Impact of Cannabis Access Laws on Opioid Prescribing*, 69 *J. HEALTH ECON.* 1, 1 (2020) (“[W]e find that recreational and medical cannabis access laws reduce the number of morphine milligram equivalents prescribed each year by 11.8 and 4.2 percent.”)

³³ *See* Liz Robbins Callahan, UNOS Policy Department, OPTN/UNOS Public Comment Proposal to Establish a National Liver Review Board, (2017) https://optn.transplant.hrsa.gov/media/2085/liver_pcproposal_review_board_policy_201701.pdf (discussing a change from regional review to national review, which could impede the ability of transplant professionals to engage in the specific types of manipulation revealed in this Article’s empirical analysis).

movements are required by existing federal law, the Article argues that the nearly forty-year-old National Organ Transplant Act should be updated. Specifically, an updated Act should formalize a role for local organ sharing while not eliminating national organ sharing altogether. Updating the Act in this way can preserve the benefits that national organ sharing confers on patients with the greatest needs while ensuring that all those who could benefit from a transplant enjoy equitable access to organs.³⁴

This Article proceeds in four Parts. Part I details the organ donation, allocation, and transplantation process, describing the rules at each stage to provide greater context for the local-versus-national debate. Part II engages with this debate by contouring the arguments offered by each side. It also updates these arguments, which have been advanced over the last several decades, with evidence developed from the most recent data on organ donation and allocation. Part III reports a novel empirical analysis of waitlist manipulation, which demonstrates the existence of such manipulation and provides an estimate of its impact. Part IV relies on this empirical evidence to offer a data-driven approach to reconfiguring organ allocation policies to better accommodate the incentives for manipulation faced by various entities.

I. ALLOCATING ORGANS

Organ transplantation represents the best (and often only) available treatment for many diseases. Over the past 60 years, organ transplantation has developed from an experimental surgery of last resort to a relatively routine treatment that surgeons perform thousands of times each year. The only limiting factor is the lack of available organs. Before delving into the policies governing the allocation of these scarce organs, this Part engages with the development of organ transplantation as a viable medical option. The complex biological and medical factors that factor into matching a donor organ with an appropriate recipient complicate the rules governing which patients get access to which organs. This Part then traces the development of the laws governing organ transplantation to provide context for the current debate over national versus local organ allocation rules. Before doing so, it is worth repeating an admonition offered by the Eleventh Circuit before it engaged in a similar review of organ allocation rules: “Fair warning: This gets complicated.”³⁵

A. Organ Transplantation

The transplantation era began in the United States in 1954 when a team at Brigham Hospital in Boston completed the first kidney transplant from one identical twin to another.³⁶ As clinical transplantation techniques developed, the next critical challenge centered on the problem of the transplant recipient’s body rejecting the

³⁴ While researchers and policymakers have cogently argued in favor of organ markets, these markets are likely not politically feasible for the time being. Accordingly, in evaluating current policy, this Article assumes that the selling organs remains illegal.

³⁵ *Callahan v. United States Dep't of Health & Human Servs. through Alex Azar II*, 939 F.3d 1251, 1254 (11th Cir. 2019).

³⁶ DAVID HAMILTON, *A HISTORY OF ORGAN TRANSPLANTATION: ANCIENT LEGENDS TO MODERN PRACTICE* 249–252 (2012).

transplanted organ.³⁷ In the 1980s, the introduction of the drug cyclosporine revolutionized organ transplantation by allowing physicians to suppress patients' immune systems and reduce the probability of rejection.³⁸

Despite these successes, many challenges to successful transplants remain. "With the development of organ transplantation from an experimental procedure into a liver-saving routine intervention, the scarcity of donor organs has become a defining issue at the heart of transplant medicine necessitating tragic choices on a daily basis."³⁹ Even with the advent of immunosuppressive drugs, organs are not fungible, and careful matching remains necessary to ensure that a patient's body does not reject a donated organ.⁴⁰ Much of the complexity of allocating organs for transplant stems from the continued necessity to carefully match donated organs to compatible transplant candidates to minimize the likelihood of rejection.⁴¹ And this complexity only compounds the problem that too few organs are available to meet the needs of all patients.⁴² Given the importance of matching organs to appropriate recipients, transplant centers quickly recognized the benefits of sharing organs more widely among centers.⁴³

During the growth of organ transplantation as a viable medical treatment in the 1960s, transplant programs increasingly gained access to organs that were medically incompatible with their current patients.⁴⁴ Eventually, transplant centers developed informal links among themselves to facilitate the sharing of organs.⁴⁵ These informal networks proved mutually beneficial to the transplant centers involved. Because fewer organs were wasted and more organs transplanted, more patients gained access to lifesaving treatment and transplant centers performed more (financially remunerative) transplants.⁴⁶

³⁷ See Christoph Fruhn et al., *The effect of HLA-C matching on acute renal transplant rejection*, 16 NEPHROLOGY DIALYSIS TRANSPLANTATION 355, 355 (2001) ("The transplantation of kidney allografts has become a standard therapy for end-stage renal disease. The acute rejection of the graft by the host's immune system remains an unsolved problem in this context.").

³⁸ CLYDE F. BARKER & JAMES F. MARKMANN, HISTORICAL OVERVIEW OF TRANSPLANTATION 13 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3684003/pdf/cshperspectmed-TRN-a014977.pdf>.

³⁹ Katrin S. Umgelter et al., *Donor organ distribution according to urgency of need or outcome maximization in liver transplantation. A questionnaire survey among patients and medical staff*, 28 TRANSPLANT INTERNAT'L 448, 448 (2015).

⁴⁰ See, e.g. WEIMER, *supra* note 5, at 100 ("Three factors are of primary importance in kidney allocation: donor and recipient blood compatibility, human leucocyte antigen (HLA) matching, and recipient sensitization. Each of these factors has a firm biological basis. Each also has a basis in clinical evidence. . . .").

⁴¹ *Matching Donors and Recipients*, HEALTH RES. & SERVS. ADMIN., <https://www.organdonor.gov/about/process/matching.html> (last visited Dec. 27, 2020).

⁴² *Transplant Trends*, UNOS, <https://unos.org/data/transplant-trends/> (last visited December 20, 2020).

⁴³ See J. Michael Dennis, *A Review of Centralized Rule-Making in American Transplantation*, 6 TRANSPLANTATION REV. 130, 130–32 (1992) (discussing early informal networks that facilitated sharing organs among transplant programs).

⁴⁴ See *id.* at 130 ("Limited surgical staff, primitive organ preservation, and small recipient lists made kidney sharing a practical alternative.").

⁴⁵ See Richard J. Howard et al., *History of Deceased Organ Donation, Transplantation, and Organ Procurement Organizations*, 22 PROGRESS IN TRANSPLANTATION 6, 10–11 (2012) (reviewing the early history of organ sharing through informal networks).

⁴⁶ *Id.*

Recognizing the importance of organ transplantation, the federal government became increasingly involved in organ allocation and transplantation.⁴⁷ In 1969, the Public Health Service funded seven different networks of existing transplant centers that were sharing organs among themselves.⁴⁸ One of these networks, the South-Eastern Regional Organ Procurement Network, eventually grew to include 18 transplant centers and began fielding requests from non-member centers to list their patients on the network's matching system.⁴⁹ The United Network for Organ Sharing (UNOS) emerged from this network and began operating the first around-the-clock computer matching system for donated organs and patients in need in the mid-1970s.

⁵⁰

By 1983, UNOS was the only organization operating nationally to match donated organs to patients in need.⁵¹ UNOS acknowledged the need to allocate organs to the sickest patients first and developed an electronic classification system to do so.⁵² As UNOS achieved national success in allocating organs in the early 1980s, Congress began to consider greater federal regulation of organ transplantation and allocation.⁵³ UNOS incorporated as a nonprofit entity in 1984 to prepare for imminent federal legislation that would fundamentally change the organ allocation landscape.⁵⁴ The next Subsection engages with this groundbreaking law, which remains in effect to this day.

B. Transplantation Under the National Organ Transplant Act

Congress passed the National Organ Transplant Act (NOTA) in 1984, effectively federalizing what had previously been a series of voluntary networks for organ sharing.⁵⁵ Though the NOTA includes “transplant” in its name, it is better characterized as an act governing the allocation of organs for transplant, rather than transplantation itself. “Indeed, it was only with [the passage of the NOTA] that the regime moved . . . to allocation.”⁵⁶ As part of the process of federalizing organ allocation and transplantation, Congress banned the sale of human organs, creating a centralized non-market allocation system.⁵⁷

⁴⁷ See Richard A. Rettig, *The Politics of Organ Transplantation: A Parable of Our Time*, 14 J. HEALTH POL. POL'Y & LAW 191, 193–204 (1989) (reviewing early federal interventions in organ transplantation).

⁴⁸ *Id.* at 44–45.

⁴⁹ *Id.* at 45; Rettig, *supra* note 47, at 196.

⁵⁰ WEIMER, *supra* note 5, at 45.

⁵¹ *Id.* See also Dennis, *supra* note 43, at 130 (“By 1983 almost all transplant programs paid a fee to SEOPF to access the UNOS program for the placement and receipt of shared kidneys.”).

⁵² WEIMER, *supra* note 5, at 45. See also Dennis, *supra* note 43, at 131 (discussing the competing goals of early organ sharing).

⁵³ James F. Blumstein, *Government's Role in Organ Transplantation Policy*, 14 J. HEALTH POL. POL'Y & L. 5, 10–11 (1989). See Rettig, *supra* note 47, at 204–07 (describing early federal involvement in organ transplantation); Dennis, *supra* note 43, at 131 (“As the transplant community began to reconsider the need for a national network, the federal government took an interest in the rules for distributing organs.”).

⁵⁴ Dennis, *supra* note 43, at 131; Rettig, *supra* note 47, at 207; WEIMER, *supra* note 5, at 45.

⁵⁵ 42 U.S.C. § 273 et seq. A comprehensive discussion of the history of the NOTA is well beyond the scope of this Article. For that discussion, see generally Rettig, *supra* note 47, at 191–227; Blumstein, *supra* note 53, at 5–39.

⁵⁶ WEIMER, *supra* note 5, at 75.

⁵⁷ The merits of the ban on selling human organs has been extensively discussed, but this discussion is beyond the scope of this Article, as there has been no indication that reversing the ban on organ sales

The NOTA operates primarily by defining and formalizing the roles of various organizations involved in organ transplantation and allocation. Accordingly, this Section begins by tracing the roles of these organizations from the imminent death of a potential donor through the final transplantation in the organ recipient. However, the NOTA itself provides little specific guidance on how organs should be allocated among patients. That guidance comes primarily from what has become what has come to be known as the “Final Rule,” which was promulgated by the Department of Health and Human Services in 1998.⁵⁸ This Section concludes by discussing the details of this rule.

1. Organizations Involved in Organ Allocation and Transplantation

As the Eleventh Circuit noted, regulating the allocation and transplantation of human organs is complicated.⁵⁹ The inclusion of multiple acronyms, consistent with most federal regulatory schemes, only adds to this complexity. Thus, before delving into the roles that various entities play in the organ allocation and transplantation system, Table 1 provides a brief overview of these entities, their names, and acronyms.

is politically feasible in the current climate. See Ilya Somin, *Laws Banning Organ Markets Kill Even More People than Previously Thought*, THE VOLOKH CONSPIRACY (Jan. 3, 2019), <https://reason.com/volokh/2019/01/03/laws-banning-organ-markets-kill-even-mor/> (discussing the merits of eliminating the ban on organ sales).

⁵⁸ The Final Rule was eventually codified in 42 C.F.R. § 121.

⁵⁹ Callahan v. United States Dep't of Health & Human Servs. through Alex Azar II, 939 F.3d 1251, 1254 (11th Cir. 2019).

Table 1: The Federal Legal Framework for Organ Donation

Acronym	Name	Summary
NOTA	National Organ Transplant Act	A federal law passed in 1984 that provides the framework for organ allocation and transplantation in the United States.
OPTN	Organ Procurement and Transplantation Network	The legal entity created by the NOTA to match donated organs to medically appropriate transplant candidates. The OPTN also develops the rules and policies that govern organ allocation in the United States. Membership rules ensure that transplant experts retain a voice in organ allocation policy. These rules also divide the country into 11 regions, as displayed in Figure 2.
UNOS	United Network for Organ Sharing	The private, nonprofit entity that operates the OPTN.
OPO	Organ Procurement Organization	A legal entity that is responsible for locating, procuring, and transporting organs for transplant. Each of the 58 OPOs has exclusive authority over a geographic area designated by the federal government as displayed in Figure 1.
DSA	Donation Service Area	The exclusive geographic area in which an OPO operates.

In its first section, the NOTA formalized the role of existing networks designed to procure organs for transplant by providing funding for organ procurement organizations (OPOs).⁶⁰ OPOs “provide the cornerstone of the U.S. organ procurement system.”⁶¹ They work with transplant centers and hospitals within their defined geographic areas to acquire, preserve, and transport organs for transplantation.⁶² The Department of Health and Human Services assigns each OPO an exclusive geographic area of responsibility, which are referred to as donation service areas (DSAs).⁶³ Within the transplant community, “[t]he term ‘local’ . . . means an Organ Procurement Organization’s . . . designated service area.”⁶⁴ Currently, 58 OPOs work within 58 separate DSAs to recover organs for transplantation.⁶⁵ Each DSA is defined as a collection of counties, and these geographic areas often cross state lines and even include non-contiguous areas of service. Figure 1 provides an overview of

⁶⁰ 42 U.S.C. § 273(a). The NOTA also requires that OPOs be nonprofit entities, and they are incorporated under state law. *Id.* at § 2732(b)(1)(B).

⁶¹ DAVID L. KASERMAN & A.H. BARNETT, THE U.S. ORGAN PROCUREMENT SYSTEM: A PRESCRIPTION FOR REFORM 13 (2002).

⁶² *See* Havekost, *supra* note 3, at 694–95 (describing the roles OPOs play); KASERMAN & BARNETT, *supra* note 61, at 13–14 (discussing the functions OPOs serve).

⁶³ 42 U.S.C. § 273(b)(1)(E). Historically, these geographic areas overlapped, but OPOs now generally have exclusive authority within their assigned DSA.

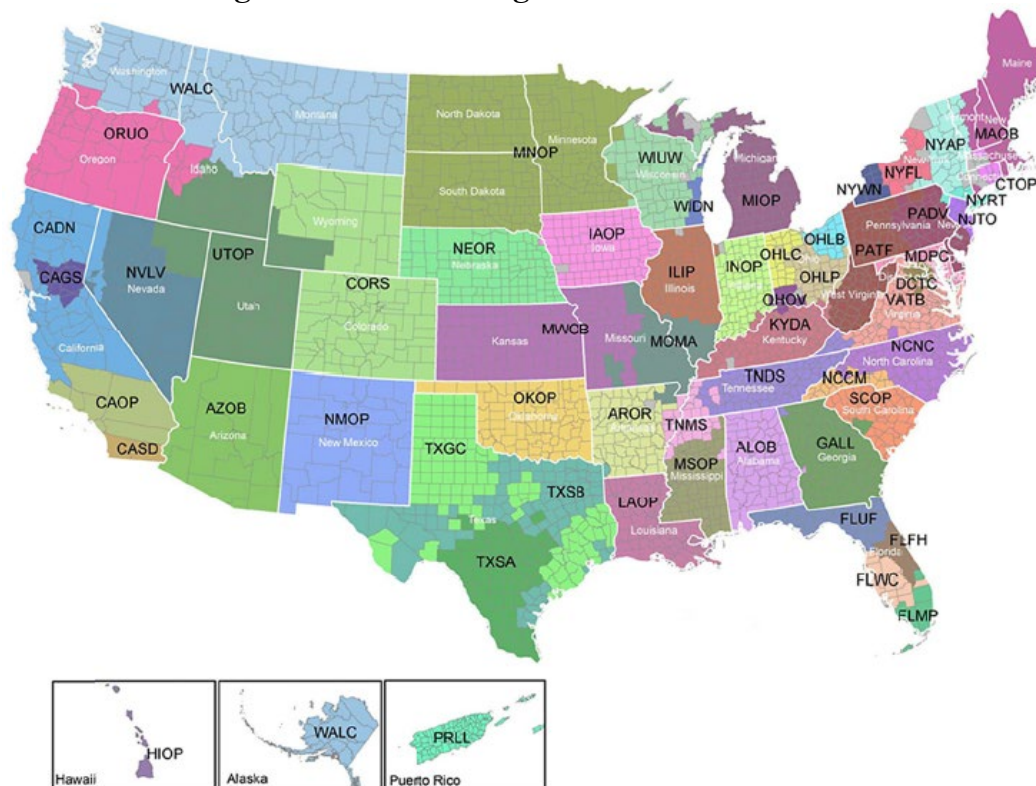
⁶⁴ Glazier, *supra* note 4, at 140.

⁶⁵ ORGAN PROCUREMENT ORGANIZATIONS, <https://unos.org/transplant/opos-increasing-organ-donation/> (last visited Feb. 15, 2021).

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OPOs and the DSAs they serve. While OPOs have longer names, transplant professionals often refer to them by four-letter codes, which are listed in Figure 1.

Figure 1: Donation Service Areas Served by Organ Procurement Organizations



Notes: Each color-coded DSA is served by the listed OPO.⁶⁶

Within its assigned DSA, each OPO interfaces with hospitals to identify potential organ donors. Federal regulations require hospitals to notify their local OPO of patients who have died or will soon die so that the OPO can begin the process of securing organs.⁶⁷ This process may only begin after “the donor is declared medically and legally brain dead.”⁶⁸ Once the OPO becomes involved, it must first determine whether the deceased has elected to donate their organs.⁶⁹ If the patient consented to donation prior to death or the patient’s next of kin consents after death, the transplant team harvests the organs for transplant.⁷⁰ In addition to their critical functions in

⁶⁶ NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, OPPORTUNITIES FOR ORGAN DONOR INTERVENTION RESEARCH 29 (2017).

⁶⁷ 42 C.F.R. § 482.45 (detailing the procedures hospitals must follow when working with OPOs to identify potential donors).

⁶⁸ Havekost, *supra* note 3, at 695.

⁶⁹ See Havekost, *supra* note 3, at 695–96 (discussing the process of identifying donors). See also, e.g., CAL. HEALTH & SAFETY CODE § 7150 (describing the process of organ donation under the Uniform Anatomical Gift Act in California).

⁷⁰ THE DECEASED DONATION PROCESS, <https://www.organdonor.gov/about/process/deceased-donation.html> (last visited Feb. 15, 2021).

securing organs, OPOs serve other important functions, such as educating the public on the importance of organ donation.⁷¹ They do not, however, determine to whom the harvested organs will be allocated. That responsibility falls to a different entity created by the NOTA.

Under the NOTA, the Department of Health and Human Services must contract with an appropriate organization to operate an Organ Procurement and Transplantation Network (OPTN).⁷² The OPTN functions primarily to match organs procured by OPOs to medically appropriate transplant candidates.⁷³ Since Congress passed the NOTA, only UNOS has held the contract to operate the OPTN. Once an OPO recovers an organ, the OPTN must match the organ to a transplant candidate and inform the recovering OPO where it should send the organ. “Using the combination of donor and candidate information, the UNOS computer system generates a ‘match run,’ a rank-order list of candidates to be offered each organ. This match is unique to each donor and each organ.”⁷⁴ The higher a candidate appears on this rank-order list, the more urgent that candidate’s need for a given organ is.⁷⁵ “Blood type and other medical factors weigh into the allocation of every donated organ, but each organ type has its own individual distribution policy, which reflect factors that are unique to each organ type.”⁷⁶

In addition to charging the OPTN with allocating individual organs, Congress delegated to it another, equally important, function: developing organ allocation rules and policies.⁷⁷ Unusual in the realm of federal regulation, the OPTN wields significant authority to determine how organs are allocated despite its status as a private organization.⁷⁸ Indeed, “[s]ince it began operations in 1986, the OPTN has exercised de facto authority over the content of rules governing the procurement and allocation of cadaveric organs.”⁷⁹

The rulemaking bodies within the OPTN include various transplant professionals from different parts of the country, and the NOTA provides strict instructions on the OPTN’s membership generally. These membership rules divide the country into regions and thereby guarantee that transplant centers across the country have a voice in organ allocation policy.⁸⁰ Additionally, the individual regions

⁷¹ See Howard et al., *supra* note 45, at 14 (describing the various functions performed by OPOs).

⁷² 42 U.S.C. § 274(a). As with OPOS, the OPTN must “be a private nonprofit entity.” *Id.* at § 274(b)(1)(A).

⁷³ See *id.* at § 274(b)(2)(A) (“The Organ Procurement and Transplantation Network shall . . . establish . . . a national list of individuals who need organs, and . . . a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list. . . .”).

⁷⁴ HOW WE MATCH ORGANS, UNOS, <https://unos.org/transplant/how-we-match-organs/> (last visited Feb. 15, 2021).

⁷⁵ *Id.*

⁷⁶ *Id.* See also 42 C.F.R. § 121.8 (directing that the OPTN’s allocation policies “[s]hall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate.”).

⁷⁷ See 42 U.S.C. § 274 (detailing the policymaking functions of the OPTN). The framework within which the OPTN develops policy is set forth in 42 C.F.R. § 121.4.

⁷⁸ 42 C.F.R. § 121.4.

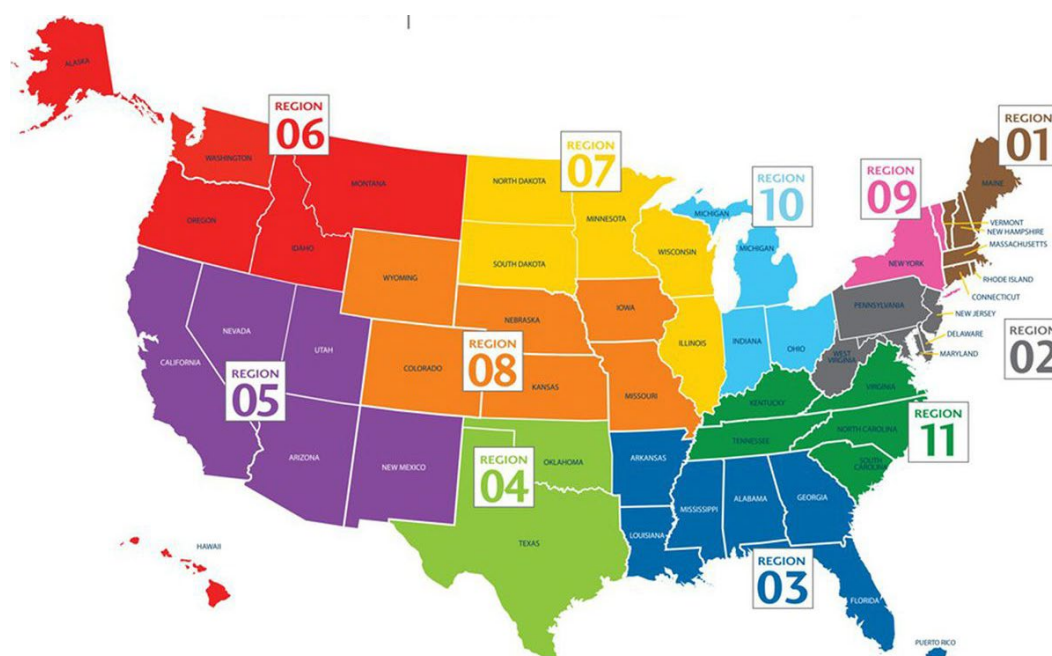
⁷⁹ WEIMER, *supra* note 5, at 73.

⁸⁰ See REGIONS, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, <https://optn.transplant.hrsa.gov/members/regions/> (last visited Feb. 16, 2021) (describing the role of regions within the OPTN).

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serve important administrative functions within the OPTN.⁸¹ These functions include, for some organs, reviewing local requests to change patients' ranking on the transplant waitlist. The term "regional" refers to this level of geography within the transplant community, and Figure 2 provides an overview of the different regions within the OPTN.

**Figure 2: Regions Within the
Organ Procurement and Transplantation Network**



Notes: Each overlaid number refers to the region with the same color-code.⁸²

The process by which the OPTN develops organ allocation policy under the NOTA resembles that seen in federal agencies. For example, the OPTN must “[p]rovide opportunity for the OPTN membership and other interested parties to comment on proposed policies and shall take into account the comments received in developing and adopting policies for implementation by the OPTN.”⁸³ The Department of Health and Human Services exercises a degree of oversight with respect to policies developed by the OPTN, but the OPTN bears primary responsibility for the development for the rules and policies governing organ allocation in the United States. The OPTN lacks the enforcement authority wielded by some federal agencies, but it nonetheless can enforce its policies through its power to regulate membership in the OPTN.⁸⁴

⁸¹ *Id.*

⁸² *Id.*

⁸³ 42 C.F.R. § 121.4(b)(1).

⁸⁴ A federal law passed several years after the NOTA requires hospitals with transplant programs to be members of the OPTN and to “abide[] by the rules and requirements of” the OPTN. 42 U.S.C. § 1320b-8(a)(1)(B).

The next Subsection addresses the substance of organ allocation policies developed by the OPTN and the beginnings of the local-versus-national debate. Before delving into these substantive issues, however, Table 1 provides a summary of the various organizations and terms that are relevant to the legal framework around organ allocation policy.

2. Ethics, Economics, and the Final Rule

With the ban on any market for human organs implemented by the NOTA and the creation of a centralized framework for the allocation of donated organs within the OPTN, the policies of that body have taken on central role in American organ transplantation. The NOTA itself, however, provides relatively little guidance on the content of allocation rules. Instead, allocation rules are governed by a framework that emerged from federal regulations and internal OPTN principles. Early disagreements over allocation rules⁸⁵ led to the promulgation of what has come to be known as the “Final Rule” by the Department of Health and Human Services in 1998.⁸⁶ And this Rule continues to play a key role in how the OPTN develops organ allocation policy.

At its most basic level, the Final Rule requires the OPTN “to develop . . . [p]olicies for the equitable allocation of cadaveric organs.”⁸⁷ Within this equity-focused framework, the Final Rule requires the development of “[p]olicies that reduce inequities resulting from socioeconomic status”⁸⁸ and that these “policies . . . be based on sound medical judgement” and “seek to achieve the best use of donated organs.”⁸⁹ It further directs that “policies . . . be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement.”⁹⁰ In addition to directing the OPTN to develop policies along these lines, the Final Rule sets specific goals that allocation policies should seek to achieve. For example, it directs the OPTN to develop policies “[s]etting priority rankings expressed, to the extent possible, through objective and measurable medical criteria,” with “[t]hese rankings . . . ordered from most to least medically urgent.”⁹¹ It also directs that policies be seek to “[d]istribut[e] organs over as broad a geographic area as feasible.”

In connection with its guidance on allocation policies, the Final Rule provides an oversight role for the Department of Health and Human Services.⁹² Though the oversight mechanism is fairly complex, it essentially allows the Secretary of the Department of Health and Human Services, at their discretion, to direct that the OPTN forward certain policies to the Secretary for review.⁹³ “If the Secretary concludes that a proposed policy is inconsistent with the National Organ Transplant

⁸⁵ See WEIMER, *supra* note 5, at 73–95 (discussing some of these disagreements).

⁸⁶ The Final Rule was eventually codified in 42 C.F.R. § 121.

⁸⁷ *Id.* at § 121.4.

⁸⁸ *Id.* at § 121.4.

⁸⁹ *Id.* at § 121.8(a).

⁹⁰ *Id.*

⁹¹ *Id.* at § 121.8(b)(2).

⁹² *Id.* at § 121.4(b).

⁹³ Callahan v. United States Dep't of Health & Human Servs. through Alex Azar II, 939 F.3d 1251, 1257–64 (11th Cir. 2019).

Act or [the Final Rule], the Secretary may direct the OPTN to revise the proposed policy consistent with the Secretary's direction.”⁹⁴

While the guidance in the Final Rule is more specific than that provided by the NOTA, it is still not sufficiently specific to develop individual allocation policies. To fill these gaps, the OPTN has developed ethical principles to guide the development of allocation policy.⁹⁵ Three general ethical principles guide the OPTN in setting allocation policy: “1) utility; 2) justice; and 3) respect for persons (including respect for autonomy).”⁹⁶ Weighing these various principles against one another when formulating organ allocation policy often results in heated debates. None of the debates over organ allocation policy has proved more contentious than the disagreement over the role of geography in organ allocation.⁹⁷ The next Section provides an overview of the application of these principles to the policies governing liver allocation.

C. Livers: Allocating a Scarce National Resource

Before delving into the debate over the role of geography in the allocation of organs in the next Section, this Subsection reviews recent policy changes in the allocation rules for livers. Geography played an important role in these policy changes. And having a concrete instantiation of the geography debate over livers provides important context and clarity to the sometimes abstract and arcane arguments over the role of geography generally. Liver allocation policy has changed several times since the OPTN assumed responsibility for it. Two important points of significant change happened in 2002 and 2019, with the 2019 change representing a major shift from a primarily local allocation system to one focused on sharing organs nationally.

1. The MELD-Based Allocation System

In 2002, the OPTN introduced the first medically objective scoring system to measure which patients were sickest and therefore had the greatest need for a donated liver.⁹⁸ The Model for End-Stage Liver Disease (MELD) score is calculated from “objective clinical laboratory values” and these scores can be used “to rank patients on the waiting list by their short-term risk of death.”⁹⁹ A patient’s MELD score “incorporates 3 widely available laboratory variables including the international normalized ratio (INR), serum creatinine, and serum bilirubin.”¹⁰⁰ MELD scores used

⁹⁴ 42 C.F.R. 121.4(b)(2). The Final Rule further provides a mechanism by which the Secretary can review a proposed OPTN policy following a comment on that policy by a member of the public. *Id.* at § 121.8(d).

⁹⁵ ETHICAL PRINCIPLES IN THE ALLOCATION OF HUMAN ORGANS, <https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/> (last visited Jan. 21, 2021).

⁹⁶ *Id.*

⁹⁷ WEIMER, *supra* note 5, at 75 (“More than any other issue, the role of geography in allocation has been central in debates over the appropriate goals of organ allocation rules.”).

⁹⁸ Pullen, *supra* note 16, at 1252.

⁹⁹ Pullen, *supra* note 16, at 1252.

¹⁰⁰ Patrick S. Kamath & W. Ray Kim, *The Model for End-Stage Liver Disease (MELD)*, 45 HEPATOLOGY 797, 797 (2007). “The original mathematical formula for MELD is: $MELD = 9.57 \times \text{Log}_e(\text{creatinine}) + 3.78 \times \text{Log}_e(\text{total bilirubin}) + 11.2 \times \text{Log}_e(\text{INR}) + 6.43$ ” *Id.*

by the OPTN range from 6 to 40, with 40 indicating the sickest patients.¹⁰¹ In general “MELD has been validated as a predictor of survival in independent groups of patients with a wide variety of liver diseases,” making it a useful way to rank patients by medical urgency.¹⁰² However, a MELD score does not accurately capture mortality risk for patients with certain medical conditions. To address this concern, the OPTN created a process by which patients could be awarded an “exception” MELD score which can increase their MELD score to better approximate their medical urgency.¹⁰³ A patient’s “allocation” MELD score—the score that actually determines where they rank in priority to receive a donated liver—is the higher of the laboratory MELD and the exception MELD.¹⁰⁴

The OPTN implemented the MELD system in 2002 to respond to a 1999 conclusion by the National Academy of Medicine¹⁰⁵ that organ allocation be based on a sickest first policy.¹⁰⁶ Carrying over some vestiges of the former system, the new MELD system created two classes of patients: “status 1” and all other patients. The sickest patients—those with a life expectancy of less than seven days—were classified as “status 1.”¹⁰⁷ Donated livers were first offered to status 1 patients in the same DSA where the liver was recovered. Livers were then offered to status 1 patients in the region where the liver was recovered.

If the liver remained available after offering it to all relevant status 1 patients, it was then offered to all other patients. A patient’s MELD score determined their priority for the donated liver.¹⁰⁸ Geography continued to play a role in the MELD era, and a donated liver would first be offered to patients in the same DSA as the recovering OPO in descending order of MELD scores. The liver would then be offered to regional patients in descending order of MELD scores.¹⁰⁹ After exhausting these lists of local and then regional patients, the liver would be offered to all other patients in descending MELD order.

¹⁰¹ *Id.* at 798. UNDERSTANDING THE MELD SCORE, PENN MEDICINE (last visited Feb. 18, 2021) (“The MELD score ranges from 6 to 40, and is a measure of how severe a patient’s liver disease is.”), [pennmedicine.org/updates/blogs/transplant-update/2020/may/understanding-the-meld-score#:~:text=The%20MELD%20score%20ranges%20from,worsening%20of%20your%20liver%20disease\).](https://pennmedicine.org/updates/blogs/transplant-update/2020/may/understanding-the-meld-score#:~:text=The%20MELD%20score%20ranges%20from,worsening%20of%20your%20liver%20disease).)

¹⁰² *Id.* at 798.

¹⁰³ See Massie et al., *supra* note 26, at 2362 (“Although MELD was adopted to estimate the short-term (90-day) risk of waitlist mortality, it is believed to underestimate such risk for certain patients with non-normative conditions. Moreover, some diseases have low risk of short-term mortality, but require transplant before progression to the point of irreversible complications. As such, additional MELD points can be granted, and these patients ultimately receive priority based on the exception MELD rather than the calculated MELD.”).

¹⁰⁴ Allan B. Massie et al., *Early Changes in Liver Distribution Following Implementation of Share 35*, 15 AM. J. TRANSPLANTATION 659, 660 (2015) (explaining that the allocation MELD score is “the higher of lab MELD or exception points”).

¹⁰⁵ At the time, the National Academy of Medicine was known as the Institute of Medicine.

¹⁰⁶ INST. OF MED., ORGAN PROCUREMENT AND TRANSPLANTATION: ASSESSING CURRENT POLICIES AND THE POTENTIAL IMPACT OF THE DHHS FINAL RULE 10–11 (1999)

¹⁰⁷ *Id.* at 92.

¹⁰⁸ For patients at the same MELD score, various other factors, such as waiting time, determined who received an available liver for which multiple patients qualified. *Id.* See also ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN) POLICIES https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf (last visited Feb. 20, 2021) (describing current tiebreaking mechanisms).

¹⁰⁹ WEIMER, *supra* note 5, at 92.

The new MELD system proved largely successful. It followed the National Academy of Medicine’s directive to prioritize the sickest patients first,¹¹⁰ and it improved various transplant outcomes.¹¹¹ Equally important, the new system addressed concerns that various transplant centers were engaged in behaviors to manipulate liver waitlists to gain priority for their patients.¹¹² Because the MELD score is based on laboratory values, it became more difficult to manipulate a patient’s position on the waitlist.

For example, Jason Snyder examined the potential for manipulation under the old allocation system.¹¹³ Because admission to an intensive care unit could move a patient toward the front of the waitlist, Snyder considered whether intensive care unit admissions declined following the implementation of the MELD system, which gives patients no priority based only on an intensive care admission. He found that such admissions dropped precipitously after the MELD system became operational. This evidence is consistent with transplant centers unnecessarily admitting their patients to intensive care to move them up the wait list, i.e., manipulating the allocation system. While it is certainly possible to manipulate patients’ position on the waitlist in the MELD era—that is the focus of this Article’s empirical analysis—such manipulation at least became more difficult.

2. A New National Allocation System

The MELD-based regional system of allocation persisted, with several modifications, until 2019. In 2016, the OPTN began to reevaluate its liver allocation policies. This reevaluation led to a new allocation system that retained geography as a factor but expanded the areas where livers would be offered to patients in need.¹¹⁴ The OPTN scheduled the new policy using expanded regions for allocation purposes to become effective in late 2018.¹¹⁵ Before the effective date, however, several patients filed a comment with Secretary of Health and Human Services Alex Azar, criticizing

¹¹⁰ Others had argued in favor of a “sickest first” policy before the National Academy of Medicine took up the question, but the National Academy of Medicine’s statement has been the most forceful on the issue. INST. OF MED., *supra* note 106, at 10–11.

¹¹¹ See Richard B. Freeman et al., *Results of the First Year of the New Liver Allocation Plan*, 10 LIVER TRANSPLANTATION 7, 7 (2004) (“In conclusion, by eliminating the categorical waiting list prioritization system that emphasized time waiting, the new system has been associated with reduced registrations and improved transplantation rates without increased mortality rates for individual groups of waiting candidates or changes in early transplant survival rates.”); Richard B. Freeman et al., *Excellent Liver Transplant Survival Rates Under the MELD/PELD System*, 37 TRANSPLANTATION PROCEEDINGS 585, 585 (2005) (“We conclude that patient and graft survival have remained excellent since implementation of the MELD/PELD system.”).

¹¹² Aaron Ahearn, *Ethical Dilemmas in Liver Transplant Organ Allocation: Is it Time for a New Mathematical Model?*, 18 AM. MED. ASS’N J. OF ETHICS 126, 126 (2016) (“Essentially, transplant professionals were escalating the level of care pretransplant patients were receiving in order to exaggerate their patients’ illness acuity and move their patients “up” the waitlist.”).

¹¹³ Jason Snyder, *Gaming the Liver Transplant Market*, 26 J.L. ECON. & ORG. 546, 546 (2010)

¹¹⁴ See Sommer E. Gentry, *The Impact of Redistricting Proposals on Health Care Expenditures for Liver Transplant Candidates and Recipients*, 16 AM. J. OF TRANSPLANTATION 583, 584 (2016) (reviewing the impact of using larger geographic areas on liver transplant outcomes).

¹¹⁵ *Callahan v. United States Dep’t of Health & Human Servs. through Alex Azar II*, 939 F.3d 1251, 1255 (11th Cir. 2019).

the continued role that geography played in allocation decisions.¹¹⁶ Using his authority to review the OPTN's proposed policy following the filing of a comment, the Secretary ordered OPTN to adopt a new policy that did not rely on either regions or DSAs in allocation decisions.¹¹⁷

The result of this reevaluation was the "Acuity Circles" allocation policy.¹¹⁸ Following the development of the Acuity Circles policy, a new group of patients filed a comment with the Secretary, challenging the policy.¹¹⁹ This time, the Secretary refused to intervene. His refusal led to a lawsuit filed by aggrieved patients and multiple transplant centers challenging the new allocation policy on the grounds that the Secretary was required to intervene under the NOTA and Final Rule.¹²⁰ Eventually, the Eleventh Circuit determined at the preliminary injunction stage that the Secretary was not required to take any action that the plaintiffs argued he was.¹²¹ On remand, the district court denied plaintiffs injunctive relief.¹²² The Acuity Circles model has governed liver allocation since February 2020.¹²³

The Acuity Circles model eschews the use of DSAs or regions altogether and only uses geography to the extent that donated organs do not remain viable for long periods, limiting the distance they can travel.¹²⁴ Under this model, patients receive a MELD score just as they did before, and livers are allocated to patients with higher MELD scores as before. However, instead of relying on DSAs and regions when allocating livers, the Acuity Circles model draws circles around the location of the donor.¹²⁵ The first circle has a radius of 150 nautical miles. Transplant candidates with a MELD score of 37 or higher have first access to the liver. If no candidates are compatible (or refuse), the circle is extended to 250 nautical miles. Again, if no candidate receives the liver in that circle, the circle is extended to 500 nautical miles. If no candidate receives the liver, the process restarts with a circle of 150 nautical miles for patients with MELD scores of at least 33. The process of drawing larger and larger circles around lower and lower MELD-score cutoffs is determined by a table adopted by the OPTN.¹²⁶

The Acuity Circles model is not a true national allocation policy. It still favors local patients to a degree, but it does not do so based on established DSAs or regions. This new model de-emphasizes locality to a much greater extent than prior allocation models and moves closer to national allocation than any previously used model. Given that the Acuity Circles model has been in place less than one year, thorough evaluations of its effects are not yet available. Additionally, the fact that this model

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 1256.

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.* at 1259–65.

¹²² *Callahan v. United States Dep't of Health & Human Servs. Through Azar*, 434 F. Supp. 3d 1319, 1373 (N.D. Ga. 2020).

¹²³ SYSTEM NOTICE: LIVER AND INTESTINAL ORGAN DISTRIBUTION BASED ON ACUITY CIRCLES IMPLEMENTED FEB. 4, <https://unos.org/news/system-implementation-notice-liver-and-intestinal-organ-distribution-based-on-acuity-circles-implemented-feb-4/> (last visited Feb. 23, 2021).

¹²⁴ ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN) POLICIES https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf (last visited Feb. 20, 2021).

¹²⁵ *Id.*

¹²⁶ *Id.*

became effective at nearly the same time as the beginning of the COVID-19 pandemic may confound analyses of its overall impact. Despite these challenges, researchers have completed early evaluations, and these evaluations have not yielded encouraging results.¹²⁷ One study found evidence that the Acuity Circles model has resulted in livers flowing from rural to urban areas and that “that the projected impact of the [this] policy based on mathematical simulations may not match what occurs in practice.”¹²⁸ The study also warned of “[t]he potential for unintended consequences of new allocation policies.”¹²⁹

As the OPTN has moved toward a national approach to liver allocation, medical experts,¹³⁰ health policy researchers,¹³¹ and policymakers continue to object to the de-emphasis of geography in allocation policies.¹³² These objections, in conjunction with the arguments proffered by the proponents of the Acuity Circles model and national sharing more generally echo the more general debate over the role of geography in organ allocation policy. The next Section delves into this debate.

II. LIVER TRANSPLANT POLICY: THE LOCAL-NATIONAL DEBATE

When engaging with the primary arguments proffered by those in favor of a nationally focused allocation system and those in favor of a locally focused system, this Section does not simply recite existing arguments and cite outdated statistics. Instead, it offers the each side’s key arguments and enriches them with the most current evidence from the Scientific Registry of Transplant Recipients—the statutory body responsible for gathering and organizing nearly comprehensive data on organ donation, allocation, and transplantation in the United States.¹³³ This Section begins with an overview this dataset before tracing the contours of each side’s arguments with respect to geography and the allocation of livers. Engaging with the primary arguments offered by each side of the debate in this Section sets the stage for addressing, through

¹²⁷ Darius Chyou et al., *A 6-month report on the impact of the OPTN/UNOS Acuity Circles policy change*, 27 LIVER TRANSPLANTATION (forthcoming 2021) (“Longer-term data are needed to fully measure the impact of [the Acuity Circles policy], especially given COVID-19 concerns. However, these early data raise the question that the projected impact of the [Acuity Circles] policy based on mathematical simulations may not match what occurs in practice.”).

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ For example, Seth Karp, professor and chair of the Section of Surgical Sciences at Vanderbilt University Medical Center and director of the Vanderbilt Transplant Center, stated that “the Acuity Circles Policy is predicted to increase deaths in rural areas, decrease the number of overall transplants throughout the country, needlessly increase the risk of teams traveling to procure organs and increase costs.” VUMC Reporter, *Transplant centers and patients unite to stop new organ sharing policy that threatens transplant patients waiting for a liver* (Apr. 23, 2019, 1:46 PM), <https://news.vumc.org/2019/04/23/transplant-centers-patients-unite-to-stop-new-organ-sharing-policy-that-threatens-longer-waits-for-a-liver/>.

¹³¹ See, e.g., Ladin et al., *supra* note 25, at 2277 (“Policies calling for organ redistribution from high-supply to low-supply regions may exacerbate existing social and health inequalities by redistributing the single benefit (greater organ availability) of greater exposure to environmental and contextual risks (e.g. violent death, healthcare scarcity). Variation in liver availability may not be an ‘accident of geography’ but rather a byproduct of disadvantage.”).

¹³² See, e.g., Grassley, *supra* note 21 (expressing concern over the move to nationally focused allocation policies).

¹³³ See 42 U.S.C. § 274a (creating the scientific registry of organ transplants).

an empirical analysis in the following Section, a core point of contention: waitlist manipulation.

A. A Data-Driven Approach to Liver Allocation Policy

The Scientific Registry of Transplant Recipients (SRTR) has gathered a wealth of data in connection with all transplant-related activities in the United States since 1988.¹³⁴ Using information provided by the OPTN and other sources, the SRTR organizes information on donors, waitlisted transplant candidates, and those who receive a transplant into a comprehensive dataset.¹³⁵ That dataset is the subject of this Article’s empirical analysis.¹³⁶ It contains nearly comprehensive information on those donating, waiting for, and receiving livers.¹³⁷

Beginning with donors, the dataset includes information on each donor’s demographics, medical history, cause of death, and the location of the donation. Importantly, the dataset includes which OPO recovered a given donor’s liver. With respect to transplant recipients, the dataset similarly provides information on the recipient’s medical history, including MELD score(s) and demographic information. It also identifies the transplant center that performed the transplant, the OPO serving that transplant center, and information on which OPO recovered the donated liver. By comparing a recipient’s location to a donor’s location, it is possible to examine the role geography in liver allocation policy. Using this information, I can identify whether a patient received a “local” liver (one that was recovered in the same DSA where the patient received their transplant) or a “shared” liver (one that was recovered in a different DSA or region from where the patient received their transplant).

Most of the empirical analysis below focuses on transplant candidates who have joined liver waitlists. Among this group, the SRTR dataset includes information about each individual from each separate listing. A single individual can register on the waitlist any number of times, with the information about the individual potentially changing while they are on the waitlist or between separate listings. For example, a patient may join the waitlist initially with a MELD score of 15 but become sicker and rejoin the waitlist at a higher MELD score. For each listing, the SRTR dataset includes information on the current laboratory MELD score (based only on laboratory values obtained from a blood test), the current allocation MELD score with any relevant exception points awarded, and information on the patient’s demographic and medical

¹³⁴ SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS, STANDARD ANALYSIS FILES, <https://www.srtr.org/about-the-data/the-srtr-database/> (last visited Feb. 25, 2021). This study used data from the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donor, wait-listed candidates, and transplant recipients in the US, submitted by the members of the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors.

¹³⁵ *Id.*

¹³⁶ For a complete list of all available information, variables, structure, and coding, see STANDARD ANALYTICS FILE, <https://www.srtr.org/requesting-srtr-data/saf-data-dictionary/> (last visited Feb. 2, 2021)

¹³⁷ The data reported here have been supplied by the Hennepin Healthcare Research Institute (HHRI) as the contractor for the Scientific Registry of Transplant Recipients (SRTR). The interpretation and reporting of these data are the responsibility of the author and in no way should be seen as an official policy of or interpretation by the SRTR or the U.S. Government.

history. Each listing also includes the patient's location, so that it is possible to match candidates with DSAs.¹³⁸

The various aspects of the SRTR dataset are contained in separate units, so I took several steps to organize the dataset. I matched all of the relevant donor and transplant candidate information using encrypted patient and donor identifiers within the dataset. The primary dataset I analyze is organized by DSA and month.¹³⁹ It includes information about MELD scores (both laboratory and allocation), number of donor livers recovered, number of transplants completed, number of patients on the waitlist, and time spent on the waitlist. The discussion below includes more details on the different ways these data are organized to provide context for various arguments made by each side of the allocation debate and to answer specific empirical questions.

Throughout that discussion, I limit the time period I analyze to 2002 through 2017. Because MELD scores are both central to the arguments made by both sides of the geography debate and key to my empirical analysis, the discussion and analysis focuses only on the MELD era. That era began in March 2002, when the OPTN officially began allocating livers based on MELD scores. The data period ends in 2017 because the a new, more nationally focused, allocation policy was originally scheduled to take effect in 2018 and because of data availability issues that begin in 2018.¹⁴⁰ I also exclude status 1 patients, who receive livers outside of the MELD-score system, all patients who do not receive a MELD score (including pediatric patients),¹⁴¹ and all patients from Hawaii and Alaska.¹⁴²

Figure 3 provides a general overview of the MELD era. Since 2002, the number of liver transplants completed in the United States has steadily increased. At the beginning of the MELD era, transplant centers completed approximately 400 liver transplants each month. This number increased to approximately 650 transplants each month by the end of 2017. Against this background, both sides of the geography debate have offered vigorous arguments.

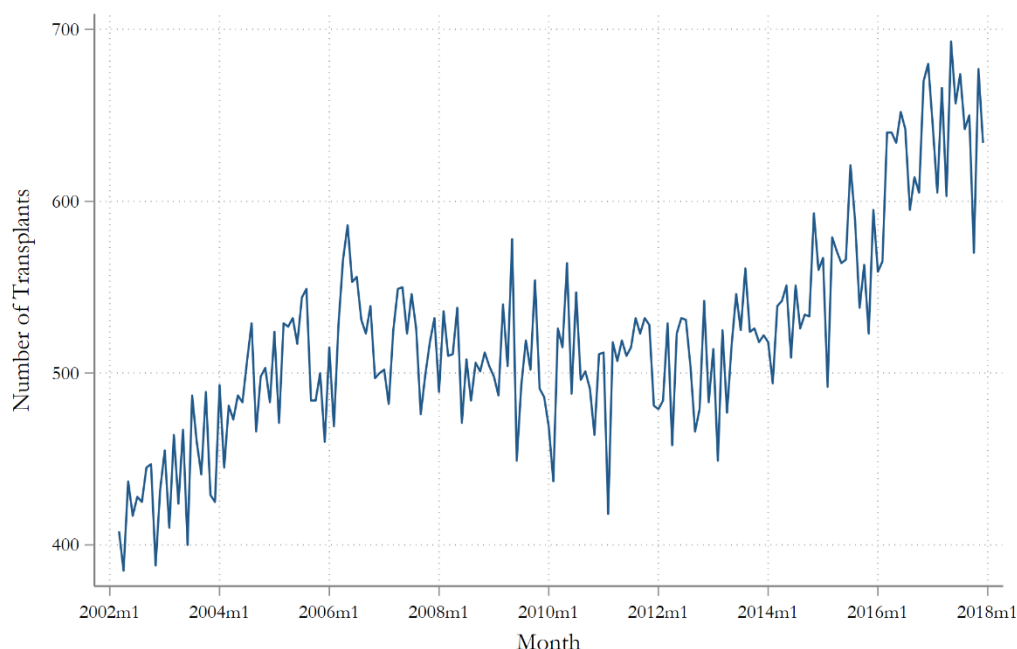
¹³⁸ Each patient is assigned to the DSA where their listing transplant center is located.

¹³⁹ Each observation represents a value for a particular OPO in a particular month.

¹⁴⁰ See Part I.C. *supra*.

¹⁴¹ Pediatric patients receive priority on waitlists based on a different score—the “PELD” score—and are thus excluded from my analysis.

¹⁴² Because these two states are so far from the continental United States, separate considerations govern organs allocated to those states.

Figure 3: Number of Liver Transplants in the United States

Notes: Data on the total number of liver transplants across the United States by month come from the Scientific Registry of Transplant Recipients.¹⁴³

B. Sickest First: The Case for Nationally Focused Allocation Policy

The loudest voices in favor of broader national sharing of organs tend to come from transplant centers located in the Northeast and on the West Coast, such as transplant centers in New York City and San Francisco.¹⁴⁴ For example, as part of the recent regulatory and legal battle of liver allocation policies, “Motty Shulman, the New York Greater Hospital Association’s counsel . . . sent a letter to [the] Acting Secretary of HHS,” requesting that “HHS . . . immediately direct the OPTN to set aside the OPTN’s ‘arbitrary geographic limitations’ in its . . . allocation policy.”¹⁴⁵ Advocates of national allocation policies offer two general arguments. First, they contend that existing federal law requires the broadest possible sharing of organs across the country.¹⁴⁶ Second, they offer the more general argument that medical ethics dictate the sickest patients receive the first available organs regardless of where those patients are located.¹⁴⁷ This Section addresses these series of arguments in turn.

¹⁴³ See SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS, *supra* note 134.

¹⁴⁴ Pullen, *supra* note 16, at 1251–56.

¹⁴⁵ *Id.*

¹⁴⁶ See Sommer E. Gentry et al., *Addressing Geographic Disparities in Liver Transplantation Through Redistricting*, 13 AM. J. TRANSPLANTATION 2052, 2052 (2013) (“Geographic disparities violate the Code of Federal Regulations.”).

¹⁴⁷ See *Id.* at 2052 (“Geographic disparities violate the . . . ethical principles of organ allocation.”); Glazier, *supra* note 4, at 142 (“The founding principle under the federally established framework is that donated organs are a national resource and should be allocated based on a system that is focused on the patients.”).

1. Current Law Envisions a National Policy

Beginning with the first argument, the text of the NOTA and Final Rule clearly require broad sharing of human organs. The NOTA directs the OPTN to “establish . . . a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals.”¹⁴⁸ The text of the Final Rule imposes even stricter requirements, providing that “allocation policies . . . [s]hall not be based on the candidate's place of residence or place of listing.”¹⁴⁹ It further requires “[d]istributing organs over as broad a geographic area as feasible.”¹⁵⁰ These provisions in the statutory and regulatory framework leave little room for doubt that the OPTN must focus on allocating organs across the country.

Proponents of national organ allocation interpret these provisions narrowly, arguing that allocation policies must consider only the distribution of organs that are actually recovered to patients who are already on waitlists. This narrow interpretation generally excludes consideration of whether a policy would increase the overall number of organs donated, recovered, or transplanted. It further excludes consideration of whether the policy would increase the availability of organs to patients who need them but are not currently waitlisted. For example, Alexandra K. Glazier—the CEO of a New England OPO—argued that “[b]y definition allocation and distribution policy is about determining where a defined pool of a resource goes.”¹⁵¹ She further explained that “[t]his does not mean efforts should not be focused on increasing the organ pool, but whatever size the pool is, the allocation and distribution policies are designed to rank order patients to receive actual organs that become available.”¹⁵²

Consistent with a narrow interpretation of the legal framework, federal officials show a decided preference for national allocation. In the recent litigation over the implementation of a new liver allocation policy, the Secretary of Health and Human Services clearly favored the de-emphasis of geography.¹⁵³ The first policy proposed by the OPTN retained geography as a factor in allocating livers.¹⁵⁴ When aggrieved patients filed a comment challenging any use of geography in the allocation scheme, the Secretary used his authority to order the OPTN to develop a new policy.¹⁵⁵ Once the OPTN had done so, the Secretary refused to similarly intervene when a group of aggrieved patients (under the new policy) challenged the policy for failing to include a role for geography.¹⁵⁶ A similar dispute with similar results unfolded in the 1990s.¹⁵⁷

¹⁴⁸ 42 U.S.C. § 274(b)(2).

¹⁴⁹ *Id.* at § 121.8(a)(8).

¹⁵⁰ *Id.* at § 121.8(b)(3).

¹⁵¹ Glazier, *supra* note 4, at 143.

¹⁵² *Id.* at 143.

¹⁵³ *Callahan v. United States Dep't of Health & Human Servs. through Alex Azar II*, 939 F.3d 1251, 1255 (11th Cir. 2019).

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.* at 1256.

¹⁵⁷ Pullen, *supra* note 16, at 1252.

2. Medical Ethics Favors a Sickest First Policy

Though the existing law favors a national allocation policy, the mere existence of a law directing the pursuit of a specific goal does not, in itself, establish the desirability of achieving that goal. Recognizing this, those in favor of national allocation policies offer cogent ethical arguments that geography should play no role in organ allocation. Commenting on recent changes to liver allocation policy that de-emphasized geography, two experts who have been involved in organ allocation decisions in the past—John R. Lake and Sandy Feng—stated their positions on national allocation bluntly.¹⁵⁸ Lake argued that “a policy that prioritizes transplanting the sickest patients will save lives.”¹⁵⁹ Feng added that “[p]eople are dying. It’s just not fair.”¹⁶⁰

These positions align well with previous medical ethicists who have weighed in. One group of medical ethicists argued that “[r]easonable people could well differ on the precise criteria for allocating such a scarce, life-saving resource as donated livers, but it is hard to make a case that the patient’s place of residence should be a criterion.”¹⁶¹ In support of this argument, the group pointed to statistics on measures of sickness and death rates, which demonstrated geographic inequity.¹⁶² Updating their arguments to the most recent data considered here, they remain valid.

Figure 4 illustrates the geographic inequity in measures of sickness—MELD scores—and death rates emphasized by advocates of national sharing using the most recently available data. Panel A reports the average allocation MELD score for all patients on waitlists within each DSA in 2017.¹⁶³ The data reported in Panel A clearly demonstrate a disparity in MELD scores, with darker shades indicating higher average MELD scores. The average MELD score among patients in some DSAs is as low as 13, while the highest average MELD score is over 21 in others. Panel B similarly paints a picture of disparity. It reports the number of deaths that occurred per 100 unique patients on waitlists in 2017.¹⁶⁴ The highest death rate was more than an order of magnitude larger than the lowest death rate across all DSAs.

¹⁵⁸ *Id.* at 1253.

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ Bruce C. Vladeck et al., *Rationing Livers: The Persistence of Geographic Inequity in Organ Allocation*, 14 AM. MED. ASS’N J. OF ETHICS, 245, 245 (2012).

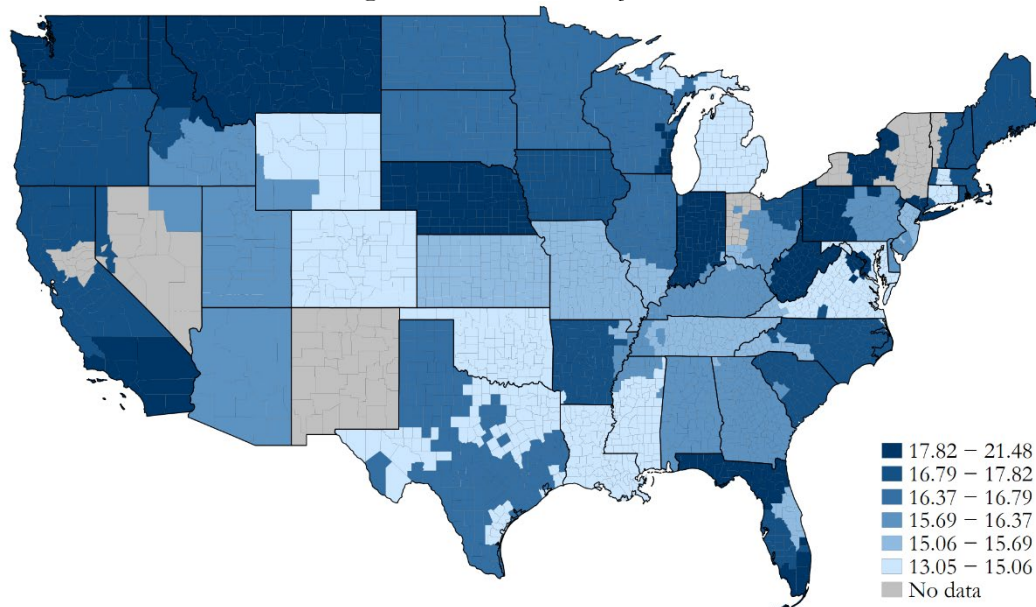
¹⁶² *Id.*

¹⁶³ Each OPO-specific MELD score is calculated as the mean allocation MELD score for all patients who were actively listed on a given OPO’s waitlist, weighted by the number of days out of the year a patient spent on the waitlist. The OPOs that are listed as having “No data” are those that do not include any liver transplant programs within their DSAs and therefore do not have waitlists for livers.

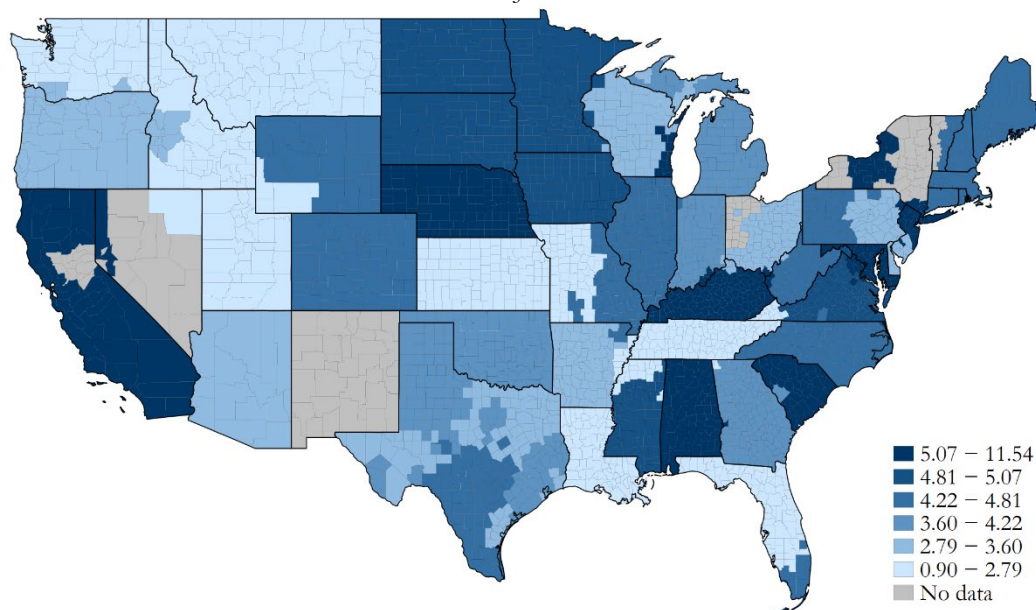
¹⁶⁴ “Unique patients” refers to the total number of different patients that actively appeared on a waitlist within a given OPO for at least one day in 2017. To calculate the death rate, I divide the number of people who were recorded as leaving the waitlist as a result of death any time in 2017 by the number of unique patients on the waitlist in 2017.

Figure 4: Waitlist Outcomes Across the United States

Panel A: Average Allocation MELD of Patients on Waitlists



Panel B: Number of Deaths on Waitlists



Notes: Data on the total number of liver transplants across the United States by month come from the Scientific Registry of Transplant Recipients.¹⁶⁵ The average allocation MELD is calculated based on the allocation MELD score of every waitlisted patient in 2017 and is weighted by the number of days each patient was actively listed. The number of deaths per 100 patients is defined as the number of waitlist deaths divided by the total number of unique patients that appeared on a waitlist within a given OPO in 2017.

¹⁶⁵ See SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS, *supra* note 134.

Figure 4 offers important insight into the evidence underlying the arguments of those in favor of national allocation policies. And this evidence seems to be winning the day, as the allocation policies for livers,¹⁶⁶ hearts,¹⁶⁷ and lungs¹⁶⁸ have recently shifted to de-emphasize geography. These shifts, however, have only emboldened those in favor of retaining a role for geography, as discussed in the next Section.

C. Socioeconomic Status, Access, and Incentives: The Local Case

Those in favor of a continued local focus in organ allocation policy tend to hail from the South and Midwest. The list of plaintiffs in the recent case challenging the adoption of greater national organ sharing is particularly telling, as transplant centers from Georgia, Indiana, Iowa, Kansas, Kentucky, Michigan, Missouri, Tennessee, and Virginia (among other states) joined to oppose greater national organ sharing.¹⁶⁹ Perhaps because they have not seen much success recently, those in favor of maintaining locally focused allocation have offered a wider array of arguments than those opposed. First, they have opposed the ethical and legal arguments discussed above. Second, they have offered additional arguments that encompass a broader scope of ethical considerations and that focus specifically on the incentives created by various allocation frameworks. This Section reviews these arguments seriatim.

1. Ethical and Legal Considerations Around Socioeconomic Status

Beginning with local proponents' responses to the ethical arguments outlined above, one of their central arguments concerns the reliability of the current system. In particular, they have challenged the use of MELD scores to classify the medical urgency of transplant patients.¹⁷⁰ More than a decade ago, researchers identified a consistent increase in MELD scores, which they termed "MELD inflation."¹⁷¹ This "inflation effectively raises the threshold at which liver transplantation occurs."¹⁷² Building on this concerning trend, medical experts "worry that MELD scores do not accurately reflect risk of death on the waitlist and that the fact that MELD scores are baked into the allocation policy means that certain regions will be disadvantaged."¹⁷³ Indeed, Figure 4 bears out these concerns. The states with the highest average allocation MELD scores do not necessarily have the highest waitlist death rates.

¹⁶⁶ See *supra* Part I.D.2.

¹⁶⁷ Clyde W. Yancy & Gregg C. Fonarow, *United Network for Organ Sharing 2018 Heart Transplant Reallocation Policy Aiming for Evidence-Based Policy*, 6 JAMA CARDIOLOGY (forthcoming 2021), <https://jamanetwork.com/journals/jamacardiology/article-abstract/2772382>.

¹⁶⁸ Varun Puri et al., *Unintended consequences of changes to lung allocation policy*, 19 AM. J. TRANSPLANTATION 2164, 2164 (2019).

¹⁶⁹ *Callahan v. United States Dep't of Health & Human Servs. through Alex Azar II*, 939 F.3d 1251, 1251 (11th Cir. 2019).

¹⁷⁰ Pullen, *supra* note 16, at 1255 ("Many have contended that the median MELD at transplant is a flawed metric to assess the geographic equity of a liver allocation policy.").

¹⁷¹ Scott W. Biggins & Sandy Feng, *In a MELD-Based Economy, How Can We Fight Off Inflation?*, 13 LIVER TRANSPLANTATION 2, 2 (2007).

¹⁷² *Id.*

¹⁷³ *Id.*

Overall, though, Figure 4 suggests that funneling livers to the patients with the greatest need may not be straightforward, given competing measures of need.

Turning next to their legal arguments, those in favor of a local focus in organ allocation must fight an uphill battle, given the text of the NOTA and Final Rule. Local proponents contend that considering only patients currently on waitlists omits an important population that could benefit from liver transplants.¹⁷⁴ This group “believes that allocation should encompass access to transplant centers, an access that may be threatened in less populated states if centers are forced to close due to a lack of organs to transplant.”¹⁷⁵ In connection with this concern, proponents of local allocation argue that socioeconomic factors may prevent some patients from ever joining a waitlist.¹⁷⁶ Therefore, focusing exclusively waitlisted patients necessarily disadvantages certain socioeconomic groups.¹⁷⁷ Advocates of this broader approach to allocation find legal support from clause within the Final Rule directing the OPTN to develop “[p]olicies that reduce inequities resulting from socioeconomic status.”¹⁷⁸ They contend that this directive extends beyond those patients currently on a waitlist to include all patients who may benefit from a transplant.¹⁷⁹

In support of their claims, advocates of this broader legal approach point to evidence that organs tend to flow from poor, rural areas of the country to wealthy, urban areas. Figure 5 reports the net imports of each of the 58 DSAs in 2017. Net imports is defined as the number of livers recovered within a given DSA that were shared with patients in other DSAs minus the number of livers that other DSAs shared with patients inside a given DSA. A positive number indicates that the DSA imported more organs than it exported, and a negative number indicates more exports than imports. Warm colors represent net imports (positive numbers), and cool colors represent net exports (negative numbers).

¹⁷⁴ Pullen, *supra* note 16, at 1253 (“Those who oppose the new allocation policy feel that HRSA was wrong to define the allocation problem in terms of patients on the waitlist.”).

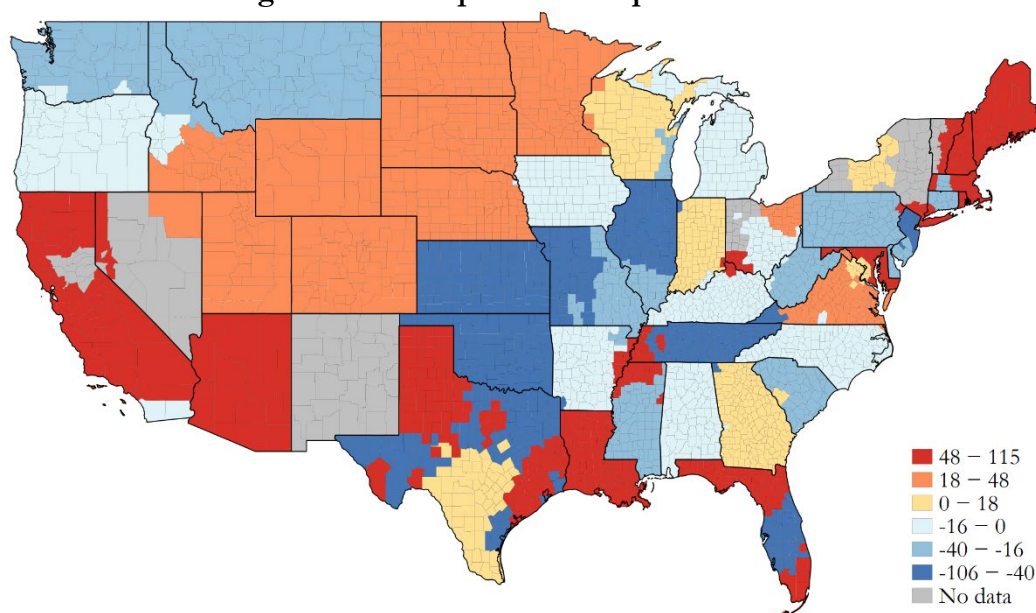
¹⁷⁵ *Id.*

¹⁷⁶ Ladin et al., *supra* note 25, 2281 (“Disparities in social determinants contribute to differential risk of liver failure, and thus demand for transplantation, a factor somewhat obscured by focusing exclusively on waitlisted patients.”).

¹⁷⁷ *Id.* at 2282 (“Redistributing organs based solely on waitlist characteristics may also violate the Maximin principle, which prioritizes concern for the worst-off, who, due to socially determinants, may never reach the waitlist.”).

¹⁷⁸ 42 C.F.R. § 121.4(a)(3).

¹⁷⁹ Pullen, *supra* note 16, at 1254 (“They feel that OPTN incorrectly narrows the focus to candidates on the waitlist when the Final Rule mandates patient access in a more general sense. This argument turns on the Final Rule’s charge that OPTN design allocation policies ‘to promote patient access to transplantation,’ without defining ‘patient.’ By this argument, the policy should also increasingly promote avoidance of transplant in tandem with access to those who fail preventive care.”).

Figure 5: Net Imports and Exports of Livers

Notes: Data on the total number of liver transplants across the United States by month come from the Scientific Registry of Transplant Recipients.¹⁸⁰ Net imports and exports are calculated as the total number of livers imported into or exported from a given DSA in 2017.

In general, Figure 5 demonstrates substantial disparity in the number of organs that DSAs import and export. That disparity is broadly consistent with the arguments of local proponents who contend that livers generally flow from poorer areas to wealthier areas of the country. It also demonstrates that the areas of the country who strongly oppose greater national organ sharing have the most to lose from such a system. For example, the DSAs containing areas like Boston, Los Angeles, and New York fall into the highest category of net importers. On the hand, the DSAs that include most of the counties in states like Tennessee, Alabama, South Carolina, Kansas, and Oklahoma export more organs than they import. While not all urban areas import more organs than they export, Figure 5 generally supports the concerns raised by local proponents that organs flow from rural to urban areas. National sharing would only exacerbate this, as the local advantage patients previously enjoyed disappears. Indeed, an early evaluation of the new, nationally focused liver allocation policy indicates that urban areas import more livers than under the old, locally focused policy.¹⁸¹

2. Incentives Matter

Beyond addressing the specific arguments leveled in favor of a nationally focused allocation policy, those in favor of a local focus argue that moving towards greater national organ sharing will create perverse incentives in at least two ways. First, they argue that, with a national allocation policy in place, there will be little incentive to correct underperforming OPOs. The size and quality (in terms of number of organs

¹⁸⁰ See SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS, *supra* note 134.

¹⁸¹ Chyou et al., *supra* note 127, at 3.

recovered) of OPOs varies significantly across the country.¹⁸² This has important implications for organ transplantation because OPOs represent the “frontlines of organ donation” and therefore the best avenue through which to increase the supply of available organs. “Not surprisingly, regions with better-performing OPOs tend to resent sending organs to regions with OPOs that perform poorly, as it is difficult to accept policies that allocate a scarce resource without taking into consideration variations in OPO performance.”¹⁸³

When allocation policies are geared towards the national distribution of organs, the incentives for local members of the transplant community to improve OPOs and increase the number of organs recovered are blunted. Instead of taking steps to increase the local supply, they can simply requisition organs from the national supply. While this may help their patients in the short run, it does little to increase the supply of available organs.¹⁸⁴ Indeed, this behavior over time can decrease the availability of organs across the country. The Centers for Medicare and Medicaid Services has recognized these incentives and taken some steps to address underperforming OPOs by increasing regulatory oversight and competition for OPO contracts.¹⁸⁵ While these marginal steps may improve the performance of OPOs to some extent, they cannot address the underlying incentives that transplant professionals have to raid the national supply instead of improving the local supply of organs.

Beyond the incentives a nationally focused allocation policy creates for transplant professionals at the termination of the transplant process, such a policy also has implications for those at the origination of this process—donors. The sickest first approach that the United States has always taken in the organ allocation context is often treated as an ethical maxim that requires little justification among those responsible for organ allocation policy.¹⁸⁶ This is not necessarily the case among potential donors who may consider other factors important when allocating livers. A 2019 study included a survey of potential donors that inquired about their views on the relative importance of various factors when allocating livers to transplant candidates.¹⁸⁷ While survey respondents reported that the relative sickness of patients should matter in allocation decisions, they also reported that geographic proximity

¹⁸² Pullen, *supra* note 16, at 1255; Seth J. Karp et al., *Fixing Organ Donation: What Gets Measured, Gets Fixed*, 155 JAMA SURGERY 687, 987 (2020).

¹⁸³ Pullen, *supra* note 16, at 1255.

¹⁸⁴ UNOS, *supra* note 26, at 7.

¹⁸⁵ ORGAN PROCUREMENT ORGANIZATION (OPO) CONDITIONS FOR COVERAGE FINAL RULE: REVISIONS TO OUTCOME MEASURES FOR OPOS CMS-3380-F, <https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos> (last visited Feb. 2, 2021). Recently, the Biden administration paused the new rules governing OPOs. Michael Brady, CMS pauses organ procurement, Part D e-prescribing rules (Jan. 29, 2021, 4:49 PM), https://www.modernhealthcare.com/policy/cms-pauses-organ-procurement-part-d-e-prescribing-rules?utm_source=modern-healthcare-daily-dose-friday&utm_medium=email&utm_campaign=20210129&utm_content=article3-image.

¹⁸⁶ Ethical Principles in the Allocation of Human Organs, <https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/> (last visited Feb. 21, 2021). See Heather W. O'Dell et al., *Public attitudes toward contemporary issues in liver allocation*, 19 AM. J. TRANSPLANTATION 1212, 1213 (2019) (“Current organ allocation almost exclusively prioritizes risk of waiting list death without clear ethical justification.”).

¹⁸⁷ O'Dell et al., *supra* note 186, at 1213.

mattered just as much as sickness and mortality risk in how these potential donors would choose to allocate livers.

In addition to demonstrating that “public preferences [for liver allocation policies] differ significantly from current practice,” the results of this study have implications for the overall supply of donated organs.¹⁸⁸ Public trust in the organ donation and allocation system is necessary for potential donors to buy into that system.¹⁸⁹ Without this trust, the number of donors may stagnate or even decline, implying that restoring a role for geography in the allocation system may be key to increasing the availability of donated organs.¹⁹⁰ Indeed, in response to the recent change in allocation policy, the Kansas legislature introduced a bill that would have allowed organ donors to limit their consent to donate only to in-state patients (effectively banning the exportation of some donated organs from the state).¹⁹¹ Though the bill did not become law, it signals the importance of taking the public opinion seriously because the public is ultimately the source of all donated organs.

While the incentives faced by OPOs and potential donors in the wake of the move to a national organ allocation policy are undeniably relevant, they are not as important as the incentives facing transplant hospitals and physicians, who make many of the most important decisions in the transplant system. The next Section examines the incentives facing them and addresses how these incentives weave throughout all the arguments that both sides have made in the national-local allocation debate.

III. EMPIRICAL ANALYSIS OF WAITLIST MANIPULATION

Those in favor of moving toward greater national sharing of livers rely heavily on the sickest first argument. And many of the rejoinders offered by opponents center primarily on MELD scores failing to capture the actual sickness of patients on waitlists. This Section reports an empirical analysis of this common thread running through both sides of the argument—whether the MELD score accurately reflects degree of sickness and, therefore, need for transplantation. It does so by directly addressing the most important concern over the reliability of MELD scores in representing medical urgency: waitlist manipulation.¹⁹²

The OPTN has explicitly recognized the potential for waitlist manipulation but recently noted that “[n]o studies have assessed the prevalence of waitlist manipulation.”¹⁹³ This Article addresses this critical gap in the existing evidence, contributing important new information to the debate over organ allocation policy. It focuses on manipulation that occurs in the gray areas of the organ allocation system. While such manipulation may not qualify as obviously illegal, it is particularly troubling because it may be both ubiquitous and clandestine, thus having a salient impact on the

¹⁸⁸ *Id.* at 1216.

¹⁸⁹ *Organ Donation Depends on Trust*, 387 THE LANCET P2575 (2016), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)30886-8/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)30886-8/fulltext)

¹⁹⁰ *Id.* See also UNOS, *supra* note 26, at 1 (noting that “jeopardizing public trust in the organ allocation system . . . could reduce organ donation rates”).

¹⁹¹ S.B. 194, 2019 Leg., Reg. Sess. (Kan. 2019).

¹⁹² The Institutional Review Board (IRB) evaluated the protocols and data analysis involved in this project and granted “exempt approval” (approval number 20-09-3951).

¹⁹³ UNOS, *supra* note 26, at 3.

functioning of organ allocation.¹⁹⁴ Indeed, manipulation of patients' status on transplant waitlists may impact more than just the next patient in line for an organ.¹⁹⁵ Following a scandal involving manipulation of the liver allocation system in Germany, for example, "[d]onation rates declined by 20 to 40 percent and resulted in a significant decline in the number of overall organ transplants performed."¹⁹⁶

This Section begins by examining the potential for waitlist manipulation, the factors that incentivize such manipulation, and a description of what that manipulation may look like. It then delves into a series of empirical analyses designed to elucidate that manipulation.

A. Manifestations of Manipulation

Before engaging with the specifics of liver waitlist manipulation, understanding the reasons for that manipulation can provide important context. From the outside, it may seem easy to blame the transplant physicians and centers responsible for manipulative tactics. However, they face powerful incentives to engage in these behaviors. Physicians have "fiduciary obligations to their own patients," and these often conflict with their "obligations of stewardship of organs in the OPTN allocation system."¹⁹⁷ When faced with a choice between the two obligations, it is hard to blame physicians for choosing the very real victims in front of them—their patients—over a relatively abstract concern about a faceless allocation system. Indeed, this choice is likely a simple example of the "identifiable victim effect" in which people are willing to save an "identifiable victim" at the expense of a larger number of unidentifiable "statistical victims."¹⁹⁸

Beyond this important incentive, the OPTN identified three other independent incentives to manipulate liver waitlists. First, physicians and transplant centers "benefit financially based on number of transplants performed."¹⁹⁹ Recent estimates place the charges connected with a liver transplant at over \$800,000.²⁰⁰ Second, "[t]here exists an incentive for transplant hospitals to increase transplant volume in order to . . . enhance the institution's reputation."²⁰¹ Third, increasing a hospital's transplant volume can "decrease the risk of regulatory scrutiny from adverse outcomes by growing the transplant denominator."²⁰² With more transplants

¹⁹⁴ To be clear, none of the evidence reported in this Article should be interpreted as allegations of illegal behavior by any person or entity. The data analyzed here cannot, and do not, provide sufficient information to uncover the type of deliberate activity that would violate existing laws.

¹⁹⁵ *Id.* at 7 ("While an individual patient may stand to benefit, the aggregate waitlist as a whole derives no net benefit when manipulation occurs.").

¹⁹⁶ *Id.* at 4. See also David Shaw, *Lessons from the German Organ Scandal*, J. INTENSIVE CARE SOC'Y 200, 201–02 (2013) (reviewing the scandal).

¹⁹⁷ *Id.* at 2.

¹⁹⁸ See Karen E. Jenni & George Lowenstein, *Explaining the "Identifiable Victim Effect"*, 14 J. RISK & UNCERTAINTY 235, 235–39 (1997) (describing the "identifiable victim effect").

¹⁹⁹ UNOS, *supra* note 26, at 7.

²⁰⁰ THE COST OF ORGAN AND TISSUE TRANSPLANTS IN AMERICA, https://www.milliman.com/-/media/Milliman/importedfiles/uploadedFiles/insight/2017/milliman-transplants_infographic-new.ashx (last visited Feb. 2, 2021).

²⁰¹ UNOS, *supra* note 26, at 7.

²⁰² *Id.* at 7.

completed, hospitals can effectively dilute their adverse outcomes through a higher volume of transplants.

Only rarely do ethical, economic, reputational, and regulatory incentives align as perfectly as they do in the context of manipulating liver waitlists. Unfortunately, this alignment weighs in favor of more manipulation. The OPTN recognized the possibility that transplant centers might manipulate MELD scores in a 2018 white paper.²⁰³ And “[m]any in the transplant community perceive, as expressed explicitly in the medical literature, that this [manipulation] is widespread.”²⁰⁴

The OPTN provided multiple examples of transplant physicians and centers engaging in duplicitous behavior,²⁰⁵ but this Article focuses on the manipulation of waitlists via MELD exception points. As described above, exception points can be awarded to individual patients if their MELD score does not accurately reflect their mortality risk.²⁰⁶ One common condition is hepatocellular carcinoma—a type of liver cancer for which liver transplants are the best treatment.²⁰⁷ However, exception points can be awarded for a variety of conditions.²⁰⁸ Awards of exception points for various conditions became standardized over time, but many conditions do not have standardized exception points. Instead, transplant physicians request and review boards award a customized number of points.²⁰⁹

During the data period analyzed here (2002–2017), the process of awarding exception points occurred at the OPTN regional level.²¹⁰ Once a physician diagnosed a patient with a relevant condition, that patient would apply for exception points based on that condition. A regional review board, comprised of transplant professionals from the region where the patient was awaiting a transplant, would review the application and grant exception points (or not) based on its medical judgment. If the review board awarded the patient exception points (either initially or after an appeal), the patient’s MELD score would increase. This exception MELD score would become the patient’s allocation MELD score, i.e., the one that determines waitlist priority, replacing the patient’s laboratory MELD score.²¹¹

Because exception points were awarded based on specific applications, often for conditions that did not have a standardized number of points, transplant professionals could manipulate this process in various ways to make their patients appear sicker than they were. A detailed review of all the clinical decisions that comprised individual exception point awards is well beyond the scope of this Article.²¹² In general, however, professionals had at least two major avenues of manipulation available. First, they could request exception points when those points were not (or

²⁰³ *Id.* at 6.

²⁰⁴ *Id.* at 1.

²⁰⁵ *See id.* at 3 (“Evidence that competition for organs drives physicians’ clinical behavior has been reported for both liver and heart transplantation.”).

²⁰⁶ Massie et al., *supra* note 26, at 2362.

²⁰⁷ David S. Goldberg & Kim M. Olthoff, *Standardizing MELD Exceptions: Current Challenges and Future Directions*, 1 CURRENT TRANSPLANTATION REPS. 232, 233 (2014).

²⁰⁸ *Id.*

²⁰⁹ *Id.*

²¹⁰ Massie et al. (2015), *supra* note 104, at 660.

²¹¹ It is possible to have an exception-based MELD score that is lower than a laboratory MELD score. This does not occur often, but when it does, the laboratory MELD score remains the patient’s allocation MELD score.

²¹² *Id.*

only marginally) medically warranted. Second, they could request a number of exception points that was too high for the patient's condition, i.e., overstate a patient's mortality risk.

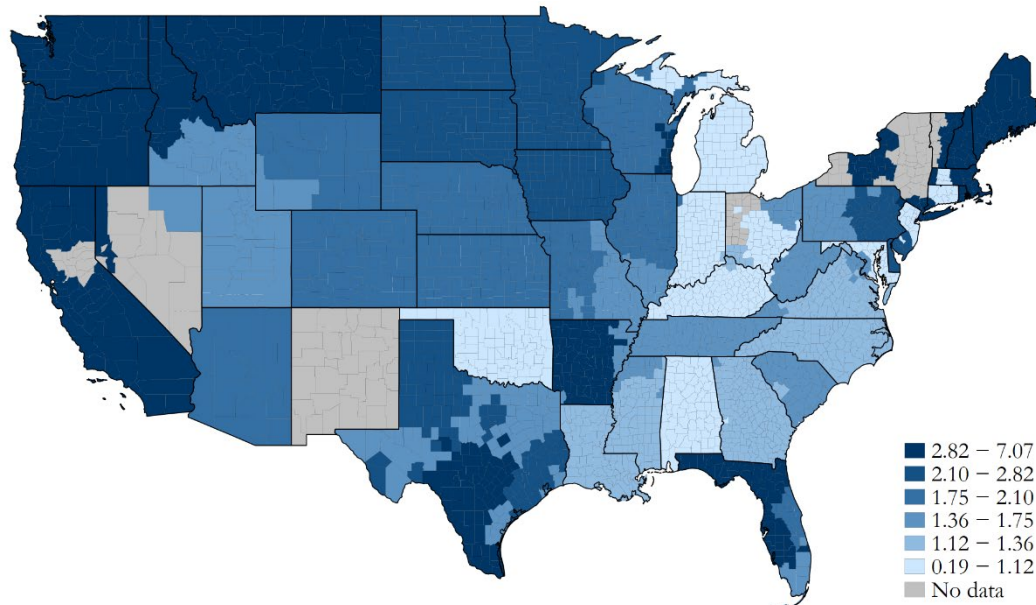
In theory, the regional review boards would deny inappropriate applications as neutral arbiters of medical urgency. However, these boards had an incentive to grant requests for exception points to patients in their region. By doing so, they could increase the apparent medical urgency of regional patients and thereby increase the likelihood that these patients could obtain livers. Increasing MELD scores across an individual region may not help those patients compete against one another but doing so could make those patients more competitive for livers donated outside the relevant region. In other words, regional review boards had an incentive to grant exception point applications that, while in the gray area, were not obviously inappropriate. Granting those requests would make their patients more competitive for livers and increase the number of transplants across the region generally.

This Article focuses on this margin of manipulation. In particular, the empirical analysis below examines the difference between the laboratory MELD score, which was difficult to manipulate, and the allocation MELD score, which could be manipulated by exception points. As detailed above, those in favor of local allocation rules have emphasized the phenomenon of "MELD inflation" as a reason that MELD scores do not accurately reflect medical urgency. The analysis here takes an important step beyond this. Simple MELD inflation across all patients does not necessarily disadvantage any particular set of patients. However, differential inflation whereby transplant professionals in certain areas of the country are more likely to exploit exception points could advantage patients in those areas.

My empirical analysis engages directly with this potential differential advantage to examine the existence and pervasiveness of waitlist manipulation within the liver allocation system. Throughout the analysis, I examine the average laboratory MELD, average allocation MELD, and average difference between the two at the DSA level. While review of exception point applications takes place at the regional level, the decision of whether to engage in manipulative tactics (and, if so, what kind of tactics to employ) would occur below the regional level. Additionally, because transplant centers within a given DSA compete over the same livers, the relevant margin of manipulation to consider is at the OPO level.

Before delving into that analysis, Figure 6 provides an overview of waitlist manipulation across the country in 2017—the last year of the data period examined here. This figure reports the average difference between the allocation and laboratory MELD scores in each DSA—I refer to this average difference as the "allocation-laboratory-MELD gap." This gap is calculated across all patients who appeared on waitlists in each DSA and is weighted by the number of days each patient spent on the waitlist in 2017. Figure 6 illustrates substantial geographic variation in the allocation-laboratory-MELD gap.²¹³ Certain patterns in this figure are worth noting.

²¹³ The evidence reported in Figure 6 is generally consistent with prior work, which has found regional variability in exception point applications and awards. See Curtis K. Argo et al., *Regional Variability in Symptom-Based MELD Exceptions: A Response to Organ Shortage?*, 11 AM. J. OF TRANSPLANTATION 2553, 2255–58 (2011) (reporting evidence of regional variation in MELD scores using data through 2006).

Figure 6: Average Allocation-Laboratory-MELD Gap

Notes: Data on the total number of liver transplants across the United States by month come from the Scientific Registry of Transplant Recipients.²¹⁴ The average allocation-laboratory MELD gap is calculated as the average gap among all patients actively waitlisted for a liver in 2017, weighted by the number of days each patient was listed.

DSAs that include wealthy, urban areas tend to have larger allocation-laboratory-MELD gaps than DSAs that include large, rural areas. Similarly, northeastern and western DSAs have larger gaps than midwestern and southern DSAs. These patterns are consistent with some of the criticisms leveled against current trends in allocation policy and with the argument that organs tend to flow from poor, rural areas to wealthy, urban areas. However, Figure 6 does not prove that these gaps are the result of greater manipulation of liver waitlists in wealthy, urban areas. The differences in the allocation-laboratory-MELD gaps may stem from different disease burdens across the country or other innocuous factors. Separating increases in MELD scores due to manipulation from these innocuous factors requires a more sophisticated empirical strategy. And that strategy must also address other important problems.

In general, any analysis of manipulative behavior will necessarily encounter two important problems in addition to the one just described. First, and perhaps most obviously, “[u]ncovering evidence of ethically dubious strategies is quite difficult because these practices are usually hidden under a veil of secrecy.”²¹⁵ Few transplant professionals would admit to manipulating a patient’s position on a waitlist, so looking for this type of evidence would be all but useless. To address this problem, this Article’s analysis focuses on administrative data to distill evidence of systematic manipulation in the allocation system that would appear if transplant professionals routinely, but surreptitiously, manipulate liver waitlists. Changes across the entire

²¹⁴ See SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS, *supra* note 134.

²¹⁵ Snyder, *supra* note 113, at 547.

allocation system can elucidate manipulative behavior, even if investigating any specific case would not necessarily yield evidence of the same.

However, using administrative data creates a second important problem: distinguishing routine changes in MELD scores (such as general MELD inflation) from changes in MELD scores that likely stem from manipulation. A general increase in MELD scores or in allocation-laboratory-MELD gaps may evince manipulation or it may simply stem from generic MELD inflation. To address this issue, the analysis here concentrates on changes in MELD scores following the adoption of policies that impact the availability and allocation of livers. By examining how different transplant professionals respond to policy changes that could affect the supply of livers for transplant, it is possible to estimate the extent of manipulative behavior within the allocation system. Identifying relevant policy and legal changes is key to an empirical strategy that can effectively isolate manipulation from other factors that influence MELD scores. An ideal policy (for this purpose) would clearly impact the incentives facing transplant professionals. The next Section examines responses to a change in a national allocation policy that meets this requirement. The following Section examines responses to changes in state laws that similarly meet this requirement.

B. Share 35: National Policy and Evidence of Manipulation

The OPTN often adjusts the allocation rules governing livers (and other organs). Not all of those changes in allocation policy are useful in examining potential waitlist manipulation. One recent change, however, did sufficiently change the incentives facing the transplant community that manipulative tactics may appear in administrative data: the Share 35 policy. This Section begins by discussing the details of this policy and the empirical strategy used to waitlist manipulation in the context of this policy change. It then reports the results of a series of empirical models.

1. Policy Context and Empirical Strategy

In 2013, the OPTN implemented the Share 35 policy, which changed the rules governing liver allocation for certain patients. Prior to the implementation of this policy, livers were first offered to transplant candidates in descending order of MELD scores within the DSA where the liver was recovered.²¹⁶ “Under Share 35, deceased donor livers [were] offered first to all candidates in the [OPTN region where the liver was recovered] with MELD of 35 or higher, regardless of DSA, before being offered to other local candidates and then regional candidates.”²¹⁷ Following the implementation of the Share 35 policy, transplant centers had a much greater incentive to ensure their patients achieved allocation MELD scores of 35 or higher. At this score, those patients would become eligible to compete for a much larger pool of livers than patients with MELD score of 34 or lower.

My empirical analysis exploits this change in allocation policy that created an important discontinuity in eligibility at a MELD score of 35. If manipulation occurs, it should become apparent at this discontinuity in eligibility. General manipulation could be disguised as generic MELD inflation. But changes in allocation MELD scores

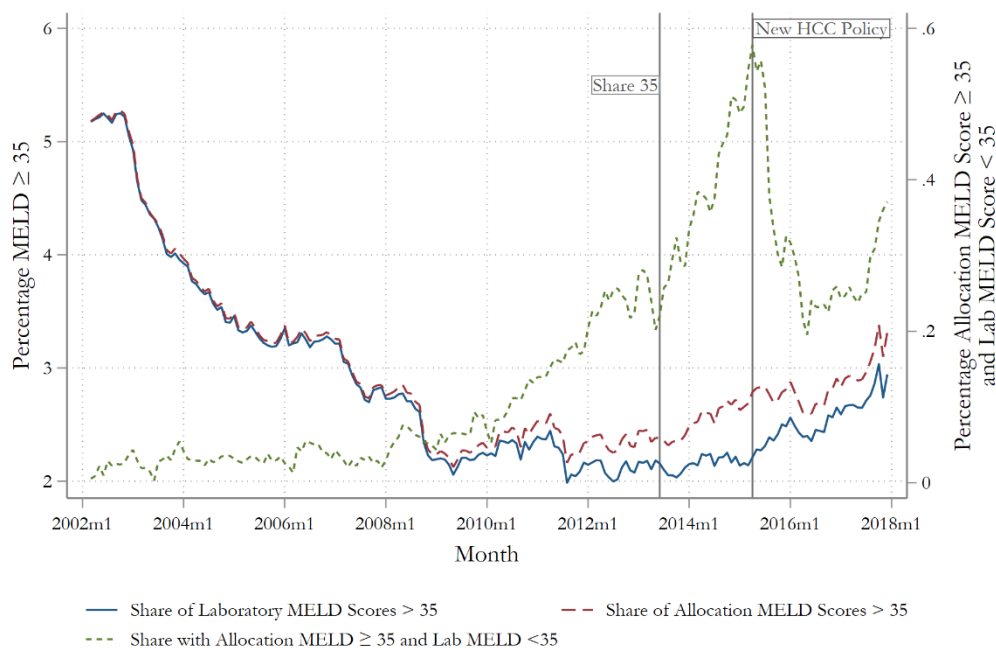
²¹⁶ Massie et al., *supra* note 104, at 659.

²¹⁷ *Id.*

unaccompanied by commensurate changes in laboratory MELD scores following a policy specifically designed to increase liver sharing at higher scores would suggest manipulation in liver waitlists. A gap between these two scores should exist naturally—the purpose of exception points is to raise a patient’s allocation MELD score to match their mortality risk. An increase in this gap following the implementation of a policy that makes crossing a specific allocation MELD threshold critical, however, suggests manipulation.

Figure 7 offers insight into MELD scores and the Share 35 policy. The solid blue line represents the percentage of patients nationally who had laboratory MELD scores of 35 or higher. Only about 5% of patients had a laboratory MELD score this high at the beginning of the MELD era in 2002. This percentage declined thereafter to between 2% and 3% before ticking up gently after 2009. The percentage of patients with allocation MELD scores of 35 or higher, represented by the red dashed line, follows the same general trend as laboratory MELD scores. However, in 2007, the percentage with allocation MELD scores of 35 or higher begins to diverge from the percentage with laboratory MELD scores of 35 or higher. This could be consistent with manipulation but may also simply reflect MELD inflation more broadly.

Figure 7: Waitlist MELD Scores Over Time



Notes: Data on the total number of liver transplants across the United States by month come from the Scientific Registry of Transplant Recipients.²¹⁸ MELD scores are calculated as the average score of all patients waitlisted for a liver transplant in the United States in the given month.

To separate potential manipulation from general MELD inflation, the green dotted line tracks the percentage of patients who had a laboratory MELD score less than 35 and an allocation MELD score of 35 or higher—this line is calibrated to the right axis in Figure 7. In other words, this line represents the percentage of patients

²¹⁸ See SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS, *supra* note 134.

who qualify for a donated liver under the Share 35 policy with their allocation MELD score but *not* with their laboratory MELD score. The share of patients with an allocation-laboratory-MELD gap that spans a score of 35 begins to increase along with the general increase in the difference between the two percentages around 2009. Importantly, however, when the OPTN changed its allocation policy around the 35 threshold in 2013 (indicated by the first vertical line), the percentage of patients who had an allocation MELD score of 35 or higher and a laboratory MELD score less than 35 spikes almost immediately. Given the new significance of achieving a MELD score of 35, this sudden increase in patients who failed to meet the threshold with their laboratory score but satisfied it with their allocation score suggests manipulation.

The spike following the implementation of the Share 35 program did not abate until the introduction of a new policy regarding the award of exception points for hepatocellular carcinoma (HCC). HCC represents the most common condition for which exception points are awarded and therefore was a potential point of widespread manipulation.²¹⁹ Given this concern, the OPTN “implemented a revised policy in October 2015 to modify the timing and maximum value of exception points for hepatocellular carcinoma (HCC) candidates.”²²⁰ These changes required that patients wait longer to receive exception points in connection with HCC and reduced the maximum exception points available.²²¹ Thus, the OPTN made HCC a less attractive avenue of manipulation, which helps explain the precipitous drop in the percentage of patients whose allocation-laboratory-MELD gap spans the critical 35 threshold.

The increase and decrease in connection with the Share 35 policy and HCC policy revision visible in Figure 7 strongly suggest the existence of manipulation in the liver allocation system. They do not, however, prove this existence because trends alone cannot rule out the possibility that changes in unrelated factors happened to occur around the same time as these policy changes and caused the increase and decrease in Figure 7. To control for these potentially confounding factors, I estimate a series of regression models. These models focus on potential changes in manipulative tactics around the Share 35 policy. The revisions in the HCC policy are certainly important, but I exclude them from my analysis for two important reasons.²²² First, the policy revision included an unusual change in the implementation of exception

²¹⁹ David S. Goldberg & Kim M. Olthoff, *Standardizing MELD Exceptions: Current Challenges and Future Directions*, 1 CURRENT TRANSPLANTATION REPS. 232, 233 (2014) (“The most common indication for MELD exception points is HCC.”). See also *id.* at 235–36 (expressing concern about regional variation in exception point awards and the potential for this variation to impact liver allocation).

²²⁰ Tanveen Ishaq et al., *Liver transplantation and waitlist mortality for HCC and non-HCC candidates following the 2015 HCC exception policy change*, 18 AM J. TRANSPLANTATION 564, 565 (2018).

²²¹ *Id.* at 565 (“Before the policy change, HCC candidates received exception points of 22 for the first 3 months after initial application, followed by exception points of 25 for the first 3-month extension, 28 for the second 3-month extension, and 29 for the third 3-month extension. Since the October 2015 policy change, HCC candidates are listed at their calculated MELD scores for the first 3 months after initial application and for the first 3-month extension. Subsequently, they receive exception points of 28 for the second 3-month extension at 6 months and 29 for the third 3-month extension at 9 months. The revised policy also reduces the maximum exception points for HCC candidates from 40 to 34.”).

²²² Throughout the remainder of my analysis, I retain all patients who had HCC exception points. However, excluding all patients who received these points from the analysis does not meaningfully affect the empirical results described below. Similarly, including HCC patients but eliminating any exception points in connection with an HCC diagnosis does not meaningfully impact the results described below.

points for HCC patients, and this complicates the estimation of the policy's true effect. Second, the policy change (coupled with a 6-month delay) occurs near the end of the data period considered here. Without sufficient post-implementation data, it is not possible to estimate policy effects reliably.

Ideally, the models focusing on the Share 35 policy would estimate the effect of this policy on a subset of transplant candidates and use the remaining candidates as a control group. The control group serves the important function of providing information on what would have happened to the treated group (i.e., those subject to the new policy) if the policy have never been enacted. In the case of changes to national allocation policy, unfortunately, there is no obvious control group because all transplant candidates became subject to the new policy at the same time.

To address this problem, I adopt a strategy used in a previous investigation of potential manipulation.²²³ I examine changes in MELD scores following the adoption of the Share 35 policy in DSAs that contain different numbers of transplant centers. As the number of centers within a DSA—all of which rely on a single OPO for local liver procurement—increases, the pressure to engage in manipulative tactics increases. “If one center in [a DSA] decided not to engage in strategic[behavior], that center would face the prospect of losing opportunities to perform liver transplants. More centers should lead to more competition.”²²⁴ Thus, following the Share 35 policy, the response to the incentives created by that change should be stronger in DSAs that contain larger numbers of transplant centers. Given that the Share 35 policy created an incentive to raise allocation MELD scores by way of exception points to meet the 35-point threshold, this line of reasoning leads to the following hypotheses: If transplant centers manipulate MELD scores, (1) DSAs containing more transplant centers should see a larger increase in the average allocation-laboratory-MELD gap than DSAs with fewer transplant centers following the Share 35 policy, and (2) DSAs containing more transplant centers should see a larger increase in the percentage of patients with an allocation MELD score of 35 or higher and a laboratory MELD score of 34 or lower.

To test these hypotheses, I estimate regression models that can effectively control for other factors that may also influence MELD scores. Specifically, I estimate models akin to the difference-in-differences models used by social scientists to isolate the effect of specific policies from confounding factors. Traditional difference-in-differences models compare trends in the relevant outcome variable among groups subject to a new policy and groups not subject to that policy, with the latter group serving as a control group.²²⁵

Instead of this traditional approach, the models estimated here compare trends in the relevant outcome variables among DSAs with different numbers of transplant centers to examine whether centers subject to more competition respond differently to the Share 35 policy.²²⁶ Within this framework, DSAs with only a single transplant center (and therefore subject to no competition) serve as the baseline comparator group. The models estimate how DSAs with greater numbers of transplant centers

²²³ Snyder, *supra* note 113, at 554.

²²⁴ *Id.*

²²⁵ The control group generates a counterfactual of what would have happened in the group subject to the new policy had that policy never become effective.

²²⁶ Snyder, *supra* note 113, at 554. (employing a similar strategy)

(and thus subject to more competition) respond to the Share 35 policy relative to this baseline group.

To implement these models, I estimate a series of multivariate linear regressions. Separate regression models include as dependent variables the following: the average allocation-laboratory-MELD gap and the percentage of patients who have a laboratory MELD score below 35 with an allocation MELD score at or above 35. Each average is separately calculated for each DSA in each month.²²⁷ The primary independent variables include: an indicator variable for whether the Share 35 policy had become effective and a series of indicator variables for the number of transplant centers operating in a given DSA in a given month. Throughout the data period considered here, DSAs had between one and nine transplant centers operating within their borders. The models also include interaction terms between the Share 35 indicator variable and the number-of-transplant-centers indicator variables. These interaction terms allow the models to estimate the differential impact of the Share 35 policy across DSAs with different numbers of transplant centers. In addition to these variables of interest, each model includes a control variable for the average number of days that patients have spent on the waitlist in a given DSA. This variable controls for the impact longer waiting times may have on MELD scores.

In addition to the variables of interest and control variable, every model includes a complete set of indicator variables for individual DSAs and months. The DSA variables control for observed and unobserved characteristics of individual DSAs. For example, if transplant centers with a certain DSA have idiosyncratic tendencies in how they request exception points, the DSA indicator variables will control for these tendencies even though they are unobserved. The month variables control for observed and unobserved temporal trends that may impact MELD scores. For example, if the supply of livers unexpectedly increases in a particular month, the month indicator variables will control for this, even though the reason for the spike in supply remains unknown. The DSA and month indicator variables absorb much of the idiosyncratic variation present in average MELD scores, obviate the need for many control variables, and allow the models to isolate potential manipulative tactics in connection with the Share 35 policy.²²⁸

2. Results and Discussion

Figure 8 reports the results from the primary regression model. Each pair of bars represents the difference between the allocation-laboratory-MELD gap in DSAs with a single transplant center and DSAs with the number of transplant centers listed below the bars. The blue bars represent this difference prior to the implementation of the Share 35 policy,²²⁹ and the red bars represent this difference after the

²²⁷ These averages are calculated for all patients actively waitlisted for a liver and are weighted by the number of days each patient was actively waitlisted in a given month.

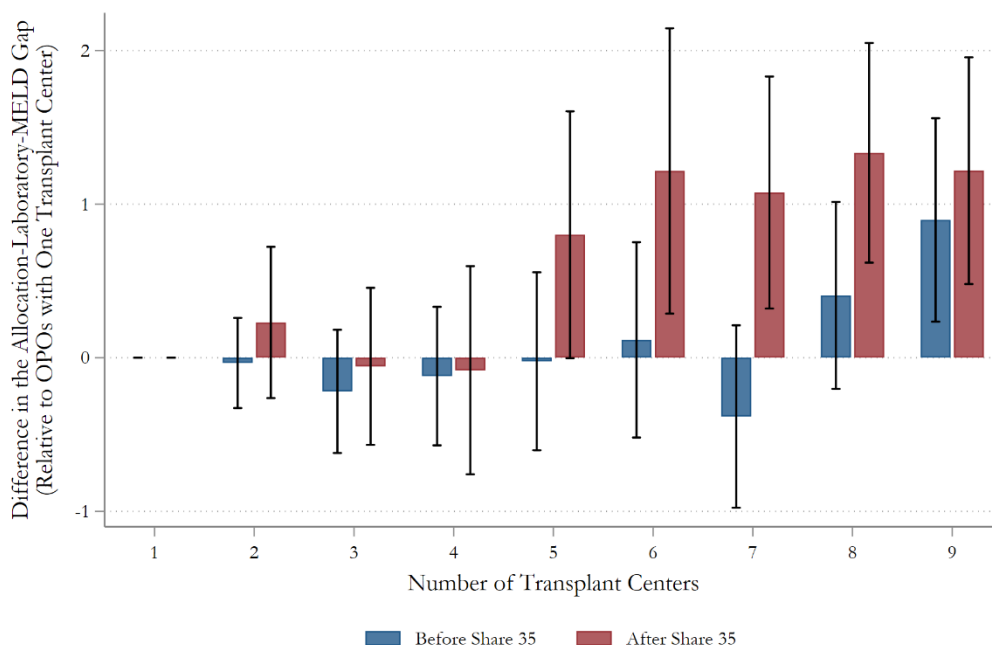
²²⁸ Throughout the analysis, I calculate standard errors clustered at the DSA level to correct for serial autocorrelation.

²²⁹ Each blue bar represents the transformed coefficient of the indicator variable for the relevant number of transplant centers.

implementation of the Share 35 policy.²³⁰ For example, consider the bars associated with DSAs containing five transplant centers. The blue bar is quite small, indicating that the allocation-laboratory-MELD gap in DSAs with five transplant centers was essentially the same as this gap in DSAs with a single transplant center prior to the Share 35 policy. The red bar is much larger and indicates that the allocation-laboratory-MELD gap in DSAs with five transplant centers was approximately 1.2 points larger than this gap in DSAs with a single transplant center. The capped black lines overlaying each bar represent 95% confidence intervals. If this line does not cross the horizontal line indicating zero, then the associated effect is statistically significant.²³¹

²³⁰ Each red bar represents the transformed sum of the coefficient of the indicator variable for the relevant number of transplant centers, the Share 35 indicator variable, and the interaction between these two indicator variables.

²³¹ Here, statistical significance indicates that the allocation-laboratory-MELD gap in DSAs with the indicated number of transplant centers is statistically significantly different from this gap in DSAs with a single transplant center.

Figure 8: Effect of Share 35 Policy on Allocation-Laboratory-MELD Gap

Notes: Each pair of bars represents the difference between the allocation-laboratory-MELD gap in DSAs with a single transplant center and DSAs with the number of transplant centers listed below the bars. Each pair of bars represents coefficient estimates from a regression model with the average allocation-laboratory-MELD gap at the DSA-month level as the dependent variable. The model includes an indicator for the implementation of the Share 35 policy, a full set of indicators for different number of transplant centers within DSAs, and an interaction between these indicators and the Share 35 indicator. The blue bars represent the coefficients on the number-of-transplant-center indicator variables. The red bars represent the sum of these indicator variables with the associated interaction between the number-of-transplant-center indicator and the Share 35 indicator. The model also includes the natural logarithm of the average number of days spent on the waitlist, calculated at the DSA-month level, and a full set of DSA and month indicator variables. The capped black lines overlaying each bar represent 95% confidence intervals, and confidence intervals are calculated via the delta method. Data on the total number of liver transplants across the United States by month come from the Scientific Registry of Transplant Recipients.²³²

In general, the results in Figure 8 demonstrate that the Share 35 policy widened the gap between allocation and laboratory MELD scores to a greater extent in DSAs with more transplant centers. Prior to the Share 35 policy, only DSAs with nine transplant centers had an allocation-laboratory-MELD gap that was statistically significantly different from DSAs with a single transplant center. The allocation-laboratory-MELD gaps in DSAs with eight or fewer transplant centers were statistically indistinguishable from the gap in DSAs with a single transplant center.

Following the implementation of the Share 35 policy, a very different pattern emerges. DSAs with five or more transplant centers see a meaningful and statistically significant spike in the allocation-laboratory-MELD gap relative to DSAs with a single transplant center. These results suggest that transplant centers in DSAs with more competition for donated livers (i.e., those with a greater number of transplant centers)

²³² See SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS, *supra* note 134.

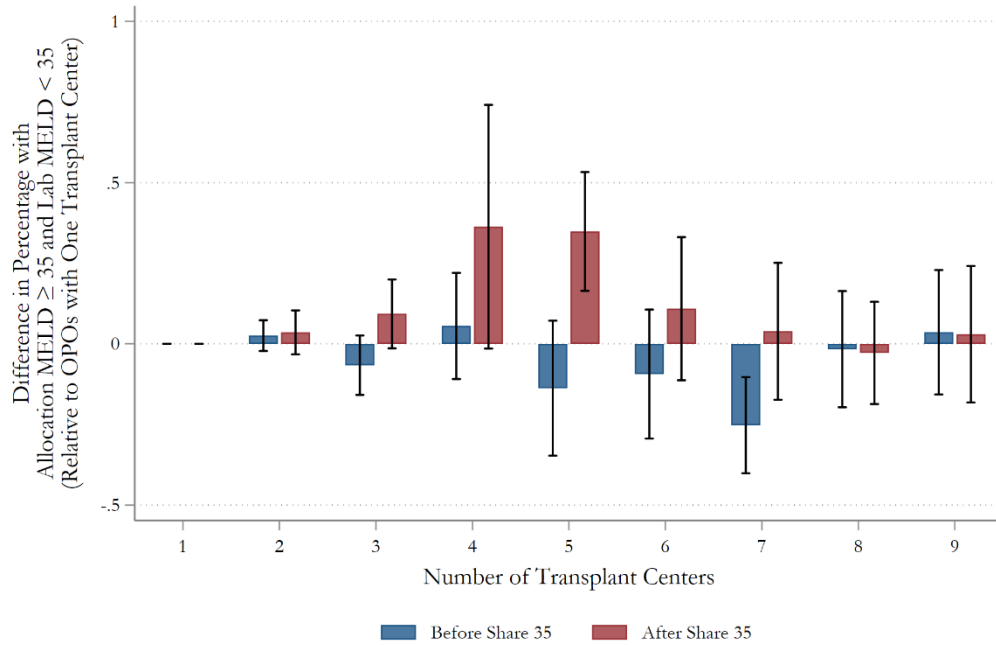
change their behavior with respect to exception points to a greater degree than transplant centers facing less competition. This change in behavior is consistent with the use of manipulative tactics to maintain or increase the number of liver transplants in the face of competition. The Share 35 policy provided transplant centers with a clear target of manipulation, and the results presented in Figure 8 suggest that transplant centers facing more competition for livers responded with greater manipulation.

To better understand these results as evidence of manipulation, consider a DSA with a single transplant center and a DSA with six transplant centers. The results imply that the Share 35 policy increased the average mortality risk of patients waitlisted in the six-center DSA relative to those in the single-center DSA commensurate with a one-point increase in the average MELD score. Under the assumption that allocation MELD scores accurately reflect mortality risk, these results make little intuitive sense. A greater number of transplant centers should, if these centers provide effective healthcare, be associated with a decline in mortality risk. Under the alternative assumption that MELD scores are manipulated, however, the results make more intuitive sense. A greater number of transplant centers within a DSA leads to more competition among those centers, which leads to greater manipulation of liver waitlists via exception points. In other words, the results in Figure 8 suggest that liver waitlist priority is subject to manipulation via exception points.

To further explore the existence and pervasiveness of manipulation, Figure 9 reports the results from a regression model with an indicator for whether a patient has an allocation MELD score of 35 or higher and a laboratory MELD score of 34 or lower as the dependent variable. Except for the change in the dependent variable, the model reported in Figure 9 is the same in all respects as the one reported in Figure 8. Each pair of bars represents the difference in the proportion of patients who have an allocation MELD of 35 or higher and a laboratory MELD of 34 or lower in DSAs containing the number of transplant centers listed below relative to single-center DSAs.²³³ As before, the blue bars represent this difference prior to the implementation of the Share 35 policy, and the red bars represent this difference after the implementation of the Share 35 policy.

²³³ The blue and red bars are calculated the same way as above.

Figure 9: Effect of Share 35 Policy on Percentage of Patients with Allocation MELD ≥ 35 and Laboratory MELD < 35



Notes: Each pair of bars represents the difference between the allocation-laboratory-MELD gap in DSAs with a single transplant center and DSAs with the number of transplant centers listed below the bars. Each pair of bars represents coefficient estimates from a regression model with the proportion of patients with an allocation MELD score of at least 35 and a laboratory MELD score below 35 at the DSA-month level as the dependent variable. The model includes an indicator for the implementation of the Share 35 policy, a full set of indicators for different number of transplant centers within DSAs, and an interaction between these indicators and the Share 35 indicator. The blue bars represent the coefficients on the number-of-transplant-center indicator variables. The red bars represent the sum of these indicator variables with the associated interaction between the number-of-transplant-center indicator and the Share 35 indicator. The model also includes the natural logarithm of the average number of days spent on the waitlist, calculated at the DSA-month level, and a full set of DSA and month indicator variables. The capped black lines overlaying each bar represent 95% confidence intervals, and confidence intervals are calculated via the delta method. Data on the total number of liver transplants across the United States by month come from the Scientific Registry of Transplant Recipients.²³⁴

The results reported in Figure 9 do not as clearly suggest the occurrence of manipulation as do the results in Figure 8. In general, DSAs with more transplant centers saw their percentages of patients with allocation MELD scores of 35 or higher and laboratory MELD scores of 34 or lower increase relative to single-transplant-center DSAs. These increases are concentrated in DSAs with between four and six transplant centers. DSAs with seven or more transplant centers saw relatively little change. While this evidence does not imply the occurrence of manipulation to the same degree that the evidence in Figure 8 does, it does provide some support for the increased use of manipulation in connection with the Share 35 policy. Importantly, this evidence captures the essence of that manipulation, as it demonstrates a greater

²³⁴ See SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS, *supra* note 134.

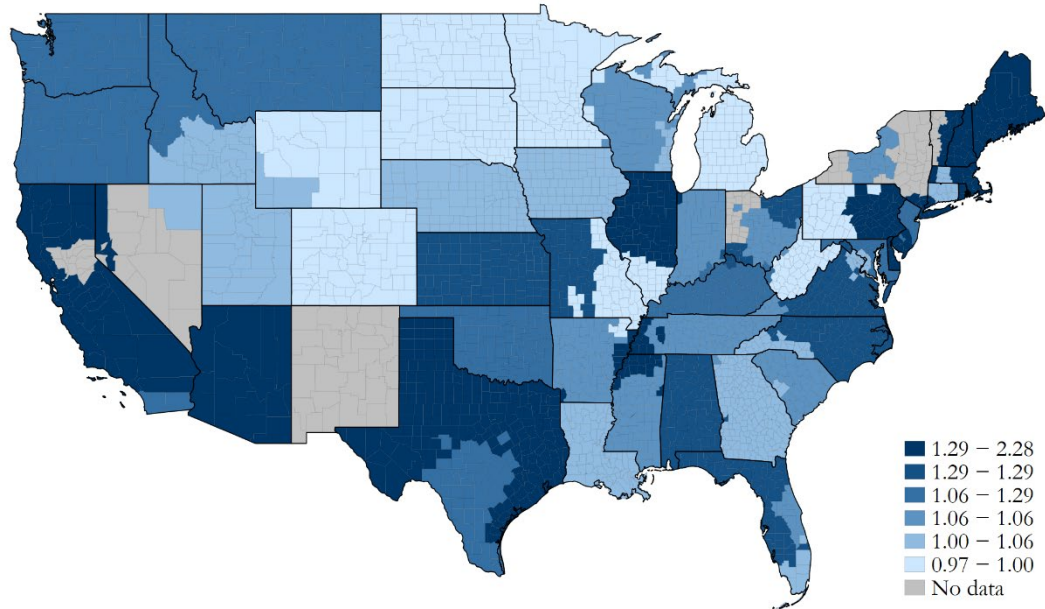
increase in patients that qualify for a liver transplant under the Share 35 policy with their allocation MELD score but not with their laboratory MELD score among DSAs subject to more competition for donated livers.

Under the hypothesis that MELD scores accurately capture medical need, the Share 35 program should have reduced the percentage of patients who had an allocation MELD score of at least 35 but a laboratory MELD score below 35. Patients with this set of scores would have more easily qualified for a liver under the Share 35 policy, meaning that the overall percentage of these patients should have declined. Under the hypothesis that manipulation occurs, the share of patients with a 35 or higher allocation MELD score and sub-35 laboratory MELD score should increase, as transplant centers target the 35 threshold with manipulation of exception points. This second hypothesis better explains the results reported in Figure 9.

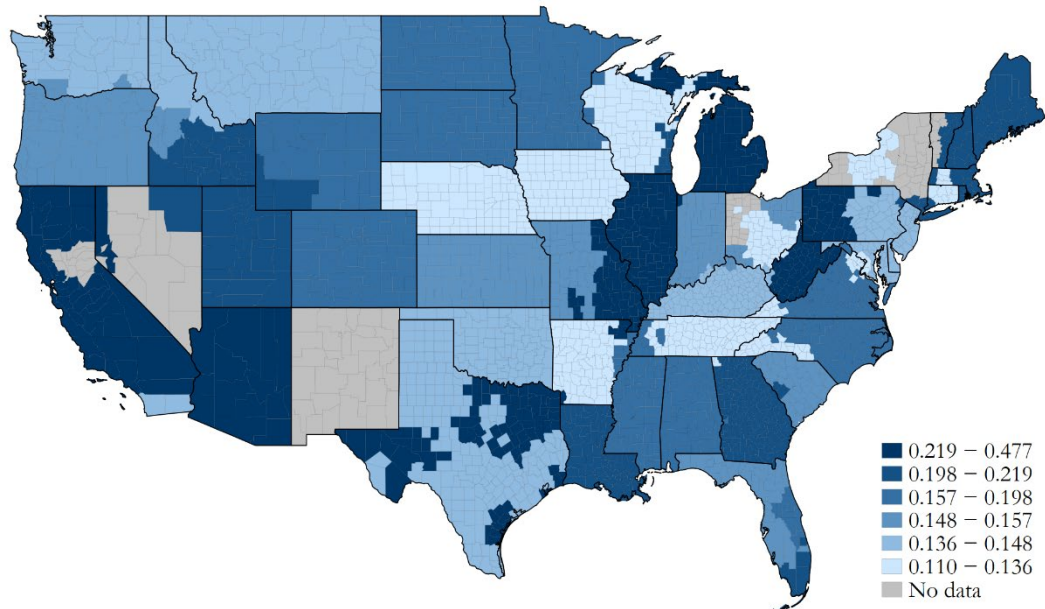
In general, the results in Figures 8 and 9 demonstrate the occurrence of waitlist manipulation. To better situate that evidence within the overall organ allocation debate, Figure 10 translates the regression results into predictions. Specifically, Panel A reports the predicted allocation-laboratory-MELD gap for all 58 DSAs in 2017, using the regression results reported in Figure 8. Similarly, Panel B reports the predicted percentage of patients with an allocation MELD score of at least 35 and a laboratory MELD score below 35. By translating the regression results into specific predictions, Figure 10 clearly demonstrates the relevance of those results to the current allocation debate. In general, darker areas of the country have higher predicted waitlist manipulation in both panels than do lighter areas of the country.

Figure 10: Predicted Changes in MELD Outcomes in Connection with the Share 35 Policy

Panel A: Predicted Changes in the Allocation-Laboratory-MELD Gap



Panel B: Predicted Changes in the Percentage of Patients with Allocation MELD ≥ 35 and Laboratory MELD < 35



Notes: Predicted changes are based on regression results reported in Figures 8 and 9. All predictions are for the year 2017

Overall, the evidence derived from changes in national allocation policy suggests the occurrence of waitlist manipulation. The presence of manipulation has salient implications for the arguments presented in favor of and against the movement toward national organ allocation policies. Given the importance of these implications

(and the literal life-and-death consequences), I extend the analysis to examine manipulation with other empirical strategies before discussing the policy ramifications of the results. These other analyses can provide either support for the presence of manipulation or evidence against the existence of manipulation.

C. Cannabis Access: State Policy and Evidence of Manipulation

State law plays no direct role in the allocation of livers or other organs, but it nonetheless can impact the organ allocation system. For example, state governments can increase or decrease the supply of organs through various policies. These impacts are often unintended, and this unintentional effect can prove useful in the empirical context because these effects can elucidate how the transplant system adjusts to changes in the availability of organs that are unrelated to changes in OTPN policy. Over the last several decades, the opioid crisis has ravaged the United States. For all of the tragedy inflicted by this crisis, however, it has represented a boon in organ supply. As states have begun addressing this crisis in various ways, they have restricted a previously increasing supply of organs. This phase of the analysis focuses on reductions in organ supply associated with these state policy changes to examine potentially manipulative behavior to maintain or increase the supply of livers. This Section begins by detailing the relevant policy changes and empirical strategy before reporting the results from a series of empirical models.

1. Policy Context and Empirical Strategy

Though the opioid crisis has caused hundreds of thousands of deaths since it began approximately two decades ago, one small “silver lining” has been an increase in donated organs in connection with overdose deaths.²³⁵ A recent study “found a 24-fold increase in [overdose-death donor] transplants, from 149 in 2000 to 3533 in 2016.”²³⁶ While some experts have expressed concern that organs recovered from those dying overdose-related deaths may pose higher risks to transplant recipients,²³⁷ recent work has demonstrated that these organs are comparable in quality to organs recovered from other donors. One study concluded that “[u]nadjusted rates of 5-year patient and graft survival for recipients of [overdose-death donor] organs were equivalent to or marginally higher than those for recipients of [trauma-death donor] organs (who are generally considered optimal donors) and [medical-death donor] organs.”²³⁸

As the opioid crisis progressed, those dying from overdose deaths contributed larger and larger shares of the overall pool of donated organs. One OPO reported that

²³⁵ Katharine Q. Seelye, *As Drug Deaths Soar, a Silver Lining for Transplant Patients*, N.Y. TIMES (Oct. 6, 2016), <https://www.nytimes.com/2016/10/06/us/as-drug-deaths-soar-a-silver-lining-for-organ-transplant-patients.html> (“As more people die from overdoses than ever before, their organs — donated in advance by them or after the fact by their families — are saving lives of people who might otherwise die waiting for a transplant.”).

²³⁶ Christine M. Durand et al., *The Drug Overdose Epidemic and Deceased-Donor Transplantation in the United States: A National Registry Study*, 168 ANN. INTERNAL MED. 702, 707 (2018).

²³⁷ See, e.g., Scott G. Weiner et al., *The Opioid Crisis and Its Consequences*, 101 TRANSPLANTATION 678, 679 (2017) (noting the organs recovered from those dying of overdose may pose higher risk due to concerns over disease transmission (HIV, hepatitis B, and hepatitis C virus)).

²³⁸ Durand et al., *supra* note 236, at 708.

drug users accounted for 4% of all donations in 2010 but 27% in 2016.²³⁹ Based on these increasing proportions, policies aimed at curbing opioid abuse and opioid-related deaths could pose serious threats to the supply of transplantable organs. And as the opioid crisis deepened, states began enacting policies aimed at ameliorating the effects of this crisis. These policies included passing pain clinic legislation and creating prescription drug monitoring programs.²⁴⁰ However, one policy that has, somewhat unexpectedly, proven effective at combatting the opioid crisis is the enactment of cannabis access laws.²⁴¹ These laws remove state-law barriers to obtaining and using cannabis, and evidence suggests that opioid users can more easily substitute cannabis for opioids,²⁴² thereby reducing the risk of overdose death.²⁴³

The passage of cannabis access laws by different states provides a useful setting in which to examine the impact of shocks to the supply of donated organs and estimate the existence and pervasiveness of waitlist manipulation. Because states pass cannabis access laws for reasons wholly unrelated to organ transplantation, they represent nearly random shocks to organ supply, akin to a laboratory setting. This near randomness from the perspective of transplantation allows an analysis to examine changes in manipulative behavior without substantial concerns that other factors may change contemporaneously with cannabis access laws and thereby confound the analysis. By focusing on changes in MELD scores in connection with the organ supply shocks created by cannabis access laws, an empirical analysis can examine potentially manipulative behavior as transplant professionals adjust to these shocks.

Despite these advantages, examining the impact of cannabis access laws on potential manipulation requires overcoming a salient empirical obstacle. States pass cannabis access laws, while DSAs determine eligibility for certain organs. Because the borders of DSAs are not co-extensive with state borders, I cannot estimate traditional difference-in-differences models as described above. These models assume that changes in the relevant policy (the “treatment”) becomes effective within an entire unit at the same time. The unit of analysis here is the DSA, while the unit for cannabis access laws is the state. To address this critical problem, I follow the lead of a recent study on organ waitlists and estimate difference-in-differences models akin to dose-response models.

Stacy Dickert-Conlin and colleagues recently examined the effect of state motorcycle helmet laws on transplant waitlists and transplant recipients.²⁴⁴ While the focus of their study differs from the focus of this Article, they encountered a similar problem of estimating the impact of state laws on transplant outcomes at the DSA

²³⁹ Seelye, *supra* note 235.

²⁴⁰ Thomas C. Buchmueller & Colleen Carey, *The Effect of Prescription Drug Monitoring Programs on Opioid Utilization in Medicare*, 10 AM. ECON. J. ECON. POL’Y 77, 109 (2018).

²⁴¹ Hefei Wen & Jason M. Hockenberry, *Association of Medical and Adult-Use Marijuana Laws With Opioid Prescribing for Medicaid Enrollees*, 178 JAMA INTERNAL MED. 673, 675–78 (2018).

²⁴² See McMichael, Van Horn & Viscusi, *supra* note 32, at 16 (“One of the primary—though, not the only—mechanisms by which RCLs and MCLs may reduce opioid prescriptions is by allowing those suffering from pain, particularly chronic pain, to substitute cannabis for opioids in the treatment of their pain.”).

²⁴³ See Bachhuber et al., *supra* note 32, at 1668 (“Medical cannabis laws are associated with significantly lower state-level opioid overdose mortality rates.”).

²⁴⁴ Stacy Dickert-Conlin et al., *Allocating Scarce Organs: How a Change in Supply Affects Transplant Waiting Lists and Transplant Recipients*, 11 AM. ECON. J. APPLIED ECON. 210, 210 (2019).

level.²⁴⁵ To address this issue, they defined their state-law variable based on the population within a given DSA that was covered by the relevant state law.²⁴⁶ Counties comprise DSAs, and the researchers determined whether the relevant law was binding based on the state in which a county was located. Using population data for individual counties, they calculated the share of each DSA that was bound by the relevant state law.²⁴⁷

Following the lead of Dickert-Conlin and colleagues, I construct a variable for medical cannabis access laws using a population-weighted approach. I do so at the year level, as did the Dickert-Conlin team, and similarly rely on yearly population data from the National Cancer Institute.²⁴⁸ This variable takes values between 0 and 1, commensurate with the proportion of a DSA's population covered by a cannabis access law. My analysis focuses on medical cannabis access laws and excludes recreational cannabis access laws because relatively few states have adopted the former type of cannabis access law. With few states adopting recreational cannabis access laws prior to the end of my data period in 2017, estimates based on the adoption of these laws may not be robust.²⁴⁹ Data on cannabis access laws come from a recent study, which categorized all such laws through 2018.²⁵⁰

Next, recognizing that transplant centers in one DSA will respond to supply shocks in neighboring DSAs, the Dickert-Conlin team also considered the impact of the share of a given DSA covered by the relevant law on neighboring DSAs.²⁵¹ Following their lead, I construct a variable that measures the share of the population covered by a cannabis access law in DSAs that share a border with a given DSA. This contiguous measure is particularly important in my analysis because manipulative behavior may often be designed to increase the number of livers imported from other DSAs. Indeed, this has been one of the primary arguments leveled against those in favor of national organ allocation policies.²⁵² Livers may be imported from any other DSA, but neighboring DSAs are the most obvious targets based on their proximity and the fact that livers do not remain viable for long periods after they are recovered. Accordingly, I construct a measure of the proportion of the population in contiguous DSAs that is covered by a cannabis access law.²⁵³

The construction of these two variables—the proportion of a DSA covered by a cannabis access law and the proportion of neighboring DSAs covered by a cannabis access law—allows the analysis to test hypotheses about manipulative

²⁴⁵ *Id.* at 217.

²⁴⁶ *Id.* (explaining that the relevant legal variable “is the share of the DSA’s population not covered by a universal helmet law for at least six months in [a given] year.”).

²⁴⁷ *Id.* at 217–18.

²⁴⁸ *Id.* at 217.

²⁴⁹ See Benjamin J. McMichael et al., “*Sorry*” Is Never Enough: How State Apology Laws Fail to Reduce Medical Malpractice Liability Risk, 71 STAN. L. REV. 341, 356 (2019) (noting similar concerns when few states had enacted one type of apology law).

²⁵⁰ McMichael, Van Horn & Viscusi, *supra* note 32, at 5.

²⁵¹ See, e.g., Dickert-Conlin et al., *supra* note 244, at 227 (reporting estimates of this effect).

²⁵² See *supra* Part II.C.

²⁵³ This approach has been employed in studies beyond those focusing on organ transplantation. See Ethan M. Lieber, *Medical Malpractice Reform, the Supply of Physicians, and Adverse Selection*, 57 J.L. & ECON. 501, 503–06 (2014) (examining changes in bordering jurisdictions); Benjamin J. McMichael, *Beyond Physicians: The Effect of Licensing and Liability Laws on the Supply of Nurse Practitioners and Physician Assistants*, 15 J. EMPIRICAL L. STUD. 732, A31 (2018) (same).

behavior in a straightforward manner. As the share of the population covered by a cannabis access law increases, the supply of organs from overdose deaths will decrease.²⁵⁴ If waitlist manipulation occurs, then the allocation-laboratory-MELD gap should increase. As transplant centers increase manipulation via exception points to ensure their patients maintain access to livers as the supply of livers dwindles, the allocation MELD will increase more than the laboratory MELD.²⁵⁵ On the other hand, if manipulation is not widespread, then the allocation-laboratory-MELD gap should not increase as a greater proportion of the population becomes subject to cannabis access laws. The allocation and laboratory MELD scores may increase as patients must wait longer to receive a liver, but the gap between the two should will not widen significantly.²⁵⁶

One specific, but important, question is whether the share of a DSA's own population covered by a cannabis access law or the share of contiguous DSAs' populations covered by cannabis access laws will have a stronger effect on potentially manipulative behavior. A DSA's own population may, at first glance, appear to be more important, but the contiguous population may prove more relevant for at least two reasons. First, to the extent manipulation is designed to increase organ importation from other DSAs, the contiguous population is more relevant than a DSA's own population. If transplant centers manipulate waitlists via exception points in response to changes within their own DSAs, they may not gain much, since their patients would generally have first access to these organs in any event. By manipulating waitlists in response to changes in nearby DSAs, however, transplant centers can maintain or increase their supply of imported livers and increase the number of transplants they perform. Second, David L. Weimer has explained that, in the context of organ transplantation, the salience of losses often plays a central role.²⁵⁷ This suggests that transplant centers may respond more strongly to the losses in organ imports from other DSAs.

To evaluate these hypotheses and questions, I again estimate a series of linear regression models. Separate models include as dependent variables the following: the average laboratory MELD score, the average allocation MELD score, and the average allocation-laboratory-MELD gap. The unit of observation in all of these models is the DSA at the year level. These averages are calculated for all patients actively waitlisted for a liver and are weighted by the number of days each patient was actively waitlisted in a given year. The primary independent variables include the proportion of a DSA's population that is subject to a medical cannabis access law and the proportion of the population in bordering DSAs that is subject to a medical cannabis access law. In addition to these variables of interest, each model includes a control variable for the average number of days that patients have spent on the waitlist in a given DSA. This variable controls for the impact longer waitlists may have MELD scores.

²⁵⁴ Bachhuber et al., *supra* note 32, at 1668.

²⁵⁵ The laboratory MELD itself may increase, as cannabis access laws decrease the availability of donated livers, forcing patients to wait longer and become sicker.

²⁵⁶ This gap may widen because patients, having to wait longer given a smaller supply of livers, may be more likely to become eligible for legitimate exception points. To address this concern, all models include a control variable for average waitlist time.

²⁵⁷ See WEIMER, *supra* note 5, at 137 (discussing the salience of losses in the organ transplantation context in the context of prospect theory developed by Daniel Kahnem and Amos Tversky).

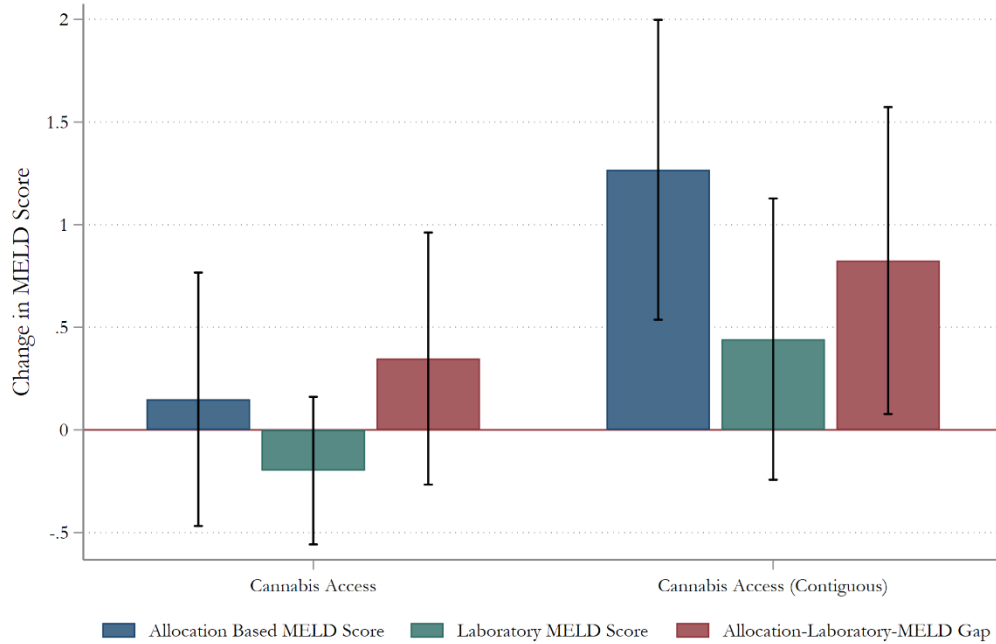
Beyond the variables of interest and control variable, every model includes year and DSA indicator variables.²⁵⁸ As before, the DSA variables control for observed and unobserved characteristics of individual DSAs. Similarly, the year variables control for observed and unobserved temporal trends that may impact MELD scores.²⁵⁹

2. Results and Discussion

Figure 11 reports the results from the three separate regression models. Each model includes the proportion of a DSA's own population covered by a medical cannabis access law and the proportion of contiguous DSAs' populations covered by a medical cannabis access law. The models only differ in their dependent variables, which include the average allocation MELD, laboratory MELD, and allocation-laboratory-MELD gap. The blue bars report the effect of an increase in the proportion of a DSA's own population and contiguous DSAs' populations covered by a medical cannabis access law on the allocation MELD score. The green and red bars similarly report these effects on laboratory MELD scores and allocation-laboratory-MELD gaps, respectively.

²⁵⁸ I replace the month indicator variables used in the previous analysis with year indicator variables for several reasons. First, the county-level population data that is key to the state-law analysis is only available on a yearly basis. Second, the study by Dicker-Conlin and colleagues relied on year indicator variables, and I largely follow their empirical strategy. *See* Dickert-Conlin et al., *supra* note 244, at 217–18 (“The DSA and year indicators, α_d and δ_t , respectively, account for unobserved parameters that are constant within a DSA across time and within a year across DSAs.”). Third, medical cannabis access laws likely take longer to influence potentially manipulative behavior because they change the incentives for this behavior by changing death rates. This differs markedly from the Share 35 policy which created a nearly instantaneous change in incentives for manipulation.

²⁵⁹ Throughout the analysis, I calculate standard errors clustered at the county level to correct for serial autocorrelation.

Figure 11: Effect of Medical Cannabis Access Laws on MELD Scores

Notes: Each bar represents the marginal effect of cannabis access laws within a DSA and in contiguous DSAs on the dependent variable listed below. Ninety-five percent confidence intervals are reported as capped lines for each bar. Each pair of estimates is derived from a separate regression model. All regression models include a full set of DSA and year fixed effects and a control variable for the average number of days spent on the waitlist at the DSA-year level. Data on the total number of liver transplants across the United States by month come from the Scientific Registry of Transplant Recipients.²⁶⁰

In general, the results reported in Figure 11 suggest the occurrence of manipulation. The enactment of cannabis access laws within a DSA does not have a statistically significant impact on allocation MELD scores, laboratory MELD scores, or the gap between the two. The enactment of cannabis access laws in bordering DSAs does, however, impact MELD scores. These laws have no statistically significant effect on laboratory MELD scores. But both the average allocation MELD score and allocation-laboratory-MELD gap see statistically significant increases following the enactment of contiguous cannabis access laws. The results in Figure 11 imply that, relative to a DSA with no bordering population covered by a medical cannabis access law, the average allocation MELD in a DSA with all of its neighboring populations covered by a cannabis access law is 1.2 points higher. Similarly, the allocation-laboratory-MELD gap is nearly a point larger.

The fact that contiguous cannabis access laws have no statistically significant effect on the average laboratory MELD score but a positive and statistically significant effect on the average allocation MELD score is consistent with manipulation. Of course, shrinking the available supply of organs through a reduction in overdose deaths with medical cannabis access laws may increase MELD scores generally, as patients must wait longer to receive an organ. But the fact that allocation MELD scores see a statistically significant increase, while laboratory MELD scores do not, is difficult to

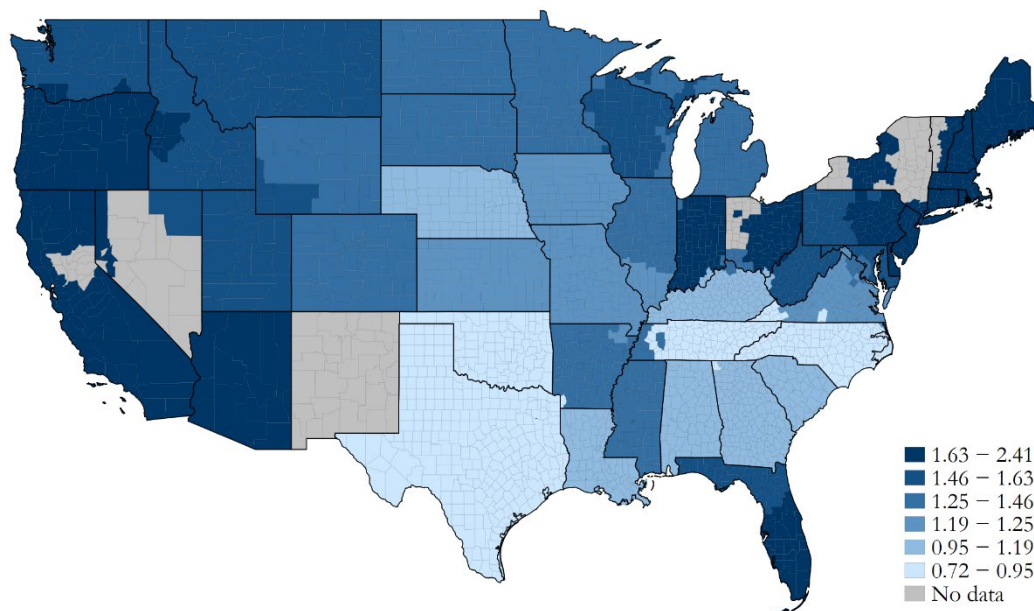
²⁶⁰ See SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS, *supra* note 134.

explain in the absence of manipulation. The increase in the size of the gap between these MELD scores is also troubling, as it implies a significant increase in mortality risk only among patients whose laboratory MELD scores fail to represent their risk. Again, the best explanation is manipulative behavior designed to preserve access to a dwindling supply of imported livers following the enactment of medical cannabis access laws in contiguous areas.²⁶¹

To better contextualize the regression results reported in Figure 11, Figure 12 reports the predicted changes in the allocation-laboratory-MELD gap based on these results. In general, DSAs in the Northeast and along the West Coast are predicted to see the largest gaps between their average allocation and laboratory MELD scores. DSAs in the South and Midwest, however, are generally predicted to have smaller allocation-laboratory-MELD gaps. This evidence has important implications for the local-versus-national allocation debate, and the next Section situates the evidence reported here firmly within that debate.

²⁶¹ To further explore these results and confirm that other state laws are not responsible for the changes in MELD scores observed in connection with medical cannabis access laws, I estimate several additional models. These models include, in addition to the medical cannabis access variables described above, variables for other state laws that may impact opioid prescriptions, opioid-related deaths, or the supply of organs more generally. These other laws include: laws creating prescription drug monitoring programs that mandate providers access them before prescribing opioids (among other drugs), laws regulating pain clinics, and laws adopting the Uniform Anatomical Gift Act of 2006. The first two laws may impact opioid-related deaths in the same way as medical cannabis access laws by reducing opioid-related deaths. The third law may, by facilitating organ donation, increase the supply of organs. I constructed all variables for these other laws using the same population weighting approach described in connection with medical cannabis access laws. In general, none of these other laws have statistically significant effects on MELD scores, and more importantly, their inclusion of these other laws in the empirical model has no meaningful effect on the results for medical cannabis access laws derived above. In the interest of succinctness, I do not report the results from these alternative models.

Figure 12: Predicted Changes in the Allocation-Laboratory-MELD Gap in Connection with Medical Cannabis Access Laws



Notes: Predicted changes are based on regression results reported in Figure 11. All predictions are for the year 2017

IV. TOWARD A NEW NATIONAL ORGAN TRANSPLANT ACT

The results of the empirical analysis reported in this Article evince a troubling trend: the systematic occurrence of manipulation within the liver allocation system. Do these results definitively prove that individuals within that system intentionally manipulate it in unethical and illegal ways? Absolutely not, and they should not be interpreted in this manner.²⁶² The evidence reported above demonstrates a bigger problem, however. The systematic manipulation within the bounds of discretion by individuals inside the transplant system fundamentally undermines that system in ways that a few bad actors intentionally manipulating the system for a few patients could not. The systematic manipulation demonstrated above renders the system itself unreliable in terms of allocating livers to the sickest patients. Of course, all empirical studies—including this one—have limitations. And this study did not, and could not, examine all facets of potentially manipulative behavior. Collectively, however, the results reported above evince troubling behavior that undermines confidence in the organ allocation system and recent policy changes based on information from that system.

With respect to the current local-versus-national allocation debate, the results have important implications for proponents of both allocation approaches. This Section begins by situating the empirical evidence firmly within the context of this debate. The results generally support those favoring local priority in liver allocation. Given these results, this Section concludes with a call for a new National Organ

²⁶² That type of evidence could only be found deep within patients' medical records—evidence and data that are well beyond the scope of this Article.

Transplant Act. The current Act is approaching its forty-year anniversary—a longer period than elapsed between the first successful transplant and the passage of the current Act. And the current Act represents an important impediment to addressing current problems. A new National Organ Transplant Act need not depart substantially from its predecessor. The current Act’s requirement to pursue national allocation schemes, however, simply cannot address the problems uncovered in the empirical analysis in more than a superficial way.

A. The Empirical Results in the Context of the Organ Allocation Debate

The empirical analysis reported above speaks directly to a key point of disagreement in the local-versus-national allocation debate: the importance of allocating organs to the sickest patients first. While advocates of a locally focused allocation scheme have offered other, independent arguments for local organ sharing—e.g., national organ sharing redistributes organs from impoverished, rural areas to wealthy, urban areas²⁶³—the sickest first argument has proved one of the most contentious points in the allocation debate. More importantly, this argument has been the primary basis for the move towards greater national organ sharing. And it has prevailed over arguments that greater national sharing transfers scarce resources from poorer to wealthier communities, undermines the incentives to increase organ donation and recovery rates, and creates barriers to accessing transplants for rural and underserved communities.²⁶⁴ In other words, the United States has decided that accepting increasing levels of socioeconomic inequity in the healthcare system is justified by the need to provide organs to the sickest patients first.

The results from my empirical analysis tend to vitiate the sickest first arguments offered by those in favor of greater national sharing. Advocates of national sharing have argued that maintaining a role for geography in organ allocation is fundamentally unfair because organs may not go to patients who have the greatest need for them.²⁶⁵ The evidence above demonstrates, however, that the measures of sickness relied upon in these arguments have been manipulated and therefore suffer from significant biases. Accordingly, relying on these measures to determine which patients have the greatest need for organs may result in inequitable and fundamentally biased allocation decisions. Given this evidence, the sickest first arguments offered by national advocates lack the evidentiary foundation that would warrant acting on these arguments by changing allocation policy. With these arguments lacking a clear evidentiary foundation, policymakers should take much more seriously the arguments offered by those in favor of a continued role for local areas in allocation decisions. These arguments remain valid in light of the results described above.

Though the empirical results favor the local advocates’ position over that of the national advocates by undermining the latter’s primary arguments, national advocates may point to a recent change in allocation policy in support of their arguments. This change was designed to mitigate the type of manipulation observed in the empirical analysis above. In 2019, the review process for MELD exception points shifted from regional review boards to a national liver review board. This

²⁶³ See *supra* Part II.C (recounting the various arguments offered by local-sharing advocates).

²⁶⁴ See *supra* Part II.C (discussing these arguments and the evidence used to support them).

²⁶⁵ See *supra* Part II.B.

change was “intended to increase consistency in providing exception scores nationwide and better balance transplant access for candidates with and without exception scores.”²⁶⁶ By moving from a regional to a national review process, the OPTN mitigated, to some extent, the incentives within the allocation system to award unwarranted exception points to benefit one’s own region. Under the old system, regional review boards had an incentive to award exception points to increase the number of transplants within their borders (at the expense of other regions). A national review process mitigates this incentive and should, in theory, make manipulating waitlists in the ways described in previous sections more difficult.

However, to think that simply undermining this one potential avenue of manipulation will address the more fundamental problems within the allocation system is best described as technocratic myopia. This potential avenue of manipulation no longer exists in its previous form, but other avenues continue to exist. More importantly, the MELD scores manipulated under the old system served as the basis for moving from locally focused allocation to broader national sharing in the first place. The old system and its scores were also the basis of numerous studies favoring such a policy change.

Advocates of greater national organ sharing have argued that “a policy that prioritizes transplanting the sickest patients will save lives”²⁶⁷ and that “[p]eople are dying, [and] [i]t’s just not fair.”²⁶⁸ Translating these sickest first arguments from general concerns about fairness into policy recommendations, advocates of national organ sharing have focused on changing allocation policy to minimize variation in MELD scores or to ensure that MELD scores dictate which patients receive available livers.²⁶⁹ Indeed, prior to the adoption of the new national liver allocation system in 2019, numerous studies evaluated redistricting, acuity circles, and other non-locally focused allocation systems based on the ability of those systems to minimize variation in MELD scores.²⁷⁰ These systematic studies supplemented anecdotal comments on disparities between specific cities, and all of this (manipulated) evidence was marshalled in support of a greater policy goal—the permanent move to national allocation.

Thus, the recent move toward greater national organ sharing represents manipulation on a grander scale. Instead of individual transplant centers requesting and (often) receiving unwarranted exception points for their patients, transplant centers with sufficient resources banded together to rewrite the allocation rules to their benefit (with the help of federal officials). The geography of patients and centers that support and oppose greater national organ sharing is particularly telling as to whether the recent policy change represents a neutral amendment designed to accomplish neutral policy goals or a larger attempt at reorganizing the system to advantage certain transplant centers at the expense of others.

²⁶⁶ NATIONAL LIVER REVIEW BOARD IS IMPLEMENTED, <https://optn.transplant.hrsa.gov/news/national-liver-review-board-is-implemented/> (last visited Feb. 4, 2021).

²⁶⁷ *Id.*

²⁶⁸ *Id.*

²⁶⁹ See, e.g., Gentry et al., *supra* note 146, at 2053–57 (analyzing data to estimate the optimal way to redistribute livers to minimize variation in MELD scores).

²⁷⁰ See, e.g., Gentry et al., *supra* note 114, at 584 (reviewing various redistricting proposals).

As noted above, patients and transplant professionals in the Northeast and on the West Coast have offered the loudest and strongest arguments in favor of national organ sharing.²⁷¹ Conversely, patients and transplant professionals in the South and Midwest have offered the loudest and strongest arguments in favor of maintaining a local focus in organ allocation.²⁷² A quick review of the evidence reported in the empirical analysis above demonstrates that those in favor of national organ sharing generally engage in more manipulative behavior than those opposed.

Figure 6 shows that southern and midwestern transplant patients have smaller gaps between their allocation and laboratory MELD scores than do northeastern and western patients. By itself, this evidence proves little, but the predicted effects of the Share 35 policy—which provided a clear target for manipulation—reported in Figure 10 and medical cannabis access laws reported in Figure 12 augment this evidence. In general, following the adoption of policies that could incentivize more manipulation, northeastern and western DSAs generally had higher predicted allocation-laboratory-MELD gaps than did DSAs in the South and Midwest. This suggests that the allocation-laboratory-MELD gap is not random. Rather, it is likely related to the differential use of waitlist manipulation across the country, with DSAs in areas that largely favor a national organ allocation scheme appearing to manipulate waitlists more often. And this manipulation appears to yield substantial benefits. As reported in Figure 5 above, northeastern and western DSAs tend to be net importers (or small net exporters) of livers, while midwestern and southern DSAs tend to be net exporters (or small net importers) of livers.

Collectively, this evidence casts serious doubt on the recent move toward greater national organ sharing. The champions of this policy change largely came from areas of the country that appear to be exploiting allocation mechanisms, while the opponents of this move largely hail from areas that exhibit less manipulative behavior. This suggests that the recent sea change in organ allocation policy was not the result of a considered evaluation of neutral policy goals. Instead, the evidence supports the conclusion that that change was motivated by the transplant centers in certain DSAs attempting to rewrite the rules in their favor. In other words, the evidence developed here suggests that the move to a national allocation system was not only unsupported by reliable evidence but may have been the result of a concerted effort to effect manipulation of the allocation system on a grander scale.

While this may be a troubling conclusion, it is supported by the data. Importantly, this conclusion is *not* intended in any way to morally blame transplant centers that supported the move toward national organ sharing or suggest that they have committed any illegal acts. Instead, the concerted effort exerted by transplant centers supporting the recent change likely stems from a series of perverse and self-reinforcing incentives, as discussed in detail above.²⁷³ Strong incentives such as these require equally strong policy solutions to combat them. Reinstating a role for local areas in organ allocation policy represents a viable option for pushing back against these perverse incentives. The next Section discusses a new National Organ Transplant Act to accomplish this reinstatement.

²⁷¹ See *supra* Part II.B.

²⁷² See *supra* Part II.C.

²⁷³ See *supra* Part III.A.

B. Formalizing a Role for Local Allocation

The evidence reported above undermines the primary policy arguments that advocates have used in moving allocation policy from locally focused to nationally focused. It does not, however, undermine the legal arguments offered by national allocation advocates. They are correct that the NOTA and the administrative regulations governing its implementation envision a national allocation policy. The NOTA directs the OPTN to “establish . . . a national system.”²⁷⁴ And the Final Rule requires “[d]istributing organs over as broad a geographic area as feasible.”²⁷⁵ Under these directives, the march toward national organ allocation is legally required. Livers became subject to national allocation following a heated court battle,²⁷⁶ and other organs have similarly proceeded down that path. Reversing course to reinstate local allocation would prove exceedingly difficult under current law.

Given these constraints under the current legal regime, this Section begins by exploring the legislative details of a new National Organ Transplant Act. The current Act is not completely unworkable, and the goal of the first Subsection is simply to detail some of the changes needed to align a revised act with locally focused donation. Following those details, the next Subsection addresses the specific ways in which a new NOTA would eliminate or mitigate the perverse incentives present in the current system. Finally, this Section concludes by outlining additional advantages of returning to a locally focused system. Primarily, such a return would reinvigorate the federal-state balance in organ allocation and transplantation. Returning to the principles of federalism offers several advantages that have been lost within the current system, only to appear as roadblocks as states voice their concerns over national allocation policies.

1. Legislative Details

Rewriting the entire NOTA is well beyond the scope of this Article, and even if it were not, much of the NOTA works as currently written. Indeed, the NOTA’s primary innovation—imbuing a private organization with substantial authority over organ allocation policy—has worked well and should be preserved. Evaluating the OPTN’s ability to handle complex allocation and transplantation problems, David Weimer concluded that it outperforms any reasonable or feasible public regulatory scheme.²⁷⁷ Perhaps the most recent fight over liver allocation policy best exhibits the private OPTN’s ability to manage complex problems. Its preferred reform to allocation policy was to de-emphasize DSAs as the focus of local allocation but maintain local primacy within expanded areas of geography. It only implemented the current nationally focused policy after being forced to do so by the Department of Health and Human Services.

A new NOTA should eliminate any requirement for national allocation policies and allow the OPTN to develop policies that reach the optimal level of transplantation across the country, given the various medical, logistical, and economic constraints. Imposing an artificial requirement that organs be shared nationally can

²⁷⁴ 42 U.S.C. § 274(b)(2).

²⁷⁵ 42 C.F.R. § 121.8(b)(3).

²⁷⁶ *Callahan v. United States Dep’t of Health & Human Servs. through Alex Azar II*, 939 F.3d 1251, 1254 (11th Cir. 2019).

²⁷⁷ WEIMER, *supra* note 5, at 135–46.

only hinder the OPTN in its ability to effectively and equitably allocate organs. In the future, changing medical technology or innovations in logistics may lead to the conclusion that a national allocation policy is best, but the OPTN should be given room to make that decision based on the available evidence. Forcing it to implement nationally focused allocation policies, however, leads to the problems identified by the opponents of such schemes. For example, one of the first evaluations of the new liver allocation policy found that it led to poorer, more rural areas exporting organs to wealthy urban areas, vindicating the concerns of those who warned against such an outcome *ex ante*.²⁷⁸

To remove the artificial restriction on the OPTN's ability to develop effective allocation policies, a new NOTA should eliminate any requirement that the OPTN "establish . . . a national system."²⁷⁹ Prohibiting the development of a national system would be a step too far, but that decision should remain with the OPTN. Similarly, the new NOTA should abrogate the current Final Rule and direct the Department of Health and Human Services to develop new regulations governing organ allocation and transplantation. Given the complexity of organ policies, eliminating any role for the Department would likely prove infeasible. However, the Department should be limited to overturning rules developed by the OPTN based primarily on procedural problems, with only minimal oversight of the substance of OPTN rules. Of course, the Department should be prohibited from requiring the OPTN to focus on national (or local) allocation policies. To put a fine point on it, the new NOTA should categorically prohibit the Department from imposing any requirement to "[d]istribut[e] organs over as broad a geographic area as feasible."²⁸⁰

With these simple changes, which only involve removing text that requires or implies that organs be distributed nationally, the OPTN will be free to reinstate policies that have a local focus. As noted above, this does not mean that allocation policies should consider only local patients—a mixture between a local and national focus is both inevitable and desirable. Instead, it only means that local patients receive some degree of priority over national patients. The nature and extent of that priority will depend heavily on the minutiae of organ transplantation, which the OPTN is uniquely well qualified to evaluate. Similarly, permitting a local focus does not imply that DSAs or current OPTN regions are the most appropriate geographic areas. Again, however, the OPTN is in a better position than Congress or the Department of Health and Human Services to evaluate the best geographic areas. With the authority to act without a focus on national allocation, the OPTN can begin to mitigate the perverse incentives that drive the manipulative behavior revealed in the empirical analysis and that undermine the allocation system more generally. The next Subsection discusses these incentives and steps that can mitigate them.

2. Mitigating Perverse Incentives

Transplant professionals face multiple, interrelated incentives that can combine to have a deleterious effect on the organ allocation and transplantation system. Returning to a locally focused allocation system can eliminate or mitigate some

²⁷⁸ Chyou et al, *supra* note 127.

²⁷⁹ 42 U.S.C. § 274(b)(2).

²⁸⁰ 42 C.F.R. § 121.8(b)(3).

of these perverse incentives that ultimately undermine the system overall. Of course, a local focus cannot address all perverse incentives facing the transplant system, but it can push back on some of the most problematic ones.

First, moving to a locally focused allocation policy may increase the overall number of transplants. Currently, transplant professionals faced with too few organs to meet the needs of their patients face two general choices. They can work with local OPOs to increase the local supply of organs, or they can increase the number of organs imported from other areas of the country. The result of making either choice is that local patients receive more transplants. However, the first choice achieves this goal by increasing the overall number of transplants across the country. The second benefits local patients but harms distant patients who would have received the organs. To be sure, professionals in different areas of the country face different challenges in increasing the organ supply, and these challenges should not be minimized. However, allocation policy should encourage professionals and OPOs to confront these challenges by increasing donation and recovery rates. Addressing these challenges may require innovative approaches, but an allocation policy that inhibits the importation of organs will mitigate the perverse incentive to do so. Instead, it will incentivize the growth of local organ supplies.

Second, a locally focused allocation policy will relieve transplant professionals of some of their heaviest ethical burdens. As noted above, these professionals have duties both as stewards of scarce organs and as providers treating transplant patients. Given the choice between protecting a faceless allocation system and advocating for their patients, professionals naturally tend toward the latter at the expense of the former. It is hard to blame professionals for making this choice, but it should be easy to blame the transplant system for forcing them into this choice at all. By moving to a locally focused system, transplant professionals will have less access to the national supply of organs. This may reduce the pressure on these professionals to manipulate the MELD scores of their patients. Doing so would prove less beneficial in a locally focused system because it would not create access to the national pool of donated organs. This may relieve transplant professionals of unnecessary ethical burdens and decrease the use of manipulative tactics overall.

Unfortunately, a local allocation policy will not purge all perverse incentives from the transplant system. It will not, for example, eliminate the incentive to procure more transplantable organs for financial or reputational reasons. It will, however, re-align these incentives to encourage the development of larger local organ supplies and thereby increase the number of transplants overall. Thus, although it cannot eliminate all perverse incentives, a local allocation policy will at least put them to better use. In addition to re-aligning incentives within the transplant system itself, locally focused allocation policies may have broader benefits by encouraging greater state-level changes to spur more transplants. The next Subsection discusses these benefits.

3. Reinvigorating Federalism in Organ Allocation

Organ allocation policy is primarily a creature of federal law, or at least private law supported by a federal framework. States, however, have important roles to play in promoting organ transplantation more generally. The empirical analysis above illustrated an important, though unintended, role of state law in affecting organ allocation and transplantation. States have, however, taken more direct and intentional

approaches in the context of organ allocation. For example, state, not federal, law defines “death,” and determining when someone has died—which is harder than it first appears—is a critical first step to organ donation.²⁸¹ More importantly, determining that someone has died while ensuring that their organs remain viable for transplant has critical implications for the transplant system. States play important roles in all of these issues and have largely adopted the Uniform Anatomical Gift Act to streamline the organ recovery and transplantation process.²⁸² States also play a role in promoting organ donation, lending the support of their departments of motor vehicles to quickly and easily identify organ donors with specific indicators on drivers licenses.²⁸³ Even the fact that these departments inquire about donation preferences can lead to increases in donation rates.²⁸⁴

Historically, states have cooperated with promoting organ donation and transplantation, but they need not do so. And in the face of losing a large supply of their organs to other areas of the country, states have become recalcitrant. For example, in response to the change in liver allocation policy, the Kansas Senate considered a bill that would have allowed Kansans to consent to organ donation but limit that consent to include only other Kansans.²⁸⁵ Essentially, the bill would have allowed organ donors to prohibit their donated organs from leaving the state. Advocates of the bill explained that “[t]he practical effect of the new [liver allocation] policy will be to redistribute livers from states and regions with high rates of organ donation to areas that have historically underperformed,” particularly those “on the East and West coasts.”²⁸⁶ They also expressed concern that “[t]he new policy would disproportionately affect patients in rural areas,” including those in Kansas.²⁸⁷

The Kansas legislature eventually abandoned the bill, but it nevertheless serves as a warning that states will not necessarily sit idly by if they feel their supply of organs is being unfairly shipped elsewhere.²⁸⁸ This state response has been seen before. When the Final Rule was developed in the late 1990s, seven states responded by enacting laws similar to the more recent Kansas bill that would have prevented or inhibited organs from leaving state borders.²⁸⁹ It remains questionable whether states

²⁸¹ See, e.g., OKLA. STAT. ANN. TIT. 63, § 3122 (defining death under Oklahoma law).

²⁸² See ANATOMICAL GIFT ACT, UNIFORM LAW COMMISSION, <https://www.uniformlaws.org/committees/community-home?CommunityKey=015e18ad-4806-4dffb011-8e1ebc0d1d0f> (last visited Feb. 6, 2021) (listing states that have adopted the Uniform Anatomical Gift Act).

²⁸³ See ORGAN DONOR PROGRAM, <https://dds.georgia.gov/organ-donor-program> (last visited Feb. 6, 2021) (detailing Georgia’s organ donation program, which provides a driver’s license option).

²⁸⁴ See Leigh Anne Dageforde et al., *Organ Procurement Organization Run Department of Motor Vehicle Registration and Drivers Licensing Offices Leads to Increased Organ Donor First Person Authorization Registrations*, 104 TRANSPLANTATION 343, 343 (2020) (discussing the role of departments of motor vehicles in organ donation).

²⁸⁵ Jim McLean, *Lawmakers Could Side With KU Hospital Officials To Keep Transplant Livers In Kansas*, KCUR 89.3 (Mar. 4, 2019, 2:14 PM), <https://www.kcur.org/health/2019-03-04/lawmakers-could-side-with-ku-hospital-officials-to-keep-transplant-livers-in-kansas#stream/0>. See also Andy Marso, *Law would let Kansans donate organs only to Kansans. Is that legal?*, KAN. CITY STAR (Mar. 14, 2019, 4:39 PM) <https://www.kansascity.com/news/politics-government/article227462499.html>

²⁸⁶ McLean, *supra* note 285.

²⁸⁷ *Id.*

²⁸⁸ S.B. 194, 2019 Leg., Reg. Sess. (Kan. 2019).

²⁸⁹ Roderick T. Chen, *Organ Allocation and the States: Can the States Restrict Broader Organ Sharing?*, 49 DUKE L.J. 261, 263 (1999).

can interfere directly in a federal regulatory scheme in this way, and even if they can under current law, Congress could always preempt those laws. While states may not be able to interfere in allocation schemes directly in these ways, they are under no obligation to aid Congress in implementing a federal policy with which they do not agree. Even if Kansas cannot prevent organs from leaving its borders, it could thwart congressional efforts by refusing to offer its department of motor vehicles as a convenient avenue through which to acquire consent for donation. It could also create indirect roadblocks to organ donation that Congress may have difficulty removing.

Instead of fighting with states to pursue a goal everyone agrees should be achieved—increasing organ donation and transplantation rates—Congress can reinvigorate federalism in organ donation policy by maintaining a locally focused allocation scheme. By allowing most (though not necessarily all) organs donated in Kansas, or other states, to remain within state borders, Congress can more readily rely on state legislatures to pass laws conducive to organ donation and transplantation. Indeed, if Congress or the OPTN decides to reconsider relevant geographic regions, states or groups of states may be a good starting point. Though state boundaries certainly were not drawn in a way to optimize organ allocation, regions drawn around state lines would acknowledge the important roles of states and encourage them to pursue transplantation goals jointly with federal policy.

Overall, reinstating local priority in organ allocation policy can reinvigorate federalism in the allocation system. This federalism is not absolutely necessary for the organ allocation system to function, but having states support allocation policies will make it less likely that they undermine those policies. It can also only increase the probability that states actively assist with federal allocation goals.

CONCLUSION

As the United States continues to debate the best way to allocate the scarce national resource of donated organs, understanding the evidence supporting those in favor of locally focused and nationally focused allocation policies will become increasingly important. This Article presented compelling new evidence that the most recent move to a nationally focused policy in the context of donated livers was based on manipulated evidence. Examining how transplant centers responded to changes in both federal and state law, the empirical analysis reported here revealed consistent evidence of manipulation. In particular, the results suggest that transplant centers have manipulated the MELD scores of their patients to gain priority for those patients on liver waitlists. In gaining priority for their patients, these transplant centers increase the likelihood that organs will be imported from other DSAs for use by their patients.

Beyond demonstrating the existence of waitlist manipulation, the empirical analysis reported in this Article suggests that the areas of the country most likely to engage in waitlist manipulation are those that argue most vehemently for national allocation policies. This suggests that the move toward greater national organ sharing, which was based on MELD score data that had been manipulated, was an extension of waitlist manipulation. By requiring more organ sharing across the country, these transplant centers can ensure a steady supply of imported organs without needing to manipulate waitlists to the same extent.

This evidence by itself is troubling, but when considered in a wider social context, it is even more so. The transplant centers that the analysis suggests engage in

the most waitlist manipulation and that offered the strongest arguments in favor of national allocation policies are generally located in wealthier, more urban areas. The transplant centers that engage in less manipulation and stand to lose more organs to exportation under the new nationally focused policy are generally found in poorer, more rural areas. Thus, the manipulation revealed in this Article's empirical analysis suggests that the new national policy serves to exacerbate inequities that already pervade the organ allocation system.

Combating the continued spread of these inequities through national allocation schemes will require a new National Organ Transplant Act. While those in favor of nationally focused allocation have relied on manipulated data to make their arguments, they have correctly concluded that current federal law envisions a national allocation scheme. Accordingly, the time has come to update existing law. By eliminating requirements for national organ allocation, Congress can blunt the perverse incentives that undermine the current system and better focus on the goal of increasing transplantations across the country.