Transplant Candidates and Substance Use: Adopting Rational Health Policy for Resource Allocation

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Organ transplant candidates are often denied life-saving organs on account of their medical marijuana drug use. Individuals who smoke medicinal marijuana are typically classified as substance abusers, and ultimately deemed ineligible for transplantation, despite their receipt of the drug under a physician's supervision and prescription. However, patients who smoke cigarettes or engage in excessive alcohol consumption are routinely considered for placement on the national organ transplant waiting list. Transplant facilities have the freedom to regulate patient selection criteria with minimal oversight. As a result, the current organ allocation system in the United States is rife with inconsistencies and results in disparities in allocation decisions. This Article reviews the history and underlying rationale of organ allocation in the United States and the National Organ Transplant Act. It then examines ill-founded policies regarding transplant candidates who present issues of substance “abuse” compared with substance “use,” and the resulting disparities in waiting-list criteria. In response, a model rule for a national set of patient selection guidelines is provided. Definitions of terms, distinctions regarding proper patient classification, and protocols for a second chance policy to be used in the event of a relapse among wait-listed patients are addressed. Finally, stipulations that require designated abstinence periods as well as random drug screenings in relation to subsequent relisting are also included. This policy distinguishes between candidates who present issues of substance use versus substance abuse. The use of such a model allocation policy will promote equity and scientific bases in the organ allocation process.

I. Introduction

In April 2008, Timothy Garon, a Seattle musician, succumbed to liver failure after a lengthy battle with Hepatitis C.¹ Garon was

unable to obtain a liver transplant at the University of Washington Medical Center because of his continued use of medical marijuana. The hospital agreed to reconsider Garon's application if he enrolled in a sixty-day drug treatment program. Yet Garon maintained his need for the drug and was ultimately disqualified as a candidate. Garon was also turned down by Harborview Medical Center for similar reasons.

Jonathan Simchen is another Seattle resident suffering from renal failure. Simchen is prescribed marijuana to combat the side effects of dialysis and regulate his blood pressure. Like Garon, the University of Washington Medical Center declined to give Simchen a transplant because he actively smokes medical marijuana. Virginia Mason Hospital also rejected Simchen because he would not agree to a six-month abstention period.

Garon's death and Simchen's denials raise a host of ethical and legal implications regarding the patient selection criteria used by organ transplant centers across the nation. Hospitals and organ procurement organizations are virtually free to set their own standards with minimal oversight. As a result, an individual's chance of being denied a transplant varies between facilities because of inconsistent assessment practices.

The definition of "substance abuse" is one key area where transplant centers conflict in terms of evaluation. Hospitals often diverge with regard to the categorization of abusive substances, length of acceptable sobriety periods, contraindication definitions, and modes of relapse management. Such deviations result in unequal access to transplantation for individuals who use these substances under a wide array of conditions.

3. Id.
4. Id.
5. Id.
7. Johnson, supra note 2.
10. See Richard S. Mangus et al., Wide Disparity in Substance Use Policies for Liver Transplant Candidates at U.S. Centers (Oct.-Nov. 2008) (poster presentation at American Association for the Study of Liver Disease) (on file with authors); see also Kinkopf-Zajac, supra note 9, at 512.
11. See Mangus et al., supra note 10.
12. See id.
The disparate treatment of organ transplant candidates is evident when policies on medical marijuana use are examined. Many centers will reject individuals who regularly smoke medical marijuana. Most physicians base such denials on the possibility of aspergillosis, a serious infection that may occur if marijuana is used after surgery. Others feel smoking marijuana causes cognitive distortions, which can lead to patient noncompliance and threaten organ vitality following transplantation. Although medical evidence suggests marijuana-induced health problems can affect recovery post-transplantation, there are no data that show marijuana has a direct toxic effect on allografts.

In contrast, a majority of transplant facilities will routinely consider patients who exhibit signs of alcoholism or smoke cigarettes on a daily basis. The preferential treatment given to patients who consume these clearly harmful and non-clinically beneficial substances is contrary to the equitable underpinnings of the U.S. organ allocation system. Ongoing shortages in organ supplies have led to some distribution strategies that result in biased allocations. In the area of substance use and abuse, transplant refusals occur despite the comparative absence of risk factors that warrant exclusion.

Unfortunately, the lack of a single rational paradigm for patient selection can lead to premature elimination, or even death, among individuals in need of life-saving organs. Current systems used to establish such rules are convoluted, are often arbitrary, and do not reflect sound medical policy. Patients who use marijuana under supervised medical care are especially vulnerable within this context, as current methodologies work to inhibit their chances of procuring effective treatment. If this situation remains unaddressed, viable candidates will continue to be denied access to life-saving organs.

This Article delineates the issue and provides a model guideline for wait-listing practices undertaken by hospitals for patient selection criteria. Section II provides a background on current U.S.

13. See Johnson, supra note 2.
15. See id. at 218-19.
17. See Mangus et al., supra note 10.
organ allocation practices, as governed by the National Organ Transplant Act ("NOTA"). Despite its passage, the inconsistencies in transplant center policies for recipient selection, and the rippling effects it can have on listing status, create disparities and the very circumstances that NOTA was designed to address.

Section III examines how institutional waiting list policies are highly inconsistent and inequitable based on substance use and abuse, second chance listing, and inappropriate science. Specifically, the effects tobacco and marijuana have on organ recipients are analyzed to illustrate the disconnect between science and treatment of these transplant candidates.

A set of model guidelines for transplant wait-listing and allocation is then provided in Section IV. This proposal specifically focuses on resolving discrepancies in contradicting taxonomies, expanding the depth of candidate review, and reconciling interpretive dilemmas surrounding the definition of substance abuse versus substance use. A detailed plan for policy decision-making that calls for physician discretion and interdisciplinary collaboration is then delineated. Finally, in Section V, we call for a focus on science in transplantation policy to ensure equity for patient access to organs.

II. THE PATHWAY TO DISPARITY

A. The National Organ Transplantation Act and the Organ Procurement and Transplantation Network

During the mid-1980s, a great deal of public discord surrounded the organ rationing techniques utilized in the United States.\textsuperscript{19} At the time, the country lacked a single authority for organ distribution.\textsuperscript{20} Individual transplant centers were free to set their own procurement criteria, which led to organ hoarding, varying and inconsistent standards, and rifts in sharing practices within the transplant community.\textsuperscript{21} Distribution tactics that favored the wealthy and foreign nationals over American citizens were also common.\textsuperscript{22} Patients with limited financial resources and minimal

\textsuperscript{19} See Kinkopf-Zajac, supra note 9, at 509.
\textsuperscript{20} See Grantham, supra note 18, at 754.
\textsuperscript{22} See Kinkopf-Zajac, supra note 9, at 509; see also Gross, supra note 21, at 149.
health care coverage ultimately turned to the government for help with donor location and funding.\textsuperscript{23}

In response to these issues, Congress enacted the National Organ Transplant Act ("NOTA") in 1984.\textsuperscript{24} NOTA was designed to streamline the organ allocation process and provide Americans with a fortified regime for transplantation.\textsuperscript{25} This legislation also attempted to promote an equitable system for organ allocation based on sound medical criteria.\textsuperscript{26}

Among other things, NOTA established a task force on organ transplantation whose members were to be appointed by the Secretary of Health and Human Services.\textsuperscript{27} After an extensive investigation, this task force recommended the creation of a national Organ Procurement and Transplantation Network ("OPTN").\textsuperscript{28} The task force also delineated an agenda for organ procurement that required patient selection strategies to be based on sound medical criteria.\textsuperscript{29} Factors to be considered included an individual's need, likelihood of success, and time spent on the waiting list.\textsuperscript{30} Moreover, the task force emphatically advised against weighing an individual's social worth when rendering such decisions.\textsuperscript{31}

\textbf{B. OPTN, OPOs, UNOS, and Allocation}

OPTN currently maintains the national waiting list for individuals in need of organ transplants.\textsuperscript{32} OPTN also regulates allocation standards that organ procurement organizations ("OPOs") must follow throughout the transplantation process.\textsuperscript{33} The United Network for Organ Sharing ("UNOS") is the non-profit organization contracted to administer OPTN.\textsuperscript{34} UNOS compiles data on all

\begin{itemize}
  \item \textsuperscript{23} See Neal R. Barshes et al., Justice, Administrative Law, and the Transplant Clinician: The Ethical and Legislative Basis of a National Policy on Donor Liver Allocation, 23 J. Contemp. Health L. & Pol'y 200, 208 (2007).
  \item \textsuperscript{25} See Grantham, supra note 18, at 754.
  \item \textsuperscript{26} See 42 U.S.C. § 273(b)(3)(E).
  \item \textsuperscript{27} See National Organ Transplant Act §§ 101–105, 98 Stat. 2339–42.
  \item \textsuperscript{28} See Kinkopf-Zajac, supra note 9, at 510. The Network was created by 42 U.S.C. § 274(a). See generally 42 U.S.C. § 274.
  \item \textsuperscript{29} See Barshes et al., supra note 23, at 213.
  \item \textsuperscript{30} See id.
  \item \textsuperscript{31} Id.
  \item \textsuperscript{32} See 42 U.S.C. § 274(b)(2)(A)(i)-(ii).
  \item \textsuperscript{33} See id. § 274(b)(2)(B).
  \item \textsuperscript{34} History of OPTN, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, http://optn.transplant.hrsa.gov/optn/history.asp (last visited Dec. 28, 2010).
\end{itemize}
transplants that occur in the United States and facilitates organ matching and placement among candidates. UNOS has also established policies that promote equitable allocation to individuals on the national waiting list.

OPO membership within UNOS is divided into eleven geographic areas throughout the country. Once an OPO secures an organ, UNOS is contacted, and donor/recipient information is entered into a national database, called UNet. A match is then conducted for the organ. The search results for potential candidates are ranked in accordance with objective medical criteria, such as blood type, tissue size, and medical emergency. The time a patient has spent on the waiting list and the distance between donors and recipients are also considered during the allocation process. Each organ also has its own specific criteria.

The match list of potential recipients is used to identify the highest ranked recipient, who is then offered the organ. That pa-

36. See Douglas J. Norman, UNOS: The Development, Objectives and Future of The National Organ Transplant Network, NEW DEV. TRANSPLANTATION MED., Spring 1994, available at http://www.centerspan.org/pubs/news/sp94a.htm ("UNOS has formulated policies to ensure equitable organ allocation to patients who are registered on the national patient waiting list. These policies forbid favoritism based on political influence, race, sex, or financial status, relying instead on sound medical and scientific criteria.").
39. See id.

Overall allocation protocol [based on] degrees of medical urgency [are] consistent with the following factors: sound medical judgment, best use of donated organs, preservation of physician judgment in declining organ offers or use for the potential recipient, suitability for the specific organ . . . , avoidance of organ waste and futile transplants and promotion of candidate access to transplantation and efficient management of organ placement, periodic review and revision as appropriate, and disassociation with candidate's place of residence or place of listing as feasible in light of the previously listed elements.

41. See How the Transplant System Works, supra note 40.
42. See id.
43. See id.
tient's local transplant center is then contacted. If accepted, the organ is transported, and surgery is scheduled.

C. The Nature of Organ Procurement and Allocation

OPTN's administrative efforts have been nominally successful since its creation. However, challenges remain with respect to actual allocation due to the scarcity of organs available for transplants. For example, in 2007, there were 28,369 patients that underwent organ transplants. Yet, that same year, 52,860 individuals were added to the national waiting list. Approximately 7,295 candidates died while waiting for a transplant in 2007. Given the scarcity of organs, patients who will benefit most from transplantation should theoretically be given priority.

D. Geographic Disparities

Yet disparities abound. For example, geographic location can weigh heavily against a patient's ability to receive an organ. The median wait time for Region 5 Heart Status 1A candidates from 2003 to 2004 was twenty-nine days. In contrast, the median wait

44. See id.
45. See id. If the organ is turned down, the next potential recipient's transplant center on the match list is contacted and the process repeats itself until the organ is accepted. Cf. id.
46. See Liliana M. Kalogjera, New Means of Increasing the Transplant Organ Supply: Ethical and Legal Issues, HUM. RTS., Fall 2007, at 19, 20 (noting that organ shortage continues to grow despite multifaceted efforts to increase the transplant organ supply); see also John M. Coombes & James F. Trotter, Development of the Allocation System for Deceased Donor Liver Transplantation, 3 CLINICAL MED. & RES. 87, 88 (2005); Gross, supra note 21, at 147-48.
47. Transplants by Donor Type, ORGAN PROCUREMENT & TRANSPLANT NETWORK, http://optn.transplant.hrsa.gov/latestData/step2.asp (select “Transplant” from the “Category” list; then follow “Transplants by Donor Type” hyperlink) (last updated Dec. 17, 2010).
50. See Bramstedt et al., supra note 14, at 217.
time for Region 1 Heart Status 1A candidates during this same period was fifty-four days.\textsuperscript{52} From 2003 to 2004, Region 5 Liver Status 1 patients waited an average of nine days for a transplant.\textsuperscript{53} In contrast, Region 1 Liver Status 1 patients waited an average of thirty-seven days.\textsuperscript{54} Thus, candidates in the northeast have a greater chance of succumbing to liver and/or heart failure than candidates on the west coast.

Even within regions, discrepancies in wait time are also present among local transplant centers within a single state. For example, 689 people are wait-listed for a kidney transplant at Cedars-Sinai Medical Center in Los Angeles, California.\textsuperscript{55} Approximately twenty patients are expected to wait less than thirty days before receiving a kidney.\textsuperscript{56} Sixty-seven candidates are estimated to receive a kidney within the next thirty to ninety days.\textsuperscript{57}

Yet over 5000 patients are on the waiting list for a kidney transplant at the University of California San Francisco Medical Center.\textsuperscript{58} Roughly ninety candidates are anticipated to receive a kidney within thirty days.\textsuperscript{59} Almost 151 patients will wait between thirty and ninety days before obtaining a transplant.\textsuperscript{60} Accordingly, candidates in southern California are more likely to receive a kidney transplant within the next ninety days, compared to individuals in northern California.

\textsuperscript{52} Median Waiting Time for Region 1, ORGAN PROCUREMENT \& TRANSPLANT NETWORK, http://optn.transplant.hrsa.gov/latestData/stateData.asp?type=region (select "Region 1"); then select "Median Waiting Time" from the "Category" list; then follow "Waiting Time by UNOS Status at Listing" hyperlink (last updated Dec. 17, 2010). Region 1 includes Connecticut, Maine, Massachusetts, New Hampshire, and Rhode Island. See Regions, supra note 37.

\textsuperscript{53} Median Waiting Time for Region 5, supra note 51.

\textsuperscript{54} Median Waiting Time for Region 1, supra note 52.

\textsuperscript{55} Kidney Transplant Waitlist at Cedars-Sinai Medical Center, ORGAN PROCUREMENT \& TRANSPLANT NETWORK, http://optn.transplant.hrsa.gov/latestData/stateData.asp?type=center (select "Califonia"); then select "CACS-TX1 Cedars-Sinai Med Center" from "Center" list; then select "Waiting List" from "Category" list; then select "Candidates" from "Count" options; then follow "Organ by Waiting Time" hyperlink (last updated Dec. 17, 2010) (all data cited from the OPTN website are accurate as of December 28, 2010 but the numbers are updated regularly).

\textsuperscript{56} Id.

\textsuperscript{57} Id.

\textsuperscript{58} Kidney Transplant Waitlist at UC San Francisco Medical Center, ORGAN PROCUREMENT \& TRANSPLANT NETWORK, http://optn.transplant.hrsa.gov/latestData/stateData.asp?type=center (select "California"); then select "CASF-TX1 Univ of CA San Francisco Med Ctr" from "Center" list; then select "Waiting List" from "Category" list; then select "Candidates" from "Count" options; then follow "Organ by Waiting Time" hyperlink (last updated Dec. 17, 2010).

\textsuperscript{59} Id.

\textsuperscript{60} Id.
There are several explanations for disparities based on geographic location. Despite NOTA and OPTN, a hospital’s and an OPO’s size, procurement policies, and procurement practices can lead to differences in candidate prioritization. In addition, wealthier patients in less densely populated areas often have minimal wait times, compared to those in larger communities. Further, competition for organs tends to be greater in more densely populated areas. Some facilities may also have trouble identifying and obtaining consent from potential donors.

In sum, a wide array of factors, including a hospital and OPO’s procedural operations, patient wealth, and geographic population density can all affect the length of time candidates spend waiting for an organ. Consistency is not an attribute easily applied to organ allocation efforts in the United States. Hence, despite NOTA, equitable distribution of organs for transplants still remains an elusive goal.

E. Disparities

Hospital and OPO policies, geography, and wealth are not the only hurdles faced by potential organ recipients. An individual’s probability of merely becoming listed fluctuates between transplant centers throughout the country. Thus, beyond actual organ allocation, simply obtaining a spot on the national waiting list is rife with inconsistencies.

One reason for the lack of homogeneity in patient selection tactics may be attributed to the absence of federal oversight. National directives tend to establish restrictions that govern the medical care used to determine transplant candidate selection criteria. For example, state programs or facilities that receive federal funding cannot exclude disabled individuals solely on the basis of their disabilities.

While this provision applies to hospitals that receive government subsidies, it provides little structure to the formation and implementation of patient selection criteria. Other federal legislation

61. See Coombes & Trotter, supra note 46, at 89.
62. See id.
63. See id.
64. See id.
65. See Mangus et al., supra note 10; see also Kinkopf-Zajac, supra note 9, at 513.
68. See id. § 794(b)(3)(A)(ii).
that addresses procurement practices of hospitals and OPOs is considered advisory, not mandatory.\textsuperscript{69}

Hospitals and OPOs are also free to apply their own patient evaluation modalities for waiting list placement.\textsuperscript{70} For example, Ochsner Health System in New Orleans avoids detailing a set list of contraindications that would otherwise preclude acceptance of potential kidney or pancreas recipients.\textsuperscript{71} Instead, Ochsner indicates that “[t]he list of absolute and relative contraindications for Kidney or Kidney/Pancreas transplant is continually evolving as [the hospital's] experience with certain pre-existing conditions and diseases grows.”\textsuperscript{72} The only specific contraindications Ochsner feels would inhibit allocations are excessive body mass index, active malignancies, and/or active infection.\textsuperscript{73}

In contrast, Henry Ford Hospital in Detroit lists a host of contraindications for kidney and pancreas recipients.\textsuperscript{74} In addition to active malignancies and infection, potential candidates may be denied for substance dependency, non-compliance, inadequate support system, and an inability to adhere to post-transplantation immunosuppression regimens and follow-up care.\textsuperscript{75}

Because of the significant variations in listing assessments, many candidates may be rejected by one center and still be accepted at another facility.\textsuperscript{76} Yet, the option of selecting multiple transplant


\textsuperscript{70} See Kinkopf-Zajac, \textit{supra} note 9, at 513.


\textsuperscript{72} Id.

\textsuperscript{73} See id.

\textsuperscript{74} See \textit{Are You a Transplant Candidate?}, HENRY FORD Hosp., http://www.henryfordhealth.org/body.cfm?id=49331 (last visited Dec. 28, 2010).

\textsuperscript{75} See id. The differences in contraindication classification exemplify how hospitals vary in terms of patient listing evaluation. Here, both Ochsner and Henry Ford view kidney and pancreas candidates with active malignancies and/or infections as questionable in terms of listing potential. Yet issues of substance dependency, non-compliance, or an inability to adhere to follow-up care routines may be seen as contraindicative at Henry Ford, but not Ochsner, if surrounding circumstances support listing status.

\textsuperscript{76} See Kinkopf-Zajac, \textit{supra} note 9, at 515 ("Each local transplant team formulates and applies its own criteria for waiting-list placement and patient selection." For this reason, criteria used generally 'vary from center to center, and a candidate rejected at one center may be accepted at another." (quoting Developments, \textit{supra} note 66, at 1630-31 & n.110). A recent case study tracked a liver candidate who simultaneously gained listing status at an east coast hospital and two Midwestern facilities. The patient's marijuana use prompted him to seek multiple listings because of how each hospital classified individuals who consumed the drug. This patient was placed on hold by the east coast hospital after failing multiple drug tests, but was later relisted. The same patient, however, was deferred at an Ohio hospital and recommended for chemical dependence treatment because he lacked active participation in
centers is not open to everyone. Patients are often limited to seeking admittance at facilities within their health maintenance organizations. Candidates who can afford to go through the evaluation process several times are more likely to achieve dual listings than patients limited to hospitals within their insurance networks.

F. Affluence

Affluence is a factor that can improve a patient’s chances of gaining waiting list status. For instance, Yankee’s legend Mickey Mantle received a liver transplant within weeks of being placed on a waiting list. Despite years of battling alcohol abuse, liver cancer and hepatitis C, Mantle was released from the hospital with a new liver exactly one month after being approved for a transplant.

Although Mantle’s blood type and physical condition made him the number one liver candidate within his geographic region, his financial state may have tipped the scales in his favor. Organ recipients absorb hundreds of thousands of dollars in medical bills within the first year of care following transplantation. Newly approved candidates must demonstrate their ability to finance such expenses, which include travel costs and anti-rejection drugs. Given Mantle’s financial state, his chances of covering anticipated medical bills may explain why he received a liver so quickly.

Despite a successful transplant, Mantle succumbed to cirrhosis-induced liver cancer two months after surgery. Mantle’s cancer...
spread to both lungs five weeks following the transplant and metastasized to his abdomen just before he died.\(^8^5\)

While doctors claim Mantle's cancer showed no signals of progression prior to surgery, critics believe otherwise.\(^8^6\) Most individuals with primary liver cancer evince signs the cancer has spread to areas outside the liver when the disease is first detected.\(^8^7\) Moreover, relatively few patients with rare types of liver cancer respond to transplantation.\(^8^8\)

Those with cirrhosis-induced liver cancer are seldom viewed as prospective candidates for liver transplants.\(^8^9\) Most often, such patients' prognoses are extremely poor.\(^9^0\) In addition to the scarcity of donor organs, immunosuppression regimes can interfere with the body's ability to combat cancer cells.\(^9^1\) Even if a candidate has microscopic cancer cells before surgery, these malignances enlarge after transplantation.\(^9^2\) The chances a new liver will bring lasting cures to patients with this type of cancer are minimal.\(^9^3\) Mantle's transplant, and subsequent death, further illustrates this point.

Steve Jobs, founder and CEO of Apple, is yet another example of how financial status can facilitate waiting list placement. Jobs was diagnosed with pancreatic cancer in 2004,\(^9^4\) and had a cancerous tumor removed from his pancreas that same year.\(^9^5\) In some cases, cancerous cells in the pancreas can metastasize to the liver, which


\(^8^5\). Id.


\(^8^7\). See id.

\(^8^8\). See id.


\(^9^0\). See Brody, supra note 86, at B12.

\(^9^1\). See id.

\(^9^2\). See id.

\(^9^3\). See id.


necessitates the need for a transplant.\textsuperscript{96} Thus, it was no surprise when Jobs underwent a liver transplant in March 2009 at a hospital in Memphis, Tennessee.\textsuperscript{97}

A great deal of controversy soon followed. Many liver transplant candidates consider Tennessee a Mecca because it harbors one of the shortest waiting lists in the country.\textsuperscript{98} Contrast California, where Jobs resides, which maintains one of the longest lists in the United States.\textsuperscript{99} Critics believe Jobs was able to reduce his wait time because he could afford to engage in multiple listing tactics at transplant hospitals outside his home state, an option that only exists for the wealthy.\textsuperscript{100}

A patient's notoriety can also increase his or her probability of being admitted to a waiting list. Former governor of Pennsylvania Robert P. Casey received a heart and liver transplant while in office.\textsuperscript{101} Casey underwent surgery hours after he was placed on a waiting list.\textsuperscript{102} When Casey received the organs, the median wait time for a liver transplant in his region was sixty-seven days.\textsuperscript{103} Heart recipients waited an average of 198 days.\textsuperscript{104} But for the former governor, it was less than twenty-four hours.

While the effects of organ failure are the same for all candidates vying for listing status, their chances of actually receiving a transplant remain uneven. Lack of federal oversight, coupled with the ability of hospitals and OPOs to set their own standards for organ allocation, patient selection, and waiting list criteria have led to preferential treatment of the rich and famous—a situation that reflects the very circumstances before NOTA was passed and that it was designed to address.

III. IMPACT: INSTITUTIONAL ORGAN POLICIES AND SUBSTANCE USE AND ABUSE

A. Inconsistency: Abstinence and "Second Chance" As Examples

The autonomy OPOs and hospitals have in formulating selection criteria has led to a striking divergence in selection tactics, especially with regard to individuals who present issues of substance use and abuse. These differences range from absence of any policies to those that do not bear scrutiny when assessed from a medical policy perspective. The lack of official guidelines in this area is of grave concern given the nature of substance abuse and the potential repercussions it can have on a person's overall quality of health, as well as survival with the transplanted organ.¹⁰⁵

Approximately 2.5 million deaths worldwide are attributable to alcohol.¹⁰⁶ For example, alcoholic liver disease is one of the most common indicators for liver transplantation among patients in the United States and Europe.¹⁰⁷ It is therefore a critical area to have clear standards on its use and abuse to ensure appropriate allocation and candidate listing for transplantation potential.

Yet how alcohol is addressed represents one of the most dramatic examples of variation in transplant policy.¹⁰⁸ A recent survey assessed variations in substance use policies for liver transplant centers across the United States.¹⁰⁹ Ninety-six U.S. adult liver trans-

¹⁰⁵. Organ transplantation has become a common treatment strategy for patients suffering from diseases caused by prolonged substance abuse. Yet, many are concerned that substance abusers who receive these life-saving organs will return to drug or alcohol use after surgery. Such behavior may have harmful effects on graft function, organ health, or survival rates. However, available data reflects inconsistencies with respect to how often patients return to substance abuse post-transplantation, and what predictors can be used to identify such outcomes. See Mary Amanda Dew et al., Meta-Analysis of Risk for Relapse to Substance Use After Transplantation of Liver or Other Solid Organs, 14 LIVER TRANSPLANTATION 159, 159-60 (2008).


¹⁰⁷. See Dew et al., supra note 105, at 159.

¹⁰⁸. No clear agreement exists among medical professionals regarding how long a patient must abstain from alcohol use prior to undergoing a transplant. Some critics feel that arbitrary abstinence periods should not be set for patients suffering from alcohol-induced cirrhosis. This belief is based on the nature of cirrhosis, which can cause unexpected infection and/or death among cirrhotics. These risk factors make it difficult to determine an accurate life span or an ideal time to perform surgery on such patients. As a result, many patients have died waiting for a liver because they were forced to fulfill criteria for predetermined sobriety periods. See Lawrence K. Altman, Doctor's World; A Question of Ethics: Should Alcoholics Get Transplanted Livers?, N.Y. TIMES, Apr. 3, 1990, at C3, available at http://www.nytimes.com/1990/04/03/science/doctor-s-world-a-question-of-ethics-should-alcoholics-get-transplanted-livers.html.

¹⁰⁹. Mangus et al., supra note 10.
Transplant candidates performing ten or more annual liver transplants were identified and contacted through UNOS. Of the responding centers, 16% had no written policies on substance abuse.

Those centers with written initiatives required 100% alcohol abstinence prior to surgery. But such abstinence periods varied. For instance, 81% of responding centers had six-month sobriety periods. Yet 6% of hospitals had policies that ranged from six to twelve months. The remaining facilities had abstinence requirements that were less than six months or were determined on a case-by-case basis.

Other discrepancies were also present. Roughly 74% of the responding transplant centers carved out exceptions to requisite abstinence periods for candidates with cirrhosis-induced liver cancer. Approximately 80% of responding liver transplant centers also have second-chance policies for individuals who drank alcohol after a previous agreement to cease consumption.

The above variations, coupled with “case-by-case” analyses, create significant room for alterations in candidate priority within and across transplant facilities. Thus, some individuals who continue to drink in the months leading up to surgery may still be able to receive a liver despite their continued alcohol consumption, while others face lengthy abstinence periods, and even death, in the event of a relapse.

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10. See id.
11. See id.
12. See id.
13. See id.
14. See id.
15. See id.
16. See id. This exception is shocking, as a leading cause of cirrhosis is alcoholism. See Hepatocellular Carcinoma, MEDLINEPLUS, http://www.nlm.nih.gov/medlineplus/ency/article/000280.htm (last updated Dec. 15, 2010).
17. See Mangus et al., supra note 10. For example, Loma Linda University Medical Center in southern California has implemented a second chance policy for patients wait-listed for liver transplants. Candidates must initially submit to a six-month abstinence period and are subject to urine and drug screening. If a patient tests positive for either drugs or alcohol, they must return to their assigned social worker and complete six months of AA before they can be relisted. However, none of the candidates at Loma Linda who were subjected to a second six-month abstinence period made it back on the list. Telephone Interview with Jennifer Stuart, Transplant Coordinator, Loma Linda Univ. Med. Ctr. (Jan. 18, 2010) (interview notes on file with author).
18. Tobacco is similar to alcohol. Tobacco continues to cause the most damage to physical health on a global scale. Tobacco Abuse Facts and Figures, WHO, http://www.who.int/substance_abuse/facts/tobacco/en/index.html (last visited Dec. 28, 2010). However, despite the clear relationship between poor health and tobacco use, only 31% of the surveyed hospitals required applicants to completely abstain from tobacco use prior to surgery. See Mangus et al., supra note 10. Indeed, among the same facilities, only 6% require patients with lung disease to stop smoking cigarettes, while 63% permit continued
B. Marijuana and Cigarettes: Lack of Rational Foundation for Transplant Policy

However, one of the greatest areas of transplantation regulation that lacks medical and policy foundation relates to medicinal marijuana use and cigarette smoking. The evidence and breadth of cigarette smoking harm is overwhelming. Among other things, tobacco use causes 8.8% of deaths worldwide and "kills more than 450,000 U.S. citizens each year—more than alcohol, cocaine, heroin, homicide, suicide, car accidents, fire, and AIDS combined." It also impacts virtually every human organ and affects wound healing.

Yet candidates who smoke cigarettes are much more readily accepted by liver transplant centers than those who use marijuana. In contrast to cigarettes, which have lethal implications and no medicinal effects, marijuana has been shown to have significant benefits associated with its health care use and limited tobacco use in such cases. See id. These contradictory, but otherwise permissible actions give patients mixed signals as to what constitutes acceptable behavior.


120. See Tobacco Abuse Facts and Figures, supra note 118.


123. See Mangus et al., supra note 10 (noting that 31% of liver transplant centers affirmatively oppose tobacco use, while marijuana use is explicitly prohibited in 88% of such facilities).

Like those for alcohol, transplantation policy and procedures related to marijuana use are highly variable. Almost 90% of liver transplant centers surveyed specifically proscribed marijuana use, while 13% do not routinely test for this substance. Further, nearly 77% of responding facilities have implemented secondary chance policies for wait-listed patients who tested positive for marijuana. In effect, patients face either possible drug tests and categorical denials or minimal screening and an additional opportunity to maintain listing status in the event of a failed drug test.

Transplantation access and policy variability regarding medical marijuana are complicated by policy developments that implicate illegal drug use. For example, all liver transplant hospitals surveyed exclude patients who use “illicit” substances. Even here, requisite sobriety periods vary: some facilities require just one negative screen (which may be achieved with only a few months of sobriety), while others require a full year.

In the case of marijuana, the drug remains illegal under federal statute. But fourteen states have legalized marijuana use for medicinal purposes. This creates the anomaly that some users may be able to obtain access to transplant organs after one negative screen, while others using the drug under a physician’s care may be summarily rejected for organ transplant allocation and listing.

among a handful of east coast states to do so. While the availability of medical marijuana is limited to a narrowly defined set of illnesses, both voters and lawmakers felt such legislation was necessary to improve the quality of life for citizens who are in extreme pain. David Kocieniewski, New Jersey Vote Backs Marijuana for Severely Ill: Both Houses Pass Bill: Gov. Corzine to Sign It—State to Be 14th to Legalize Drug, N.Y. TIMES, Jan. 12, 2010, at A1, available at http://www.nytimes.com/2010/01/12/nyregion/12marijuana.html.

125. See, e.g., Syed F. Ali et al., Chronic Marijuana Smoke Exposure in the Rhesus Monkey IV: Neurochemical Effects and Comparison to Acute and Chronic Exposure to Delta-9-Tetrahydrocannabinol (THC) in Rats, 40 Pharmacology Biochemistry & Behav. 677, 681 (1991) (finding no brain abnormality in animal models from cannabis smoke exposure); Editorial, Deglamourising Cannabis, 346 LANCET 1241, 124I (1995) (“The smoking of cannabis, even long term, is not harmful to health.”); cf. Andrew R. Morral et al., Reassessing the Marijuana Gateway Effect, 97 Addiction 1493, 1493–94 (2002) (“[A]vailable evidence does not favor the marijuana gateway effect over the alternative hypothesis that marijuana and hard drug initiation are correlated because both are influenced by individuals’ heterogenous liabilities to try drugs.”).
Such variations mimic the confusion over methadone treatment and heroin use. Heroin is an illegal, addictive, illicit drug, whereas methadone is a legal synthetic narcotic used to treat individuals suffering from heroin withdrawal. Yet some transplant centers equate methadone treatment with heroin use and will not place candidates on transplant waiting lists unless they cease consumption. Other centers will permit such placements or will allow those on methadone maintenance programs to potentially be eligible for transplantation upon completion of treatment.

C. Marijuana and Cigarettes: Inequity and Science

The inequity and inappropriate basis of medical marijuana transplant policies is most evident when the physiological effects of marijuana and tobacco are compared.

Both substances pose risks to organ recipients following transplantation. Medical marijuana users are primarily denied listing status because of reported complications that arise when marijuana is consumed after surgery. For example, invasive pulmonary aspergillosis ("IPA") is a rare infection that can be fatal to transplant recipients. Some marijuana contains high levels of aspergillus and has been known to compromise immunosuppressive agents following transplantation. Although mortality rates for immunocompromised patients with IPA are nearly 90%, recent evidence

135. See id.
136. See id.
138. See Bramstedt et al., supra note 14, at 218-19 (stating that marijuana use post transplantation can potentially wreak havoc on every physiological system in the body, and may lead to the development of invasive pulmonary aspergillosis in kidney recipients, a potentially lethal fungal infection whose only known cause is marijuana consumption after surgery); see also Weinrieb & Lucey, supra note 137, at S81.
140. See id. at 1773.
suggests transplant patients can be successfully treated for the disease.\textsuperscript{141}

More importantly, although touted as a rationale for rejecting medical marijuana users from transplant candidacy, incidents of IPA are exceedingly low.\textsuperscript{142} Medical professionals speculate the infrequency of IPA outbreaks is attributable to the body’s resilience against this agent.\textsuperscript{143} As a result, some experts maintain transplants should not be withheld solely on account of its use.\textsuperscript{144}

Tobacco use, in contrast, is responsible for a host of post-transplant potential issues.\textsuperscript{145} Similar to IPA, vascular ailments and hepatic artery thrombosis can seriously impede a liver recipient’s ability to recover.\textsuperscript{146} But in contrast to the rare event of IPA in medical marijuana users, patients with a history of cigarette smoking are more likely to incur vascular problems than non-smoking patients.\textsuperscript{147} In fact, it is recommended that a transplant candidate remain smoke-free for two years prior to surgery to lessen the onset of a vascular disorder.\textsuperscript{148}

Further, a smoker’s prospect of long-term survival following transplantation is also undercut by cardiac mortalities and death from malignancies associated with smoking.\textsuperscript{149} Hence, active smokers critically impact the potential success of transplants due to the extensive harm associated with cigarette smoking.

Habituation is also a factor that needs to be taken into account when addressing medical marijuana versus tobacco use. Patient compliance following transplantation is a critical factor that plays heavily into listing decisions.\textsuperscript{150} Among other things, psychological

\textsuperscript{141} For a case study documenting the successful treatment of a renal transplant patient who contracted aspergillosis from marijuana, see Marks et al., supra note 139. This patient was also the first documented case of marijuana-induced invasive pulmonary aspergillosis involving a solid organ transplant recipient.

\textsuperscript{142} For an account of an isolated report of aspergillosis contamination in a bone marrow recipient that was linked to marijuana, see Weinrieb & Lucey, supra note 137, at S81.

\textsuperscript{143} See Marks et al., supra note 139, at 1773.

\textsuperscript{144} See Weinrieb & Lucey, supra note 137, at S81.

\textsuperscript{145} See id.

\textsuperscript{146} See Surakit Pungpapong et al., Cigarette Smoking Is Associated with an Increased Incidence of Vascular Complications After Liver Transplantation, 8 LIVER TRANSPANTATION 582, 582 (2002).

\textsuperscript{147} See Weinrieb & Lucey, supra note 137, at S81.

\textsuperscript{148} Cf. Andrea DiMartini et al., Tobacco Use Following Liver Transplantation for Alcoholic Liver Disease: An Underestimated Problem, 11 LIVER TRANSPLANTATION 679, 682 (2005) (noting that doing so reduces risk of vascular complications by 58%).

\textsuperscript{149} See Karen F. Murray & Robert L. Carithers, Jr., AASLD Practice Guidelines: Evaluation of the Patient for Liver Transplantation, 41 HEPATOLOGY 1407, 1411 (2005); cf. supra notes 119–125 and accompanying text (describing the extensive harm of smoking cigarettes versus use of medical marijuana).

\textsuperscript{150} See Murray & Carithers, supra note 149, at 1413.
issues can severely inhibit transplantation success rates.\footnote{151}{See id.} As a result, some hospitals are hesitant to consider individuals who demonstrate addictive behavior.\footnote{152}{Id.}

Marijuana use has been linked to behavioral, psychological, and social issues.\footnote{153}{See AM. PSYCHIATRIC ASS'N, PRACTICE GUIDELINE FOR THE TREATMENT OF PATIENTS WITH SUBSTANCE ABUSE DISORDERS 103 (2d ed. 2006), available at http://www.psychiatryonline.com/pracGuide/loadGuidelinePdf.aspx?file=SUD2ePG_04-28-06.} Cannabis abuse and dependence are also reported to be associated with an increased risk of addiction to other substances.\footnote{154}{Id.} Yet treatment of marijuana-related dependencies remains understudied.\footnote{155}{Id.}

A recent study showed marijuana intake rates are relevant when analyzing psychological or physiological issues.\footnote{156}{See Nicole Walden \& Mitch Earleywine, \textit{How High: Quantity as a Predictor of Cannabis-Related Problems}, HARM REDUCTION J., May 2008, available at http://www.harmreductionjournal.com/content/pdf/1477-7517-5-20.pdf.} Quantity and frequency correlate with dependence levels experienced by recreational users.\footnote{157}{See id.} But such results were not readily applicable to individuals who consumed medicinal marijuana, as medical users were not incorporated into this study.\footnote{158}{Id.} Researchers speculated, however, that patients who are prescribed marijuana might require large quantities, but incur few negative side effects.\footnote{159}{Id.} Analysts also suggested that a responsible medical user could consume large amounts without experiencing social dependence or respiratory problems.\footnote{160}{Id.}

This study also emphasized limitations on quantitative assessments of marijuana use. Unlike packs of cigarettes, or cans of beer, marijuana consumption is difficult to reliably measure.\footnote{161}{See id.} Factors such as amount and potency make it difficult to produce homogenized assessments on how the amount of marijuana consumed affects users.\footnote{162}{Id.}

In contrast to marijuana, tobacco users face well-known dependency issues. Tobacco and its active ingredient nicotine have been found to be more addictive than alcohol, cocaine, and marijuan-
Nicotine abuse is considered a chronic relapse disorder, as 70% of smokers make more than one attempt to quit. In fact, most smokers must try to stop five to seven times before succeeding. Individuals who suffer from nicotine dependence are also susceptible to a host of physical issues not attendant to marijuana.

Unfortunately the adverse effects of nicotine addiction are difficult to overcome, even in the context of a transplant. Research indicates that nearly 50% of liver transplant candidates who smoke cigarettes will continue to do so three months after surgery. Over 25% of heart transplant recipients also resumed smoking following transplantation, with an average intake rate of eleven cigarettes per day.

Clearly, patients who use tobacco before surgery have a high chance of continuing their habit after transplantation. Yet as a matter of transplantation policy, nicotine addiction through cigarette smoking appears to have tremendous negative ramifications that will adversely affect the success of the transplant compared to the relatively limited impacts of medical marijuana. Accordingly, the current system for patient selection does not reflect sound medical or public policy.

IV. A PROPOSED POLICY

To address these concerns regarding equity and consistency, a science-oriented model policy that relates to medical marijuana and transplantation should be adopted by OPTN. This approach would standardize decision-making with respect to medical marijuana use and organ transplant eligibility. Here, we provide one such policy and discuss these provisions in a subsequent section.

Facility Transplantation Policy on Candidate Substance Use and Abuse

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163. See, e.g., Denise Kandel et al., Prevalence and Demographic Correlates of Symptoms of Last Year Dependence on Alcohol, Nicotine, Marijuana and Cocaine in the U.S. Population, 44 DRUG & ALCOHOL DEPENDENCE 11, 23–24 (1997).
164. AM. PSYCHIATRIC ASS'N, supra note 155, at 74.
165. Id. at 73.
166. Id. at 74.
167. Cf. id. at 129.
168. See DiMartini et al., supra note 148, at 681.
169. Id. at 679.
Objective
To standardize patient placement onto the transplantation waiting list and eligibility for organ transplant with regard to candidate substance use and abuse. For specific clinical characteristics for eligibility, please see Organ Transplant Program policies for the specific organ, clinical criteria, and laboratory assessment.

Definitions
"Candidate" is an individual who wishes to be placed on the transplant waiting list for organ transplantation and is subject to all clinical protocols associated with the Organ Transplant Program.

"Substance Abuse" is use of an external substance by a candidate for non-medicinal purposes without supervision of a treating physician.

"Substance Use" is use of an external substance by a candidate for medicinal purposes under the supervision of a treating physician that coordinates with the Organ Transplant Team.

Policy
To become a candidate, patients must agree to adhere to this policy with respect to substance abuse and substance use.

Substance Abuse
1. Six-Month Abstinence. If a patient wishes to become a candidate, if the patient is engaged in substance abuse, including but not limited to the use of alcohol, cigarettes, cocaine, heroin, and/or marijuana, the patient must agree to a period of six months of abstinence from substance abuse before being considered to become a candidate.

2. Random Verification. If a patient wishes to become a candidate, the patient agrees to be subject to random verification of abstinence during the six months as noted in (1) above. At the end of six months of abstinence, the patient will be evaluated using the clinical protocol relevant to the organ to be transplanted, and if he/she fulfills those criteria, shall be placed upon the transplantation waiting list for that organ. Patients who are listed as candidates at the end of six months of abstinence are continuously subject to random verification of their abstinence at all times they are on the transplantation
waiting list and, if relevant, at all times after receiving an organ transplant.

3. ‘Second Chance’ Policy. If a patient is engaged in substance abuse and begins the process of abstinence, if he/she abstains for at least three months but upon random verification between three and six months, or, after being listed as a candidate and during random verification after such listing, is found to be engaged in substance abuse, the patient, upon request by the patient and approval by his/her primary care physician, shall be eligible for a “second chance” under this section. This “second chance” shall be a second six-month abstinence period with random verifications as in the original abstinence period. If the patient was listed as a candidate, the patient shall be removed from the transplantation waiting list. The patient shall be considered to be a candidate again if he/she engages in abstinence for this second six-month abstinence period. No patient will be allowed any further potential to be a candidate if he/she fails the second six-month abstinence or under random verification after the second six-month abstinence is completed fails any random verification test.

Substance Use

1. Treatment Supervision. If a patient wishes to become a candidate and is engaged in substance use, including but not limited to the use of medical marijuana and methadone, the patient must agree to verification by his/her treating physician that the patient is engaged only in the use and not abuse of the substance, and that he/she is participating completely in any treatment program, including treatment for addiction in a methadone maintenance program. If the patient agrees to such treatment supervision and subject to the approval of his/her treating physician, the patient will be evaluated using the clinical protocol relevant to the organ to be transplanted, and if he/she fulfills those criteria, shall be placed upon the transplantation waiting list for that organ.

2. Random Verification. Patients who are candidates engaged in substance use will be subject to random verification of their compliance with physician orders and treatment associated with their substance use as long as such use is continued. Candidates who are engaged in substance use who are not compliant with physician orders and treatment associated
with their substance use upon verification shall be taken off the transplantation waiting list. Candidates who complete substance use treatment are continuously subject to random verification for any substance abuse, and any such substance abuse shall be assessed according to the policy on Substance Abuse indicated above.

3. “Second Chance” Policy. If a candidate engaged in substance use for at least three months, but upon random verification is found to be not compliant with physician orders and treatment associated with their substance use, the candidate will be taken off the transplantation waiting list. The patient taken off the waiting list under this section, upon request by the patient and approval by his/her primary care physician, shall be eligible for a “second chance” under this section. The patient may be given a “second chance,” and be provided with a six-month period in which he/she must be compliant with physician orders and treatment associated with his/her substance use. The patient shall be considered for candidacy again if he/she engages in substance use compliant with physician orders and treatment during this period. No patient will be allowed any further potential for candidacy if he/she fails this “second chance” six-month period of substance use compliant with physician orders and treatment.

If the candidate engaged in substance use is found to have engaged in substance abuse, he/she shall be subject to the provisions of the Substance Abuse Policy, “second chance” policy.

V. DISCUSSION OF THE PROPOSED POLICY

A. Rationalization

Several reasons are attributable to the lack of standardization in patient selection criteria. Many hospitals want a patient evaluated from a wide array of perspectives before listing status is even considered. The need for a thorough analysis is premised upon the cost of transplantation and the limited supply of organs. A tre-

171. See id.
mendous amount of attention is also devoted to an individual’s likelihood of compliance of medical advice after surgery.\textsuperscript{172}

Substance abuse has been linked to nonconformity, high recidivism rates, and poor outcomes following transplantation.\textsuperscript{173} While the recognition of contraindications is structured around an impartial set of criteria, the process itself involves much subjectivity in application.\textsuperscript{174} The information reviewed\textsuperscript{175} suggests medical facilities and personnel are taking a varied, and not altogether rational approach, on how substance use and abuse plays into patient candidacy and listing for organ transplantation. The arbitrary application of medical information and the intermittent use of second chance policies create tremendous potential for inequities to be perpetuated and hidden within the decision-making process.

The resulting uneven approaches are exacerbated by the very arbitrariness of the decision-making system itself. Each center’s own experience is likely to play a major role in policy determinations, which further contributes to variations in evaluative criteria.\textsuperscript{176} A hospital that has experienced successful transplantation and/or compliance rates among patients who engage in certain high risk behavior will be more likely to approve such candidates for future transplantation, as opposed to those who have not.\textsuperscript{177} Hence, the irrationality of candidate choice by transplantation facilities is propagated by their own irrationality in earlier choices, and justified by them, creating a circle of uneven candidates based on questionable factors and science.

To bring the decision-making process on use of medical marijuana and transplantation into the realm of medical rationality, a policy should be structured to ensure uniformity in assessment and judgment with respect to substance use and abuse. This approach should focus on using reimbursement means to incentivize the appropriate adoption of organ transplant allocation policy, as was done originally in the Omnibus Budget Reconciliation Act with OPTN policy.\textsuperscript{178}

\begin{footnotesize}
\begin{enumerate}
\item \textsuperscript{172} See id.
\item \textsuperscript{173} Leslie W. Miller, \textit{Listing Criteria for Cardiac Transplantation: Results of an American Society of Transplant Physicians—National Institutes of Health Conference}, 66 \textit{Transplantation} 947, 949 (1998).
\item \textsuperscript{174} See Nelson Interview, \textit{supra} note 170.
\item \textsuperscript{175} See \textit{supra} Sections II & III, and particularly III.B.
\item \textsuperscript{176} See \textit{supra} Section III.
\item \textsuperscript{177} See Kinkopf-Zajac, \textit{supra} note 9, at 513.
\item \textsuperscript{178} The Omnibus Budget Reconciliation Act added a section to the Social Security Act that controlled Medicare and Medicaid reimbursement for hospitals and OPOs. See Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9318(a), 100 Stat. 1874, 2009
\end{enumerate}
\end{footnotesize}
B. A Model Policy

As indicated above, a model policy that relates to medical marijuana and transplantation should be adopted by OPTN to standardize decision-making with respect to medical marijuana use.

Objective
To standardize patient placement onto the transplantation waiting list and eligibility for organ transplant with regard to candidate substance use and abuse. For specific clinical characteristics for eligibility, please see Organ Transplant Program policies for the specific organ, clinical criteria, and laboratory assessment.

Here, the objective of the policy is stated. The focus is upon ensuring the use of organs is standardized with relationship to substance use and abuse to avoid the highly variable, potentially abused process applied currently to organ allocation across the United States. This policy expressly points the reader to clinical protocols for data associated with particular organ states.

Next, operationalization of the policy must occur. The distinctions and definitions associated with substance use versus abuse should be distinguished by how these substances are used. This is covered next in the policy.

Definitions
“Candidate” is an individual who wishes to be placed on the transplant waiting list for organ transplantation and is subject to all clinical protocols associated with the Organ Transplant Program.

“Substance Abuse” is use of an external substance by a candidate for non-medicinal purposes without supervision of a treating physician.

“Substance Use” is use of an external substance by a candidate for medicinal purposes under the supervision of a treating physician that coordinates with the Organ Transplant Team.

(codified as amended at 42 U.S.C. § 1320b-8 (2006)). Specifically, payment was conditioned upon OPTN membership and compliance with its rules on transplantation. Id.
It is apparent that a transplant facility's interpretation of the term "abuse" is critical when evaluating candidates who use certain substances. For example, the Revised Code of Washington State permits the use of medical marijuana for patients diagnosed with a terminal, or otherwise debilitating, illness. \(^{179}\) Licensed medical professionals regulate its consumption through prescriptions \(^{180}\) and discuss the benefits and risks of medical marijuana with patients before any decision to prescribe and use the drug in the patient's care regimen is made. \(^{181}\) In this situation, medical oversight is focused and should be considered a "use.”

This definition is in contrast to "abuse," which is considered by WHO as a recreational or otherwise unsanctioned pattern of consumption, irrespective of consequences. \(^{182}\) Hence, in this context, abuse of a particular substance is consistent with perpetual or intermittent extreme drug use contrary to acceptable medical practice. \(^{183}\) This, of course, also includes use of materials that are of no clinical benefit. This distinction is therefore adopted here.

Once the distinction is made between substance abuse and substance use, substantive policy can be promulgated that focuses on ensuring the maximum potential use and success of an organ transplantation. Abstinence and "second chance" are the two key issues to be addressed.

**Policy**

To become a candidate, patients must agree to adhere to this policy with respect to substance abuse and substance use.

**Substance Abuse**

1. Six-Month Abstinence. If a patient wishes to become a candidate, if the patient is engaged in substance abuse, including but not limited to the use of alcohol, cigarettes, cocaine, heroin, and/or marijuana, the patient must agree to a period of

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179. *Wash. Rev. Code* § 69.51A.005 (2008) ("Some of the illnesses for which marijuana appears to be beneficial include chemotherapy-related nausea and vomiting in cancer patients; AIDS wasting syndrome; severe muscle spasms associated with multiple sclerosis and other spasticity disorders; epilepsy; acute or chronic glaucoma; and some forms of intractable pain.").


183. See id.
six months of abstinence from substance abuse before being considered to become a candidate.

Here, substance abuse patients must adhere to a regimen that includes a six-month abstention period from the harmful drug(s) they are taking. This is a critical component of evaluation to ensure they are able to avoid the abuse of drugs and are in the physical and non-dependent condition that can promote the best chance of success for organ transplantation.

To ensure the patient is, in fact, abstaining from substance abuse, random verification procedures must be put into place.

2. Random Verification. If a patient wishes to become a candidate, the patient agrees to be subject to random verification of abstinence during the six months as noted in 1. above. At the end of six months of abstinence, the patient will be evaluated using the clinical protocol relevant to the organ to be transplanted, and if he/she fulfills those criteria, shall be placed upon the transplantation waiting list for that organ. Patients who are listed as candidates at the end of six months of abstinence are continuously subject to random verification of their abstinence at all times they are on the transplantation waiting list and, if relevant, at all times after receiving an organ transplant.

Here, any substance abuse patient wishing to be a candidate for organ transplantation agrees to be subject to random verification of his/her abstinence status. This is a crucial requirement to ensure compliance with the abstinence mandate and to ensure that patients are acting for the best use of the organ itself. In addition, so as to ensure continued abstinence, any substance abuse patient who becomes a candidate is also expressly subject to random verification.

If, however, the substance abuse patient does not fulfill the requirements fully under this policy, but shows promise through abstinence for at least three months, a "second chance" policy is available.

3. "Second Chance" Policy. If a patient is engaged in substance abuse and begins the process of abstinence, if he/she is abstinent for at least three months but upon random verification between three and six months, or, after being listed as a candidate and during random verification after such listing, is found to be engaged in substance abuse, the patient, upon
request by the patient and approval by his/her primary care physician, shall be eligible for a “second chance” under this section. This “second chance” shall be a second six-month abstinence period with random verifications as in the original abstinence period. If the patient was listed as a candidate, the patient shall be removed from the transplantation waiting list. The patient shall be considered to be a candidate again if he/she engages in abstinence for this second six-month abstinence period. No patient will be allowed any further potential to be a candidate if he/she fails the second six-month abstinence, or under random verification after the second six-month abstinence is completed fails any random verification test.

Here, a second chance is given to substance abuse patients. If they meet the three-month cutoff, they may restart the six-month period of abstinence. If they complete this period, and maintain abstinence, they may become a candidate for organ transplantation. Note that this is a bright line rule: failure under this section of the policy completely eliminates the substance abuse patient from any consideration as a candidate for organ transplantation.

Substance Use
1. Treatment Supervision. If a patient wishes to become a candidate and is engaged in substance use, including but not limited to the use of medical marijuana and methadone, the patient must agree to verification by his/her treating physician that the patient is engaged only in the use, and not abuse of the substance, and that he/she is participating completely in any treatment program, including treatment for addiction in a methadone maintenance program. If the patient agrees to such treatment supervision, and subject to the approval of his/her treating physician, the patient will be evaluated using the clinical protocol relevant to the organ to be transplanted, and if he/she fulfills those criteria, shall be placed upon the transplantation waiting list for that organ.

The critical issues here are ensuring these patients are under physician supervision, do not subject themselves to substance abuse, and are subject to an equitable “second chance” policy. In this case, patients engaged in substance use must agree to treatment
supervision. Because of the medical nature of such substance use, the abstinence provisions of the substance abuse provisions do not apply. Hence, substance use patients are eligible for transplantation candidacy and waiting list placement if they agree to verification of participation in treatment using the specific substance, subject to their treating physician’s approval.

Verification is a necessary component in the substance use situation as in the substance abuse circumstance. This is particularly true because substance use may become substance abuse.

2. Random Verification. Patients who are candidates engaged in substance use will be subject to random verification of their compliance with physician orders and treatment associated with their substance use as long as such use is continued. Candidates engaged in substance use who are not compliant with physician orders and treatment associated with their substance use, upon verification, shall be taken off the transplantation waiting list. Candidates who complete substance use treatment are continuously subject to random verification for any substance abuse, and any such substance abuse shall be assessed according to the policy on Substance Abuse indicated above.

Like in the substance abuse case, random verification of the substance use patients is also important to ensure best potential use of organs. These patients must be compliant with physician treatment orders and treatment strategies so the optimal outcome results when using these substances. Further, again similar to the substance abuse case, all substance use patients who become candidates are continuously subject to random verification. However, because there is the potential for substance use to become substance abuse, the policy expressly notes that in such a case, the patient becomes subject to the substance abuse policy.

Finally, second chance policies for substance use are also addressed. A six-month period is used in this section as well, similar to the substance abuse section.

3. “Second Chance” Policy. If a candidate engaged in substance use for at least three months but upon random verification is found to be not compliant with physician orders

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184. This provision would address the case of Timothy Garon. While Garon had previous issues with substance abuse, a physician monitored his use of medical marijuana at the time of his denial. See Johnson, supra note 2.
and treatment associated with their substance use, the candidate will be taken off the transplantation waiting list. The patient taken off the waiting list under this section, upon request by the patient and approval by his/her primary care physician, shall be eligible for a “second chance” under this section. The patient may be given a “second chance” by being provided with a six-month period in which he/she must be compliant with physician orders and treatment associated with his/her substance use. The patient shall be considered for candidacy again if he/she engages in substance use compliant with physician orders and treatment during this period. No patient will be allowed any further potential for candidacy if he/she fails this “second chance” six-month period of substance use compliant with physician orders and treatment.

If the candidate engaged in substance use is found to have engaged in substance abuse, he/she shall be subject to the provisions of the Substance Abuse Policy, “second chance” policy.

In this situation, if the substance use patient is found to be non-compliant with physician orders and treatment, he or she is given a “second chance” through a six-month period to show compliance to become listed as a transplantation candidate once again. However, if the patient has violated the policy and becomes engaged in substance abuse, he or she is subject to the second chance provision in the substance abuse section.

VI. Conclusion

The impediments faced by transplant candidates are numerous. It is clear that a more equitable starting point in the patient selection process should be put into place. Transplant centers across the country are currently given boundless discretion to set their own criteria for organ allocation allowing each to avoid transplant candidates based upon arbitrary medical or other characteristics. A uniform system is clearly needed to ensure that equity is a goal the organ transplant community is striving for, despite the challenges of geography, population density, and other factors at play.

Of course, a unified method would not only coincide with the rationale behind the organ allocation process as mandated by NOTA, OPTN, and UNOS, but would also level the playing field for candidates who have issues of substance abuse raised against
Hospitals should also be compelled to codify these provisions. Differentials between those who engage in substance abuse and those under medical care who are merely using similar substances should be expressly taken into account. The result would be another step toward equity and away from systems that inappropriately allocate organs to alcohol abusers and heavy cigarette smokers over those who use medical marijuana for treatment.

A policy that takes into account issues of substance use versus substance abuse, abstinence periods, and compliance with treatment regimens, random verification, as well as potential “second chance” allowances can yield significant benefit for patients and the transplant efforts in this country. A uniform set of standards creates equal expectations and requirements across facilities and limits gaming of the system, such as multiple efforts at being placed on a wide array of waiting lists, which drive inefficiency and disparities.

Patient education should also be at the forefront of these efforts. Patients who seek organ transplants need to be aware of the potential obstacles they face when attempting to be considered for an organ transplant and waiting list placement at facilities that perform these activities. With clear standards on substance use, abuse, and their associated requirements, individuals will be able to make well-informed choices and have a clear understanding of the challenges they may be confronted with when attempting to become candidates for transplantation.

It has been nearly twenty-five years since NOTA’s enactment. Yet this country’s organ procurement and allocation efforts remain plagued by the same injustices that existed before its passage. Organ shortages, high demand, disparities, and uneven policies and procedures lacking scientific integrity continue to prevent the needs of many candidates from being met, particularly patients engaged in substance use despite being under a physician’s care and treatment protocol. Medical science must be brought back into the system. Policies must be created that provide for rational selection of transplant candidates, which will ensure that the tragedy of Timothy Garon’s death is not wasted, and the hope of a second chance for Jonathan Simchen is fulfilled.