INTRODUCTION

At its best, the medical practice of organ transplantation demonstrates the most gracious qualities of generosity and sacrifice, where a decision by a living organ donor or a deceased donor’s grieving family can mean the difference between a second chance at life or years spent waiting before time runs out. Fundamentally, organ transplantation also remains a stark example of the classic economic theory of supply and demand. Despite medical advancements, the growing acceptance of organ donation, and policy efforts to increase the donation rate, the waiting list of potential recipients grew 64% over the past ten years while the number of donors rose by only 39% during that same span of time. More than 100,000 individuals are listed currently on the national organ transplant registry. Last year alone, 6,453 candidates died waiting for an organ donor match, or an average of 18 patients per day. For these reasons, the life and death decisions behind how to allocate available organs for transplantation must be sensitive to the ethical and policy interests of objectivity, efficiency and fairness.

The health insurance sector plays a critical role in the organ transplantation specialty. Insurance may interact with this medical field in ways which yield significant benefits, assisting patients in funding otherwise prohibitively expensive procedures or setting appropriate

---

* J.D., University of Connecticut School of Law, 2010; B.A., University of Pennsylvania, 2001. I would like to thank Professor Susan Schmeiser for her valued input as well as my family and friends for their support and encouragement. This Note is dedicated to my father, Jerry Wong, a healthy kidney transplant recipient since 1991.

standards of care in this practice. Still, insurance coverage issues also tend to expose glaring disparities with how organs are allocated among potential recipients based on the ability to pay for these life-saving procedures.

This Note examines both the positive and negative consequences which result when insurance matters intersect with the practice of organ transplantation. Part I summarizes the medical developments behind organ transplantation and subsequent legislative efforts to support the infrastructure and health policies of this field. Part II examines the primary forms of insurance coverage for both organ donors and recipients and the most commonly litigated issues which arise based on each funding option. Part III then addresses the unexpected and unintended connections formed as a result of this interaction, such as the correlation between insurance status and the likelihood of receiving or donating an organ. Finally, Part IV proposes recommendations to promote the beneficial interplay between insurance and organ transplantation while minimizing the more negative effects of the relationship.

I. MEDICAL AND LEGISLATIVE HISTORY OF ORGAN TRANSPLANTATION

While the earliest attempts at organ and tissue transplantation date back thousands of years, the era of modern transplant surgery has been established only in the past few decades. In 1954, the kidney was the first major organ to be transplanted successfully, followed rapidly by the first transplants for the pancreas, heart and liver all within the next fifteen years. Further advancements stalled due to the complications of future organ rejection, but with the development of Cyclosporine and other anti-rejection immunosuppressive drug therapies in the 1970s and 1980s, as well as other surgical improvements such as the use of laparoscopic or single-incision techniques, the practice of organ transplantation has grown to include lung and intestinal transplants, dual organ transplants, artificial or animal organ transplants, stem-cell transplants, and most recently, face,

---

4 Laurence A. Turka, M.D., Historical Overview, PRIMER ON TRANSPLANTATION 1 (2nd ed. 2001).
6 Jed Adam Gross, E Pluribus Unos: The National Organ Transplant Act and Its Postoperative Complications, 8 YALE J. HEALTH POL‘Y, L. & ETHICS 145, 170 (2008). With the introduction of cyclosporine therapy, one-year kidney transplant survival rates climbed from 55% from 85% while five-year liver transplant survival rates increased from 18.2% to 68%. Id.
limb and ovary transplantation. Today, more than 250 medical facilities across the United States perform major organ transplant procedures at a rate of 27,000 per year.

A. THE UNIFORM ANATOMICAL GIFT ACT

Shortly after the first successful heart transplant procedure and as major organ transplantation became more commonplace, the National Conference of Commissioners on Uniform State Laws established the Uniform Anatomical Gift Act (UAGA) in 1968. The UAGA represents the first attempt to codify in some form the standards and guidelines for the donation and receipt of anatomical gifts. The UAGA provides that any individual aged eighteen years or more, may give all or any part of his or her body upon death for any purpose specified in the Act. This is a right that was not clearly recognized in common law at the time. The UAGA also mandates that surgeons remove the gifted organ “without unnecessary mutilation” and that the time of death of the potential donor be determined by a physician who does not participate in the transplant procedure itself. This stipulation is intended to combat fears that overeager doctors could declare brain or cardiac death prematurely in the hopes of salvaging organs for donation. The UAGA also exempts from criminal or civil liability a hospital, physician, public health officer or other person who acts in good faith in accordance with the terms of the Act or a similar anatomical gift statute of another state or foreign country, presumably in the public interest of encouraging medical professionals to

---

8 UNOS FACTS AND FIGURES, supra note 5, at 1, 10; United Network for Organ Sharing, supra note 2.
9 UNIF. ANATOMICAL GIFT ACT, at p. 3 (amended 2009).
10 Id. § 4.
11 Id. at p. 3.
12 Id. § 14(h).
13 Id. § 14(i).
14 See id. at p. 3.
15 See id. § 18.
participate in the removal of organs after death for the purpose of donation.\textsuperscript{16}

While all jurisdictions had enacted into state law the Uniform Anatomical Gift Act of 1968, only twenty-six states adopted the later 1987 revisions to the UAGA.\textsuperscript{17} Several states have since incorporated their own non-uniform amendments to original statutes.\textsuperscript{18} As a result, there is significance divergence in previously consistent state anatomical gift laws, posing a serious impediment to organ transplant processes extending beyond state lines. Since only a short window for transplantation exists, as brief as four to six hours for a heart or lung,\textsuperscript{19} there may not be enough time for extensive research into and compliance with each state’s policy. The UAGA has been revised again in 2006 and 2009 in attempts to re-secure more uniform adoption across the states and to align more closely with federal laws regulating organ transplantation.\textsuperscript{20} Thirty-seven states have enacted this latest set of revisions to the Uniform Anatomical Gift Act, with five more states scheduled to introduce the bill in 2010.\textsuperscript{21}

B. THE NATIONAL ORGAN TRANSPLANT ACT

The National Organ Transplant Act (NOTA) of 1984 sets federal guidelines for organ donation and transplantation. Congress enacted NOTA to address the growing competition for donor organs and the unequal distribution of available organs.\textsuperscript{22} The Act set a new national health policy to ensure the equitable allocation of organs through the

\textsuperscript{16} See Williams v. Hoffman, 223 N.W.2d 844, 848–49 (Wis. 1974) (stating that the “limitation on liability ... is justified by the legitimate public purpose of encouraging doctors to participate in the removal of organs following death, and therefore increasing their supply.”). See also Ramirez v. Health Partners of Southern Ariz., 972 P.2d 658, 666 (Ariz. 1998) (“There is a critical state interest in encouraging organ donation and protecting procurement personnel who engage in that important work.”).

\textsuperscript{17} UNIF. ANATOMICAL GIFT ACT, at p. 1 (amended 2009).

\textsuperscript{18} Id.

\textsuperscript{19} UNITED NETWORK FOR ORGAN SHARING, PARTNERING WITH YOUR TRANSPLANT TEAM: THE PATIENT’S GUIDE TO HEALTH 10, http://www.unos.org/resources/brochures.asp. For example, the liver or pancreas lasts for 12-24 hours and the kidney up to 72 hours. Id.

\textsuperscript{20} See UNIF. ANATOMICAL GIFT ACT, at p. 4 (amended 2009).


establishment of a national organ procurement and transplantation network, while at the same time working to increase the overall number of organs available for transplantation. The Act also authorized funding for fifty-nine regional Organ Procurement Organizations (OPOs) to consolidate and coordinate donation efforts and help foster public awareness about the critical need for organ donors. Finally, NOTA expressly forbids the buying and selling of human organs and body parts, imposing up to a $50,000 fine or five years imprisonment for organ trafficking and other actions to commercialize the donative process.

Prior to the enactment of NOTA, private regional transplant networks managed the donor matching process but were limited by strict regional borders and a lack of coordination across systems. As a result, medical facilities in some areas were forced to compete for available organs while in other localities, donor organs went unused. NOTA authorized the creation of a centralized Organ Procurement and Transplantation Network (OPTN) to better facilitate organ matching, delivery, and transplant surgeries. Congress contracted with a private entity, the United Network for Organ Sharing (UNOS), to oversee this network in the hopes that management by a private entity would be the fastest method to establish nationwide coordination given bureaucratic delays with federal ownership and the initiative of the private sector in establishing original networks in the first place.

UNOS is responsible for coordinating organ transplant efforts among 58 organ procurement organizations (OPOs) and 250 hospital and medical facilities which maintain organ transplant programs. UNOS also formulates the network’s membership criteria and the ensuing medical standards for transplant procedures. Each hospital with a transplant program is a member of the OPTN and must adhere to the standardized

---

24 Id. § 273(a).
25 Id. § 274(e).
26 United Network for Organ Sharing, supra note 2.
27 Id.
29 See UNITED NETWORK FOR ORGAN SHARING, supra note 5, at 5.
31 Id. at 4.
criteria for patient eligibility and wait-list priority. Eligibility and priority factors include the degree of medical compatibility between the donor and donee and the urgency for medical intervention. The patient’s location is also an important consideration, since decreased transfer time leads to better preservation of the organ and better survival rates. Additionally, the network measures the amount of time a donee spends on the waiting list to determine priority over other potential recipients. In certain cases, the highest-ranked patient on the waiting list may be passed over if the individual cannot be located, is temporarily sick, would likely reject a transplanted organ, or would benefit only minimally from the procedure because of age or medical condition as determined by his or her transplant team.

C. ORGAN TRANSPLANTATION TODAY

As thousands of patients join the organ transplant list each year, the continual shortage of available organs lingers as a major challenge despite widespread efforts to increase the rates of donation. Some of the reasons behind diminished donation numbers are attributable to positive medical advancements, such as more rigorous medical screening processes, an overall decrease in accidental death, and the increase in survival rates for infants delivered prematurely. Other explanations reflect problems which

---

34 Id.
35 Id.
36 See id.
37 Additional efforts to promote organ donation include the Organ Donation Insert Card Act, which established a national initiative through the Department of Health and Human Services to increase donation by 20% by 2000 and authorized the mailing of organ donor cards along with income tax refunds. Organ Donation Insert Card Act, Pub. L. No. 104-91 (1996).
have plagued the donation process for decades, including common scenarios where potential donors fail to sign directives or medical personnel neglect to search for donor cards, leaving the decision in the hands of family members who may refuse consent or are unaware of the patient’s wishes.\(^{39}\) Meanwhile, the demand for organs continues to grow. To cite just one statistic, the national diagnosis rate for diabetes, a leading cause of kidney failure, has increased from 2.7\% in 1985 to 5.5\% in 2005 and will continue to rise based on obesity, aging and ethnic demographic trends.\(^{40}\)

Still, there is little to justify the overwhelming deficit in the overall number of donors. Almost every religion supports organ donation as consistent with its beliefs, though some may not be aware of their particular religion’s support for the practice or instead experience general reluctance to donate based on other principles.\(^{41}\) Non-traditional donors, such as living donors and donors over 50 who would have been previously ineligible to donate due to age, are compensating for lower donation rates elsewhere. For example, the number of living donors increased by 245\% over the past twenty years, while donors aged 50 and older increased by 456\% over the same period of time.\(^{42}\) Comparatively, the average rate of growth in the amount of all donors increased only by 125\% overall.\(^{43}\) Additionally, hospitals are evaluating new protocols which allow for organ donation after cardiac death instead of brain death, creating an expanded class of donors beyond the diminishing number of eligible brain-dead patient-donors.\(^{44}\)

---


\(^{40}\) Gross, *supra* note 6, at 241.


\(^{42}\) Organ Procurement and Transplantation Network, http://optn.transplant.hrsa.gov (select “View Data Reports,” “National Data,” “Waiting List Removals” in Step 1 drop-down menu; then follow “All Donors By Donor Type” hyperlink in Step 2) (last visited Mar. 10, 2010).

\(^{43}\) Id.

Even without incorporating new subsets of organ donors, according to the medical and ethical standards set by the National Organ Transplant Act, current donor eligibility guidelines are in fact expansive enough to include 13,091 patients who died under the age of 70 and were otherwise eligible for donation in 2005. Of that subset, only 58%, or 7,593 patients, became actual donors, generating a supply of over 23,000 organs for transplantation. Living donors, primarily for the donation of a kidney, contributed about 6,800 more organs to yield a combined total of about 28,000 organs transplanted that year. This data suggests that there were still 5,498 eligible individuals who died in 2005 without donating their organs upon death. That number of individual donors would have generated 17,000 additional organs for transplantation, more than enough to make up for the deficits in our donated organ supply.

II. INSURANCE COVERAGE AND ORGAN TRANSPLANTATION

The following section will focus on private and government-funded insurance options for organ donors and recipients. While private insurers serve as major sources of funding for organ transplant procedures, disputes between insurers and insureds often arise due to ambiguities in policy language which dictate coverage or professional disagreement in the health care and insurance sectors as to whether a certain transplant procedure should be covered given its experimental nature or predicted success rate. In addition, government benefit programs like Medicaid and Medicare come with its own host of conflicts, including whether the federal government or the state may set its own coverage criteria in jointly funded and administered programs. Ultimately, the affected parties are forced to balance legitimate concerns of cost and funding health care for the masses with the most intrinsic ideals of saving the life of one identifiable human being.

---

46 Id.
47 Id.
48 Id.
49 Id.
A. PRIVATE OR EMPLOYER-BASED INSURANCE

As the court in Delmarva Health Plan v. Aceto\(^{50}\) notes, insurers “must make difficult, and at times excruciating, decisions about which medical services to cover.”\(^{51}\)

It is a regrettable reality that the more extensive the coverage that is provided under a health insurance policy, the higher the cost of that policy and the fewer individuals who can afford to purchase it. The question of how to balance this tension between access and adequacy is an enormous one with which health insurers and our society as a whole grapple.\(^{52}\)

Organ transplants are expensive. A heart transplant can cost up to $300,000.\(^{53}\) Lung or liver transplants come in at $250,000 per procedure while a kidney transplant is priced at $100,000.\(^{54}\) The cost of a bone marrow transplant, a procedure with its own extensively litigated body of case law, is estimated at around $500,000.\(^{55}\) In some cases, a patient must provide a down payment or prove coverage that guarantees payment even before he or she can be listed on the active transplant list.\(^{56}\)

1. Express Coverage

Most insurers provide coverage for traditional organ transplant procedures, even if they are not expressly listed as covered benefits, as long as the treatments are considered medically necessary and non-experimental. For example, in Aceto, a Delaware court held that an insured’s lung transplant was an included benefit even though the health insurance policy listed coverage only for kidney, bone marrow and cornea transplants.\(^{57}\) While the insurer argued for the maxim *inclusio urius est exclusio*, asserting that the inclusive list for organ transplant coverage automatically

\(^{50}\) 750 A.2d 1213 (Del. Ch. 1999).
\(^{51}\) *Id.* at 1218.
\(^{52}\) *Id.*
\(^{54}\) *Id.*
\(^{55}\) *Id.*
\(^{56}\) See, e.g., Montoya v. Johnston, 654 F. Supp. 511 (W.D. Tex. 1987); *see also* Ellis ex rel. Ellis v. Patterson, 859 F.2d 52 (8th Cir. 1998).
\(^{57}\) Delmarva Health Plan v. Aceto, 750 A.2d 1213, 1216 (Del. Ch. 1999).
excludes items not on the list, the court instead found the lung transplant, “a medically necessary, non-experimental, surgical procedure,” falls within the policy’s broader definition of covered services.\textsuperscript{58}

At the same time, private insurers have no obligation to provide coverage if it is specifically excluded, even if the transplant is determined to be medically necessary. In \textit{Hawaii Medical Serv. Assoc. v. Adams},\textsuperscript{59} the health insurer denied coverage for an allogenic stem-cell transplant to treat the insured’s multiple myeloma.\textsuperscript{60} Policy guidelines specifically classified the use of this procedure as “investigational” when used as a treatment for multiple myeloma, though the therapy would be covered by the insurance policy if used to treat a listed set of other conditions.\textsuperscript{61} The court in \textit{Adams} held that if the language of the plan “‘specifically excluded’ from coverage the requested allo-transplant for treatment of . . . multiple myeloma,” the insurer had “no obligation to provide coverage.”\textsuperscript{62} Here, the insurer successfully claimed \textit{inclusio urius est exclusio} where this argument failed in \textit{Aceto}. If the insurer were required to list every special medical exclusion instead of including only the conditions that the policy would cover, then the insurer would have to list “every conceivable medical condition for which coverage for allo-transplants would be excluded,” an expectation the court found neither “practical” nor “reasonable.”\textsuperscript{63}

\textbf{2. Contract Ambiguities}

Where policy exclusions and inclusions are not as specific, insureds challenging coverage decisions argue that, according to \textit{contra proferentem}, ambiguities in the policy language are construed against the insurer and in favor of the insured, since the insurer drafts the language and “must suffer the costs of its own drafting imprecision.”\textsuperscript{64}

In \textit{Simkins v. NevadaCare, Inc.},\textsuperscript{65} the insured sought coverage for high-dose chemotherapy with peripheral stem cell rescue (HDC/PSCR) as a treatment for breast cancer.\textsuperscript{66} As part of the HDC/PSCR procedure, stem

\begin{itemize}
\item \textsuperscript{58} \textit{Id.}
\item \textsuperscript{59} 209 P.3d 1260 (Haw. Ct. App. 2009).
\item \textsuperscript{60} \textit{Id.} at 1263. During an allogenic stem-cell transplant, stem cells from a matched donor are harvested and transplanted into the recipient. \textit{Id.}
\item \textsuperscript{61} \textit{Id.} at 1263–65.
\item \textsuperscript{62} \textit{Id.} at 1268.
\item \textsuperscript{63} \textit{Id.} at 1271.
\item \textsuperscript{64} Delmarva Health Plan, Inc. v. Aceto, 750 A.2d 1213, 1218 (Del. Ch. 1999).
\item \textsuperscript{65} 229 F.3d 729 (9th Cir. 2000).
\item \textsuperscript{66} \textit{Id.} at 731-32.
\end{itemize}
cells are harvested and filtered as blood is drawn from the patient’s body and later reintroduced in the system after chemotherapy, in the hope that the stem cells will grow to produce healthy red and white blood cells and platelets.67 While the insurance policy included coverage for the administration of blood and blood plasma and chemotherapy, the only transplants approved for coverage under the policy were for heart, kidney, cornea, liver, and tissue transplants limited to allogenic bone marrow only.68 The court in Simkins found that a “person of average intelligence and experience” would not understand stem cells to be tissue under the policy’s tissue transplant exclusion.69 Instead, the court believed the average person would consider stem cells to be a component of the patient’s blood. Especially since the policy “specifically discusses blood transfusions separately from tissue transplants and places tissue transplant coverage within the organ transplant section,” the policy retained the “distinct potential of misleading and confusing average plan participants” (emphasis omitted).70 “[T]he insurer should be expected to set forth any limitations on its liability clearly enough for a common layperson to understand; if it fails to do this, it should not be allowed to take advantage of the very ambiguities that it could have prevented with greater diligence.”71

On the other hand, in Hilliard v. BellSouth Medical Assistance Plan,72 the court refused to find a similar insurance policy description ambiguous.73 The insured was diagnosed with multiple myeloma and sought coverage for an autologous bone marrow transplant (ABMT), where the patient’s own bone marrow is extracted for reinfusion.74 Similar to Simkins, the insurance policy only covered cornea, heart, kidney and bone marrow transplants, further specifying coverage for autologous bone marrow transplants in the treatment of three specific conditions: Hodgkin’s disease in individuals where conventional therapy has failed, resistant non-Hodgkin’s lymphomas, and acute leukemia in remission but with a high probability of relapse.75 The court in Hilliard agreed with the plan

67 Id. at 732.
68 Id.
69 Id. at 735.
70 Id.
71 Simkins, 229 F.3d at 736 (quoting Kunin v. Benefit Trust Life Ins. Co., 910 F.2d 534, 540 (9th Cir. 1990)).
73 Id. at 1024-25.
74 Id. at 1019-20.
75 Id. at 1020.
administrator that the plan provided coverage only for these three
conditions and that multiple myeloma was “simply not covered.” It also
noted that the insured’s employer offered a Supplemental Transplant
Assistance Plan at a nominal premium for the purpose of providing
additional coverage for autologous transplants and other medical
procedures not covered by the primary plan.

B. MEDICARE AND MEDICAID

Government benefits programs, including Medicare and Medicaid,
may be used to finance an organ transplant procedure. Medicare is a
federally run program that provides health insurance coverage to
individuals who are age 65 and older as well as individuals with who meet
other special criteria, including patients who suffer end-stage renal disease
(ESRD) and require either dialysis or a kidney transplant. Medicaid is a
cooperative program between the federal government and individual states
to fund certain health care expenses for low-income or disabled persons
who qualify. The state pays medical facilities for health care provided to
those eligible under Medicaid. The federal government subsequently
reimburses the state for a substantial portion of that outlay as long as the
state is compliant with federal statutory and regulatory requirements.

1. State Discretion in Medicaid-Funded Organ Transplants

While the federal government may set broad policies and ensure
state compliance with the Medicaid statute, it is up to the states to develop
state eligibility and coverage criteria subject to federal approval and
reimbursement. For instance, the Medicaid statute was amended in 1985
to include specific organ transplant criteria that states were required to
adopt in order to receive for federal financial assistance for these types of
procedures. Under this provision, the federal government will not

76 Id. at 1023.
77 Id. at 1027.
79 C. David Flower, State Discretion in Funding Organ Transplants Under the
Medicaid Program: Interpretive Guidelines in Determining the Scope of Mandated
80 42 C.F.R. § 430.0 (2009).
82 Flower, supra note 79, at 1240-41.
reimburse states for organ transplants unless the state develops written standards for transplant coverage where similarly situated individuals are treated alike and the accessibility of high quality care is maintained. Whether this statute functions as an express grant of discretion to the states in their decisions to fund organ transplants under Medicaid, or merely sets forth the conditions for federal matching funds in transplant procedures, remains unsettled. The Eighth Circuit in Ellis by Ellis v. Patterson and the Ninth Circuit in Dexter v. Kirschner have held that states have complete discretion in choosing whether or not to fund organ transplants within state Medicaid plans. However, the Fourth Circuit in Pereira v. Pereira v. Kozlowski and the Eleventh Circuit in Pittman by Pope v. Secretary, Florida Department of Health and Rehabilitative Services have held that states must fund organ transplants that are medically necessary, albeit for different reasons.

In Ellis, the Eighth Circuit held Arkansas was not required to fund through Medicaid a liver transplant for a ten-month-old infant suffering from a fatal liver condition. The court found that the federal organ transplant provision governing payment for organ transplants, 42 U.S.C. § 1396b(i), “can be read as merely laying out additional standards the states must meet to receive federal funds for organ transplants, but the legislative history of the provision reveals that Congress intended the states to have discretion whether to include organ transplants in the Medicaid plans.” Just as states are permitted to limit other medically necessary services, such as the number of doctor visits or the length of hospital stays, state discretion in funding medical procedures was found to be consistent with an overarching policy to “provide the largest number of necessary medical services to the greatest number of needy people.” Furthermore, the court

---

84 Id.
85 Flower, supra note 79, at 1246; see also Lisa B. Deutsch, Medicaid Payment for Organ Transplants: The Extent of Mandated Coverage, 30 COLUM. J.L. & SOC. PROBS. 185, 191, 194 (1997).
86 Ellis ex rel. Ellis v. Patterson, 859 F.2d 52, 55 (8th Cir. 1988); Dexter v. Kirschner, 984 F.2d 979, 983 (9th Cir. 1992).
87 Pereira ex rel. Pereira v. Kozlowski, 996 F.2d 723, 725 (4th Cir. 1993); Pittman ex rel. Pope v. Secretary, Fla. Dep’t of Health & Rehabilitative Servs., 998 F.2d 887, 891 (11th Cir. 1993).
88 Ellis, 859 F.2d at 53, 55. By the time that Ellis reached the Eighth Circuit, Arkansas was in the process of modifying its state Medicaid criteria to provide additional funding for organ transplants. Id. at 56.
89 Id. at 54-55.
90 Id.
in *Ellis* determined Congress “did not intend to require states to provide funds for exotic surgeries which, while they might be the individual patient’s only hope for survival, would also have a small chance of success and carry an enormous price tag.”

The Ninth Circuit adopted the Eighth Circuit’s line of reasoning and held in *Dexter* that Arizona likewise retained discretionary power to fund autologous bone marrow transplants but not allogenic bone marrow transplants through its Medicaid program. The same federal statute cited in *Ellis* applicable to payments for organ transplants “does not make payments mandatory [but] . . . states only what must occur in the event a state should decide, in its discretion, to pay for organ transplants.” The court in *Dexter* also found compelling the fact that while medical facilities in Arizona could perform autologous bone marrow transplants, no corresponding program for allogenic bone marrow transplants existed in the state at the time. “Arizona’s decision not to fund the additional expenditures despite the similarity in cost for both types of bone marrow transplants was . . . rational.”

One year later, the Fourth Circuit in *Pereira* expressly rejected the findings of the Eighth and Ninth Circuits and held that Virginia was required to fund medically necessary organ transplants for patients who qualify under Medicaid. The court rejected “the . . . contention that section 1396b(i)(1) affirmatively confers upon the states the unqualified discretion whether to fund transplants.” Even if “Congress intended . . . to afford the states absolute discretion whether to fund organ transplants . . . (and there is no evidence in either the statute or its history that this was its intention), it did not embody that intention in statute.”

The Eleventh Circuit in *Pittman* drew the same conclusion as the Fourth Circuit and mandated Medicaid coverage for a fifteen-month-old child’s liver-bowel transplant based on statutory requirements that states provide medically necessary services to children receiving early and periodic screening, diagnostic, and treatment (EPSDT) services under

---

91 *Id.*  
92 *Dexter v. Kirschner*, 984 F.2d 979, 987 (9th Cir. 1992).  
93 *Id.* at 983.  
94 *Id.* at 987.  
95 *Id.*  
97 *Id.* at 725.  
98 *Id.* at 727.
Medicaid.\textsuperscript{99} Even where courts have granted state discretion in coverage determinations, Medicaid participants under the age of 21 would still be funded for organ transplants since the EPDST program requires coverage for all medically necessary treatment for eligible recipients.\textsuperscript{100}

2. Arbitrary and Unreasonable Standard

Even in jurisdictions where courts have decided in favor of state discretion in their ability to set their own coverage criteria for funding organ transplants, Medicaid participants nevertheless are protected against standards that result in arbitrary or unreasonable outcomes. A state Medicaid agency “may not arbitrarily deny or reduce the amount, duration or scope of a required service . . . to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition.”\textsuperscript{101} “[O]nce a state has adopted a policy to cover a category of organ transplants, it may not arbitrarily or unreasonably deny services to an otherwise eligible Medicaid recipient.”\textsuperscript{102}

In \textit{Montoya v. Johnston},\textsuperscript{103} two plaintiffs aged six months and six years, respectively, could not be listed on the liver transplant waiting list because of a required $100,000 pre-payment or insurer guarantee of coverage.\textsuperscript{104} The children were covered under Medicaid but Texas capped in-patient hospital services at $50,000 over the course of twelve months.\textsuperscript{105} The court held that this state cap violated federal standards which “prohibit the arbitrary and/or unreasonable denial of services to otherwise eligible recipients.”\textsuperscript{106} Since the cost of the medically appropriate and non-experimental liver transplants would cost approximately $200,000, the $50,000 cap would functionally deny otherwise eligible recipients benefits even though liver transplants are covered under Texas Medicaid.\textsuperscript{107} Similarly, the Eighth Circuit in \textit{Ellis} held that any state-imposed cap on funding that would prevent a patient from being listed on a transplant

\textsuperscript{99} Pittman v. Secretary, Fla. Dep’t of Health & Rehabilitative Servs., 998 F.2d 887, 891-92 (11th Cir. 1993).
\textsuperscript{100} Id.
\textsuperscript{101} 42 C.F.R. § 440.230(c) (2009).
\textsuperscript{102} Meusberger v. Palmer, 900 F.2d 1280, 1282 (8th Cir. 1990).
\textsuperscript{103} 654 F. Supp. 511 (W.D. Tex. 1987).
\textsuperscript{104} Id. at 512.
\textsuperscript{105} Id.
\textsuperscript{106} Id. at 514.
\textsuperscript{107} Id.
waiting list would functionally deprive that patient of the procedure and therefore result in an arbitrary and unreasonable denial of that benefit.\textsuperscript{108}

In addition to reimbursement caps, plaintiffs have successfully challenged specific state Medicaid criteria for transplant eligibility using the arbitrary and unreasonable standard. Michigan, for example, employed patient selection criteria which required that a prospective liver transplant recipient suffering from alcoholic cirrhosis must have a documented two-year period of abstinence from alcohol.\textsuperscript{109} In \textit{Allen v. Mansour}, the court deemed this requirement arbitrary and unreasonable since it would screen “out an entire class of otherwise qualified liver transplant applicants” who would die before completing that two-year period or would develop such severe complications that they would be rendered ineligible for an operation anyway.\textsuperscript{110} Although the state retained “substantial discretion to choose the proper mix of amounts, scope, and duration limitations for the services offered in its Medicaid plan,”\textsuperscript{111} the court deemed this two-year abstinence requirement as arbitrary due to a lack of expertise on alcoholism and recidivism or statistical data to make a rational and scientific decision on the proper length of an abstinence requirement.\textsuperscript{112} The court also found significant that “[i]f a potential donee could survive two years without a transplant, the donee did not need the transplant in the first place.”\textsuperscript{113}

3. Medicare Designations of Experimental or Investigational Treatments

Organ transplantation coverage under Medicare is most frequently invoked by litigants to support or rebut a contention that a specific transplant procedure should be considered experimental or investigational and therefore excluded under most private insurance and government benefit program policies. These insurers may utilize the expert determinations and findings of Medicare’s oversight and quality assurance agency, the Health Care Financing Administration (HCFA), to help define or inform how they view unproven medical technologies or procedures.

For instance, in \textit{Bechtold v. Physicians Health Plan of Northern Indiana, Inc.},\textsuperscript{114} the private insurer “chose to link the experimental nature

\textsuperscript{108} Ellis \textit{ex rel.} Ellis v. Patterson, 859 F.2d 52, 56 (8th Cir. 1988).


\textsuperscript{110} \textit{Id.} at 1235.

\textsuperscript{111} \textit{Id.} at 1237.

\textsuperscript{112} \textit{Id.} at 1238.

\textsuperscript{113} \textit{Id.} at 1235.

\textsuperscript{114} 19 F.3d 322 (7th Cir. 1994).
of a treatment to the neutral (third party) determination of the medical experts responsible for drafting the HCFA Medicare Coverage Issues Manual.\textsuperscript{115} The insurer’s express intent was to avoid resorting to a “case-by-case battle of the experts each time a self-proclaimed ‘expert’ publishes a new article” about a new procedure.\textsuperscript{116} The court in Bechtold allowed the insurer to rely on HCFA opinions to determine whether a procedure should be considered experimental because this deference was unambiguously expressed in the policy language.\textsuperscript{117}

Other courts, however, have looked for reasons to circumvent HCFA classification of experimental procedures. The Third Circuit in Heasley v. Belden & Blake Corp.\textsuperscript{118} explained why reliance on Medicare guidelines could be problematic:

First, the guidelines themselves are, by their terms, directory rather than mandatory... Second, expert witnesses for both sides agreed Medicare relied on dated literature and data in determining the appropriate conditions for coverage of liver transplants... Third, Belden & Blake's health coverage expert admitted it is “not uncommon in the health care industry” for insurers to approve treatments even though Medicare has not approved them.\textsuperscript{119}

In Meusberger v. Palmer, Iowa’s Medicaid agency denied coverage of a participant’s pancreatic transplant because their policy was “to fund only those organ transplants designated non-experimental by Medicare.”\textsuperscript{120} The Eighth Circuit upheld the district court’s holding that reliance on Medicare’s designation of non-experimental was “intended as an administrative convenience rather than an inalterable adherence.”\textsuperscript{121} “A state cannot avoid scrutiny and evade review of unreasonable policies by simply delegating absolutely the decision-making to a federal agency charged with a substantially different mission.”\textsuperscript{122} Furthermore, in Nichols

\begin{footnotesize}
\begin{enumerate}
\item \textsuperscript{115}Id. at 326.
\item \textsuperscript{116}Id.
\item \textsuperscript{117}Id. at 326-27.
\item \textsuperscript{118}2 F.3d 1249 (3d Cir. 1993).
\item \textsuperscript{119}Id. at 1261 n.13.
\item \textsuperscript{120}Meusberger v. Palmer, 900 F.2d 1280, 1282 (8th Cir. 1990).
\item \textsuperscript{121}Id.
\item \textsuperscript{122}Id. at 1283.
\end{enumerate}
\end{footnotesize}
v. Trustmark Insurance Company, the court noted that the actual language of the insured’s policy granted coverage for “drugs, therapies or other treatments... that are approved for reimbursement by the Health Care Financing Administration.” However, the policy did not specify HCFA approval under Medicare as opposed to Medicaid. In this case, Ohio’s Medicaid policy did cover the insured’s high-dose chemotherapy with autologous bone marrow transplant (HDC/ABMT) procedure where the federal Medicare policy did not.

C. INSURANCE COVERAGE FOR DONORS

The medical procedures involved with extracting an organ from a donor for transplantation is considered part of the recipient’s overall procedure and is funded as such. Still, insurance coverage becomes a significant issue in the event that a living donor experiences unanticipated post-transplant complications.

Any costs incurred by an organ donor, from medical evaluation and testing to the actual surgery, are covered by the eventual organ recipient. After an organ donation, the hospital will bill the organ procurement organization, which then bills the recipient or recipient’s insurer. In Zwerin v. Group Health Incorporated, the insurer was obligated to reimburse the costs of tests performed on the insured’s sister in the course of an evaluation to determine her suitability as a potential bone marrow transplant donor. The insurer had claimed that since the sister was not a covered dependent under the insurance policy, her medical tests, “even if for the claimant’s benefit or as part of his overall treatment,” would be excluded from coverage. The court in Zwerin, however, rejected the insurer’s “illogical and tenuous position” and instead relied upon the insurance policy’s broad provision for the coverage of “general medical

---

124 Id. at 693.
125 Id. at 696.
126 Id. at 696-97.
127 United Network for Organ Sharing, supra note 3.
130 Id. at 1015.
131 Id.
care” and “treatment of illness.”132 These tests were “a necessary step in exploring the possibility of a bone marrow transplant operation as part of the claimant’s treatment.”133 The insured “is permitted to explore all reasonable avenues of treatment which might arrest and reverse the progress” of his debilitating disease and therefore entitled to recover the costs of the medical tests performed for his benefit.134

While the costs of the immediate tests and procedures related to organ donation are funded by the recipient, additional costs incurred as a result of unexpected complications or adverse long-term effects may fall to the living donor. The number of living organ donors have matched or exceeded the number of traditional cadaveric donors since 2001, mostly through directed donations by family members.135 The probability of adverse effects continues to be quite low and most complications are minor when they do occur, especially since unlike most surgeries, living organ donors are usually in excellent health before undergoing the operation.

Even so, in an analysis conducted by Seoul National University College of Medicine, the morbidity rate of a specific type of liver transplant, where the right section of the liver of the living donor is extracted, reached a high of 78.3%.136 While most of this subset experienced only minor post-operative complications, several patients suffered potentially life-threatening complications which required additional treatment.137 Even organ donation through less-invasive laparoscopic procedures versus conventional open operations has its risks. In a medical comparison study of these two technologies, two out of twenty patients who underwent laparoscopic donor nephrectomies still experienced poor oxygen saturation in the immediate postoperative period and unilateral pulmonary congestion.138

Despite the low incidence of post-surgical complications for an organ donor, health problems related to but following the actual donation may not be covered by the recipient’s insurer. If a recipient’s insurance policy provides coverage for a limited time but the recipient dies, coverage

---

132 Id.
133 Id. at 1016.
134 Id.
135 United Network for Organ Sharing, supra note 3.
136 Kyung-Suk Suh et al., Three-Quarters of Right Liver Donors Experienced Postoperative Complications, 13 LIVER TRANSPLANTATION 797 (June 2007).
137 Id.
for the donor may also disappear.\textsuperscript{139} In theory, a kidney transplant donor who suffers the loss of the remaining kidney later in life moves to the top of the transplant waiting list, but the patient must cover the cost of the operation herself, even though the original donation necessitated the second transplant.\textsuperscript{140} Other financial expenses, including the personal expenses of travel, housing and lost wages or even the increased difficulty and cost in obtaining health, disability or life insurance, remain the responsibility of the living donor.\textsuperscript{141}

III. UNINTENDED CONSEQUENCES WHEN INSURANCE AND ORGAN TRANSPLANTATION INTERSECT

Insurance intersects with the medical practice of organ transplantation to yield surprising connections beyond the more basic issues of coverage and funding. This section reveals the insurance sector’s unintended or unexpected influence in determining which entities or individuals have the opportunity to participate in the organ donation and receipt process.

A. INSURERS MAKE MEDICAL DETERMINATIONS

While assessments of a patient’s need for certain procedures seem best left to the expertise of medical practitioners, many of the cases discussed above demonstrate that insurers act at least as a key participant, if not the final arbiter, in the medical decision-making process. Both public and private insurers include explicit requirements of medical necessity for coverage and insert exclusions for procedures considered experimental or investigational. In the field of organ transplantation, these exclusions may serve to preclude reimbursement or access to emerging transplant technologies, like dual organ transplants, or accepted therapies applied for the treatment of certain conditions, such as the use of bone marrow or stem-cell transplants to treat cancer.

Experimental treatment exclusions originally arose out of concerns that procedures have limited or no medical value and that this potentially unnecessary medical care might actually be harmful to patients.\textsuperscript{142} Today,

\textsuperscript{139} United Network for Organ Sharing, \textit{supra} note 2.
\textsuperscript{140} \textit{Id.}
\textsuperscript{141} \textit{Id.}
the economics of health care play a bigger role. “By requiring clinicians to prove that new procedures are efficacious before they are covered, the hope is that existing resources will be better allocated to maximize the health status of the overall population.”

Either way, insurers still act as gatekeepers where medical professionals must petition for the approval of non-medical entities on medical matters.

B. INSURANCE STATUS DETERMINES ACCESS TO DONATED ORGANS

A potential organ recipient’s access to donated organs is determined in large part by the patient’s ability to fund the life-saving transplant procedure through insurance. An uninsured patient or one subject to reimbursement caps may be excluded from a transplant waiting list without a substantial deposit or proof of insurance coverage. More than 99% of organ recipients are covered by insurance at the time of the procedure. Private insurance and Medicare were equally the most common sources of payment for organ recipients at 44.2% each. Only 9% of total organ recipients were covered by Medicaid, even though Medicaid participants comprised 18.5% of the general in-patient population. Consequently, Medicaid organ recipients are less likely to be funded for organ transplants than other procedures requiring hospital admission.

While some organ transplant recipients may be funded through specific benefit programs, such as Medicare’s ESRD Program or similar state benefit plans, or through the admirable efforts of transplant social workers and financial coordinators to obtain financing on a patient’s behalf, the highly disproportionate number of insured versus uninsured organ recipients is troubling in a system that is explicitly mandated to ensure equality in access.

---

143 Id. at 1639.
144 See, e.g., Montoya, 654 F. Supp. at 512; Ellis, 859 F.2d at 56. But see McLaughlin v. Williams, 801 F. Supp. 633 (S.D. Fla. 1992) (granting motion to require Florida Medicaid agency to provide hospital with financial guarantee required to begin organ search).
146 Id.
147 Id.
148 Id.
149 Id. at 645.
ESRD patients revealed for the first time the strong correlation between health insurance status and access to organ transplant procedures. Nearly all ESRD patients are entitled to benefits offered under Medicare’s ESRD program, though about 8% of ESRD dialysis patients were ineligible for the program in 1992, the year the analysis was conducted. Many of these individuals who lack Medicare coverage are forced to rely on state Medicaid programs for financial support, though beneficiaries must meet financial eligibility criteria first.

The 1999 California study separated all California ESRD patients under the age of 65 into three, mutually exclusive cohorts: Medicaid participants, Medicare participants, and patients enrolled in both Medicaid and Medicare. Only 31.4% of all Medicaid patients were eventually listed on the OPTN transplant waiting list, compared to 45% of Medicare patients and 38.8% of the dually eligible patients. This disparity is even more exaggerated when examining subsets within these patient cohorts. Only two-thirds of all patients under 15 years old insured by Medicaid were placed on the transplant waiting list while 91.7% of Medicare patients under age 15 were listed.

Further examination of pertinent socio-economic factors revealed important differences in the Medicaid patient population. Medicaid participants show a higher incidence of HIV/AIDS, mental illness and non-compliance based on past dialysis attendance, all important considerations which weigh against a patient’s eligibility for transplant. They are also “clearly more disadvantaged, less likely to be highly educated, potentially more apprehensive about the transplant procedure, and less assertive about being wait-listed.” However, once an ESRD patient makes it onto the transplant waiting list and is entered into the system, insurance status does not influence the receipt of a cadaveric kidney transplant.

151 Id. at 880.
152 Id. at 881.
153 Thamer, supra note 150, at 897.
154 Id. at 886.
155 Id. at 88-89.
156 Id. at 888-89.
157 Id. at 898.
158 Id. at 897.
C. **Insurance Coverage Predicts Who Will Donate**

The extent of coverage also plays a significant role in which individuals are most likely to donate. Unlike presumed consent systems in other countries, primarily in Europe, where an individual is automatically presumed to be a donor unless the individual or a representative opts out, an organ donor in the United States must make an affirmative gift.\(^{159}\) This reflects the free choice of the individual to elect for donation upon death, and the latest set of revisions to the Uniform Anatomical Gift Act strengthens this right even further by barring others from making a gift after death if the individual donor previously refused.\(^{160}\)

For those who do elect to donate their organs at death, lack of insurance coverage was a stronger predictor for donation than any other characteristic or demographic factor except for age. Americans without health insurance are much more likely to donate a liver or kidney for transplant than to receive one.\(^{161}\) Nearly 17% of organ donors in 2003 lacked health insurance, but only 0.8% of organ recipients are uninsured.\(^{162}\) Additionally, the percentage for uninsured organ transplant recipients, at 0.8%, is far less than the overall 4.6% uninsured rate for all in-patient hospitalizations.\(^{163}\) Since transplantation is markedly different than other procedures in that the operation requires a scarce resource that can only come from other human beings, the pressure for fairness in patient access to this treatment is even more pronounced. Instead, while the uninsured tend to donate organs at relatively high rates, they are much less likely to receive an organ if they are in need of one.

This disparity is noteworthy particularly given that the 47 million Americans without health care tend to suffer from illnesses and conditions that otherwise exclude them from the organ donor pool.\(^{164}\) The uninsured suffer from higher mortality rates and more restrictive access to preventative and essential care, increasing the rates of chronic disease in this subset.\(^{165}\) They are less likely to have regular check-ups, less likely to see personal physicians managing their long-term care and less likely to

\(^{159}\) **REVISED UNIFORM ANATOMICAL GIFT ACT**, supra Note 9.

\(^{160}\) *Id.*

\(^{161}\) Herring et al., *supra* note 145, at 641.

\(^{162}\) *Id.*

\(^{163}\) *Id.* at 644.

\(^{164}\) **TOM KOCH, SCARCE GOODS: JUSTICE, FAIRNESS AND ORGAN TRANSPLANTATION** 139 (2002).

\(^{165}\) *Id.*
benefit from early diagnosis when diseases are most treatable.\textsuperscript{166} Their ability to pay for advanced treatment is also compromised, so that overall, “the uninsured poor are more likely to suffer untreated health problems that will disqualify them medically as donors.”\textsuperscript{167} Yet, the opposite is true, that while the health care system “denies adequate care to many of the uninsured during life..., in death, the uninsured often give strangers the ultimate gift.”\textsuperscript{168}

IV. RECOMMENDATIONS

This last section suggests several options, which address some of the more troubling effects and negative externalities exposed when insurance and organ transplantation intersect. The nature of the public and private insurance sector’s business model presents significant obstacles in obtaining full or even expanded coverage for organ transplantation, since the needs of one insured in need of a transplant must be balanced against the stark economics required to fund health care for the rest. With this in mind, the following recommendations attempt to promote and prioritize efforts to establish greater clarity, consistency and fairness in both the organ donation and transplantation process.

A. CLEAR COVERAGE POLICIES, INFORMED POLICYHOLDERS

Insurance contract language should be drafted with as much clarity as possible to indicate to the policyholder whether organ transplants are covered and if so, the extent of coverage as it relates to the type of procedures and for the treatment of which specific conditions. Undoubtedly, insurers have the right to exclude coverage for certain procedures as long as their exclusionary policies are non-discriminatory, properly disclosed and otherwise consistent with the law. If the insurer elects to incorporate organ transplant exclusions, at the very least “it should do so conspicuously and unambiguously so a reasonable insured can determine this fact by looking at her policy.”\textsuperscript{169}

Well-drafted insurance policies permit the parties the freedom to fairly contract according to their own terms without the interference of the court system. If confronted with unambiguous policy language, courts

\textsuperscript{166} Id.
\textsuperscript{167} Id. at 140.
\textsuperscript{168} Herring et al., supra note 145, at 645.
\textsuperscript{169} Simkins, 229 F.3d at 736.
“need not look outside the policy for indications of the intent of the parties.”\footnote{170} However, once the court system is brought in to interpret the relevant contract language, courts may “out of deference to treating physicians... refus[e] to respect the mechanism the parties have chosen to define the scope of coverage, forcing them to contract in ways they prefer not to, and even then refusing to enforce the provisions other courts have imposed.”\footnote{171} The risk of “judge-made insurance” then is that the court’s newly defined parameters of coverage may very well serve to create policies that “informed consumers in the private marketplace would have chosen not to purchase.”\footnote{172}

Courts have imposed a higher standard for drafting insurance contracts specifically if such an agreement is considered a contract of adhesion, where a standardized contract is “written entirely by a party with superior bargaining power... [while] the weaker party to an adhesion must ‘take it or leave it’... without an opportunity to bargain.”\footnote{173} Language, and especially exclusionary language where a limitation of coverage may disappoint an insured’s expectations, must be precise, conspicuous and worded in language that is plain and clear.\footnote{174} For example, an insurer may be expected to position and format an important exclusion in a way that would attract a reader’s attention and offer proper notification that a procedure may not be covered by the insurance policy.\footnote{175}

Still, even the best contracting practices will fail to generate completely unambiguous and consistent policy language. Too much precision or specificity only creates complexity and confusion. Using the context of organ transplantation, an insurer pursuing the highest level of

\footnote{170} Wota v. Blue Cross and Blue Shield of Colorado, 831 P.2d 1307, 1310 (Colo. 1992).
\footnote{171} Hall and Anderson, \textit{supra} note 142, at 1711. \textit{See} Romo v. Amedex Ins. Co., 930 So.2d 643 (Fla. Dist. Ct. App. 2006). In \textit{Romo}, the court found cause for claims of promissory estoppel, fraudulent misrepresentation, negligent misrepresentation and negligent procurement of insurance when an insurer refused to provide coverage for an insured’s liver transplant despite an express exclusion. \textit{Id}. The court even allowed a motion to reform the contract to include coverage for organ transplants after the fact, since it was seen that the unilateral mistake by the insured coupled with the inequitable conduct of the insurer resulted in a contract which failed to express the agreement of the parties. \textit{Id}. at 649-50.
\footnote{172} Hall and Anderson, \textit{supra} note 142, at 1657.
\footnote{174} \textit{Id}. at 719.
\footnote{175} \textit{See id}. at 722.
precision would have to create a “laundry list” of covered services and exclusions, classifying, at a minimum, each type of organ transplant, each condition for which an organ transplant may be used to treat, and each medical procedure or technology employed to execute the transplant.\textsuperscript{176} A policy containing all these exponential combinations would result in a “sea of print” where important policy conditions are so densely packed that they could be easily overlooked.\textsuperscript{177} Additionally, given the rapid progress of new medical research and technology, detailed lists of inclusions and exclusions would have to be updated constantly to reflect the latest developments.\textsuperscript{178}

Instead, insurers can more fairly communicate contract terms by including direct information about their coverage decision processes in the policy itself.\textsuperscript{179} Policyholders may not understand arguably vague language like “medical necessity” or “experimental” unless they are educated as to how insurers may make these determinations should the need arise. Rather than listing every experimental procedure that falls outside of the policy’s coverage, insurers may supplement general exclusions with greater detail about what the insurer may do to classify a treatment as experimental, such as whether the insurer relies on data in peer-reviewed academic procedures or technology assessments performed by reliable third-party governmental agencies or private organizations.\textsuperscript{180}

Additionally, insurers as well as employers and associations who maintain health benefit programs for their employees and members should have mechanisms in place which clearly inform policyholders as to their organ transplant coverage, especially if insureds were to lose coverage with the selection of a new insurer or policy. In \textit{Swanson v. Sioux Valley Empire Electric Association}, a member organization was forced to switch to a new health care plan when its previous health insurer sought to raise premiums by 38\%.\textsuperscript{181} The organization informed all its members through direct mailings and member newsletters that the new plan excluded coverage for liver transplants.\textsuperscript{182} The plaintiff in \textit{Swanson} therefore could not sustain claims against the association for negligent misrepresentation or

\begin{itemize}
\item \textsuperscript{176} Hall and Anderson, \textit{supra} note 142, at 1685.
\item \textsuperscript{178} Hall and Anderson, \textit{supra} note 142, at 1684-85.
\item \textsuperscript{179} \textit{Id.} at 1686.
\item \textsuperscript{180} \textit{Id.} at 1687-88.
\item \textsuperscript{181} 535 N.W.2d 755, 756 (S.D. 1995).
\item \textsuperscript{182} \textit{Id.} at 757.
\end{itemize}
a breach of good faith and fair dealing since the organization acted to provide notice of the terms of the new health policy.\textsuperscript{183}

B. \textbf{CONSISTENT MEDICAID COVERAGE OF ORGAN TRANSPLANTATION}

Despite the circuit split over the question of state discretion in the funding of organ transplants under Medicaid, coverage should be required in every state for transplant procedures that are medically necessary, appropriate, and non-experimental. The Eighth and Ninth Circuit decisions in \textit{Ellis} and \textit{Dexter} respectively fail to look to the plain language of the federal Medicaid transplant funding provision under 42 U.S.C. § 1396b(i)(1) or account for the political backdrop and legislative intent when the statute was enacted.\textsuperscript{184} In addition, consistency across state borders minimizes existing disparities in access to organ transplants for Medicaid beneficiaries based on state funding criteria.

First, § 1396b(i)(1) only provides that the federal government will not supplement state payments “for organ transplant procedures unless the State plan provides for written standards,” primarily standards to ensure that “similarly situated individuals are treated alike” and that any restrictions imposed are at least “consistent with the accessibility of high quality care to individual eligible for the procedures.”\textsuperscript{185} Whether a state has discretion to fund or exclude organ transplants in their programs is a question that lies outside the scope of this statute. Instead, “by its plain terms, the statute simply provides that federal Medicaid payments will not be made for organ transplants unless the state has promulgated the specified written procedures.”\textsuperscript{186}

Furthermore, the federal transplant funding provision was enacted in 1985 during continuing legislative efforts to expand Medicaid coverage, offering additional services including hospice care, case management services and ventilator care for institutional children.\textsuperscript{187} Congress also approved expanded eligibility criteria to extend coverage to individuals who did not qualify previously.\textsuperscript{188} Finally, Congress by this time already took steps to address public concerns over the shortage of donor organs and

\textsuperscript{183} \textit{Id.} at 758-59.
\textsuperscript{184} Deustch, \textit{supra} note 85, at 200-02; Flower, \textit{supra} note 79, at 1267-69.
\textsuperscript{186} \textit{Periera v. Kozlowski}, 996 F.2d 723, 725 (4th Cir. 1993).
\textsuperscript{187} Flower, \textit{supra} note 79, at 1268.
\textsuperscript{188} \textit{Id.}
the cost of organ transplants, enacting both NOTA in 1984 and the Omnibus Budget Reconciliation Act (OBRA) in 1986. OBRA extended Medicare coverage for drug therapy related to transplant procedures and required that hospitals which received Medicare funding to encourage organ donation and conform to the appropriate organ procurement protocol. These actions combined “demonstrate a congressional preoccupation with the ability of needy individuals to obtain and pay for transplants and a genuine commitment to facilitating the procedure.”

The Seventh Circuit in *Miller by Miller v. Whitburn* offers perhaps the best justification for federally mandated coverage of organ transplantation in state Medicaid programs. In *Miller*, the Seventh Circuit argued that reliance on §1396b was inappropriate given that organ transplants that are medically necessary and non-experimental already fall into the mandatory service category of in-patient hospital service, one of seven mandatory medical services a state must provide in order to qualify for federal funding. Consequently, the Seventh Circuit limited review of Wisconsin’s decision to deny funding for the plaintiff’s liver-bowel transplant only as to whether or not a liver-bowel transplant could be considered a “necessary treatment” if its effectiveness was unproven.

C. COURTS SHOULD AVOID MAKING MEDICAL DETERMINATIONS

1. Courts Exhibit Biases and Lack Scientific Expertise to Make Medical Determinations

While the court system provides an important mechanism which works to produce fair results in transplant coverage disputes, judicial review should accord high deference to the insurers who make coverage determinations in consultation with independent medical experts. Because of understandable biases in favor of a plaintiff seeking a life-saving operation, judges are inclined “to adopt every conceivable argument in favor of coverage..., essentially preclud[ing] insurers from exercising any meaningful oversight of medical appropriateness.”

---

189 Id. at 1269.
190 Id.
192 10 F.3d 1315 (7th Cir. 1993).
193 Id. at 1316-17.
194 Id. at 1318.
First, courts tend to “balance the equities between the parties in a manner that inevitably favors avoiding the possible loss of life over the insurers’ monetary loss.”\(^{196}\) It is easy to be influenced by a sympathetic plaintiff who has exhausted all other avenues in the treatment of a serious illness. In *J.D. by Devantier v. Sherman*, the plaintiff was an eight-year-old boy afflicted with a debilitating genetic disorder which could be cured by a liver transplant.\(^{197}\) However, Missouri Medicaid considered the transplant an elective option rather than a medical necessity since the disease could be managed through careful dietary restrictions.\(^{198}\) The court in *J.D.* held that “even if it were obvious that the state could save some money by treating, as opposed to curing J.D., the fiscal harm suffered by Missouri Medicaid is outweighed by the harm to J.D. should he not receive a liver transplant.”\(^{199}\)

In addition, judges are forced to rely on expert testimony presented in an adversarial setting that often devolves into a battle of the experts. In this scenario, experts do not present objective and balanced scientific perspectives focused on truth-finding and accuracy, but rather introduce arguments most persuasive in supporting their party’s side.\(^{200}\) The Seventh Circuit in *Bechtold* proposes an interesting alternative:

In order to resolve the question of whether health insurance providers should cover treatments..., the prudent course of action might be to establish some sort of regional cooperative committees comprised of oncologists, internists, surgeons, experts in medical ethics, medical school administrators, economists, representatives of the insurance industry, patient advocates and politicians. Through such a collective task force perhaps some consensus might be reached concerning the definition of experimental procedures, as well as agreement on the procedures, which are so cost prohibitive that requiring insurers to cover them might result in the collapse of the healthcare industry. While such a committee would in no way be a panacea for our skyrocketing health care costs, it may help to reduce the incidence of suits in which one

\(^{196}\) *Id.* at 1655.

\(^{197}\) No. 06-4153-CV-C-NKL, 2006 WL 3163053, at *1 (W.D. Mo. Oct. 27, 2006).

\(^{198}\) *Id.* at *1.

\(^{199}\) *Id.*, at *8.

\(^{200}\) Hall & Anderson, *supra* note 142, at 1675.
“expert” testifies that a procedure is experimental and another equally qualified “expert” testifies to the opposite effect. This so-called battle of the experts occurs all too frequently in federal court.\footnote{Bechtold v. Physicians Health Plan of N. Ind., Inc., 19 F.3d 322, 328 (7th Cir. 1994) (emphasis added).}

But are insurers capable of making educated, independent assessments of medical necessity when those same companies profit from avoiding payment of claims? In order to minimize conflicts of interest, the insurance sector should make sure to engage outside independent medical experts for consultation before making determinations of medical necessity.\footnote{See Hall & Anderson, supra note 142, at 1670.} These consultants help assure neutrality in the decision-making process, particularly if practitioners are compensated in a manner that does not reward or incentivize the number of claim denials.

2. Coverage of HDC/ABMT

There is perhaps no better example of court interference in medical decisioning than the substantial case law surrounding high-dose chemotherapy with autologous bone marrow transplant (HDC/ABMT) as a last resort treatment for cancer.\footnote{Note that the court in \textit{Lubeznik v. HealthChicago, Inc.}, 644 N.E.2d 777 (Ill. App. Ct. 1994), treats HDCT/ABMT not as an organ transplant but a rescue operation, because unlike these treatments, a transplant in which something is taken from one patient and given to another. \textit{Id.} at 781.} During HDC/ABMT, a patient’s bone marrow cells are extracted and stored temporarily before the patient undergoes high-dose chemotherapy, after which the stored cells are transplanted back into the patient to counter the toxic effects of the chemotherapy.\footnote{O’Rourke v. Access Health, Inc., 668 N.E.2d 214, 217 n.1 (Ill. App. Ct. 1996).} While Phase II clinical studies supported the use of this procedure at the time, many insurers refused to pay for the treatment based on exclusions for experimental procedures, since there was a lack of evidence that HDC/ABMT was superior to chemotherapy alone or safe and effective in its own right.\footnote{Peter D. Jacobson & Stefanie A. Doebler, “\textit{We Were All Sold a Bill of Goods:}” \textit{Litigating the Science of Breast Cancer Treatment}, 52 WAYNE L.REV. 43, 51 (2006).} Denials of coverage led to intense litigation...
and lobbying which in turn led to “unpredictable and inconsistent” court decisions about coverage.\textsuperscript{206}

Rather than fight litigants in this arena, insurers instead quietly decided to include HDC/ABMT as a covered service anyway despite their own misgivings about the efficacy of the treatment.\textsuperscript{207} This trend was due in large part to the courts’ readiness to regard HDC/ABMT as the legal standard of care.\textsuperscript{208} To be fair, both sides could validly argue for and against the suggestion that HDC/ABMT represented the standard of care for the treatment of breast cancer.\textsuperscript{209} The procedure was indeed used to treat more than 30,000 women before studies discounting HDC/ABMT were published, showing the “medical community’s inability to control the procedure’s diffusion.”\textsuperscript{210} Still, the courts often succumbed to the more emotional appeals of plaintiffs desperate for this treatment and discounted medical expert after medical expert presented by defendant-insurers.\textsuperscript{211}

Had the courts, for instance, adopted a standard based on what a reasonable managed care organization would have decided..., the result may have been entirely different. Taking this approach could have had the salutary effect of compelling a more productive dialogue between physicians and plans, along with accelerating the clinical trials process.\textsuperscript{212}

D. CONTINUING COVERAGE FOR ORGAN RECIPIENTS

Insurance coverage for organ transplants should extend beyond the transplant operation itself to include continuing coverage for follow-up care and immunosuppressive drug therapies required to protect rejection of the

\textsuperscript{206} Id. at 52.
\textsuperscript{207} Id.
\textsuperscript{208} Id. at 78.
\textsuperscript{209} Id.
\textsuperscript{210} Id. at 45, 111.
\textsuperscript{211} See, e.g., Kulakowski v. Rochester Hosp. Svc. Corp., 779 F. Supp. 710 (W.D.N.Y. 1991). In Kulakowski, the insurer presented the testimony of the insurer’s medical director, a registered nurse who worked as a medical affairs administrator, the vice-president for Medical Affairs of BCBS of the Rochester area and an oncologist recognized for his expertise in the field of breast cancer. Id. at 713. The plaintiff presented only the testimony of the plaintiff’s treating physician. Id.
\textsuperscript{212} Jacobson & Doeble, supra note 205, at 80.
transplanted organ. While courts have found prohibitively low insurance caps to be arbitrary or unreasonable, insurance coverage could still be limited based on the specific procedure, treatment or total amount of subsidized drugs per year. Medicare, for example, currently covers the cost of anti-rejection drugs for participants only 36 months after transplant even though it fully funds the cost of the transplant itself.

These restrictions yield particularly harsh results on organ recipients who may receive transplants at a young age. Younger recipients have a longer lifespan during which to maintain the costs of on-going care, since they must be medicated against organ rejection for the rest of their lives. Pediatric patients could lose coverage once their plans expire or when the patient becomes an adult. Additionally, subsequent coverage may be difficult to obtain as an organ transplant is considered a pre-existing condition. Some states offer high-risk insurance pools which guarantee coverage regardless of prior medical history, but such coverage varies widely by state and premiums remain 50% to 200% higher with more restricted benefits than the more traditional insurance options available.

According to a recent study in Pediatric Transplantation, young transplant recipients who lose their insurance coverage are more likely to stop taking anti-rejection drugs. Transplant recipients between the ages

---

214 Kevin Sack, U.S. Cost-Saving Policy Forces New Kidney Transplant, N.Y. TIMES, Sep. 14, 2009, at A12. According to the Congressional Budget Office, unlimited coverage would add $100 million a year to the $23 billion Medicare ESRD program based on the average expenditure of $17,000 a year on anti-rejection drugs for kidney transplant recipients. Id. However, that compares with $71,000 a year for dialysis patients and $106,000 for a kidney transplant. Id. Both the Senate and House of Representatives have introduced bills to “provide continued entitlement to coverage for immunosuppressive drugs furnished to beneficiaries under the Medicare Program that have received a kidney transplant and whose entitlement to coverage would otherwise expire.” S.565, 111th Cong. (2009). See also, H.R. 1458, 111th Cong. (2009).
215 Lisa M. Willoughby et al., Health Insurance Considerations For Adolescent Transplant Recipients As They Transition to Adulthood, 11 PEDIATRIC TRANSPLANTATION 127 (Mar. 2007).
216 United Network for Organ Sharing, supra note 2.
217 Id.
218 PEGGY ROSSI, CASE MANAGEMENT IN HEALTH CARE: A PRACTICAL GUIDE 541.
219 Willoughby, supra note 210, at 128.
of eighteen and twenty-three years face the greatest risk, since one-third of this subset lacks coverage to begin with. Even if pediatric transplant recipients are insured, coverage is likely to run out 36-44 months after the transplant or when the child becomes an adult. In a study of 1,001 children who underwent kidney transplants between 1995 and 2001, one-half lacked insurance coverage and experienced a nine times greater chance of organ failure and death.

Whether payment is from private insurance, Medicaid, or Medicare, almost all providers discontinue insurance coverage for health care and immunosuppressive medications as these young people complete school and leave their parent’s care. These patients are frequently faced with the challenges of transition to independent life, changing from pediatric to adult transplant centers, with no clear means of payment for their expensive care and medications.

Even if an organ transplant recipient funds the actual procedure without insurance reimbursement, the Seventh Circuit held that an insurer can deny coverage for subsequent expenses connected to an underlying illness or procedure that was not covered in the first place. In *Loyola University of Chicago v. Humana Insurance Company*, in the middle of cardiac bypass surgery, the insured’s heart surgeon decided to insert a Jarvik-7 artificial heart once it was determined that the patient could not survive the operation otherwise. The artificial heart would serve to prolong the patient’s life until a suitable organ donor could be found. The insurer, however, denied coverage for all expenses after the insertion of the artificial heart, including the subsequent human heart transplant one month later, because it believed all following expenses were connected to the experimental procedure and therefore excluded by the policy.

---

220 Id.
221 Id.
222 Id. at 129.
224 Loyola Univ. of Chicago v. Humana Ins. Co., 996 F.2d 895, 903 (7th Cir. 1993).
225 Id. at 896-97.
226 Id.
227 Id. at 897.
The court agreed with the insurer’s refusal of coverage.\textsuperscript{228} While the policy ordinarily covers expenses connected to a major organ transplant, an exclusionary clause stated that “no benefit is payable for or in connection with a major transplant” if the coverage for the original transplant is denied based on the procedure’s experimental nature.\textsuperscript{229} The Seventh Circuit admits that its decision could seem “callous,” essentially finding the insurer is justified in refusing coverage because the patient “should be dead.”\textsuperscript{230}

It is unfortunate that a transplant recipient’s insured status impacts the sustainability of a donated organ so directly, especially since post-transplant mortality rates otherwise are extremely low.\textsuperscript{231} In the event of organ failure, a transplant recipient must be placed back on the waiting list for retransplantation. From 1995 to 2005, retransplant candidates represented 13.5%, 7.9%, 4.2% and 5.5% of all newly registered candidates on the kidney, liver, heart and lung transplant waiting lists respectively.\textsuperscript{232} In addition, the survival rates for repeat transplants are much lower than the rates for first-time transplantation.\textsuperscript{233} Since re-transplantation increases the overall demand for an already scarce supply of donated organs, and the benefits for repeat transplant patients are so limited, resources are better allocated if the original organ transplantation procedure is given the best possible chance to succeed.

E. CONTINUING COVERAGE FOR ORGAN DONORS, REMOVE DISINCENTIVES

Despite the rarity of post-transplant complications, living donors who are generous enough to donate an organ for the benefit of another should be protected from any adverse results post-donation. Organ donors may face many of the same concerns as organ recipients. In one study sampling a subset of living organ donors, 29% of donors had concerns about financial repercussions from time missed from work, while 2% worried about job security and another 2% reported anxiety about future

\textsuperscript{228} Id. at 898.
\textsuperscript{229} Id. at 903.
\textsuperscript{230} Loyola Univ. of Chicago, 996 F.2d at 903.
\textsuperscript{231} Id.
\textsuperscript{233} Id. at 1424.
health insurance coverage. Prospective donors who ultimately did not donate reported similar concerns. Addressing these concerns would not only satisfy a degree of moral or ethical responsibility we owe to organ donors for their own sacrifice, but would minimize some of the disincentives which affect a potential donor’s willingness to donate as well.

At the same time, any actions taken to assist organ donors must strike a delicate balance between removing disincentives and providing a form of remuneration. First, according to NOTA, the acquisition of human organs for valuable consideration is illegal. In addition, the use of incentives or a more deliberate move to an organ market system would generate unintended but harmful consequences that would undercut any short-term increase in the total organ supply. In a study of both paid and unpaid blood donation, Antonio Fernández-Montoya references continuing donor concerns in Spain, where 20% of blood donors still fear the possibility of commercial exploitation even twenty years after the switch from a paid donation model. Even a small decrease in the number of donors repelled by the notion of payment in a traditionally voluntary blood donation system “would severely compromise the service” given that donor numbers are so hard to maintain now. A paid donation model also creates greater vulnerability in the system through decreased safety and quality in the supply of donated blood or organs. Paid donors are often “poorly monitored, belong to lower social classes and often malnourished.” They tend to donate in inferior sanitary conditions and experience higher rates of transmittable disease. All parties in the transplant infrastructure must then assume additional risk and expenses that come with managing higher-risk donations, including increased monitoring and testing as well as liability issues if contaminated organs are mistakenly transferred to recipients.

Instead, we should consider longer-term donor health insurance as part of “a package of benefits that would not enrich anyone... but rather is designed to leave the donor as well off (fiscally and physically) as before

235 Id.
236 42 U.S.C. § 274(e).
238 Id. at 383.
239 Id.
240 Id.
donation.” To offset the slight but present risk of medical complications after donation, donors should be insured against catastrophic medical expenses which may occur as a result of organ donation. This specific type of supplemental, non-transferrable policy would be designed solely to cover any gaps in an insured’s existing coverage should problems arise in the future.

As one option, Medicare’s existing ESRD program could be modified to allow coverage for kidney donors as well as patients suffering from renal disease. A 2006 analysis in the *American Journal of Transplantation* calculated the estimated cost of this additional coverage. Given that the current median donor age is 40 years, on average, Medicare would have to fund benefits until the donor reaches age 65, the standard age that all citizens become eligible for Medicare. The projected cost of extended coverage based on the current cost of coverage for disabled beneficiaries is $18,124, but since many donors already have private insurance and represent an extremely healthy segment of the general population, actual costs will be much less. Additionally, with benefits targeted to cover only donation-related complications, the comparatively small number of donors, and the rarity of adverse outcomes post-donation, the final amount is a small price to pay to ensure living donors are protected well after their donation.

CONCLUSION

When insurance and organ transplantation intersect, the most essential principles of both fields collide. Insurance requires a sense of objectivity and steadfast adherence to policies that serve to sustain its own survival in economic reality, where the decision to fund one patient’s life-saving operation will force trade-offs in coverage for the rest of the insured base. Meanwhile, the practice of organ transplantation necessitates a more emotional appeal to the values that we admire most in society - qualities of altruism and gratitude at the foundation of how our donative process functions. The by-products of the ensuing clash are real, definable and quantifiable. By recognizing how insurance impacts the practice of organ transplantation, we may start to salvage the more damaging components of

241 Gaston et. al., *supra* note 234, at 2550.
242 *Id.* at 2551.
243 *Id.* at 2552.
244 *Id.*
245 *Id.*
the relationship and reinforce the ways in which the two fields complement each other.