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Public and Private Regulation of Organ Transplantation: Liver Allocation and the Final Rule

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Liver Allocation and the Final Rule¹**

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Abstract

The allocation of cadaveric organs for transplantation in the United States is governed by a process of private regulation. Through the Organ Procurement and Transplantation Network (OPTN), stakeholders and public representatives determine the substantive content of allocation rules. Between 1994 and 2000 the Department of Health and Human Services conducted a rulemaking to define more clearly the public and private roles in the determination of organ allocation policy. Several prominent liver transplant centers that were losing market share as a result of the proliferation of transplant centers used the rulemaking as a vehicle for challenging the local priority for organ allocation inherent in the OPTN rules. The process leading to the Final Rule provides a window on the politics of organ allocation. It also facilitates an assessment of the strengths and weaknesses of private rulemaking. Overall, private rulemaking appears relatively effective in tapping the technical expertise tacit knowledge of stakeholders to allow for the adaptation of rules in the face of changing technology and information. However, the particular system of representation employed may give less influence to some stakeholders than they would have in public regulatory arenas, giving them an incentive to seek public rulemaking as a remedy for their persistent losses within the framework of private rulemaking.

Introduction

In mid-2006, the waiting list in the United States for solid organ transplants (kidneys, livers, hearts, lungs, pancreases, and intestines) had almost 92 thousand registrants, more than triple the approximately 24 thousand patients waiting in 1990, and during 2005 over 6 thousand people died while waiting for organs (OPTN 2006). While the number of liver transplants more than doubled between 1991 and 2005, the waiting list grew almost twelve-fold, and the number of deaths among those waiting for liver transplants more than tripled to 1,715 (OPTN 2006). The persistent shortage of cadaveric organs has led to substantial increases in the numbers of kidneys and livers transplanted from live donors, raising issues of donor risk, especially with respect to livers. Transplants involve substantial expenditures of health care resources. In mid-2002, the average billed charges in the United States for kidney, liver, and heart transplants were \$143,300, \$313,600, and \$391,800, respectively (Hauboldt and Ortner 2002: 23). The availability and allocation of organs for transplant are certainly important public policy issues with literally life and death implications. The creation and implementation of organ transplantation policies primarily through an organization of stakeholders makes it a particularly interesting case for students of medical governance to consider as a possible model for application in other contexts.

The governance of the procurement and allocation of solid cadaveric organs used for transplants in the United States has evolved through three phases. First, prior to the National Organ Transplant Act of 1984, solid cadaveric organs were procured and shared by a variety of loosely coordinated private organizations. Second, during the period following adoption of the 1984 Act, the Organ Procurement and Transplantation Network (OPTN), a non-governmental

organization (NGO) was created and functioned as a private rulemaking body in which stakeholders, primarily organ transplant centers and organ procurement organizations, created and implemented de facto rules for the allocation of procured organs. Third, between 1994 and 2000, the Department of Health and Human Services (DHHS), which has oversight responsibility for the OPTN, developed and finalized rules that seek to impose specific allocation criteria on the OPTN and subject it to stronger oversight. Nevertheless, the development of de facto rules governing organ allocation remains primarily a process of private rulemaking. How well does private rulemaking balance social values and the interests of stakeholders in organ allocation?

This question begs a prior question: Compared to what? Although some researchers have argued for the creation of organ markets as an alternative to the current allocation system (Kaserman and Barnett 2002; Cherry 2005), the most plausible counterfactual institution is rulemaking by a government agency under the notice and comment provisions of the Administrative Procedure Act of 1946 (PL 79-404). Indeed, DHHS is the de jure rulemaker for organ allocation policy. Work by administrative law scholars and political scientists provides some basis for predicting how agency rulemaking would operate (West 2005), as does observation of DHHS rulemaking related to the OPTN.

Private rulemaking, which has received little attention as an institutional form, has three essential elements (Weimer 2006). First, the major stakeholders participate in the rulemaking through membership in an NGO. Second, the NGO formulates the substantive content of rules under a charter that is granted by statute or administrative delegation. The charter specifies membership and the processes for decision making, such as requirements for soliciting public

comment and voting procedures. Third, rules take effect either through the actions of members as a condition of their membership or, if the NGO is subject to formal oversight, through passive acquiescence or routine approval of their substantive content by the overseeing agency.

Intervention by the overseeing agency is more likely to take the form of either changes in procedural requirements or the setting of broad policy goals than of directly mandated changes in the substantive content of rules.

To gain a better understanding of private rulemaking and how it fits within the broader U.S. political context, this article focuses on the controversy surrounding the OPTN allocation rules for livers. Several aspects of cadaveric liver allocation makes it a particularly useful window on private regulation.

First, cadaveric livers are extremely valuable goods. In contrast to kidney failure, which can be treated by either dialysis or transplant, those who suffer fulminant liver failure face immanent death without transplants. Further, in contrast to kidneys, whose double endowment makes live donations readily feasible and fairly common (over 49 percent of donated organs in the U.S. in 2005), livers for transplants are overwhelmingly cadaveric — transplants involving partial livers from live donors in 2005 accounted for just under 5 percent of donations (OPTN 2006). As cadaveric donations remain the primary source for transplant livers, their allocation is very consequential for patients.

Second, liver allocation has direct implications for the ability of transplant centers to serve their patients, and hence to promote their own professional and financial interests. Between 1990 and 2001 the number of centers performing liver transplants increased from 74 to 116, and the number doing more than ten transplants per year increased from 52 to 98 (UNOS

2003: Table 9.10). As more centers began doing liver transplants, a larger fraction of cadaveric organs stayed in the local areas where they were procured. In 2001, 63 percent of liver transplants involved organs procured locally, up from 39 percent in 1990 (UNOS 2000: Table 25; UNOS 2003: 3.7). With average billed charges of hundreds of thousands of dollars per liver transplant, the financial consequences for transplant centers and surgeons of even small shifts in transplant volumes are substantial.

Third, liver transplantation has been advancing rapidly, providing a stimulus to reconsider the scientific basis of rules in place. Of particular relevance to the geographic sharing of organs is the time that livers are viable after being procured (the cold ischemic time). The growing use of partial organs and the splitting of cadaveric organs among multiple recipients will likely induce reconsideration of rules in the future. Such changes, and the difficult issues involved in assessing them scientifically, imply that predicting and valuing the consequences of allocation rules requires considerable expertise. Thus, the normative assessment of liver allocation rules involves expertise as well as values.

Fourth, controversy over the appropriate role of geography in liver allocation expanded to include debate over the role that DHHS oversight should play in shaping organ allocation rules more generally. DHHS efforts to move the OPTN toward less geographically-based liver allocation shows both the potential influence and inherent limitations of its oversight role.

This article does not attempt to resolve the normative issue of the extent to which geography should be a factor in liver allocation for several reasons. First, uncertainty remains around the answers to many relevant questions about impacts: To what extent would wider geographic sharing result in more lives, life-years, or quality-adjusted life-years saved? Would

better matching of patients to livers result? Would longer cold ischemic times result in less graft success? Would graft success increase if more livers went to higher volume centers? Would fewer livers be procured if transplant centers kept fewer livers for their own use? What groups of patients, if any, would be disadvantaged? Second, the values that should be applied in assessing these effects are not clear. The legal framework calls for the application of medical criteria, but should these criteria be designed in an attempt to maximize the number of lives immediately saved by allocating livers to those who face imminent death, or to maximize the gains in life-years or quality-adjusted life-years by allocating livers to those who would obtain the largest marginal gains? Should the distributional consequences, to patients or to transplant centers, be considered in choosing medical criteria? Disagreement over, and uncertainty about, these questions, along with stakeholder interests, sets the stage for controversy.

Rather, this article addresses the private rulemaking and its oversight. In broad outline, the controversy involved the DHHS attempting to eliminate local priority in the allocation rules established by the United Network for Organ Sharing (UNOS), the OPTN contractor, for transplant organs generally, but most immediately for livers. The controversy involved vocal critics of the existing allocation system seeking to secure a major change in its operation, an extended rulemaking by the DHHS, congressional intercession, and efforts by a number of states to maintain local priority in allocation. Ultimately, the DHHS relaxed the specificity of its proposed rule and the OPTN made revisions in liver allocation toward regional over local priority in sharing. The immense regulatory docket and other documentary sources that amassed during the controversy provide a unique window on the politics of allocation.

Private Rulemaking

Although private rulemaking is a rather rare alternative to public rulemaking, private standard setting is a common supplement for, or complement to, public standard setting. A large number of private organizations in the United States, such as Underwrites Laboratories, the American Society for Testing and Materials, and the American National Standards Institute, maintain many thousands of standards. In order to assess the relative effectiveness of private and public standard-setting, Ross E. Cheit (1990) conducted case studies in four substantive areas in which plausible comparisons could be made. Although public standard-setting appeared to enjoy some advantages, such as greater capacity for collecting information about risks from the actual use of products, private standard-setting appeared to offer a more flexible and adaptive process:

The case studies suggest that there are significant evolutionary differences between public and private standard-setters, differences that indicate several previously unrecognized advantages of the private sector. In short, private standards-setting is prospective and ongoing, while public efforts are usually corrective and singular. Private standards-setters tend to intervene relatively early in the life cycle of an issue, adjusting the standard subsequently over time. Public standards-setters, by contrast, are likely to get involved later, often after a major disaster, adopting a “one-shot” standard without the benefit of subsequent adjustments (Cheit 1990: 202).

On the surface, this comparison of public and private standard-setting may not seem relevant to the comparison of private and public rulemaking, because the private standards by

themselves do not directly constrain behavior. Private standards gain force, however, in a number of ways. First, they may become legally binding by being adopted by regulatory agencies — a prominent example is the wholesale adoption of private standards by the Occupational Safety and Health Administration at its inception (Mendeloff 1979). Second, they may gain commercial force by becoming common requirements in private contractual relations. For example, construction contracts often require that the materials used meet standards set by Underwriters Laboratories or other private standard-setters. Third, they may gain force under civil law by reducing vulnerability to tort for those who adhere to them. Finally, private standards applied to organizations through accreditation processes may gain force when accreditation becomes a requirement for participation in government programs (Havighurst 1994).

Compliance as a prerequisite for participation in government programs has been especially important in the health area. In establishing the Medicare program, Congress followed the practice of many insurance companies in allowing participating hospitals to be deemed in compliance with the Medicare conditions of participation if they were accredited by what is now called the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), an organization composed primarily of representatives of associations of health professionals (Jost 1983; Freeman 2000: 610-611). Over 80 percent of hospitals choose to be so deemed (USGAO 2004: 7). Until 1984 it was a legal requirement rather than an option for psychiatric and tuberculosis hospitals to be accredited by JCAHO (Roberts et al. 1987: 13). Consistent with Cheit's generalization, it appears that JCAHO has continually revised its standards in response to changes in the technology of health care delivery (Jost 1983: 885).

A similar process is unfolding with respect to managed care. Since 1991 the nonprofit National Committee on Quality Assurance, with encouragement and support from corporate purchasers of employee health plans, has been developing the Health Plan and Employers Data Information Set (HEDIS) as a way of assessing the quality of care provided by HMOs and other managed care organizations. By 1994, three quarters of managed care organizations used at least some HEDIS measures (Physician Payment Review Commission, 1997: 150-151; Gormley and Weimer 1999: 180-181). The adoption of HEDIS continues to expand as states increasingly require private accreditation under their contracts with managed care organizations for the provision of services to Medicaid participants.

Private standard setting directly employs stakeholder expertise in an ongoing process of drafting and revision of the substantive content of standards that influence, and sometimes effectively become, binding. Private rulemaking also directly employs stakeholder expertise in an ongoing process of drafting and revision of the substantive content of rules that are de facto binding.

In applications of private rulemaking where rules govern the allocation of things of value — such as agricultural quotas (Caves and Salant 1995; Shepard 1986), airport landing slots (Riker and Sened 1991), internet domain names (Foomkin 2000), and transplant organs — the NGO effectively functions as a legalized cartel. When the interests of the dominant stakeholders in the cartel do not well represent the full range of social values, as in the case of agricultural quotas under marketing orders where the interests of growers in restricting supply to raise price adversely affects consumers, private rulemaking may simply offer a technically efficient way of achieving a socially undesirable allocation. The nature of the OPTN, however, is somewhat

different than that of a traditional cartel in that the primary stakeholders, transplant surgeons, seek to secure as many organs as possible for their own patients. Although there may be an incentive to restrict the entry of new transplant centers that have the potential to transplant more organs than they procure, there is no incentive to restrict supply.

Professional and financial interests, however, create strong incentives for transplant surgeons to seek rules that increase the number of organs available to their own patients. Professionally, organs enable them to improve the quality and length of their patients' lives. Financially, transplants generate revenues for surgeons and their transplant centers. As organs are the scarcest resource in the transplantation system, they are the primary source of rents to providers. In a market system, the rents would be captured by the suppliers or procurers of organs, but suppliers and procurers are legally prohibited from engaging in commercial transactions; further, procurers are reimbursed in terms of their costs by the federal government and required to transfer the organs they procure to transplant centers at average cost. As transplant centers perform more surgeries, they spread their fixed costs over more transplants so that their average costs fall. With excess demand for transplants, as evidenced by long waiting lists, the decline in average cost does not reduce the price of transplants to patients and their third-party payers, primarily the federal government. Consequently, transplant centers and their surgeons accrue rents from the organs that they are allocated.

Depending on the nature of allocation, professional and personal interests may not be as closely aligned with respect to efforts to procure organs. Professionally, surgeons seek to help procure organs because they realize that the organs are very valuable to patients, whether their own or those of other surgeons. However, exhorting and supporting the efforts of procurement

personnel requires commitments of time. In some cases, these time commitments may be substantial, as when a transplant surgeon must travel in the middle of the night to a remote trauma center to harvest organs. The financial benefits to the surgeons depend on how the organs are allocated — specifically, the degree to which the procured organs are common property available to other transplant centers. If the organs are allocated to the procuring surgeons' patients, then these surgeons receive the full rent; if they are put into a larger pool, then they receive only a fraction of the full rent depending on the size of the pool. The smaller the size of the common pool, the more likely it is that the expected financial benefit exceeds the costs borne by the procuring surgeon.

A review of a number of cases of private rulemaking suggest the technical, political, and practical factors that are relevant to the choice of private rulemaking as an alternative to public rulemaking (Weimer 2006). First, private rulemaking may offer greater technical efficiency by providing a mechanism for integrating stakeholder expertise continuously, quickly, and directly into rulemaking. Agencies face the difficult task of securing information and expertise, especially in circumstances where technological change or other factors call for frequent adjustment of rules. One strategy for supplementing in-house expertise is to employ advisory committees — over 900 such committees currently operate, including 20 advisory committees and 18 device panels that meet several times per year to advise the Food and Drug Administration about product regulation issues. Another strategy is to involve stakeholders in the design of proposed rules through negotiated rulemaking. In an effort to speed up the rulemaking process and reduce legal challenges to final rules, Congress adopted the Negotiated Rulemaking Act of 1990 (PL 101-648), which sets a framework for convening ad hoc

committees of stakeholders, citizens, and agency staff to advise the agency on the substantive content of proposed rules — though there appears to be little actual difference in terms of speed or rates of legal challenges to rules adopted through negotiated and traditional rulemaking (Langbein and Kerwin 2000). Private rulemaking pushes these two strategies further by making the committees ongoing and giving them *de facto* authority to make rules.

Second, private rulemaking may be politically attractive when politicians seek more insulation from decisions with unfavorable balances of blame and credit than public rulemaking provides. Avoiding blame is generally a more powerful political motive than claiming credit (Weaver 1986), especially in zero-sum situations in which losers can readily identify themselves. Shifting political and decision-making costs to regulatory agencies (Fiorina 1982) may not be effective if losers can return the issue to the political agenda. Politicians may seek added insulation by shifting responsibility directly to the stakeholders themselves.

Third, for private rulemaking to be a practical alternative, a model of stakeholder cooperation must be available so that a working organization can be envisioned by institutional designers. The choice of private rulemaking is likely to be an incremental one, taking advantage of existing organizational relationships rather than attempting to create a new institutional arrangement out of whole cloth. Thinking more generally, the OPTN could possibly be a model for medical governance in other contexts.

The OPTN as Private Rulemaking

Transplantation policy in the United States has evolved primarily in response to developments concerning two solid organs: kidneys and livers. Kidney transplantation initially

became important because it is a lower-cost alternative to dialysis for end-stage renal disease (ESRD) that offers higher quality of life and greater longevity. Liver transplantation initially became important because of the publicity created by desperate parents seeking organ donations and financial support for transplants needed to save the lives of their children. Livers and kidneys continue to be the focal points for debates about the allocation of transplant organs.

Experimental kidney transplantation began in 1951, with the first real success coming in 1954 in a case involving a transplant between identical twins (Prottas 1994: 2). With the introduction of immunosuppressive drugs, which provided a way of countering organ rejection, and with the development of the artificial kidney, which allowed patients with kidney failure to be kept alive through dialysis while they waited for transplant operations, kidney transplants became common during the 1960s. Kidney transplantation soon became generally recognized as a medically desirable and cost-effective alternative to dialysis. In 1969 the Public Health Service gave contracts to seven hospitals to establish organizations to procure cadaveric kidney donations and funded a computerized system for matching donors and recipients in the Western states (Rettig 1989: 194). The Social Security Act Amendments of 1972 (PL 92-603) extended Medicare coverage for either dialysis or transplantation to patients with chronic renal disease through the ESRD program. Seeking to reduce the costs of the ESRD program by encouraging more kidney transplants, amendments to the Social Security Act in 1978 (PL 95-292) extended coverage for immunosuppressive drugs following transplants from one to three years.

The powerful immunosuppressant cyclosporine, which began clinical trials in the U.S. in 1980, had a significant impact on transplantation generally. Its most immediate impact was in reversing the generally disappointing results of liver transplants. Pediatric liver transplantation

dramatically came to public attention in 1982 with the ultimately successful efforts of the parents of eleven-month old Jamie Fiske to secure a liver donation (Rettig 1989: 199). President Ronald Reagan, House Speaker Thomas O'Neill, and newscaster Dan Rather all used their influence and media access on behalf of particular families seeking donors or financial support for pediatric liver transplants. A presidential aid, who helped pressure a number of states to cover the costs of liver transplants under Medicaid, candidly remarked in a newspaper interview: "Sure, it's politics of the first order. It's whoever can get to the White House, whoever can use the media" (Wehr 1984: 455).

Several members of Congress, including Representative Albert Gore and Senators Orrin Hatch and Edward Kennedy, worked during 1984 to develop legislation to create a privately administered network, the OPTN, to encourage more effective procurement of cadaveric organs and to coordinate their allocation. The result, the National Organ Transplant Act of 1984 (PL 98-507), called for the Secretary of the Department of Health and Human Services to contract with a non-profit organization to provide for the establishment and operation of the OPTN that would, among other responsibilities, maintain a national list of patients awaiting transplants to facilitate matching them with donated organs on the basis of medical criteria. Title I of the act established a 21-member Task Force on Organ Transplantation to prepare a report with recommendations concerning the operation of the OPTN. The act also prohibited commerce in organs by making it unlawful for any person knowingly to "acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce" (Title III, Sec. 101a).

The report of Task Force on Organ Transplantation (1986) recommended that "each

donated organ be considered a national resource to be used for the public good” and that the selection of patients for inclusion on waiting lists and the allocation of organs to them “be based on medical criteria that are publicly stated and fairly applied” (p. 9). Medical criteria should “take into account both need and probability of success” (p. 10). The report strongly endorsed the prohibition against the commercialization of organs (p. 10), but rejected the creation of a national list of donors and instead argued for obtaining consent from next-of-kin so as to give them the opportunity for an altruistic act, an approach that has significant implications for the procuring of organs from those who pledged them while alive (Blumstein 1989: 27-28). It also recommended that no more than 10 percent of cadaveric kidneys be allocated to non-immigrant aliens at any transplant center and that extra-renal (other than the kidney) organs not be offered to non-immigrant aliens unless no other suitable recipient can be found (p. 10). Among the other recommendations was a call for the establishment of an advisory board to give advice on organ transplantation policy to the Secretary of DHHS (p. 13).

The contract for administering the OPTN and the Scientific Registry of Transplant Recipients, a data base for assessing transplant results, was awarded in 1986 to UNOS, a non-profit organization based in Richmond, Virginia. UNOS evolved from the Southeast Organ Procurement Foundation, an organization created in 1976 that in turn evolved from an arrangement involving the Medical College of Virginia, one of the original Public Health Service contractors, with a number of other hospitals (Rettig 1989: 195). By 1983, UNOS was already operating a computerized listing of patients awaiting kidney transplants that supported a voluntary system of nationwide sharing (Denny 1983: 26).

The status of the OPTN was strengthened somewhat in the Omnibus Reconciliation Act

of 1986 (PL 99-509), which required all hospitals performing organ transplants to be members of the OPTN and abide by its rules to receive payment under Medicare and Medicaid. It was further strengthened by Title IV of the Omnibus Health Amendments of 1988 (PL 100-607), which required the OPTN to “establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria” (Sec. 403a). The 1988 act also changed the directive of the OPTN from equitably allocating organs among transplant centers and patients to equitably allocating them among patients. Subsequently, the DHHS interpreted the laws to require any rules to be approved by the Secretary before they are binding on OPTN members (U.S. DHHS 1989), and clarified the circumstances of approval in an extended and controversial rulemaking beginning in 1994 and finalized in 2000 (U.S. DHHS 2000). Although the Secretary must approve all OPTN rules before they become enforceable as Federal rules, the OPTN can discipline members who fail to comply. As the DHHS has yet to accept formally any OPTN rule through a Federal rulemaking, the OPTN effectively retains responsibility for developing the content of the rules themselves. Thus, it continues to exercise private rulemaking.

The Controversy Over Liver Allocation Rules

More than any other issue, the role of geography in allocation has been central in debates over the appropriate goals of organ allocation rules. Why so? Recall that UNOS, and hence the OPTN, evolved from a voluntary association of procurement organizations and transplant centers that wished to secure gains for patients from sharing procured organs that could not be well used locally — indeed, it was only with the creation of the OPTN that the regime moved from one of

sharing to one of allocation. Further, relatively short cold ischemic times for livers and hearts, and the detailed testing needed to match kidneys, argued for a priority for local use in the initially developed allocation rules. So did the belief that local transplant communities would make greater efforts to procure organs when they had priority for the procured organs. The opening of more transplant centers made it possible for more patients to receive transplants near where they live, but it also diverted organs from established programs to the new ones. This diversion was especially significant for livers.

Overview of Liver Allocation Rules Through Mid-1996

Prior to the actual operation of the OPTN in 1986, the informal sharing procedures employed by UNOS members were supplemented with UNOS/STAT, a rule through which a transplant center could request that notices be sent out to the approximately 60 organ procurement organizations (OPOs) indicating that a patient required a liver within 24 hours to survive. The first general system was adopted by UNOS for the OPTN in 1986 (Edwards and Harper 1996). It was designed by Thomas Starzl of the University of Pittsburgh Medical Center, the leading liver transplant center (Burdick 1996). It established six levels of medical urgency in addition to the UNOS/STAT designation. Livers were allocated to patients in descending order of their medical urgency, first within the local area where they were procured, second within the region they were procured, and third, nationwide. Local could be as small an area as one served by a single transplant center or as large as an area served by a group of centers working together. At the time local OPOs were organized into nine regions. Within each medical urgency category, a point system based on blood type compatibility, waiting time, and logistical factors (distance

between transplant center and donor location and distance between potential recipient and transplant center) determined priority.

In 1991 the UNOS/STAT designation was eliminated and the most urgent category was expanded. Many UNOS members involved in liver transplantation believed that, in the absence of formal rules governing its use, UNOS/STAT was being abused. As many as 15 percent of patients receiving liver transplants between 1987 and 1990 obtained organs under this designation (Edwards and Harper 1996: 3). It also appeared that several transplant centers were routinely using the designation for patients with less urgent chronic, rather than more urgent acute, liver failure. After an extended policy debate involving the Liver Subcommittee of the Organ Procurement and Distribution Committee and the full committee, the UNOS Board of Directors dropped the UNOS/STAT designation in favor of expanding the most urgent category to include patients, whether suffering from acute or chronic liver disease, who were expected to die within seven days without a transplant. At the time, only two transplant centers objected to the change (Edwards and Harper 1996: 4).

UNOS made a number of additional modifications to the allocation system over the subsequent four years. With respect to its basic geographic nature, UNOS defined the local area so that it would be no smaller than the area served by an OPO and expanded the number of regions from nine to eleven; it also dropped the points awarded for closeness of the transplant center to potential recipients and to donated organs. The number of categories of medical urgency were reduced from six to four, and points for waiting time for patients in the highest category of medical emergency were changed to be based on time in category rather than time on list. Table 1 summarizes the liver allocation system as it had evolved through mid-1996.

Stakeholder Conflict in the Regulatory Arena

The 1994 notice of proposed rulemaking (U.S. DHHS 1994) received a cool reception from UNOS, with the vast majority of transplant centers favoring maintaining the governance of the OPTN with minimal federal oversight. The situation changed dramatically in 1996, however, when the OPTN Board of Directors voted to adopt a major revision of the liver allocation system that would lower the priority of Status 1 chronic liver failure patients. The political effect of the OPTN decision was to enable transplant centers disadvantaged by the geographically-based allocation rule to mobilize chronic liver failure patients' opposition to the downgrading of status and to open a public forum for more general discussion of liver allocation.

The original motivations for the geographical basis of liver allocation included relatively short acceptable cold ischemic times for livers (about 12 hours, compared to about 24 hours for kidneys) and a desire by transplant surgeons to inspect livers before transplantation. As preservation technology improved, cold ischemic time became less of a constraint. In the late-1980s the geographic structure of the liver-transplant sector began changing dramatically. Many liver transplant surgeons trained at the University of Pittsburgh Medical Center (UPMC) started liver transplant programs in areas of the country that previously did not have them. As a consequence, livers that in the past were exported from these areas to major transplant centers were now kept for local use. For example, the number of liver transplant operations performed at the UPMC declined from 471 in 1990 to 177 in 1996. As more organs were kept locally, substantial differences in waiting times across OPOs and regions appeared. For instance, one study based on data from 1990 to 1992 found that the median waiting times for patients varied

across regions from a low of 31 days to a high of 207 days (Klassen et al.1998: 285).

Opponents of the geographically-based system, including surgeons at the UPMC, argued against it on fairness grounds: patients' priorities should depend only on medical criteria and not on which centers have listed them. Sometimes patients in lower medical status categories would receive livers while patients in higher medical status categories in other OPOs did not. Patients living near each other but on opposite sides of an OPO boundary could have radically different chances of receiving an organ even though they had comparable medical conditions — livers could go to relatively healthy candidates while a much sicker patient continued waiting in another locale. The disparities induced some patients to list with more than one transplant center. Some opponents noted UNOS studies (UNOS 1994; Edwards et al. 1999) indicating higher mortality rates at transplant centers with low volumes of procedures, suggesting that more lives would be saved if transplants were done at higher volume centers, though this criticism was muted because of the political expediency of countering the argument that national sharing would result in the closure of low-volume centers.

Proponents of the geographically-based system countered with a number of arguments. National sharing would threaten the survival of smaller transplant centers that provide access to patients who would otherwise have to bear substantial costs to travel to larger centers. Local priority increases transplant survival rates by reducing the time from donation to transplant, and reduces overall transplant system costs by reducing the costs of transporting organs. Further, priority for local allocation contributes to higher rates of procurement by encouraging the local transplant community to make extra efforts to obtain organs that will go first to any appropriate local patients.

The relevant committees of the OPTN organized by UNOS were aware of these arguments, and looked for ways to make incremental changes in the existing allocation system to reduce geographic disparities. In 1993 the UMPC contracted with the CONSAD Research Corporation to develop a simulation model that would allow assessment of alternative liver allocation rules including fully national allocation; in 1995 UNOS prompted by discussions with DHHS, contracted with the Pritsker Corporation to develop its own simulation model. The Liver and Intestinal Transplantation Committee considered results from the models for a number of representative scenarios including the UPMC proposal. In June 1996, the Liver and Intestinal Transplantation Committee and the Allocation Advisory Committee recommended to the Board of Directors a number of changes in the liver allocation rule, most importantly: redefining Status 1 to include only patients with acute liver failure, moving chronic patients who previously were in Status 1 to Status 2, and eliminating Status 4; and introducing regional as opposed to local allocation for Status 1 patients, where the region would be defined as the 20 percent of Status 1 and Status 2 patients on the regional list closest to the location of the procured organ.

The removal of chronic patients from Status 1 was motivated in part by a desire to give priority to those suffering acute episodes such as adverse reactions to therapeutic drugs. The Liver and Intestinal Transplantation Committee believed that the change would result in a net saving of lives, largely because acute patients were less likely than chronic patients to require re-transplants. Additionally, many saw making the status categories more clearly defined and more homogeneous as an essential prerequisite for moving away from local priority in allocation. Separating acute from chronic patients was seen as a first step in this process.

In November 1996, after obtaining comments on the proposed changes through public

hearings, the OPTN/UNOS Board of Directors voted to accept the revisions of the status categories but to reject the regional sharing. The status revisions were to become effective as of January 1997.

Response to 1996 Call for Comments

On November 13, 1996 DHHS reopened the docket for comments related to its 1994 proposed rulemaking. It noted that the liver allocation rule changes approved by the OPTN/UNOS Board of Directors had “generated considerable controversy within the transplant community” (DHHS 1996: 58159). DHHS requested comments specifically on liver allocation and organ donation. In addition to soliciting written comments, it invited participation in a public hearing to be held the following month.

The hearings appear to have been initiated in response to a request from President Clinton to DHHS Secretary Donna Shalala that DHHS review organ allocation policies (Daubert 1998: 461). Clinton’s intervention, in turn, seems to have been prompted by an impassioned plea from a longtime friend and campaign contributor who happened to have financial ties to the UPMC (Weiss 1996).

The three-day hearing was held from December 10-12, 1996. Over 100 witnesses testified; excluding petitions and form letters, over 600 letters were submitted to the docket. Table 2 summarizes the opinions expressed. The first row reports the positions expressed in testimony by, and letters from, physicians, most of whom were associated with transplant centers or professional organizations. A large majority (89.5 percent) favored the new UNOS policy and an even larger majority (98.6 percent) opposed the government making allocation policy. The

second row shows similar, if less extreme, patterns of opinion expressed by other health professionals. The third row, which reports opinions by patients and their families, shows a very different pattern. Most strikingly, a majority (68.8 percent) of opinions opposed the new UNOS policy on grounds that it was unfair to those suffering from chronic disease. As shown in the fourth row, a majority of petition signatures (largely from patients and their families who were solicited by transplant centers) also opposed the new UNOS policy, but more because it kept local allocation than because of the status change of chronic patients. Interestingly, despite the majority of opinions expressed against the new UNOS policy, opinions expressed in testimony and letters from patients and their families and in petitions overwhelmingly opposed the federal government making allocation policy. Among the 30 national organizations that testified (not separately shown in Table 2), nine testified in favor of the new UNOS policy and ten testified against it; two testified in favor of a stronger government role while ten testified against.

One consequence of the hearings was that the OPTN Board of Directors put the changes to the liver allocation on hold and permitted two regions to experiment with broader sharing of livers for acute patients. In June 1997, however, the Board adopted a status classification similar to that adopted the previous November: Status 1 was limited to acute patients with life expectancies without transplant of less than seven days; Status 2A comprised chronic liver failure patients in intensive care units with life expectancies of less than seven days with any one of several specific conditions; Status 2B comprised patients requiring continuous medical care with any one of several specific conditions; and Status 3 comprised patients requiring continuous medical care. As with the earlier allocation system, livers would be allocated by status, first locally, then regionally, and finally nationally.

Another consequence of the hearings was that they encouraged DHHS to require the OPTN to develop less geographically-based allocation rules. Both UNOS and the UPMC invested substantially in campaigns in support of their positions. The UPMC alone spent \$260,000 to lobby Congress in the two years prior to July 1998 (Moore 1998: 1631).

Response to the “Final Rule”

In April 1998, DHHS (1998) published its “final rule” with a call for further comment. The rule dealt generally with its oversight of the OPTN, and specifically called for the OPTN to revise its liver allocation rule. Section 121.8(a)(3)(i), which was intended to apply to all organ allocation stated: “Neither place of residence nor place of listing shall be a major determinant of access to a transplant.” The rule called for the OPTN to give priority to creating a new liver allocation system:

The OPTN is required to develop proposals for new allocation policies (except for livers) within a year of the effective date of the final rule. In the case of liver allocation policies, where policy development work has been underway for several years, the OPTN is required to develop a new proposed allocation policy within 60 days of the effective date (U.S. DHHS 1998: 16297).

The final rule also included a grandfather clause: the new allocation system to be devised by the OPTN was required to include a transition plan that, to the greatest extent feasible, treated those already on the national waiting list no less favorably than they would be treated under current rules.

The final rule gave a fairly long justification for national sharing. It presented simulation results from both the Pritsker and CONSAD simulation models (U.S. DHHS1998: 16324-16327). The Pritsker model showed a larger sum of pre- and post-transplant deaths under national sharing than under either the 1996 policy or the Allocation Committee policy; it also showed national sharing offering a higher total of life-years for patients than the 1996 policy but less than the Allocation Committee policy. The CONSAD model, in contrast, showed national sharing dominating the other two allocation rules both in terms of total deaths and life-years. DHHS noted the differences in assumptions in these models and various factors that neither model included, such as changes in graft survival rates resulting from transplants to different types of patients and organ wastage resulting from transportation. As the models showed only small differences in deaths and life-years of national versus local sharing, DHHS argued that the greater equity of national sharing could be obtained without significant losses in terms of these measures of the aggregate performance of the allocation system.

The debate on the impacts of national sharing continued in the medical journals. For example, the case for national sharing and the DHHS rule was presented in the *New England Journal of Medicine* (Ubel and Caplan 1998). Opponents argued that more deaths would result because of longer storage times in transit, which would reduce graft and patient survival rates and necessitate more re-transplants, and that the “sickest first” principle as applied in national allocation would, in the presence of the great shortage of organs, force many patients to suffer long periods of decline and morbidity risk before they would have access to transplants (Turcotte 1999). Others pointed to the harm that the expected closure of smaller transplant centers would cause to medically disadvantaged patients who would be financially unable to seek transplants at

other centers (Rabkin 1999).

An examination of the docket reveals that letters were sent by physicians associated with 85 different transplant centers. Table 3 shows the distribution of these letters in terms of the opinion expressed on the DHHS liver rule (national allocation) and the proposed increased role for DHHS in overseeing the development of OPTN policies. As was the case with the 1996 testimony and letters, a large majority of transplant centers (48 against, 7 for) opposed the greater DHHS role. An even larger majority (58 against, 7 for) opposed the proposal for national allocation of livers. Confirming the clear visual impression, the common tests for independence (Fisher's exact test, Tau-b, gamma) strongly reject the hypothesis that there is no relationship between the opinions.

Table 4 compares several characteristics of transplant centers conditional on the opinions expressed in their letters. (For comparison, the middle row of the table shows the characteristics for centers that did not submit letters to the docket — they are on average smaller in terms of total number of transplants than those centers that submitted letters. In a logistic regression predicting probability of submitting a letter, total volume of transplants is a statistically significant predictor.) The first three rows consider opinions related to the DHHS role. The group opposing a greater DHHS role had roughly the same market share of liver transplants in 1998 as in 1990, while those not expressing an opinion on the rule or expressing support showed a decline in market share.

The picture is clearer with respect to the characteristics of centers conditional on their opinions on national liver allocation. As the last row shows, transplant centers as a group that supported national allocation had suffered declines both in the average number of liver

transplants performed (minus 39.0) and in their aggregate market share (minus 2.68 percentage points) from 1990 to 1998. (The UPMC alone saw a reduction of 317 liver transplants and a market share loss of 14.1 percentage points over this period.) In contrast, centers that wrote in opposition showed increases in average number of transplants (17.9) and aggregate market share (.227 percentage points). Centers that did not express an opinion on liver allocation and centers that did not submit letters to the docket had figures between these two extremes. Consequently, this gross comparison confirms the commonly expressed beliefs by both proponents and opponents of national allocation that the position of the other side was motivated by the self-interest of centers.

Although the small sample size warrants caution, simple ordered probit models provide statistical tests of the hypothesis that changes in market share affect the position of transplant centers on liver allocation. Table 5 displays the estimated coefficients for two independent variables: change in market share from 1990 to 1998 and the number of centers sharing the center's OPO. The coefficient of the first variable provides the basis for a test of the hypothesis of the role of centers' interests. The coefficient of the second variable provides the basis for a test of the hypothesis that the greater the number of centers already sharing livers from their OPO, the more likely they will be to support national sharing, either because they are already sharing more widely or because they would anticipate a smaller marginal impact on local procurement efforts. The first column shows estimates of the model treating those centers that did not submit letters to the docket as having no opinion. The statistically significant negative coefficient for market share change rejects the hypothesis that market share change has no effect in favor of the alternative hypothesis that centers that lost market share were more likely to

support national allocation and those that gained market share are more likely to oppose it. The statistically significant positive coefficient for number of centers sharing the center's OPO rejects the hypothesis of no effect in favor of more centers contributing to greater support for national sharing. The second column of the table shows similar results when the sample is restricted to only those centers that submitted letters to the docket.

Table 6 conveys the substantive impact of market share change on the probabilities of support and opposition. In the model based on all transplant centers, moving from the mean change in market share for supporters of the liver rule (-2.68 percentage points) to the mean change in market shares for opponents (.227 percentage points), almost doubles the probability of opposing the rule (28.0 versus 14.5 percent) and more than halves the probability of supporting the rule (1.9 versus 5.4 percent). The second model, which limits analysis to those centers submitting letters, shows similarly large substantive effects. These probabilities assume the mean number of centers per OPO, 5.9. The probability ranges in parentheses show the impact of moving from one standard deviation above and below the mean. These ranges are also substantively significant. Overall, the statistical evidence supports the proposition that self-interest influenced the position that transplant centers took on the issue of the national allocation of livers.

State Challenges to National Allocation

Transplant communities in a number of states, facing a possible loss of organs, sought to block the effect of the new rule by seeking legislation to keep organs procured within the state for use by transplant centers in the state. A number of states responded to these efforts, both out

of concern for state residents on the waiting list and at the urging of transplant centers that feared losses of organs. The common form of the law prohibited the export of organs to states with which the state did not have a reciprocal agreement. Such laws were adopted in 1998 and 1999 by Florida, Louisiana, Oklahoma, South Carolina, Tennessee, and Wisconsin. Several other states, including Arizona, Nevada, New Mexico, Ohio, and Texas, adopted resolutions urging Congress to block implementation of the final rule.

The effort in Wisconsin was enthusiastically supported by Governor Tommy Thompson, who had been an advocate over the years for policies to increase organ donation in the state. Wisconsin enjoyed a high donation rate relative to Illinois, which, along with Minnesota, South Dakota, and North Dakota, comprise OPTN Region 7. Wisconsin quickly established reciprocal agreements with Minnesota, South Dakota, and North Dakota. Transplant centers in these states and Wisconsin feared a large outflow of livers to Illinois under regional sharing. Eventually a threat to seek a new region that excluded Illinois encouraged the Chicago transplant centers to agree to provisions that prevented any transplant center from consistently gaining from the arrangement by requiring the regionally shared organs be paid back in kind (Marchione 1999).

Wisconsin and Louisiana also challenged the legal authority for the final rule in federal court. The Louisiana challenge, *Louisiana v. Shalala*, No. 98-802-C-3m (M.D. La. 1998), resulted in stay of the final rule on September 30, 1998, the day before it was to become effective. The judge subsequently dismissed the DHHS appeal to remove the injunction, but did allow the UPMC to join the lawsuit in favor of implementation (McMullen 1999: 408). The following month the case was administratively closed, allowing either party to reopen without prejudice. The Wisconsin suit attempted to block implementation of the revised final rule

published in October 1999 (U.S. DHHS 1999), but was dismissed on the grounds that the plaintiffs lacked standing (Grantham 2001: 764). When Thompson became the new Secretary of DHHS in the Bush Administration, the new governor, Scott McCallum, decided not to appeal the negative decision of the U.S. District Court in November 2000.

Expanding the liver allocation controversy from the OPTN to the traditional regulatory arena activated a variety of political processes — state lawmaking within federalism to protect local interests, legal challenges seeking judicial review of rulemaking , and, most consequentially, congressional intervention.

Congressional Intervention

Meanwhile, Congress had already postponed implementation of the final rule from July 1 to October 1, 1998 as an amendment to a spending bill (PL 105-174). Members of Congress lined up on both sides of the issue, largely depending on the positions of transplant centers in their states. It is probably safe to say that most members believed that decisions about transplant allocation should be made primarily by medical professionals, though this general belief could translate in very different positions on the appropriate oversight role of the DHHS.

In June 1998 Senator Robert Toricelli (D-New Jersey) introduced a rider to the fiscal-year 1999 appropriations bill for the DHHS, placing a one-year moratorium on implementation of the final rule and calling for a study of various aspects of OPTN policy by the National Institute of Medicine. During the debate over the moratorium, several congressional hearings were held on the final rule. The political battle underway between UNOS and the DHHS is evident in the unusually strident comments of Secretary Shalala, made first in prepared

testimony to a joint meeting of the Subcommittee on Health and the Environment of the House Commerce Committee and the Senate Labor and Human Resources Committee on June 18, 1998 and repeated verbatim in prepared testimony to the Labor, Health and Human Services, and Education Subcommittee of the Senate Appropriations Committee on September 10, 1998:

Unfortunately, to this point, UNOS has failed to seize the opportunity offered by the rule to develop consensus about policy improvements. In fact, UNOS has gone to great lengths to preserve the current unfair system. It has launched a cynical political lobbying campaign against the April 2 rule. This campaign has been characterized by misinformation and outright falsehoods. The essence of the UNOS campaign has been to create phantom policies and use scare tactics that have hospital administrators and patients around the country up in arms. UNOS has sent form letters, part of a self-described "legislative action kit," to surgeons and patients across the country. UNOS has been loud and vociferous in its lobbying and is working with some of the highest priced public relations and lobbying firms in town. As a result of their slick lobbying campaign, you are hearing protests about the April 2 rule.

Despite opposition from the Clinton Administration, the rider remained part of the final bill that became law in October 1998 (PL 105-277).

In February 1999 the Institute of Medicine assembled a committee of 16 medical researchers and clinicians (although no active liver transplant surgeons were included) to answer the questions on organ procurement and transplantation posed by Congress. The Committee on

Organ Procurement and Transplantation issued its report in July (IOM 1999). The report addressed the full range of issues raised by Congress, but invested most of its analytical effort in assessing liver allocation. It presented two empirical findings that undercut the case for fully national sharing. First, waiting times for Status 1 and 2A patients (Status 1 in Table 1) did not vary much geographically. Most of the variation in waiting times occurred for Status 2B and 3 patients. In other words, the patients with the most medically urgent conditions in different regions saw similar waiting times so that the major consequence of broader sharing would be reductions in waiting time variances for patients in the less medically urgent categories. Second, based on a review of published studies, the committee concluded that the “medically acceptable cold ischemic time” for livers is 12 hours (IOM 1999: 11) as opposed to the 12 to 18 hours cited in the Final Rule notice (U.S. DHHS 1998: 16304), suggesting that regional rather than national sharing was more consistent with the scientific evidence on organ viability. Therefore, rather than endorse national allocation of livers, the committee recommended that the areas for local allocation comprise populations of at least nine million people, a population larger than that served by most OPOs but smaller than OPTN regions. Recognizing the importance of relationships that have evolved among OPOs and transplant centers, however, the committee recommended that these larger areas be formed through sharing arrangements among existing OPOs. The revised final rule published by the DHHS on October 20, 1999 reflected the findings of the Institute of Medicine report. In particular, it dropped use of the controversial term national list and “directs the OPTN to overcome as much as possible arbitrary geographic barriers” (U.S. DHHS 1999: 56651).

Despite the softening on national allocation, there remained considerable opposition in

Congress to the increased role of the DHHS in allocation policy. Representative Michael Bilirakis (R-Florida) introduced a bill (H 2418) to overturn the DHHS final rule, stating in the floor debate that medical experts “and not Secretary Shalala know best when it comes to transplant policy” (Carey 2000: 838). HR 2418, as amended, nullified the DHHS rule and prevented DHHS from asserting final authority over allocation policies. It passed the House in April 4, 2000 by 275 to 147, with Republicans supporting it 187 to 26 and Democrats opposing it 120 to 87.

Was support or opposition by members of the House based on party, ideology, or the interests of transplant centers in their districts? It would be surprising if representatives were not influenced by the positions of the centers in their districts, especially on an issue for which the personnel of the centers would likely be the most vocal and credible voices they heard. At the same time, one might expect that, other things equal, Democrats would be more likely to vote against HR 2418 in support of the administration. The more interesting question, however, is whether or not ideology had an effect. Conservatives might support nullification of the DHHS rule as blocking undesirable federal interference in medical affairs; liberals might oppose nullification out of an egalitarian concern about disparities across regions.

To investigate the sources of support for HR 2418, Table 7 presents probit models of its roll call. Model 1 includes the member’s party (1 for Democrats, 0 otherwise), ideology as measured by the Americans for Democratic Action (ADA) score (0 to 100, with 100 most liberal), whether the member’s district included a transplant center that submitted a letter to the regulatory docket in opposition to the DHHS rule (1 if yes, 0 otherwise), or whether the member’s district included a transplant center that submitted a letter to the regulatory docket in

support of the DHHS rule (1 if yes, 0 otherwise). The positions of transplant centers in the district have statistically significant effects as predicted. Ideology has a statistically significant effect on the probability of supporting the bill, but party does not: more liberal members were less likely to vote yea, while Democrats were not. Overall, the model correctly predicts 77 percent of the cases with roughly symmetric errors in contrast to the 65 percent that would be correctly classified if all cases were predicted to be in the modal “yea” category. Model 2 shows stable results when party is removed from the model.

As ideology and party are highly correlated (0.91), it is worth checking to see if multicollinearity is suppressing the effect of party. Indeed, Model 3, which removes ideology, does show a statistically significant effect for party, and prevents us from completely ruling out party as an influence on the vote. Nevertheless, the statistically significant coefficient for ideology and the statistically insignificant coefficient for party in Model 1 somewhat favor ideology as an explanation.

In the other chamber, Senator Bill Frist (R-Tennessee), himself a transplant surgeon, introduced a bill (S 2366) to create a board of medical experts and patients to establish allocation policy. As part of a compromise with Senator Ted Kennedy (D-Massachusetts) and Secretary Shalala, Frist agreed to amendments that would give the Secretary a greater role in determining the composition of the board. Although the compromise version was approved 18 to 0 by the Health, Education, Labor and Pensions Committee, Senator Russ Feingold (D-Wisconsin) prevented it from being voted on in the Senate prior to the spring recess at the urging of the Coalition of Major Transplant Centers, a group of 20 hospitals organized by a Wisconsin transplant surgeon. The Coalition argued that the compromise bill would give DHHS too large a

role in allocation policy. With the anticipated difficulty of resolving the large differences between the House and Senate bills in conference committee, and the promised veto of any bill similar to the House version by President Clinton, the 106th Congress ended without legislation on organ allocation.

Denouement: Convergence of OPTN and DHHS Positions on Liver Allocation

Throughout the period of regulatory and legislative conflict, various OPTN committees continued their ongoing efforts to improve the liver allocation system. These efforts resulted in a number of changes in UNOS policy: establishment of voluntary guidelines for patient listing criteria in 1996; establishment of Regional Review Boards for retrospective reviews of status assignments; removal of chronic patients from Status 1 as previously discussed; introduction of separate medical urgency criteria for pediatric patients in 1997; introduction of a more objective scoring system for assessing severity of liver disease for non-Status 1 patients in 1998; establishment of priority of regional Status 1 patients over non-Status 1 local patients in 1999; and establishment of a separate pediatric scoring system in 2000. (The separate pediatric allocation system was based on evidence that pediatric livers produce larger gains in survival rates for pediatric patients than they do for adult patients.)

The introduction of the Regional Review Boards was an important preliminary step for sharing beyond local areas. Recall that abandonment of the UNOS/STAT designation in 1991 was due in no small part to concerns that some transplant centers were inappropriately classifying patients to obtain livers under the emergency designation. Particular concerns about such behavior at three Chicago-area hospitals were later verified in the context of a fraudulent

billing suit filed by the federal government revealing that during the 1990s liver patients listed as critically ill were actually not in the hospital (Murphy 2004). Centers would be reluctant to participate in wider sharing unless they believed that there was compliance with classification criteria. The Regional Review Boards (RRBs) include representatives from all liver transplant centers in the region. They conduct retrospective reviews of all Status 1 cases. In addition, they handle prospective requests for special treatment of exceptional cases under the severity rating system. If the RRB does not respond within 21 days, then the center may list the patient at the requested score. The RRB refers cases involving inappropriate classifications, or cases it is unable to resolve, to the Liver and Intestinal Organ Transplantation Committee for review. Centers found by the committee to be inappropriately classifying patients may be referred to the Membership and Professional Standards Committee for disciplinary action. For example, at meetings in January, May, July, and October 2001, the committee reviewed 20 cases, overturning RRBs in one case, resolving two cases the RRBs could not, and supporting them in the remaining cases. The committee voted to refer centers with multiple violations to the Membership and Professional Standards Committee.

The new liver allocation system uses the severity formula developed in the Model for End-Stage Liver Disease (MELD). Initiated by researchers at the Mayo Clinic (Forman and Lucy 2001; Kamath et al. 2001), MELD was designed to predict the probability of mortality within three months for liver patients. It provides an alternative to older Pugh-Child-Turcotte classification of medical urgency. It also offers a ranking criterion to replace waiting time as a factor in liver allocation, as recommended by the Institute of Medicine Study. A pediatric version, Pediatric End-Stage Liver Disease (PELD) was also developed. A number of

adjustments to the rating systems were made as they became part of the proposed new liver allocation rules.

The process that produced these changes involved interaction among a number of OPTN committees, particularly the Liver Disease Severity Scale Committee, the Liver and Intestinal Organ Transplantation Committee, the Liver Distribution Unit Committee, and the Pediatric Transplantation Committee. It involved the seeking of comments from interested parties and the public, and a public forum on liver allocation held in Dallas, Texas on September 28, 2000. The process is also viewed by the participants as ongoing. As noted in a UNOS Briefing Paper describing the changes, “The concept envisioned by the Committees is one that allows continuous quality improvement of the organ allocation policy, one that can and should be regularly modified in a timely manner as more data and experience is [sic] gained (UNOS 2002: 3). For example, pointing to the MELD and PELD scoring systems based on pre-transplant mortality risk, the “logical next step” is to develop models for predicting mortality among patients who receive transplants (p. 4).

The Distribution Units Committee considered a number of alternative ways to define local and regional units, but did not have data available to assess fully other than population as a basis for distribution units. Using a patient-based simulation model as a basis for analysis, the Committee concluded that there were no clear advantages from redefining distribution units to achieve the minimum population size of nine million people as recommended by the Institute of Medicine (Harper et al. 2000; Freeman et al. 2002). Further, the Committee judged it prudent to await implementation of MELD scores, which would likely have a substantial impact in directing organs to patients most in need. Therefore, it recommended that rather than redefine

distribution units, UNOS regions should be encouraged to develop broader sharing mechanisms. The OPTN/UNOS Board of Directors accepted the recommendation in November 2000.

The basic outline of the proposed liver allocation system shown in Table 8 was approved by the Liver and Intestinal Organ Transplantation Committee in October 2001 and by the OPTN/UNOS Board of Directors the following month. Additional changes were approved by the Executive Committee on February 1, 2002 and they were incorporated into the UNOS By-laws on June 28, 2002.

The new liver allocation rules show substantial movement toward broader geographic sharing — particularly with respect to giving regional Status 1 patients priority over non-Status 1 local patients. As the rules appear consistent with the revised final rule adopted by DHHS, it is likely that they will not be rejected by the board established in the revised final rule to advise the Secretary on OPTN policy, and therefore not rejected by the Secretary. Further, the liver allocation rules as implemented by the OPTN are likely to continue to evolve.

Implementation of regional sharing shows the adaptive and incremental nature of decision making in the OPTN. Procedures exist for local and regional modifications of allocation rules under UNOS Policy 3.4.6. Alternative allocation units, typically grouping OPOs together for purposes of local allocation, may be formed and provisionally approved for three years if they are deemed to correct an inequity in allocation; improvement in terms of objective criteria must be provided for continuation after the probationary period. Variances to point systems used in allocation and the formation of alternative sharing arrangements among OPOs may also be proposed and approved. These mechanisms have allowed for experimentation in allocation.

In the case of liver allocation, Region 1 (New England) has played a key role. It began an alternative sharing arrangement in 1990, and formalized it in 1995, to allocate available organs to Status 1 patients on a regional basis (Rohrer 1996). In 1999 Region 1 obtained a variance to replace the liver allocation rules then in place with a point scale that de-emphasized waiting time and employed a continuous medical urgency scale to prioritize allocation among Status 2B patients (Freeman et al. 2001). Thus, it demonstrated the feasibility of the two major components of the current liver allocation system: regional sharing for Status 1 patients and priority based on a continuous scale of medical need for other patients.

In approving regional sharing of livers for Status 1 patients in June 1999, the OPTN/UNOS Board of Directors instructed the Liver and Intestinal Organ Committee to work with regions to develop alternative sharing arrangements that would take advantage of regional experience and allay regional concerns. This process led to a variety of alternative sharing arrangements. Several regions adopted the standard allocation system with no, or only minor, changes. Region 2 (Mid-Atlantic), 4 (Texas and Oklahoma), 5 (California and Southwest), 7 (Upper Midwest), and 8 (Central), however, initially modified regional sharing to include “payback” provisions to ensure that regional allocation does not consistently favor transplant centers in any particular OPO. For example, reflecting tensions between Wisconsin and Illinois transplant centers, the Region 7 arrangement required, with some exceptions, that the OPO receiving a regionally allocated liver provide the next liver it procures of the same blood type to the donor OPO; in contrast, Region 4 required payback only when a debt of three livers had accumulated. Interestingly, such payback provisions are similar to the “rota” employed to equalize allocation among liver transplant centers in the United Kingdom (UK Transplant 1999).

Noting that under the final rule variances to allocation rules should be limited to local experiments that could potentially be used to influence nationwide rules, the Liver and Intestinal Organ Transplantation Committee recommended that the regions be required to reassess the necessity of their payback arrangements in light of the improved patient classification system that reduces the opportunity for gaming the waiting list. (All but Region 2 had adopted the payback arrangements prior to the MELD standardization and related changes to the patient classification system that substantially reduced opportunities for gaming.) The OPTN/UNOS Board of Directors voted to eliminate the use of payback provisions at its November 2005 meeting.

The implementation of the new sharing agreement also shows how the bottom-up process can result in changes in general policies. Under the rules in place in 1999, a request for an alternative sharing arrangement required unanimous support by all the OPOs and transplant centers involved. Region 5 was unable to obtain unanimity for its proposal. The committee responded by recommending to the board that the threshold for consideration of proposals be lowered to 75 percent agreement, which the board voted to accept in November 2000.

The regional agreements demonstrated the feasibility of regional sharing of livers for the sickest patients. At its June 2004 meeting, the OPTN/UNOS Board of Directors generalized regional sharing by amending liver allocation policies to give priority to patients with MELD or PELD scores of 15 or higher within the region over less medically urgent local patients with lower scores.

Would the rules have evolved as quickly and substantially as they have without the DHHS rulemaking? Of course, the argument that the rules would have remained approximately

as they were in the mid-1990s had they not become a focus of the DHHS rulemaking cannot be ruled out with absolute certainty — even though DHHS itself saw changes in OPTN liver allocation policies prior to 1996, including UNOS/STAT, as representing “attempts to favor the most urgent needs” (U.S. DHHS 1998: 16318). It should be kept in mind, however, that it was revisions of the liver allocation rules by UNOS that provided the impetus for revival of the rulemaking in 1996. More generally, the continual reassessment of policies by the OPTN committees suggests that considerable change in the liver allocation rules would have occurred, perhaps less quickly, even in the absence of the final rule.

A major impact of the controversy was almost certainly greater pressure on UNOS to strengthen the scientific basis for its rulemaking. The chair of the Liver and Intestinal Organ Transplantation Committee during the latter part of the controversy reflected: “I think the debate in 96-97 stimulated all of us to better define the variables and provide better justification for the policies we were advocating; in effect, to make us prove that we were ‘more expert’ than the public rule makers” (Freeman 2003: 5). Staff of the Office of Transplantation in DHHS see the awarding of separate contracts for the administration of the OPTN and the Scientific Registry of Transplant Recipients as facilitating independent empirical investigations in support of policy development (Durbin 2002). Several day-long committee meetings attended by the author in 2003 and 2004 showed extensive use of evidence, including reports from the staff Scientific Registry of Transplant Recipients, reports by independent researchers, data assembled by UNOS staff, and information brought to the table by committee members.

Interpretations and Implications

What does the OPTN tell us about the potential advantages and disadvantages of private rulemaking as a form of medical governance?

First, the continuous involvement of the OPTN in issues through its standing committees allows for the sort of *evolutionary change* that Cheit (1990) found in his comparison of public and private standard-setting. In the controversy over liver allocation, there were two sources of change: the internal dynamics of the members of the network and the oversight by the DHHS. One can point to other important areas of policy where the internal dynamic has dominated. For example, the OPTN changed rules twice in the 1990s to reduce the importance of antigen matching in kidney allocation in response to concerns about its consequences for racial disparities in waiting time. More recently, one can also identify cases in which DHHS has played a role in speeding up change as in prompting the OPTN to begin to set standards for live donations. Further, the potential for DHHS to reject rules has reinforced the continued move toward fully regional sharing of livers for the sickest patients.

The internal dynamic leading to evolutionary change depends on binding votes — a majority of the Board of Directors can change OPTN policies. One advantage of voting is that it can be easily applied to specific elements of any particular proposal for change. Another advantage is that it allows change in the absence of a consensus. Of course, this may also be a disadvantage if the distribution of votes does not match well the distribution of interests. As shown in the final rule controversy, for example, the UPMC was not able to achieve broader geographic sharing as quickly as it desired, despite its prominent role as a transplant center, leading it to seek change through public rulemaking where its prominence and size gave it a relatively more influential voice. This challenge to the network moved debate dramatically into

the political sphere, prompting efforts by states and Congress to protect threatened interests.

The internal dynamic is also facilitated by the use of variances by the OPTN. For example, the variance implemented by Region 1 to share livers regionally experimented with its prerequisite, more confident ranking of patients in terms of medical need, and demonstrated its feasibility; the allowance for payback provisions eased concerns about gaming within several of the regions during implementation of regional sharing until the various changes intended to reduce opportunities for gaming were shown to be effective. DHHS could also allow for variances as it did in the area of state welfare policies leading up to welfare reform, but the process would likely be less flexible because of the value of uniformity in national policy. The advantage of experimentation through variances is the opportunity to develop an empirical basis for assessing potential policy change. The disadvantage is that it results in different treatment of similar patients in different locales.

Looking to the possible use of private rulemaking in other contexts, it is important to note that the OPTN itself represents an evolutionary change, that it has a well defined substantive focus, and that stakeholder interests tend to align with patient interests. Voluntary sharing by UNOS was already underway when the OPTN was created so that its members had considerable experience with cooperating as well as plausible starting points from which allocation policy could begin to evolve. In the absence of such experience, implementing private rulemaking would likely be more difficult. The evolutionary nature of private rulemaking would also place great importance on the initial policies chosen, an uncertain task in the absence of prior cooperation. Although the technology of organ transplantation is highly complex, rulemaking by the OPTN over the procurement and allocation of solid organs gives rulemaking a clear focus.

Appropriately applying private rulemaking in other contexts would require drawing boundaries sufficiently broadly so important tradeoffs are considered, but not so broadly as to invite the shifting of issues to the larger political arena. Within the context of allocation, the interests of transplant surgeons are aligned closely to those of at least their own patients. The absence of such alignment would require more aggressive oversight to prevent the private rulemaker from acting primarily as a stakeholder cartel.

Second, the OPTN shows the effective *continuous engagement of expertise* in rulemaking. OPTN committees have a heavy representation of transplant surgeons who bring the sort of tacit knowledge — information and understanding based on first-hand experience and observation — that is extremely useful in identifying potential issues to be addressed as well as in predicting the likely consequences of proposed rule changes. Many of these surgeons also contribute to the medical literature on transplantation, giving them considerable experience in dealing with empirical evidence. Further, the OPTN committees closely connect expertise to policy questions, a feature observers see as a characteristic of the most effective federal advisory panels (Jasanoff 1990: 230-231; Smith 1992:193).

One can imagine the DHHS employing similar committees as expert panels to support public rulemaking for organ procurement and allocation. The ethos of the advisory committee would likely be for members to avoid conflicts of interest in giving advice. To the extent interests were removed from advice, the politics of rulemaking would likely appear in connection with publication of DHHS proposed rulemakings rather than within the committee. One consequence is that the stakeholders would not be able to shape as confidently the detailed content of rules because any compromises made within the committee could be undone when the

agency drafts the rule. Indeed, anticipating the possibility of challenging the agency rule in court might lead stakeholders to be less than forthcoming with their tacit knowledge — this is one of the concerns that negotiated rulemaking is intended to address, though on an episodic rather than ongoing basis. Transplant surgeons would probably be less willing to participate in advisory panels than in OPTN committees. Also, they would likely form organizations to represent their particular interests in public rulemaking as well as in the legislative process that oversees it.

The nature of the knowledge needed for effective rules is relevant to the choice between private and public rulemaking. The more important tacit knowledge as compared to general knowledge, the relatively more attractive will be the full engagement of stakeholders offered by private rulemaking.

Conclusion

Politics is about authoritative allocation. Nevertheless, when allocation raises issues of scientific knowledge or professional practice and literally involves the life and death of identifiable people, we should not be surprised that elected officials seek to delegate responsibility within some form of governance, such as public or private rulemaking, that harnesses relevant expertise but removes allocative policy from routine politics. Two trends are likely to place even greater importance on understanding the advantages and disadvantages of alternative forms of governance, including those, like private rulemaking, that may facilitate effective use of stakeholder expertise.

First, fiscal stress, currently with respect to Medicare and Medicaid, but also possibly from an expanded public role in health insurance in the future, will create pressure to make

decisions about the allocation of scarce resources such as those now faced with transplant organs. Rising public expenditures will almost certainly prompt questions about what, as well as who, is to be covered by publicly provided health insurance. Answering these questions requires the integration of expertise within the context of broader social values.

Second, researchers addressing systematic reform of the health care system usually argue for greater use of evidence-based assessments of treatments. Usually absent from these calls is attention to the nitty-gritty institutional arrangements required to implement evidence-based assessment more widely. The need to fill in the details makes clear the importance of identifying possible institutional arrangements, like the OPTN and its associated Scientific Registry of Transplant Recipients, for gathering, analyzing, and incorporating evidence into allocation decisions. The account of the controversy over the final rule is a first step in filling in the details for the OPTN, a possible model for governance in other areas of medicine.

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Table 1**Liver Allocation Rules as of June 1996**

<p>Patient Status:</p> <ol style="list-style-type: none"> 1. Patient in hospital intensive care unit due to acute or chronic liver failure with life expectancy without a liver transplant of seven days. (Patients in Status 1 automatically revert to Status 2 after seven days; may be returned to Status 1 by attending physician.) 2. Patient continuously hospitalized in an acute care bed for at least five days, or is bound for intensive care unit. 3. Patient requires continuous medical care, but is not continuously hospitalized. 4. Patient at home and functioning normally. Transplant considered elective surgery.
<p>Geographic/Status Priority:</p> <ol style="list-style-type: none"> 1. Local patients (transplant centers in OPO where organ procured): <ol style="list-style-type: none"> A. Status 1 patients in descending order of points. B. Status 2 patients in descending order of points. C. Status 3 or 4 in descending order of points. 2. Regional patients (transplant centers in region of OPO where organ procured): <ol style="list-style-type: none"> A. Status 1 patients in descending order of points. B. Status 2 patients in descending order of points. C. Status 3 or 4 in descending order of points. 3. National patients: <ol style="list-style-type: none"> A. Status 1 patients in descending order of points. B. Status 2 patients in descending order of points. C. Status 3 or 4 in descending order of points.
<p>Priority Points:</p> <p>Up to 10 points for waiting time.</p> <p>Up to 10 points blood type compatibility.</p> <p>Points by status: Status 3: 12 points; Status 4: 6 points</p>

SOURCE: Adapted from Edwards, Erick and Ann Harper, "Liver Allocation Policy in the United States: 1987-1996," Public Access File, Committee on Organ Procurement and Transplantation Policy, National Research Council, Log No. 51, October 1996.

Table 2**Response to DHHS 1996 Notice: Testimony and Docket Letters; Petition Signatures**

	Favor New UNOS Policy (percent)	Oppose New UNOS Policy: On Chronic Disease (percent)	Oppose New UNOS Policy: On Local Allocation (percent)	Favor Government Policy Making (percent)	Oppose Government Policy Making (percent)
Physicians: Letters and Testimony	136 (89.5)	5 (3.3)	11 (7.2)	4 (1.4)	281 (98.6)
Other Health Professionals: Letters and Testimony	13 (72.2)	3 (16.7)	2 (11.1)	1 (3.3)	29 (96.7)
Patients and Their Families: Letters and Testimony	31 (16.7)	128 (68.8)	27 (14.5)	2 (9.5)	19 (90.5)
Signatures on 22 Petitions	1,582 (20.1)	2,815 (35.7)	3,485 (44.2)	14 (1.6)	843 (98.4)

SOURCE: Adapted from Martin J. Frankel, "Analysis of Testimony and Written Comments: Federal Register Notice, November 13, 1996 and Public Hearings, December 10-12, 1996, on Organ Allocation Policies," Prepared for the Division of Transplantation, Public Health Service, Department of Health and Human Services, January 1997.

Table 3**Letters in Response to HHS from Transplant Centers, 1998**

	Oppose DHHS Liver Rule	No Opinion on DHHS Liver Rule	Support DHHS Liver Rule	Row Totals
Oppose Greater DHHS Role	30	18	0	48
No Opinion on DHHS Role	28	0	2	30
Support Greater DHHS Role	0	2	5	7
Column Totals	58	20	7	85

Table 4
Characteristics of Supporters and Opponents, 1998

	Total Volume of Transplants, 1998 (mean)	Liver Transplants, 1998 (mean)	Change in Liver Transplants, 1990 to 1998 (mean)	Change in Liver Market Share, 1990 to 1998 (percentage points)*
Oppose Greater DHHS Role	136.6	38.9	54.9	.006
No Opinion on DHHS Role	150.8	51.3	4.4	-.405
Support Greater DHHS Role	150.9	56.7	8.7	-.408
No letter Sent	54.0	27.0	4.5	.020
Oppose DHHS Liver Rule	124.8	38.5	17.9	.227
No Opinion on DHHS Liver Rule	161.0	42.0	4.0	-.454
Support DHHS Liver Rule	239.4	94.9	-39.0	-2.680

* Total market share in percentage points for group in 1998 minus total market share in percentage points for group in 1990.

Table 5

**Models of Opinion on National Liver Allocation:
Ordered Probits Categories (Oppose, No Opinion, Support)**

	All Transplant Centers (290)	Transplant Centers Submitting Letter (85)
	Coefficient (Standard Error)	Coefficient (Standard Error)
Change in liver market share 1990 to 1998	-16.3* (5.60)	-14.2* (5.69)
Number of centers sharing center's OPO	.038* (.020)	.047 (.039)
Cut 1	-.397 (.155)	.784 (.281)
Cut 2	2.27 (.219)	1.79 (.328)
Likelihood Ratio Test (Chi-Square, 2 d. f.)	12.60*	8.16*

* Statistically significant at the 5 percent level in a one tailed-test.

Table 6**Effects of Market Share Change on Probability of Support for DHHS Liver Rule**

All Transplant Centers: Probabilities for 5.9 Centers per OPO (2.5, 9.3)

	Oppose	No Opinion	Support
Liver Market Share Change of .227	28.0 (32.5, 23.9)	70.1 (66.2, 73.6)	1.9 (1.4, 2.9)
Liver Market Share Change of -2.680	14.5 (17.6, 11.8)	80.1 (78.2, 81.2)	5.4 (4.1, 7.0)

Transplant Centers Submitting Letters: Probabilities for 5.9 Centers per OPO (2.5, 9.3)

	Oppose	No Opinion	Support
Liver Market Share Change of .227	70.5 (75.7, 64.7)	23.4 (19.8, 27.0)	6.1 (4.4, 8.3)
Liver Market Share Change of -2.680	54.9 (61.2, 48.5)	32.2 (29.0, 34.9)	12.9 (9.8, 16.6)

Table 7**Roll Call Analysis of HR 2418 (Probit Model: 1 for yea; 0 for nay)**

Variable	Model 1	Model 2	Model 3
Party (1 Democrat, 0 otherwise)	.15 (.33)	—	-1.4* (.14)
Americans for Democratic Action Score	-2.4* (.45)	-2.2* (.21)	—
Center in District Opposes DHHS	.65* (.20)	.64* (.20)	.43* (.19)
Center in District Supports DHHS	-1.9* (.74)	-1.9* (.74)	-1.9* (.68)
Constant	1.4* (.13)	1.4* (.13)	1.1* (.11)
Observations ^a	421	421	422
Likelihood Ratio Test (Chi-Square, 4 or 3 d. f.)	143.9*	143.7*	115.4*
Correct Predictions	.77	.77	.75
* – statistically significant at the 5 percent level			
^a Vote was 275 yea; 147 nay. ADA score missing for one member.			

Table 8
Allocation of Adult Livers to Adult Patients, 2002

<p>Patient Status:</p> <p>Status 1. Fulminant liver failure with life expectancy of less than 7 days. Status 1 patients revert to most recent Model for End-Stage Liver Disease (MELD) score after 7 days.</p> <p>All other patients with MELD scores greater than 6.</p> <p>All other patients with MELD scores equal to 6 (minimum possible score) placed on common list with pediatric patients with a Pediatric End-Stage Liver Disease (PELD) score of less than or equal to 6.</p>
<p>Geographic/Status Priority:</p> <ol style="list-style-type: none"> 1. Local Status 1 patients in descending point order 2. Regional Status 1 patients in descending point order 3. All other local patients in descending point order 4. All other regional patients in descending point order 5. National Status 1 patients in descending point order 6. All other national patients in descending point order
<p>Priority:</p> <p>MELD score based on measures of creatinine, bilirubin, prothrombin time (INR), and disease etiology used to estimate risk of mortality while on transplant waiting list.</p> <p>Current MELD score formula (maximum 40):</p> $10 [0.957 \ln(\text{creatinine mg/dL}) + 0.378 \ln(\text{bilirubin mg/dL}) + 1.120 \ln(\text{INR}) + 0.643]$ <p>Allocation based on rounded MELD score. Priority among patients with same MELD score determined by waiting time at that score.</p>

SOURCE: Compiled from United Network for Organ Sharing, "Allocation of Livers: Proposed Amended UNOS Policy 3.6," Briefing Paper, February 1, 2002, 1-33.