

# Transforming Transplantation: The Effect of the Health and Human Services Final Rule on the Organ Allocation System

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ORGAN TRANSPLANTATION, once a risky and uncommon procedure, is now a routine medical procedure with a relatively high success rate.<sup>1</sup> Organ transplantation was considered an experimental procedure until 1954, when medical science made a tremendous breakthrough with the first successful kidney transplant.<sup>2</sup> Shortly thereafter, in 1967, the first human liver was successfully transplanted.<sup>3</sup> As transplantation procedures have become more successful, demand for them has increased dramatically.<sup>4</sup> The supply of available organs has proven insufficient to satisfy this demand.<sup>5</sup> As of September 2000, the number of patients awaiting an organ transplant in the United States

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\* Class of 2002. The author would like to dedicate this Comment to her parents and grandparents. She would also like to thank her entire family for their endless patience, love, and support.

1. See *Putting Patients First: Resolving Allocation of Transplant Organs: Hearing Before the Subcomm. on Health and Env't of the House Comm. on Commerce and the Sen. Labor and Human Res. Comm.*, 105th Cong. 69 (1998) [hereinafter *Putting Patients First Hearing*] (statement of the Honorable Donna E. Shalala, Secretary, U.S. Department of Health and Human Services).

2. See United Network for Organ Sharing, *Critical Data Milestones*, at <http://www.unos.org/newsroom/critdata%5Fmilestones.htm> (last visited Oct. 29, 2000) (noting that the first successful kidney transplant was performed by Dr. Joseph E. Murray at Brigham & Women's Hospital, Boston, Massachusetts).

3. See *id.* (noting that the first successful liver transplant was performed by Dr. Thomas Starzl, at the University of Colorado Health Sciences Center, Denver, Colorado).

4. See Press Release, Health Res. Serv. Admin., *Improving the Nation's Organ Transplantation System*, Oct. 18, 1999.

[T]he number of organ transplants performed each year in the United States has grown from 12,618 in 1988 to 20,961 in 1998. The number of patients awaiting transplantation has grown even more rapidly: from about 14,000 in 1988 . . . to some 66,000 persons on waiting lists for organ transplantation today, ranging in condition from non-urgent to extremely urgent.

*Id.*

5. See *id.* ("Organ donation has grown . . . slowly—from 5,906 donors in 1988 to 9,913 in 1998.").

exceeded 76,000.<sup>6</sup> A new patient is added to the list every fourteen minutes.<sup>7</sup> The number of donors who provided organs in 1999 totaled just 10,538.<sup>8</sup> This shortage of transplantable organs has reached epidemic proportions in the last decade due to technological advances that allow transplant patients to live longer while waiting for organs.<sup>9</sup>

Until very recently, organs in the United States were distributed on a regional basis to patients based upon their need. This system was greatly criticized by health professionals, members of Congress, state officials, and even the organization charged with overseeing the distribution of organs because it often resulted in discrepant distribution based solely upon a patient's location.<sup>10</sup> In an effort to improve the current transplantation system, the Department of Health and Human Services Secretary Shalala issued the Final Rule granting herself, as Secretary, the power to determine the way in which organs would be distributed.<sup>11</sup> The Final Rule was met with great opposition by members of Congress and a number of state legislatures.<sup>12</sup> Many feared the Final Rule called for a nationwide, need-based system of organ distribution. Several states proposed legislation prohibiting distribution of donated organs outside their state<sup>13</sup> and filed lawsuits

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6. See United Network for Organ Sharing, *Critical Data*, at [http://www.unos.org/Newsroom/critdata\\_main.htm](http://www.unos.org/Newsroom/critdata_main.htm) (last visited June 20, 2001).

7. See United Network for Organ Sharing, at <http://www.unos.org> (last visited June 20, 2001).

8. See United Network for Organ Sharing, *Critical Data*, at [http://www.unos.org/Newsroom/critdata\\_main.htm](http://www.unos.org/Newsroom/critdata_main.htm) (last visited Sept. 17, 2000) (observing that a total of 5,848 cadaveric donors and 4,690 living donors were received).

9. See *Organ Procurement and Transplantation Network Amendments of 1999: Hearing before the Subcomm. on Health and Env't of the House Comm. on Commerce*, 106th Cong. 23 (Sept. 22, 1999) [hereinafter *OPTN Hearing*] (statement of William F. Raub, Ph.D., Deputy Assistant Secretary for Science Policy).

10. See Health Res. Serv. Admin., *supra* note 4, at 1 ("Since there are too few organs available to provide for all patients, the Organ Procurement and Transplantation Network (OPTN) needs to allocate organs in as medically effective and fair a manner as possible, to save lives and make best use of this scarce resource.")

11. See *Organ Procurement and Transplantation Network*, 63 Fed. Reg. 16,296 (Apr. 2, 1998) (codified as amended at 42 C.F.R. § 121).

12. See Richard Willing, *State, Federal Officials Battle Over Donor Organs*, USA TODAY, Mar. 15, 1999, at A3 ("[It is] unconstitutional for a federal agency to simply override our states' laws . . . . And medically it's a bad idea. It would cause delay and lessen success if you're shipping organs all over the country." (quoting Richard Ieyoub, Louisiana's Attorney General)).

13. See, e.g., ARIZ. REV. STAT. ANN. § 36-846 (West 2000); LA. REV. STAT. ANN. § 17:2353 (West 2000); OKLA. STAT. ANN. tit. 63 § 2204 (West 2000); S.C. CODE ANN. § 44-43-420 (Law. Co-op. 2000); WIS. STAT. ANN. tit. § 157.06(9) (West 2000).

against Secretary Shalala and the Department of Health and Human Services ("HHS") to oppose the Final Rule.<sup>14</sup>

This Comment provides an overview of the organ allocation system, focusing primarily on the intense debate among the states, which favor local distribution of organs, and the Final Rule, which favors a national, need-based system. Part I of this Comment discusses the evolution of organ procurement laws, including the National Organ Transplantation Act's ("NOTA") establishment of the Organ Procurement and Transplantation Network ("OPTN"), the local Organ Procurement Organizations, and the organ transplantation process. Part II discusses the original HHS Final Rule and analyzes the various congressional attempts to delay the implementation of the Final Rule. Additionally, Part II critiques the various state laws that have been enacted in response to the Final Rule, and their constitutionality in light of the Final Rule's preemption provision. Part II examines lawsuits brought by several states against the Department of Health and Human Services and Secretary Shalala, and the validity of the claims on which they are brought. Part III discusses the amended Final Rule and the current status of the organ allocation system in light of its implementation. Moreover, Part III discusses several bills that were introduced in Congress to modify or nullify the effects of the Final Rule. Part IV provides a critical analysis of both the local organ distribution and national organ distribution systems. Finally, Part V concludes that a quasi-national, need-based system of organ distribution, managed by the United Network for Organ Sharing ("UNOS"), with limited oversight by the HHS, is necessary to overcome the deficiencies inherent in a local distribution system and provide for more equitable organ allocation.

## **I. Background**

### **A. The Uniform Anatomical Gift Act**

Congress first took action on organ transplantation in 1968 when it passed the Uniform Anatomical Gift Act ("UAGA").<sup>15</sup> The UAGA was drafted by the National Conference of Commissioners on Uniform State Laws ("NCCUSL") and was presented to Congress in an effort to achieve uniformity among state laws pertaining to organ do-

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14. See, e.g., *Wisconsin v. Shalala*, No. OO-C-155 (W.D. Wis. Nov. 22, 2000).

15. See UNIF. ANATOMICAL GIFT ACT OF 1968, 8A U.L.A. 63 (1993).

nation.<sup>16</sup> The UAGA gave individuals over age eighteen the legal right to decide whether to donate all or part of their bodies after their death.<sup>17</sup> Additionally, the UAGA provided that the family of a deceased may donate her organs posthumously unless there is evidence that the deceased did not want her organs donated.<sup>18</sup> By the mid-1970s, every state and the District of Columbia had adopted some form of the 1968 UAGA.<sup>19</sup>

## B. The National Organ Transplant Act of 1984

In the years following the enactment of the UAGA, the organ transplantation system became greatly flawed and extremely ineffective.<sup>20</sup> In particular, there was no single source of authority in the distribution of organs.<sup>21</sup> In 1984, Congress enacted the National Organ Transplant Act<sup>22</sup> to streamline the organ transplantation process.<sup>23</sup> NOTA is "designed to strengthen the Nation's health care system to provide organ transplants to thousands of patients across the country."<sup>24</sup> NOTA provides for the establishment of a network that oversees the distribution of organs and provides some governance to this flawed system.

NOTA directs the Secretary of Health and Human Services to establish a task force on organ transplantation.<sup>25</sup> The task force is to "conduct comprehensive examinations of the medical, legal, ethical, economic, and social issues presented by human organ procurement

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16. See John A. Sten, Comment, *Rethinking the National Organ Transplant Program: When Push Comes to Shove*, 11 J. CONTEMP. HEALTH L. & POL'Y 197, 204 (1994).

17. See UNIF. ANATOMICAL GIFT ACT OF 1968 § 2(a), 8A U.L.A. 63, 99 (1993).

18. See *id.* at § 2(b).

19. See Sten, *supra* note 16, at 205.

20. See 130 CONG. REC. 8740, 8742 (1984).

The Congress finds and declares that—(3) the absence of coordinated and effective systems to solicit, identify, and match organ donors with transplant patients has forced such patients to resort to public appeals through the mass media in order to procure the organs needed for transplantation; and (4) a cooperative relationship between an informed public and a receptive medical community is necessary for the identification and procurement of organs for transplantation.

*Id.*

21. See *id.* at 8740.

22. See 42 U.S.C. § 273 (1994).

23. See 130 CONG. REC. H17332, 17333 (1984) (statement of Rep. Moakley) ("One of the issues of concern in the 98th Congress is the need for a more efficient and comprehensive nationwide network to match organ donors with the many individuals in the country who are in desperate need of a transplant.").

24. 130 CONG. REC. H17333 (1984).

25. See 42 U.S.C. § 273.

and transplantation.”<sup>26</sup> Arguably, NOTA’s most important contribution to the transplantation process was the establishment of the Organ Procurement and Transplantation Network.<sup>27</sup>

### C. The Organ Procurement and Transplantation Network

The Organ Procurement and Transplantation Network maintains a list of those who need organs and matches those individuals when an organ becomes available.<sup>28</sup> The OPTN also assists organ procurement organizations in the distribution of organs which cannot be placed within their region, adopts standards of quality for the acquisition and transportation of donated organs, coordinates the transportation of organs from organ procurement organizations (“OPOs”) to transplant centers, and collects, analyzes, and publishes data concerning organ donation and transplants.<sup>29</sup>

NOTA requires that the OPTN “be a private nonprofit entity which is not engaged in any activity unrelated to organ procurement.”<sup>30</sup> The United Network for Organ Sharing (“UNOS”) is the non-profit organization legally responsible for oversight of the OPTN.<sup>31</sup> UNOS is “the ‘umbrella organization’ for organ procurement, transplantation, and statistical information since Congress established the OPTN.”<sup>32</sup> It is under a contract with the Health Resources and Services Administration (“HRSA”), a division of the HHS, to run the nation’s organ transplant system.<sup>33</sup> UNOS first contracted with HRSA in 1986<sup>34</sup> and renewed its contract in September 2000.<sup>35</sup> UNOS had previously contracted with the HRSA to run the scientific registry that “tracks transplant patients and studies how they are affected by changes in organ donation policy,” but lost the registry

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26. *Id.*

27. See 42 U.S.C. § 274(a) (1994) (“The Secretary shall by contract provide for the establishment and operation of an Organ Procurement and Transplantation Network.”).

28. See *id.* at § 274(b)(2)(A)(i)–(ii).

29. See *id.* at § 274(b)(2)(A)(iii).

30. *Id.* at § 274(b)(1)(A).

31. See United Network for Organ Sharing, *Who We Are*, at [http://www.unos.org/fram\\_Default.asp?Category=about](http://www.unos.org/fram_Default.asp?Category=about) (last visited Nov. 17, 2000).

32. Gail L. Daubert, Note and Comment, *Politics, Policies, and Problems with Organ Transplantation: Government Regulation Needed to Ration Organs Equitably*, 50 ADMIN. L. REV. 459, 466 (1998).

33. See National Journal’s Daily Briefing, *American Health Line*, at <http://nationaljournal.com/pubs/healthline/m000929.htm> (last visited Sept. 29, 2000).

34. See United Network for Organ Sharing, *Newsroom*, at [http://www.unos.org/Newsroom/allabout\\_main.htm](http://www.unos.org/Newsroom/allabout_main.htm) (last visited Nov. 17, 2000).

35. See National Journal’s Daily Briefing, *American Health Line*, at <http://nationaljournal.com/pubs/healthline/m000929.htm> (last visited Sept. 29, 2000).

contract in September 2000 to the University Renal Research and Education Association.<sup>36</sup> Though it lost this contract, UNOS has maintained its primary responsibility—the governance of the organ distribution system.

UNOS has divided the country into eleven geographic regions, which are further subdivided into smaller organ procurement organization service areas.<sup>37</sup> There are currently sixty-nine OPOs in the United States.<sup>38</sup> The transplant centers that receive organs from the OPOs are required to belong to the OPTN and abide by its rules in order to be eligible for Medicare and Medicaid funds.<sup>39</sup>

UNOS “has established various allocation systems for cadaveric kidneys, livers, thoracic organs, pancreas and intestinal organs, as well as a separate system for organs not specifically addressed.”<sup>40</sup> The Patient Access to Transplantation Coalition (“PATTC”) described UNOS’s then-existing liver allocation policy to the House Commerce Committee and Subcommittee on Health and the Environment and the Senate Committee on Labor and Human Resources as follows:

Under the current liver allocation policy UNOS keeps a list of every patient in the United States waiting for a transplant. When an organ becomes available, it is offered first to the sickest patients (ranked “Status 1”) within the local [OPO] service area. If the organ cannot be used by a Status 1 patient on the local list, it is then offered to the remaining patients on the list (which ranks patients according to severity of illness as Status 1, 2A, 2B or 3). If the OPO, working with local hospitals, is unable to find a match for the donated organ on the local list, it then offers the organ to patients in the multi-state OPTN region, again giving priority to those in the gravest physical condition. If the OPO fails to find a match within the region, it will offer the donated organ to patients nationwide, with priority again given to the sickest patients.<sup>41</sup>

This description demonstrates that the existing system is truly a “local first” system, as it focuses on the placement of organs within the local area before offering them to out-of-state patients.

The OPTN system as administered by UNOS has been severely criticized in recent years for the discrepancy in the supply of organs

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36. *Id.*

37. See United Network for Organ Sharing, *All About UNOS*, at [www.unos.org/about/what\\_txsystem.htm](http://www.unos.org/about/what_txsystem.htm) (last visited Sept. 17, 1999).

38. See *id.*

39. See Organ Transplant Amendments of 1988, Title IV, Pub. L. No. 100-607, § 401 (1988) (codified at 42 U.S.C. § 201).

40. *Putting Patients First Hearing*, *supra* note 1, available at [http://www.unos.org/newsroom/archive\\_regs\\_testimony\\_pattc.htm](http://www.unos.org/newsroom/archive_regs_testimony_pattc.htm) (last visited June 20, 2001) (testimony of Patient Access to Transplantation Coalition).

41. *Id.*

among the various OPOs.<sup>42</sup> Critics argue that the OPOs in some regions have a larger supply of transplantable organs and this disparity unfairly prejudices those that do not reside in the well-supplied regions.<sup>43</sup> Wisconsin, for example, has worked very hard to increase organ donations, and as a result, the state “has one of the nation’s highest rates of organ donation.”<sup>44</sup> Therefore, a patient residing in Wisconsin will have a decreased waiting time for an organ transplant. The UNOS allocation criterion for the organs often results in disproportionate waiting times and less medically urgent patients receiving organs.<sup>45</sup>

## II. The Final Rule

### A. The Original 1998 Final Rule

In response to criticism regarding organ allocation nationwide, HHS Secretary Shalala announced a new regulation, the Final Rule, on April 2, 1998. The Secretary indicated the transplant community must be “prepared to adjust Federal policies to meet the intent of the [NOTA].”<sup>46</sup> According to the Secretary, the purpose of NOTA was to ensure “an equitable nationwide system for the distribution of transplantable organs,”<sup>47</sup> as opposed to the current system in which “where you live and where you list can determine whether you live or die.”<sup>48</sup>

According to Secretary Shalala, the 1998 Rule was designed to:

[I]mprove the effectiveness and equity of the Nation’s transplantation system and to further the purposes of the National Organ Transplant Act of 1984, as amended. These purposes include: encouraging organ donation; developing an organ allocation system that functions as much as technologically feasible on a nationwide basis; providing the bases for effective Federal oversight of the OPTN . . . and, providing better information about transplantation to patients, families and health care providers.<sup>49</sup>

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42. See *Putting Patients First Hearing*, *supra* note 1, at 71 (statement of the Honorable Donna E. Shalala, Secretary, U.S. Department of Health and Human Services).

43. See Sarah Yang, *U.S. Seeks to Overhaul Organ Transplant Policy*, L.A. TIMES, Mar. 1, 1999, at A1.

44. John Fauber, *Court Dismisses Lawsuit Over Organ Transplants*, MILWAUKEE JOURNAL SENTINEL, Nov. 28, 2000, at 2B.

45. See *Putting Patients First Hearing*, *supra* note 1, at 71 (statement of the Honorable Donna E. Shalala, Secretary, U.S. Department of Health and Human Services).

46. *Id.* at 75.

47. *Id.*

48. *Id.*

49. Organ Procurement and Transplantation Network, 63 Fed. Reg. 16,296 (Apr. 2, 1998) (codified as amended at 42 C.F.R. § 121).

The original Rule intended to do away with the "local first" system and broaden the area in which organs are allocated.<sup>50</sup> The transplant community welcomed the provisions of the Rule that called for increased organ donation and better information for patients. It disliked, however, the aspects of the Rule that allowed for the complete transformation of the organ allocation system from a local system to a much broader, nearly national, system of allocation.

In addition to allowing for the possibility of a national distribution system, the original Final Rule set forth three performance goals to be achieved by the OPTN.<sup>51</sup> The first required the OPTN to "define objective and measurable medical criteria to be used by all transplant centers in determining whether a patient is appropriate to be listed for a transplant."<sup>52</sup> This essentially required the establishment of a list of criteria which a doctor could use to determine whether she should add a given patient to the list of those awaiting transplants.

Second, the OPTN was to "determine objective medical criteria to be used nationwide in determining the medical status of those awaiting transplantation."<sup>53</sup> Among the requirements were a specified status of urgency, probability of success of a transplant, and age. Requiring all doctors and medical facilities to abide by the same criteria assures that all patients awaiting a transplant are in as equal need as possible.

Finally, the OPTN was "required to develop equitable allocation policies that provide organs to those with the greatest medical urgency, in accordance with sound medical judgment."<sup>54</sup> It is this provision which opened the door for the establishment of a nationwide organ distribution system, because many believe the only way to effectively provide organs to the most medically needy patients is to establish broader or national distribution areas. Proponents of a broader sharing system feel that it is the only way to assure that the most medically needy patients receive priority in distribution.<sup>55</sup> The original Rule also included a provision preempting any state law that "limits organ sharing policies."<sup>56</sup>

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50. *See id.*

51. *See id.* at 16,296-97.

52. *Id.* at 16,296.

53. *Id.*

54. *Id.* at 16,296-97.

55. *See OPTN Hearing, supra* note 9, at 32-33 (statement of Robert D. Gibbons, Member, Institute of Medicine).

56. Organ Procurement and Transplantation Network, 63 Fed. Reg. 16,296, 16,338 (Apr. 2, 1998) (codified as amended at 42 C.F.R. § 121.12).



Though not explicit in the original Rule, many argued that it advocated for the abandonment of the existing "local first" organ allocation practice in favor of a national, need-based practice.<sup>57</sup> The Secretary insisted that the Rule did not contain any allocation policy, but left its creation to UNOS.<sup>58</sup>

However, these assurances that the HHS was leaving the development of allocation policies to the transplant community were less than reassuring for many. The President of UNOS, testifying at a Congressional hearing on the original Rule, stated that "the proposed HHS [Rule] causes the transplant community great concern."<sup>59</sup> UNOS objected to the HHS usurpation of the policy-making role, the expansion of the geographic areas in which organs would be distributed, and the allocation of organs to the most medically deserving patients first.<sup>60</sup> UNOS and the transplant community believed the following conclusions would result from the type of allocation system proposed by the rule: longer waiting times and more deaths; and the forced closure of small and medium-sized transplant programs, resulting in negative consequences for minorities and the poor.<sup>61</sup>

## **B. Actions Taken to Block the Implementation and Effects of the Original Final Rule**

### **1. Congressional Action**

Immediately following the announcement of the HHS's original Final Rule, Congress took action to block its implementation.<sup>62</sup> The Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 ("Omnibus Act") delayed the implementation of the original Rule until October 21, 1999.<sup>63</sup> The Omnibus Act called for independent review through the National Academy of Science's Institute

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57. See *Putting Patients First Hearing*, *supra* note 1, at 78 (statement of the Honorable Donna E. Shalala, Secretary, U.S. Department of Health and Human Services) ("UNOS has claimed that the rule creates a single national waiting list for patients that would result in more patients' deaths and longer waits for all patients across the country.").

58. See *id.* at 77 ("I reiterate that the Department does not have a preconceived notion of any allocation policies. We are relying on the transplant community to develop the policy.").

59. *Putting Patients First Hearing*, *supra* note 1, at 138 (statement of Dr. L. Hunsicker, President, UNOS).

60. See *id.* at 138-39.

61. See *id.* at 136.

62. See Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105-277, § 213(a), 112 Stat. 2681-359 (1998).

63. See *id.*

of Medicine ("IOM").<sup>64</sup> The IOM was called upon to conduct a review of the current policies of the OPTN and the original Rule in order to determine the reasons for the discrepancy in organ availability, the impact of sharing organs based on medical criteria rather than geography, and the impact on patient survival rates.<sup>65</sup> The IOM was also to make any recommendations to change the existing policies or the original Rule.<sup>66</sup> The Omnibus Act directed the HHS Secretary to conduct a series of discussions with OPTN to discuss and resolve issues raised by the original Rule.<sup>67</sup>

The IOM issued its report on July 22, 1999.<sup>68</sup> The report contains five major recommendations for improving the organ allocation system.<sup>69</sup> First, the report concludes that the transplantation system would be more effective if livers were allocated over larger populations than those existing in the current OPO structure.<sup>70</sup> The report suggests that the Organ Allocation Areas ("OAAs") for livers serve a population base of at least nine million people.<sup>71</sup> Second, the report encourages the discontinuance of waiting time as an allocation criterion for patients in Statuses 2 and 3.<sup>72</sup> Third, the report suggests the exercise of federal oversight to manage the transplantation system.<sup>73</sup> Fourth, the report states that the HHS should establish independent scientific review to ensure that the system is as effective and equitable as possible.<sup>74</sup> Finally, the report recommends the improvement of data collection and dissemination in order to increase public confidence in the system.<sup>75</sup>

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64. See *id.* at § 213(b)(1)(H).

65. See *id.* at § 213(c)(1).

66. See Institute of Medicine, *Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the HHS Final Rule* (Report of the Committee on Organ Procurement and Transplantation Policy, Division of Health Sciences Policy, Institute of Medicine) (National Academy Press 1999) [hereinafter IOM Report].

67. See Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105-277, § 213(a), 112 Stat. 2681-359 (1998).

68. See IOM Report, *supra* note 66.

69. See *id.* at 6.

70. See *id.*

71. See *id.*

72. See *id.* at 10-13. See also United Network for Organ Sharing, *Newsroom*, available at [http://www.unos.org/Newsroom/archive\\_other\\_rationale\\_objectives.htm](http://www.unos.org/Newsroom/archive_other_rationale_objectives.htm) (last visited Apr. 5, 2001) (stating that a patient deemed a Status 2 "requires continuous medical care but not continuous hospitalization." A Status 3 patient is "continuously hospitalized but not in the intensive care unit.").

73. See IOM Report, *supra* note 66, at 14.

74. See *id.*

75. See *id.* at 14-15.

## 2. State Action

### a. State Legislation

Upon the promulgation of the original Rule, a number of states enacted statutes to limit its effect.<sup>76</sup> The states were very concerned that organs donated by their residents would be used to help those outside the state, which would result in a decrease in the general willingness to donate.<sup>77</sup> Anticipating such action by the states, the HHS included a preemption provision in the original Rule which provides:

No state or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement that would restrict in any way the ability of any transplant hospital, OPO, or other party to comply with the organ allocation policies of the OPTN or other policies of the OPTN that have been approved by the Secretary under this part.<sup>78</sup>

The preemption clause leaves very little, if any, room for the states to promulgate regulations protecting use of their organs by out-of-state patients.

Despite the Rule's preemption provision, a number of state legislators introduced and succeeded in passing laws that expressly prohibited the transfer of organs out of state unless a suitable match was not found within the state.<sup>79</sup> Some of these statutes allow an out-of-state transfer only if there is a reciprocal agreement with an out-of-state OPO.<sup>80</sup>

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76. See *Kentucky Legislature Moving to Join List of States Mandating Organs be Offered to Residents First*, TRANSPLANT NEWS, Jan. 28, 2000, available at 2000 WL 14581873.

77. See Jenny Price, *State to Sue on Organ Policy Wisconsin Could Lose Under New Rules for Donation Distribution*, Wis. ST. J., Mar. 15, 2000, at A1.

78. Organ Procurement and Transplantation Network, 63 Fed. Reg. 16,338 (Apr. 2, 1998) (codified as amended at 42 C.F.R. § 121).

79. See, e.g., OKLA. STAT. tit. 63, § 2204 (2000).

Organ procurement organization may only transfer a vascular organ to an out-of-state organ procurement organization or suitable out-of-state recipient for transplantation if one of the following requirements is met: (a) a suitable recipient in the State . . . is not known to the designated [OPO] within the amount of time necessary to preserve the organ; or (b) the designated [OPO] has a reciprocal agreement.

*Id.* See also N.M. STAT ANN. § 24-6A-6.1 (Michie 2000) (same as Oklahoma's); TEX. HEALTH & SAFETY CODE ANN. § 692.0145 (West 2000) (same); LA. REV. STAT. ANN. § 17:2353 (West 2000) (same); KY. REV. STAT. ANN. § 311.236(3) (Michie 2000) (OPO "shall not be mandated to transfer an organ for transplantation to an out-of-state [OPO] . . . if a suitable recipient can be identified at a transplant center within its service area . . ."); ARIZ. REV. STAT. § 36-846 (2000) ("A vascular organ obtained by an [OPO] designated to service [in] this state must be used in this state."); S.C. CODE ANN. § 44-43-420(B) (Law. Co-op. 2000) ("The [OPO] may only transfer an organ to an out-of-state [OPO] . . . if a suitable recipient in this state cannot be found in a reasonable amount of time.").

80. See, e.g., OKLA. STAT. tit. 63, § 2204 (2000).

## b. Preemption of State Laws

The enactment of state legislation which directly conflicts with the preemption clause of the original Rule prompts serious federalism concerns.<sup>81</sup> This Comment will limit its discussion of preemption to whether the laws enacted by the States in response to the HHS Final Rule will withstand constitutional scrutiny.

The preemption power is derived from the Supremacy Clause of the United States Constitution, which states that “the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”<sup>82</sup> It has been argued by critics of the original Rule that a court considering the issue should find the preemption clause of the Rule invalid because Congress has never explicitly granted the HHS the power to preempt state law, and the statutory language of NOTA does not make a grant of such power to the HHS.<sup>83</sup> NOTA gives the HHS a limited supervisory role in the organ procurement process, not a managerial role.<sup>84</sup> Under NOTA, the HHS Secretary is to inform the public of the need for organ donations, provide technical assistance to OPOs and submit annual reports to Congress on the efficiency and effectiveness of the procurement and allocation of organs, and make known any problems that exist with the system.<sup>85</sup>

If the Rule’s preemption clause was found not to preempt the state laws prohibiting out-of-state organ transfers under the above analysis, it is arguable that the state laws would be struck down on dormant Commerce Clause grounds.<sup>86</sup> The power of Congress to regulate interstate commerce is derived from Article I, § 8 of the United

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*Id.* See also N.M. STAT ANN. § 24-6A-6.1 (Michie 2000) (same as Oklahoma’s); TEX. HEALTH & SAFETY CODE ANN. § 692.0145 (West 2000) (same); LA. REV. STAT. ANN. § 17:2353 (West 2000) (same).

81. See Roderick T. Chen, Note, *Organ Allocation and the States: Can the States Restrict Broader Organ Sharing?*, 49 DUKE L.J. 261, 274 (1999).

82. U.S. CONST. art. VI, § 1, cl. 2.

83. See Chen, *supra* note 81, at 279–80. See also *Wisconsin v. Shalala*, No. OO-C-55, at 1 (W.D. Wis. Nov. 22, 2000) (order dismissing case).

84. See, e.g., *Wisconsin v. Shalala*, No. OO-C-155, at 5.

85. See 42 U.S.C. § 274(c)(1)–(4) (1994).

86. See Chen, *supra* note 81, at 283.

States Constitution.<sup>87</sup> One of the fundamental tenets underlying the Commerce Clause is the notion that one state cannot deliberately discriminate against a citizen of another state.<sup>88</sup>

The state laws at issue essentially provide that organs donated in State A are not to leave State A for transplantation into a State B patient unless a suitable recipient cannot be found in State A, or a reciprocity agreement exists between State A and State B. Under this analysis, State A is clearly giving its citizens preferential treatment in the organ procurement process at the expense of citizens in State B. State A may argue that it is not discriminating against citizens in State B, which would be an express violation of the dormant Commerce Clause, but rather it is serving a legitimate state interest—the protection of a scarce resource.<sup>89</sup> Organs have been declared to be a “public trust,”<sup>90</sup> supporting the proposition that they are a resource worthy of protection. Whether the state statutes will survive a Supremacy Clause challenge remains to be seen. As of the date of publication, the Secretary of HHS had not brought any suits challenging the state statutes under the preemption provision of the Final Rule. Such a suit is unnecessary until the Secretary determines that a national system of organ allocation is to be used and requires the OPOs to distribute organs on a national basis. This would require organs to leave the states in direct violation of the state laws.

### c. Wisconsin Lawsuit

In March 2000, former Wisconsin Governor Tommy Thompson brought suit in federal court seeking injunctive relief against the Final Rule.<sup>91</sup> Joining the State of Wisconsin in the lawsuit were the University of Wisconsin Hospitals and Clinics Authority, Froedtert Memorial Lutheran Hospital, Oregon Health Sciences University, and the State of New Jersey.<sup>92</sup> The State of Louisiana attempted to intervene in the case, but its motion to intervene was denied by the district court.<sup>93</sup>

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87. See U.S. CONST. art. I, § 8, cl. 3 (“The Congress shall have Power to . . . regulate Commerce . . . among the several states.”).

88. See *Philadelphia v. New Jersey*, 437 U.S. 617, 624 (1978). See also Chen, *supra* note 81, at 284–85.

89. See Chen, *supra* note 81, at 288.

90. See 63 Fed. Reg. 16,296 (Apr. 2, 1998) (codified as amended at 42 C.F.R. § 121) (“Human organs that are donated for transplantation are a public trust.”).

91. See Price, *supra* note 77, at A1. See also *Wisconsin v. Shalala*, No. OO-C-155 (W.D. Wis. Nov. 22, 2000) (order dismissing case).

92. See *Wisconsin v. Shalala*, No. OO-C-155.

93. See *id.* at 2.

## (1) Legal Theory

The plaintiffs challenged the amended Final Rule<sup>94</sup> on the grounds that it violated NOTA by “promulgating rules on subjects, including organ allocation policies, that exceed the authority given [to the Secretary] under the act.”<sup>95</sup> Both Wisconsin and New Jersey brought suits in their capacity as *parens patrie*<sup>96</sup> for their citizens.<sup>97</sup> The state plaintiffs claimed they were injured because “the Secretary’s usurpation of [the network’s] policy making authority deprives Wisconsin’s citizens of the benefits of the federal system of organ allocation policy which the [NOTA] gives solely to [OPTN].”<sup>98</sup> The plaintiff hospitals are members of OPOs and the OPTN who claim that they have been injured as members of the OPTN because the defendant “has stripped the network of its final policy making authority.”<sup>99</sup>

## (2) District Court Opinion

The suit was dismissed by District Judge Barbara B. Crabb on November 22, 2000. The court dismissed the case on the ground that the plaintiffs lacked standing.<sup>100</sup> Standing is a constitutional requirement of subject matter jurisdiction,<sup>101</sup> and without a “cognizable Article III injury, [the] court has no power to hear [a] case.”<sup>102</sup> The court found that the plaintiffs did not satisfy their burden of establishing standing because they were unable to show that they suffered “an injury in fact.”<sup>103</sup> Regarding the hospital plaintiffs, the court found they had not suffered an injury in fact because they were “not suing as representatives of the [OPTN]. The only entity allegedly injured by the change in ultimate decision making authority implemented by the amended final rule is the [OPTN].”<sup>104</sup> The state plaintiffs lacked

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94. The original Final Rule, published on April 2, 1998, was delayed twice and amended and did not become effective until March 16, 2000. For further discussion on this Amended Final Rule, see discussion *infra* § III(A).

95. *Wisconsin v. Shalala*, No. 00-C-155 at 2.

96. “Parent of his country; refers traditionally to the role of the state as sovereign and guardian of persons under legal disability.” BLACK’S LAW DICTIONARY 114 (6th ed. 1990)

97. See *Wisconsin v. Shalala*, No. OO-C-155 at 3.

98. *Id.* at 16.

99. *Id.*

100. See *id.* at 2.

101. “Term refers to court’s power to hear and determine cases of general class or category to which proceedings in question belong; the power to deal with the general subject matter involved in the action.” BLACK’S LAW DICTIONARY 1425 (6th ed. 1990)

102. *Wisconsin v. Shalala*, No. OO-C-155 at 16. See also U.S. CONST. art. III, § 2, cl. 1.

103. See *Wisconsin v. Shalala*, No. OO-C-155 at 24.

104. *Id.*

standing because case law has demonstrated that “[a] state may not bring a *parens patriae* suit against the federal government.”<sup>105</sup> The issue of ripeness was raised by the defendant, arguing that the case was not ripe because the Secretary had not yet exercised the authority granted to her by the amended Final Rule.<sup>106</sup> The court declined to address this issue because it was unnecessary in light of its determination of the standing issue.<sup>107</sup>

### (3) Appeals

Former Wisconsin Governor Thompson elected to appeal the district court’s decision. However, his successor, Governor Scott McCallum, sought an end to the lawsuit.<sup>108</sup> Governor McCallum chose to end the lawsuit to avoid being in the awkward position of having to sue Thompson, his former employer.<sup>109</sup> Additionally, McCallum stated that a number of the other states named as plaintiffs in the suit had decided to discontinue it, and it would be “ineffective and inefficient” for Wisconsin to continue a suit many have deemed a sure loser.<sup>110</sup>

## III. Current Status of the Final Rule

### A. The Amended Final Rule

The Final Rule, published on April 2, 1998, and delayed by the Omnibus Act, was scheduled to become effective on October 21, 1999. It was further delayed, however, by the Ticket to Work and Work Incentives Improvement Act of 1999 (“Ticket to Work Act”), signed into law by President Bill Clinton on December 17, 1999.<sup>111</sup> The Ticket to Work Act provided that the April 2, 1998 original Final Rule, together with amendments published on October 20, 1999, would not become effective before March 16, 2000.<sup>112</sup> The HHS announced the stay of

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105. *Id.* at 22. *See also* Ill. Dept. of Transp. v. Hinson, 122 F.3d 370, 373 (7th Cir. 1997); Mass. v. Mellon, 262 U.S. 447, 485–86 (1923) (“The United States, and not individual states, represents citizens as *parens patriae* in the citizens’ relations with the federal government.”).

106. *See Wisconsin v. Shalala*, No. OO-C-155 at 25.

107. *See id.*

108. *See* John Fauber, *McCallum to End Organ Lawsuit*, MILWAUKEE J. & SENTINEL, Feb. 17, 2001, at B1.

109. *See id.*

110. *See id.*

111. *See* Ticket to Work and Work Incentives Improvement Act of 1999, Pub. L. No. 106-170 § 413 (Dec. 17, 1999). *See also* 65 Fed. Reg. 15,252 (Mar. 22, 2000).

112. *See* 65 Fed. Reg. 15,252 (Mar. 22, 2000).

the Final Rule and informed the public of the opportunity to submit comments on the amended Rule for sixty days.<sup>113</sup>

The amended Final Rule ("amended Rule") reflects the comments received by the HHS on the 1998 Rule, the recommendations made by the IOM report, and summarizes new transplant data developed during this time.<sup>114</sup> The amended Rule contains most of the provisions of the original Rule, including the three performance goals established in the original Rule.<sup>115</sup> The amended Rule also provides clarification of several provisions in the original Rule that were the source of much debate and criticism.<sup>116</sup>

One notable clarification in the Rule specifies that it does not require national lists for organ donation, but rather its goal is to achieve sharing of organs in regions broad enough to assure that those patients with greatest medical urgency are provided for.<sup>117</sup> The amended Rule further provides that it does not intend to force the closure of small or medium-sized transplant centers or diminish access to organs for those in the rural areas served by such centers.<sup>118</sup> The role of the Secretary of HHS was further clarified by the amendments.<sup>119</sup> Despite the many attempts to block its implementation, the Final Rule became effective March 22, 2000.<sup>120</sup> Although the Rule is now effective, its provisions may be short lived. Many members of Congress are unhappy with the Rule as amended, and have taken measures to nullify or modify the amended Rule.<sup>121</sup>

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113. See 64 Fed. Reg. 71,626 (Dec. 21, 1999) (codified as amended at 42 U.S.C. § 121).

114. See 64 Fed. Reg. 56,650 (Oct. 20, 1999) (codified as amended at 42 C.F.R. § 121).

115. See *id.* at 56,651.

116. See *id.*

117. See *id.* ("The final rule does not require single national lists for allocation of organs, beyond the national registry lists already utilized by the OPTN . . . [I]t is the Department's goal to achieve sharing of organs broad enough to achieve medically effective results for patient.")

118. See *id.*

119. See *id.* at 56,652.

It is not the desire, nor is it the intention, of the department to interfere in the practice of medicine. Decisions about who should receive a particular organ in a particular situation involve levels of detail, subtlety and urgency that must be judged by transplant professionals . . . This rule also has been revised to emphasize that the Secretary's review is intended to ensure consistency between OPTN policies and the [NOTA].

*Id.*

120. See 65 Fed. Reg. 15,252 (Mar. 22, 2000) (codified as amended at 42 C.F.R. § 121).

121. See generally Organ Procurement and Transplantation Network Amendments of 2000, H.R. 2418, 106th Cong. (2000) and Organ Procurement and Transplantation Network Amendments Act of 2000, S. 2366, 106th Cong. (2000).



With a new President taking office in January 2001, and with a new Secretary of HHS, speculation surrounding the fate of the Final Rule was rampant.<sup>122</sup> However, the new Secretary—former Wisconsin Governor Tommy Thompson, one of the most ardent critics of the Rule—has indicated that he has no intent at the present time to change it, and would await advice from UNOS and a committee established by former Secretary Shalala before making any policy changes.<sup>123</sup>

## **B. Pending Legislation to Modify the Final Rule**

Immediately following the announcement of the Final Rule, several bills proposed by members of Congress who opposed the HHS Rule were introduced in the United States House of Representatives and the United States Senate.<sup>124</sup> One such bill, introduced in the Senate, had the support of the Clinton administration and appeared to provide a compromise between parties favoring a local system of distribution and those favoring a national system.<sup>125</sup> In contrast, a bill that passed the House had the effect of nullifying the Final Rule issued by the HHS.<sup>126</sup>

### **1. The Senate Bill**

On April 5, 2000, Senator Bill Frist, a former transplant surgeon from Tennessee, introduced the Organ Procurement and Transplantation Network Amendments Act of 2000 in the Senate (“Senate bill”).<sup>127</sup> The Senate bill was hailed as a compromise between the Senate and the HHS.<sup>128</sup> The bill did not attempt to set forth any transplant policies, but authorized such policy decisions to be made by the OPTN board.<sup>129</sup>

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122. See, e.g., Associated Press, *Thompson May Spark Fight on Organ Donations*, RICHMOND TIMES-DISPATCH, Jan. 3, 2001, at A8.

123. See Marilyn Marchione, *Transplant Setup Won't Change Now for the Time Being, Thompson Won't Change Shalala Priority on Organ Recipients*, WIS. ST. J., Feb. 12, 2001, at A3.

124. See Organ Procurement and Transplantation Network Amendments Act of 2000, S.2366, 106th Cong. (2000).

125. See *id.*

126. See Organ Procurement and Transplantation Network Amendments of 2000, H.R. 2418, 106th Cong. § 9 (2000).

127. See generally Organ Procurement and Transplantation Network Amendments of 2000, S. 2366, 106th Cong. (2000).

128. See *A Transplant Compromise*, WASH. POST, Apr. 19, 2000, at A26. See also Marlene Cimens, *White House, Senators OK Plan for Organ Transplants*, L.A. TIMES, Apr. 13, 2000, at A12.

129. See Organ Procurement and Transplantation Network Amendments Act of 2000, S. 2366, 106th Cong. § 372(a)(2)(B) (2000).

The Senate bill required the OPTN to consult with Network participants and UNOS and to establish the policies and functions of the OPTN.<sup>130</sup> Once the policies and functions of the OPTN are proposed, the Senate bill required their submission to the Secretary.<sup>131</sup> The Secretary, after receiving the proposals, would determine if they are consistent with the proposed Senate act.<sup>132</sup> If the Secretary found the proposals inconsistent, OPTN would be given the opportunity to revise its proposals.<sup>133</sup> The Secretary would then determine whether the revised policies are consistent with the Act; if they are not, the revisions would be submitted to the Scientific Advisory Committee on Organ Transplantation ("Advisory Committee").<sup>134</sup>

The Advisory Committee would consist of twenty-one members: twelve transplant physicians or surgeons, and nine members distinguished in the health care field or who are transplant candidates, organ donors, or family members of such individuals. The members would be selected by the Secretary based in part on recommendations from the IOM and the OPTN.<sup>135</sup> Thirty days after the submission of the revisions to the Advisory Committee, the revisions would be approved or disapproved by a majority vote of the Advisory Committee.<sup>136</sup> If disapproved, the revisions would not take effect until approved by the Committee.<sup>137</sup>

While the notion of an independent Advisory Committee consisting of members knowledgeable of the transplant process is appealing, an Advisory Committee may do more harm than good. The Senate bill required that any policy proposed by OPTN be approved by the Advisory Committee before it could be enforced.<sup>138</sup> However, approval by the Advisory Committee may not be easily received on an issue that is the source of intense debate. The Senate bill has been criticized on this point because of the potential for delaying any actual changes in the transplant system.<sup>139</sup>

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130. *See id.* at § 372(c)(1)(A).

131. *See id.* at § 372(e)(1)(B)(i).

132. *See id.* at § 372(e)(1)(D)(i).

133. *See id.* at § 372(e)(1)(D)(ii).

134. *See id.* at § 372(e)(1)(E)(ii)(II).

135. *See id.* at § 372(e)(2)(C)(i)-(iii) ("The committee shall be composed of 21 members, of which (i) seven members shall be appointed . . . from nominations submitted by the [OPTN] . . . (ii) seven members . . . appointed . . . from nominations submitted by the [IOM] . . . and (iii) seven members shall be appointed by the Secretary.")

136. *See id.* at § 372(e)(1)(E)(iii).

137. *See id.*

138. *See id.*

139. *See A Transplant Compromise*, WASH. POST (Editorial), Apr. 19, 2000, at A26.

The Senate bill passed the Senate Health, Education, Labor and Pensions Committee unanimously.<sup>140</sup> However, compromise negotiations fell apart before the bill reached the Senate Floor.<sup>141</sup> The bill has not been reintroduced by Senator Frist in the 107th Congress, and as of the date of publication, Senator Frist had no plans to reintroduce the bill. Rather, he has opted to take a “wait and see” approach as to whether Secretary Thompson will overturn the Final Rule.

## 2. The House of Representatives Bill

The House version of the Organ Procurement and Transplantation Network Amendments Act of 2000 restated many of the powers of the OPTN that were given to it by NOTA.<sup>142</sup> The bill, introduced by Representative Michael Bilirakis, specifically provided that OPTN would carry out studies and demonstration projects to improve procedures for organ procurement and develop a peer review system to assure that OPOs comply with specified criteria.<sup>143</sup> The House bill reassigned the responsibility of promulgating an annual report on the status of organ transplantation from the Secretary to the OPTN.<sup>144</sup> This reassignment of responsibility demonstrates the House bill’s intent to assign a more passive role to the Secretary—that of oversight of the transplantation process.<sup>145</sup>

The most notable and controversial provision in the House bill was Section Nine, entitled “Nullification of Final Rule Relating to Organ Procurement and Transplantation Network.”<sup>146</sup> Section Nine proposed abolishing the force and legal effect of the Final Rule.<sup>147</sup> The HHS voiced its opposition to several of the provisions contained in the House bill, specifically the bill’s inaction on decreasing the reli-

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140. See Thomas, *Bill Summary and Status*, available at <http://thomas.loc.gov/cgi-bin/bdquery/z?d106:HR02418:@@L&summ2=m&> (last visited Nov. 10, 2000).

141. See *id.*

142. See Organ Procurement and Transplantation Network Amendments Act of 2000, H.R. 2418, 106th Cong. § 3 (2000).

143. See *id.* at § 3(e)(1).

144. See Organ Procurement and Transplantation Network Amendments Act of 2000, H.R. 2418, 106th Cong. § 4(a)(4)(A) (2000).

145. See Organ Procurement and Transplantation Network Amendments Act of 2000, H.R. 2418, 106th Cong. § 2(a)(3) (2000).

146. Organ Procurement and Transplantation Network Amendments Act of 2000, H.R. 2418, 106th Cong. § 9 (2000).

147. See *id.* (“Notwithstanding any other provision of law, the final rule relating to the Organ Procurement and Transplantation Network, promulgated by the [HHS] and published in the Federal Register on April 2, 1998 . . . and amended on October 20, 1999 . . . shall have no force or legal effect.”).

ance on arbitrary geographic boundaries in distributing organs,<sup>148</sup> and Section Three's erosion of HHS authority in the organ procurement process.<sup>149</sup>

The House bill was approved by the members of the House of Representatives on April 4, 2000 by a roll call vote of 275-147.<sup>150</sup> The bill was sent to the Senate Health, Education, Labor and Pensions Committee.<sup>151</sup> No action was taken on the bill prior the close of the 106th Congress, and as a result, the bill died. There has been no action taken to reintroduce this bill in the 107th Congress.

Representative Bilirakis, like Senator Frist, has elected not to reintroduce this piece of legislation into the 107th Congress. Rather, he has decided to focus on the ever-important issue of increasing organ donation. On February 14, 2001, Representative Bilirakis introduced a bill in the House that would amend the Public Health Service Act to promote organ donation.<sup>152</sup> The bill proposes that the Secretary make grants to OPOs for the purpose of "providing for the payment of travel and subsistence expenses incurred by individuals toward making living donations of their organs."<sup>153</sup> Additionally, the bill proposes several measures to increase public awareness in the importance of organ donation.<sup>154</sup>

#### IV. Analysis of National and Local Distribution Systems

As previously stated, Congress enacted NOTA to improve the organ procurement and allocation systems.<sup>155</sup> NOTA directed the HHS to establish a nationwide Organ Procurement and Transplantation Network that would keep a registry of donors and donees and distribute organs among regional organ procurement organizations.<sup>156</sup> The HHS enacted the Final Rule in response to criticism that the existing system was medically ineffective and resulted in inequitable dis-

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148. See *OPTN Hearing*, *supra* note 9, at 25 (statement of William F. Raub, Ph.D., Deputy Assistant Secretary for Science Policy) ("[T]he bill does nothing to decrease the reliance on arbitrary geographic boundaries and the equities that result.").

149. See *id.* at 26 ("H.R. 2418 would erode the role of the federal government in providing oversight of the OPTN . . . . The Department believes that it must continue to be an active partner with the private-sector in striving to fulfill the goals of the OPTN.").

150. 146 CONG. REC. H1722 (daily ed. Apr. 4, 2000).

151. See Thomas, *Bill Summary and Status*, at <http://thomas.loc.gov/cgi-bin/bdquery/z?d106:HR02418> (last visited Nov. 11, 2000).

152. See Organ Donation Improvement Act of 2001, H.R. 624, 107th Cong. (2001).

153. *Id.* at § 377(a)(1).

154. See *id.* at § 377(a)-(c).

155. See H.R. REP. NO. 575 (1983).

156. See 42 U.S.C. § 274(b)(2) (1994).

tribution.<sup>157</sup> Despite the HHS's denials that the Rule advocates for a national system of organ donation, it is apparent that the Rule vests in the Secretary alone the power to make determinations concerning the type of distribution system to be used. This raises the question as to what type of distribution system can best serve the intent of NOTA. This Section analyzes both the national and local distribution systems in an effort to provide some guidance in answering this question.

### A. Flaws in the Local Distribution System

Prior to the enactment of the HHS original Final Rule, organs were distributed through local OPOs.<sup>158</sup> The local OPO would check the list of patients awaiting transplants in the local area first.<sup>159</sup> If no match was found in the local area, the organ would be checked regionally, and if a match was still not found, it would be made available to patients nationally.<sup>160</sup> This distribution scheme has been the subject of much criticism because of the discrepancy in the supply of organs available to the various OPOs.<sup>161</sup> The "local first" system has also been criticized as unfair to low income and minority transplant patients.<sup>162</sup>

The local system of organ allocation was originally adopted because it was not scientifically feasible for organs to travel across the country for transplantation.<sup>163</sup> Organs have cold ischemic times,<sup>164</sup> varying depending upon the organ, which limit the time the organ can survive outside of the body.<sup>165</sup> Technological breakthroughs in recent years have increased the cold ischemic times for many organs, making it possible for them to live outside of the body longer, and increasing the feasibility of a national system of distribution.<sup>166</sup> As a result, the

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157. See 64 Fed. Reg. 56,650 (Oct. 20, 1999) (codified in 42 C.F.R. § 121).

158. See United Network for Organ Sharing, *Newsroom*, available at [http://www.unos.org/Newsroom/allabout\\_main.htm](http://www.unos.org/Newsroom/allabout_main.htm) (last visited Sept. 17, 2000).

159. See *id.*

160. See *id.*

161. See *OPTN Hearing*, *supra* note 9, at 34 (statement of Robert D. Gibbons, Member, Institute of Medicine).

162. See *id.* at 35.

163. See *Putting Patients First Hearings*, *supra* note 1, at 69 (statement of the Honorable Donna E. Shalala, Secretary, U.S. Department of Health and Human Services).

164. "Cold ischemic time" is the time when blood flow to the organ is stopped in the donor to the time that blood flow is restored in the recipient. See *IOM Report*, *supra* note 66, at 17.

165. See United Network for Organ Sharing, *Glossary*, at [http://www.unos.org/newsroom/glos\\_main.htm](http://www.unos.org/newsroom/glos_main.htm) (last visited Nov. 10, 2000).

166. See *IOM Report*, *supra* note 66, at 17.

notion of local allocation as the only means of organ procurement can be challenged.

### 1. Regional Discrepancies in Waiting Periods

An ardent criticism of the local first system is the fact that where a patient lives often determines how quickly she receives an organ.<sup>167</sup> The OPOs cover populations ranging from approximately one million to twelve million.<sup>168</sup> Within these populations, there are a disproportionate number of organs available for transplant. One critic noted that “liver patients needing transplants might wait 46 days in Iowa, but 721 days in western Pennsylvania. Similar disparities were found between New York, where a typical . . . wait [is] 511 days for a transplant, and . . . New Jersey, where waiting times average 56 days.”<sup>169</sup> Some states, like Wisconsin, have taken activist roles in the procurement of organs and do not wish to have their organs go to patients outside the state.<sup>170</sup> This is obviously beneficial to patients that by fortuity reside in those activist states—like Wisconsin—but it is quite unfortunate for transplant patients that live in less activist states or states that happen to have a low organ donation rate despite state encouragement of donation.

### 2. Most Needy Patients Do Not Get Organs

When organs are distributed locally first, they often go to patients in the state who are ranked as Status 2 or Status 3 patients. Status 2 and 3 patients are not nearly as ill as Status 1 patients and they do not need an immediate transplantation.<sup>171</sup> With a local distribution system, Status 2 and 3 patients in the local area get priority in receiving

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167. See *OPTN Hearing*, *supra* note 9, at 21 (statement of William F. Raub, Ph.D., Deputy Assistant Secretary for Science Policy).

168. See *id.* at 32 (statement of Robert D. Gibbons, Member, Institute of Medicine).

169. Sarah Yang, *U.S. Seeks to Overhaul Organ Transplant Policy*, L.A. TIMES, Mar. 1, 1999, at A1.

170. See *Surprise! HHS OPTN Final Rule Takes Effect March 16; What it Means and For How Long Remains Questionable*, 10 TRANSPLANT NEWS 6, Mar. 27, 2000 (quoting Wisconsin Attorney General James Doyle as stating: “Wisconsin patients are hurt by this new rule . . . . Because our state’s organ donation rates are high and our transplant centers are outstanding, Wisconsin patients usually get vital organs faster than other states. This new rule punishes us because we have been effective.”). See also John Tuohy, *Sickest to get Transplants First, Some Question Wisdom of Making Urgency, Not Location, Priority*, USA TODAY, Aug. 28, 2000, at D6 (quoting Tony Jewell, spokesman for Wisconsin Governor, stating “Wisconsin’s donor rate is double the national rate, so we feel like we are getting penalized for doing a good job if our organs go elsewhere”).

171. See *OPTN Hearing*, *supra* note 9, at 32 (statement of Robert D. Gibbons, Member, Institute of Medicine).

an organ over Status 1 patients in another state.<sup>172</sup> This system of distribution results in local, less needy patients getting an organ transplant at the expense of out-of-state patients who are in dire need of a transplant, simply because they are served by different OPOs.<sup>173</sup>

In its report, the IOM concluded that “because the probability of a suitable match between a donated liver and a [S]tatus 1 patient increases as the size of the population covered increases, . . . liver allocation should be established to cover an area large enough to serve at least 9 million people.”<sup>174</sup> Livers have one of the longest cold ischemic time of any organ, and are thus capable of transportation over a broader region.<sup>175</sup>

Critics of the local system of distribution doubt its effectiveness in providing organs to the most needy patients. The discrepancies in waiting periods between the various OPOs demonstrate the unfairness that arises in a local system of organ distribution. The problems that plague the local system of distribution are arguably lessened or eliminated by a national system of distribution; however, as discussed below, the national system is not without its share of difficulties and has been criticized as wasting organs, causing the closure of small and medium-sized OPOs, and discouraging organ donation.

## B. Flaws in a National Distribution System

The HHS justified its amended Rule as a means to overcome the “vast geographic disparities in waiting times for potential organ transplant recipients.”<sup>176</sup> The HHS also cited recent medical advances which overcome the need for local distribution of organs.<sup>177</sup> When the OPTN first established its local distribution system, the ischemic time for most organs was just a few hours. Medical advances have made it possible for livers to “be kept viable for transplantation up to eighteen hours [and] . . . [k]idneys can last from twelve to eighteen hours outside the human body.”<sup>178</sup> These tremendous scientific advances make a broader system of organ distribution more feasible. However, like the local system of distribution, a broader or national system of organ allocation is far from perfect.

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172. *See id.* at 33.

173. *See id.*

174. *Id.*

175. *See* United Network for Organ Sharing, *Glossary*, at [http://www.unos.org/Newsroom/glos\\_main.html](http://www.unos.org/Newsroom/glos_main.html) (last visited Nov. 10, 2000).

176. Chen, *supra* note 81, at 272.

177. *See id.*

178. *Id.*

## 1. Wasting Organs

During the comment period between the original Final Rule and its amendment, UNOS expressed concern that the Final Rule did not give adequate consideration to a transplant patient's survival potential in determining whether the patient is a suitable donee.<sup>179</sup> UNOS recommended that a transplant patient's survival potential be considered in determining the patient's eligibility for an organ.<sup>180</sup> Organ "wastage" is "more likely to occur when a patient's survival potential is relatively low compared to other eligible patients."<sup>181</sup> In other words, the best use of an organ may be to transplant it into a patient that is not as ill as other patients because that patient may take to the organ better and have a longer life after the transplant. There are many patients who need a transplant but are so ill that the likelihood of their surviving long with the transplanted organ is very low. The transplant story of baseball great Mickey Mantle illustrates this point. Mantle "received his liver transplant forty-eight hours after being listed on the transplant list and died two months later."<sup>182</sup> Mantle's transplant highlighted several of the serious flaws in the organ allocation system, including the potential for wastage, and the lack of clear guidelines prohibiting organ allocation based on status or fame.

## 2. Closure of Small and Medium-Sized Transplant Centers

One of the fears of opponents of a national transplant system is that local OPOs would be put out of business.<sup>183</sup> The concern is that "increasing the geographic areas over which organs are distributed would unduly favor large transplant centers,"<sup>184</sup> resulting in the closure of small and medium-sized centers.<sup>185</sup> Small and medium-sized centers often have a constituency composed of minority and low-income transplant patients; closure of these centers would be devastating to such patients.<sup>186</sup> The closing of these centers would also remove

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179. See United Network for Organ Sharing, *United Network for Organ Sharing United Network for Organ Sharing and the Organ Procurement and Transplantation Network Proposed Revised Regulations: The OPTN's Recommended Changes to the April 2, 1998, OPTN Final Rule*, at [www.unos.org/pdf/19990907\\_OPTNrevised.pdf](http://www.unos.org/pdf/19990907_OPTNrevised.pdf) (last visited Mar. 20, 2001).

180. See *id.*

181. *Id.*

182. Daubert, *supra* note 32, at 478.

183. See *Putting Patients First Hearing*, *supra* note 1, at 136 (statement of Dr. L. Hunsicker, President, UNOS).

184. IOM Report, *supra* note 66, at 43.

185. See *id.*

186. See *Putting Patients First Hearing*, *supra* note 1, at 136 (statement of Dr. L. Hunsicker, President, UNOS).



the visual reminder of the need for organs that often serves as the impetus for organ donation, "further exacerbat[ing] the existing organ shortage."<sup>187</sup>

However, under a national system of distribution, small and medium-sized centers will be benefited in ways not possible under a local distribution system. A national system will allow smaller centers with fewer donors to benefit by receiving organs from other centers to transplant into their critical patients "that would have been otherwise used by less urgent patients in the locale where the organ was donated."<sup>188</sup> Additionally, "if organs are allocated beyond the region where they are procured, a local region need not produce as many donors to ensure its patients are served."<sup>189</sup>

In addition to the benefits noted above, the IOM Report stated it found no evidence that there would be a limitation on minority or low-income patient access to organs.<sup>190</sup> The Report stated, "[f]or low-income patients, regardless of their racial or ethnic backgrounds, there is an appropriate concern that they may not be referred to a transplant center for an evaluation for transplantation."<sup>191</sup> It also concluded, based on available information, that smaller transplant centers are "not a major source of access for racial and ethnic minorities."<sup>192</sup>

### 3. Discouraging Organ Donations

Many state officials are concerned that an organ distribution system which allocates organs on a national, or even a non-national but broader allocation basis, would discourage organ donations.<sup>193</sup> They argue that organs are donated to assist those patients in a donor's

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187. Daniel Luke Geysler, *Organ Transplantation: New Regulations to Alter Distribution of Organs*, 28 J.L. MED. & ETHICS 95, 96 (2000).

188. *Id.* at 97.

189. *Id.*

190. See *OPTN Hearing*, *supra* note 9, at 33 (statement of Robert D. Gibbons, Member, Institute of Medicine). See also IOM Report, *supra* note 66, at 46.

191. *Id.* at 35.

192. *Id.* at 36.

193. See Sheryl Gay Solberg, *States Want to Keep Organs, Louisiana's Law Considered a Model*, TIMES-PICAYUNE, Mar. 11, 1999, at A11 (quoting Wisconsin Governor Tommy Thompson as saying, "in this state, we go out and aggressively encourage people to become donors, with me doing public service announcements. If I'm going to do that, I want those organs to stay in the state and take care of the patients that need it [sic] in Wisconsin.").

community, and donors will be less inclined to donate if they do not have any connection to the patient receiving the organ.<sup>194</sup>

However, a 1998 Gallup Poll on Organ Donation demonstrates that a broader system of organ sharing would not discourage donation.<sup>195</sup> The poll asked "if you were going to be an organ donor, if you learned that your organs would go to sick persons within your local region before they were offered to sicker persons elsewhere in the U.S. would you be more likely to want to donate?"<sup>196</sup> The report stated that "most adults say it would not affect their decision. However, 32% say if they knew the organ recipient was the sickest person, regardless of location, they would be more likely to donate an organ."<sup>197</sup> The poll demonstrates that donors are not as concerned with organs going to patients in their local region as they are with the organ going to the sickest patient.

Several measures have been taken in recent years by both the HHS and UNOS to encourage organ donation.<sup>198</sup> In December, 1997, Vice President Al Gore and HHS Secretary Shalala launched the National Organ and Tissue Donation Initiative ("NOTDI").<sup>199</sup> NOTDI focuses on building partnerships and increasing family discussions about decisions to donate, expanding opportunities for families to donate, and learning more about what works to promote donation and transplantation.<sup>200</sup> The goal of NOTDI is to increase organ donation by twenty percent within two years.<sup>201</sup> In 1998, the first full year of the NOTDI, organ donation increased 5.6%.<sup>202</sup>

In 1992, UNOS established the Coalition on Donation, a non-profit alliance of forty-eight national organizations and fifty local coalitions dedicated to educating the public about organ and tissue

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194. See John Tuohy, *Sickest to get Transplants First Some Question Wisdom of Making Urgency, Not Location, Priority*, USA TODAY, Aug. 28, 2000, at D6.

195. See IOM Report, *supra* note 66, at 52.

196. *Id.*

197. *Id.*

198. See Press Release, HRSA, *HHS Fact Sheet, National Organ and Tissue Donation Initiative*, at <http://www.HHS.gov/news/press/1999pres/990519.html> (May 19, 1999). See also *Coalition on Donation—Are you an organ and tissue donor?*, at <http://www.shareyourlife.org> (last visited Nov. 18, 2000).

199. See Press Release, HRSA, *HHS Fact Sheet, National Organ and Tissue Donation Initiative*, at <http://www.HHS.gov/news/press/1999pres/990519.html> (May 19, 1999).

200. See *id.*

201. See *OPTN Hearing*, *supra* note 9, at 70 (statement of the Honorable Donna E. Shalala, Secretary, U.S. Department of Health and Human Services).

202. See Press Release, HRSA, *HHS Fact Sheet, National Organ and Tissue Donation Initiative*, at <http://www.HHS.gov/news/press/1999pres/990519.html> (May 19, 1999).

donation, and encouraging organ donation.<sup>203</sup> These programs aimed at encouraging organ donation should help to alleviate the fears of those concerned that a broader allocation policy would discourage donation. As mentioned in Part III, the focus in Congress has shifted away from rejecting the Final Rule and toward a more concerted effort to increase organ donation. Such legislation, if enacted, along with the NOTDI initiative, are positive steps to ensure that organ donations will increase in the coming years.

## V. Proposal

Although a national system of organ allocation seems most able to carry out the purpose of NOTA, the HHS Final Rule allocates too much power to the Secretary to determine the distribution system to be used. A quasi-national system of organ distribution similar to that recommended by the IOM Report is the best solution.<sup>204</sup> The role of the Secretary should be circumscribed rather than expanded, and decisions concerning allocation policies should be left to the transplant healthcare specialists that are members of UNOS and the OPTN. Finally, serious efforts must be made to increase the number of organs available for transplantation—without transplantable organs, the type of distribution system used is irrelevant.

### A. Quasi-National System of Organ Distribution

Advances in medical technology have greatly increased the cold ischemic time for many organs, making it possible for them to survive outside the body for longer periods of time.<sup>205</sup> As previously stated, the relatively short ischemic time of organs was one of the reasons that a local system was proposed. However, scientific advances have made a broader system of organ distribution increasingly possible.

Due to a variance in cold ischemic time depending upon the organ, any organ allocation system must be organ specific. The IOM Report's first recommendation was the establishment of broader OAAs for livers.<sup>206</sup> The recommended population base for each OAA

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203. See *Putting Patients First Hearing*, *supra* note 1, at 148 (statement of Dr. L. Hunsicker, President, UNOS).

204. See IOM report, *supra* note 66, at 6–7.

205. See United Network for Organ Sharing, *Glossary*, at [http://www.unos.org/Newsroom/glos\\_main.htm](http://www.unos.org/Newsroom/glos_main.htm) (last visited Nov. 10, 2000) (observing that the preservation times for organs are as follows: Heart, 4–6 hours; liver, 12–24 hours; kidney, 48–72 hours; heart-lung, 4–6 hours; lung, 4–6 hours; pancreas, 12–24 hours).

206. See IOM Report, *supra* note 66, at 6.

is at least nine million people.<sup>207</sup> OPOs of this size have the ability to provide transplants to sicker patients without adversely affecting less sick patients.<sup>208</sup> The population base could be adjusted if the area served would be too large to accommodate the cold ischemic time of the organ. Though the IOM limited its recommendation to livers, if medically feasible, organs with a cold ischemic time of twelve hours or greater should be distributed to OAAs consisting of a population base of nine million people.

To alleviate concerns that broader distribution of organs would force small and medium-sized OPOs to shut down, the OAAs should be established by sharing agreements<sup>209</sup> among the OPOs, as recommended by the IOM Report,<sup>210</sup> rather than by consolidating existing OPOs. Such sharing agreements are currently in use and have been found to be effective.<sup>211</sup> In addition to sharing agreements, UNOS should take steps to create a policy to help small and medium-sized OPOs remain viable and able to serve the needs of the patients in their communities. Such a policy might provide that OPOs with too many organs on hand at a given time are required to give those organs to smaller OPOs having a difficult time satisfying the needs of their respective community. By implementing such a policy, UNOS would encourage and promote the use of sharing agreements. Additionally, a fund should be established to provide financial support to any small and medium-sized OPOs affected adversely by broader sharing.

These proposals will alleviate many of the criticisms associated with a national system of distribution. A quasi-national system provides a compromise between advocates of a local system of organ distribution and the supporters of a national system. A quasi-national system is the most medically feasible system because many organs do not have cold ischemic times that will allow them to be transported nationally. Finally, the establishment of broader OAAs through sharing agreements allows the states to maintain a large amount of control over organs donated by their citizens.

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207. *See id.*

208. *See id.* at 7.

209. A "sharing agreement" consists of two or more states agreeing to share organs donated with the other members. *See generally* IOM Report, *supra* note 66.

210. *See id.*

211. *See id.*

## B. Discontinue Use of Waiting Time As an Allocation Criterion

As recommended by the IOM Report, waiting time should not be a criterion for organ allocation because waiting time does not correlate with need, resulting in less ill patients receiving scarce organs.<sup>212</sup> The IOM report stated:

The heterogeneity and wide range of severity of illness in statuses 2B and 3 make waiting time relatively misleading within these categories. For this reason, waiting time should be discontinued as an allocation criterion for [S]tatus 2B and 3 patients. An appropriate medical triage system should be developed to ensure equitable allocation of organs to patients in these categories. Such a system, may, for example, be based on a point system arising out of medical characteristics and disease prognoses rather than waiting times.<sup>213</sup>

UNOS should undertake a study to identify criteria causing a patient to be in "more urgent" need of a transplant. The findings should then be used to promulgate a uniform point system which transplant physicians would be required to follow when adding a patient to a transplant waiting list. It is imperative that the point system be detailed to assure transplant physicians will be able to accurately diagnose their patient's needs. The system must also have an enforcement mechanism to safeguard against abuse of discretion by transplant physicians. A check must be placed on each physician's determination, and sanctions must be available for those physicians who overstate their patient's need. The purpose of NOTA was to establish "an equitable policy and system . . . so that individuals throughout [the] country have access to organ transplantation when appropriate and necessary."<sup>214</sup> This goal can only be effectuated if organs are distributed based on medical necessity.

## C. Limited Role of the HHS in the Organ Transplantation System

Though the IOM Report recommended greater federal oversight,<sup>215</sup> such oversight must be circumscribed to prevent the Secretary from unilaterally making decisions regarding the organ distribution system. NOTA gave the Secretary the authority to "make grants for the planning of qualified organ procurement organiza-

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212. *See id.*

213. *Id.* at 90.

214. 130 CONG. REC. S8742 (1984) (statement of Sen. Hatch).

215. *See* IOM Report, *supra* note 66, at 131.

tions.”<sup>216</sup> The Act also gave the Secretary the authority to “provide for the establishment and operation of an Organ Procurement and Transplantation Network.”<sup>217</sup> The Act limited the Secretary’s role to informing the public of the need for organ donations, providing technical assistance to OPOs and the OPTN, and submitting an annual report to Congress on the status of organ donation and an analysis of the efficiency and effectiveness of the procurement and allocation of organs.<sup>218</sup> The Secretary’s role as set forth in NOTA is one of oversight, not active participation.

NOTA explicitly gave the authority of recommending policies for the procurement of organs to the OPOs<sup>219</sup> and the OPTN.<sup>220</sup> The amended Rule vests policy making decisions in the OPTN contractor (UNOS).<sup>221</sup> However, it subjects any policy made by OPTN to Secretarial review.<sup>222</sup> The amended Final Rule, as codified, states that OPTN, when transmitting a proposed policy to the Secretary, should include “supporting material . . . as the Secretary may require to assess the likely effects of policy changes and as are necessary to demonstrate that the proposed policies comply with the performance indicators.”<sup>223</sup> This provision gives the Secretary the power to unilaterally accept or reject any policy proposed by OPTN.

Federal oversight is vital to ensuring an effective and fair system of organ distribution. However, the oversight of the organ donation system should be carried out by an independent scientific board as recommended by the IOM Report.<sup>224</sup> The board’s membership should include transplant physicians, scientists, representatives from the OPOs, transplant patients, and donors. The board should have primary responsibility of overseeing the organ procurement and donation process, and should have the authority to review the policies proposed by the OPTN contractor. Such an independent board will ensure fairness in the system and prevent the Secretary of HHS, a po-

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216. National Organ and Transplantation Act, Pub. L. No. 98-507, § 372 (codified at 42 U.S.C. § 273) (1984).

217. *Id.* at § 374.

218. *See id.* at § 375.

219. *See id.* at § 371 (stating that the board of directors of an OPO “has the authority to recommend policies for the procurement of organs”).

220. *See id.* at § 372 (stating that the OPTN shall “adopt and use standards of quality for the acquisition and transportation of donated organs”).

221. *See* Organ Procurement and Transplantation Network, 42 C.F.R. § 121.4(a) (2000).

222. *See id.* at § 121.4(b).

223. *Id.*

224. *See* IOM Report, *supra* note 66, at 14–15.

litical appointee, from furthering a political agenda by unilaterally electing a system of organ donation.

#### **D. Promote Organ Donation**

The most important recommendation of this Comment is to promote organ donation. If the supply of organs were adequate to meet the needs of all patients awaiting a transplant, the debate over a national or local system of distribution would be moot. Unfortunately, the available supply of suitable organs is far from adequate. It is imperative that the organizations involved in the organ donation and transplantation process work together to inform the public of the need for organ donation and to encourage the public to donate their organs.

Steps must be taken on both state and national levels to provide awareness of the need for organs. Measures, such as the one proposed by Representative Bilirakis and discussed previously, are a step in the right direction. Funds must be established to ensure donors do not bear any of the costs associated with donating their organs. Pennsylvania has proposed a controversial method to encourage organ donation.<sup>225</sup> The proposal would “help defray the organ donor’s family funeral expenses by providing \$300 from a special state fund directly to the funeral home that handles the donor’s burial arrangements.”<sup>226</sup> The controversy surrounding the proposal lies in the concern that the state is essentially paying for organs, which is prohibited by NOTA.<sup>227</sup> However, advocates of the proposal argue since the funeral home is paid directly, there is no direct compensation to the deceased’s family.<sup>228</sup>

Additionally, recognition of organ donors might provide an incentive to donate. The option to donate an organ should be available when applying for a driver’s license. Secretary Thompson has urged Americans to “talk with their families about organ donation and designate their wish to give life on their driver’s license or by signing a donor card.”<sup>229</sup> Secretary Thompson has also called on doctors to “tell Americans about the need for transplants.”<sup>230</sup> It is imperative the word be spread to all Americans about the necessity of organ dona-

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225. *See id.* at 58.

226. *Id.*

227. *See id.*

228. *See id.*

229. United Network for Organ Sharing, *Newsroom*, available at [http://www.unos.org/Newsroom/archive\\_story\\_20010314\\_tommythompson.htm](http://www.unos.org/Newsroom/archive_story_20010314_tommythompson.htm) (last visited Apr. 5, 2001).

230. *Id.*

tion. Additionally, the process of registering as an organ donor must be simplified to ensure no barriers exist to the increase of organ donations.

### **Conclusion**

The ability of physicians to take an organ from one human being and place it in another human being to save a life is truly miraculous. As medical technology advances, allowing patients waiting for an organ transplant to live longer, the need for organs will greatly increase. In an ideal world, there would be enough organs to satisfy the need. However, the world we live in is far from ideal and we must take action to ensure that those who need an organ transplant get one. There is unanimous agreement that measures to encourage and increase organ donation must be taken to save the nearly 4,000 patients that die annually while waiting for a transplant.

Parties have diverged, however, upon the issue of allocating the organs which are donated. The HHS Final Rule initially recommended a national organ allocation system, but later adopted the recommendation of the IOM Report suggesting OAAs of nine million people. Several states have taken extreme measures to see that organs donated in the state do not leave the state unless a suitable donor cannot be found there. Congress too has attempted to limit the effect of the Final Rule, but was unsuccessful in getting such legislation passed before the conclusion of the 106th Congress.

A cautious approach to organ allocation is necessary, as both the Final Rule and its opponents attempt to adjust and formulate a delicate system of organ allocation while the lives of thousands of Americans hang in the balance. The Final Rule promulgated by the HHS properly recognized that the existing system was flawed. The disparities in waiting times based on geography that resulted in the pre-Rule system clearly did not carry out the intent of NOTA in establishing an equitable organ allocation system. However, the Final Rule attempted to correct the problem in the wrong way. Rather than vest power to make decisions about organ distribution in a neutral, knowledgeable body of members of the transplant community, the Final Rule vests much of the decision-making power in a single political appointee, the Secretary of HHS. To ensure that policies regarding organ distribution are equitable and efficient, the role of the Secretary should be circumscribed rather than expanded, and the ultimate decision-making authority should lie with those most connected to the issue—transplant patients and physicians.