IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WISCONSIN

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THE STATE OF WISCONSIN, THE UNIVERSITY OF WISCONSIN HOSPITALS AND CLINICS AUTHORITY, FROEDTERT MEMORIAL LUTHERAN HOSPITAL, OREGON HEALTH SCIENCES UNIVERSITY and THE STATE OF NEW JERSEY,

Plaintiffs,

v.

DONNA E. SHALALA, Secretary, United States Department of Health and Human Services, in her official capacity,

Defendant.

OPINION AND ORDER

00-C-155-C

- -

In this civil action for declaratory and injunctive relief, plaintiffs state of Wisconsin, University of Wisconsin Hospitals and Clinics Authority, Froedtert Memorial Lutheran Hospital, Oregon Health Sciences University and the state of New Jersey challenge 42 C.F.R. part 121, which is the amended final rule governing the operation of the organ procurement and transplantation network. Plaintiffs seek to prevent defendant Donna Shalala, Secretary of the Department of Health and Human Services, from violating the National Organ

Transplant Act by promulgating rules on subjects, including organ allocation policies, that exceed the authority given her under the act. This action arises under the National Organ Transplant Act, 42 U.S.C. § 273-274g. Jurisdiction is present under 28 U.S.C. § 1331.

Presently before the court is defendant's motion to dismiss the complaint pursuant to Fed. R. Civ. P. 12(b)(1). Defendant contends that plaintiffs lack standing to challenge the regulation that is the subject of this action and that there is no ripe case or controversy with respect to that regulation. I conclude that defendant is correct. None of the plaintiffs has standing to bring this action because none has suffered an actual injury. The plaintiff states cannot sue the federal government in their parens patriae capacity and the plaintiff hospitals have no basis for their claim that they are injured by defendant's assertion of control over the policies governing the organ procurement and transplantation network.

Also before the court is the motion to intervene filed by the state of Louisiana, Louisiana Organ Procurement Agency, Louisiana State University School of Medicine at Shreveport through the Board of Supervisors of the Louisiana State University and Agricultural & Mechanical College and Louisiana State University School of Medicine at New Orleans through the Board of Supervisors of the Louisiana State University and Agricultural & Mechanical College. Because defendant's motion to dismiss will be granted, the motion to intervene will be denied as moot.

For the sole purpose of deciding this motion to dismiss, I find as fact the allegations of the complaint.

ALLEGATIONS OF FACT

I. PARTIES

Plaintiff State of Wisconsin brings this action in its capacity as parens patrie for the citizens of Wisconsin. Plaintiff University of Wisconsin Hospital and Clinics Authority is a member of the organ procurement and transplantation network and is organized under Wis. Stat. ch. 233. Plaintiff Froedtert Memorial Lutheran Hospital is a hospital licensed under Wis. Stat. ch. 50 and is a certified federal Medicare provider under the Social Security Act. Plaintiff Froedtert Hospital is a member in good standing of the organ procurement and transplantation network and is a designated organ procurement organization pursuant to section 1138 of the Social Security Act. Plaintiff Froedtert Hospital is also an organ transplant center, performing over 150 transplants annually. Plaintiff Oregon Health Sciences University is a public corporation organized and existing under the laws of the state of Oregon, with its principal place of business in Portland, Oregon. Plaintiff Oregon Health Sciences University is a certified Medicare provider, a member in good standing of the organ procurement and transplantation network, a designated organ procurement organization and a transplant center performing over

200 transplants annually. Plaintiff State of New Jersey sues in its capacity as parens patriae for the citizens of New Jersey.

Defendant Donna Shalala is Secretary of the United States Department of Health and Human Services.

II. THE NATIONAL ORGAN TRANSPLANT ACT - 1984

In 1984, Congress passed the National Organ Transplant Act. At that time, the number of patients waiting for organ transplants far surpassed the number of available organs. Congress found that organ transplants were unavailable to most persons because of the shortage of donated organs, the enormous cost involved and the small number of medical centers equipped to carry out organ transplants. In order to assist the private sector and make its efforts more efficient, Congress stated that responsibility for organ procurement and allocation should lie "in the private sector rather than in government." The bill's summary in the Senate Report stated explicitly that the act "[p]rovides that the Secretary [of Health and Human Services] shall assure the establishment and operation in the private sector of an Organ Procurement and Transplantation Registry. . ." The act provided for grants for the planning, establishment, initial operation and expansion of "qualified organ procurement organizations." The act requires organ procurement organizations to arrange with hospitals and other health

care entities in their service areas to identify all potential organ donors and to make efforts to acquire all usable organs from potential donors. The act also required organ procurement organizations to have a geographic service area large enough to include at least fifty potential donors. Finally, the act required organ procurement organizations to have a system to "allocate donated organs among transplant centers and patients according to established medical criteria."

The act directed the Secretary of Health and Human Services to contract with a private nonprofit entity with an expertise in organ procurement and transplantation to establish and operate an organ procurement and transplantation network whose board of directors would include representatives of organ procurement organizations, transplant centers, voluntary health associations and the public. The act required the organ procurement and transplantation network to establish a national list of individuals needing organs and a national system "in accordance with established medical criteria" to match organs and individuals on the list. The network is directed to "assist organ procurement organizations in the distribution of organs" that cannot be placed within the service area of the organ procurement organization. The act gave the defendant Secretary only the limited authority to establish procedures for

> (1) receiving from interested persons critical comments relating to the manner in which the Organ Procurement and Transplantation Network is carrying out the duties of the Network . . . ; and

(2) the consideration by the Secretary of such critical comments.

The act gave organ procurement organizations and the organ procurement and transplantation network the authority to create organ allocation policy. The act states that each organ procurement organization shall "have a system to allocate donated organs equitably among transplant patients" and the organ procurement and transplantation network shall "establish membership criteria and medical criteria for allocating organs" and "assist or gain procurement organizations in the nationwide distribution of organs equitably among transplant patients."

III. THE OMNIBUS BUDGET RECONCILIATION ACT - 1986

In 1986, Congress amended the Social Security Act to insert § 1138, which requires organ procurement organizations and hospitals to follow organ procurement and transplantation network policies as a prerequisite for Medicare and Medicaid reimbursement.

IV. THE NATIONAL ORGAN TRANSPLANTATION ACT AMENDMENTS - 1988

In response to the addition of § 1138 to the Social Security Act, Congress amended the National Organ Transplant Act in 1988 to require the organ procurement and transplantation network to establish a public comment and hearing process for review of its membership and organ allocation criteria that would be similar to the process required of government agencies.

The 1988 amendments required the organ procurement and transplantation network, and not defendant, 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."

Congress reaffirmed that the organ procurement and transplantation network maintained sole authority to "resolve any issues regarding the fair and effective distribution of organs." The 1988 amendments also revised the requirement that an organ procurement organization geographic service area "be large enough that it is reasonable to expect the agency to procure organs from at least 50 donors." Finally, the 1988 amendments made it clear that "the [organ procurement organization] is responsible for allocating organs equitably among the patients who are in need of a transplant."

V. THE NATIONAL ORGAN TRANSPLANT ACT AMENDMENTS - 1990

In 1990, Congress amended the act again and directed the organ procurement and transplantation network to "assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients." Congress reiterated that "[t]he [organ procurement and transplantation network] board of directors makes policy decisions on such matters as assuring that the organ sharing system is fair and equitable. . . ." The 1990 amendments made additional refinements in the organ procurement organization service areas,

requiring the Secretary of Health and Human Services to "establish criteria" by regulation to insure that an organ procurement organization "has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs. . . ."

VI. THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK'S ESTABLISHMENT OF ORGAN ALLOCATION POLICY

In 1986, the Department of Health and Human Services contracted with the United Network for Organ Sharing to establish and operate the organ procurement and transplantation network. The contract has been renewed and extended several times since 1986 and is currently in effect. The membership of the United Network for Organ Sharing includes every transplant center, organ procurement organization and tissue typing laboratory in the United States, as well as 29 medical or scientific organizations, 12 voluntary health organizations and 9 general public members. As a practical matter, the United Network for Organ Sharing membership is the organ procurement and transplantation network. United Network for Organ Sharing has a 40-member board of directors that includes donor families, transplant candidates and recipients, organ recovery professionals, histocompatibility specialists, representatives of voluntary health organizations and experts in the fields of

medicine, ethics, religion, law, social and behavioral sciences, research and health care financing.

United Network for Organ Sharing adopts organ allocation policies after hearing and considering the views of its members, the public, the federal government and interested individuals in the health care community. Its organ allocation policies balance the following principles: (1) enhancing the overall availability of transplantable organs; (2) allocating organs based on medical criteria, with equal consideration given to medical utility and equity; (3) providing transplant candidates reasonable opportunities to be considered for an organ within comparable time periods; and (4) respecting individual autonomy. The overwhelming majority of transplant centers, organ procurement organizations and other members of the transplant community support United Network for Organ Sharing's organ allocation policies.

VII. THE NOTICE OF PROPOSED RULEMAKING

On September 8, 1994, the public health service of the Department of Health and Human Services published in the Federal Register a notice of proposed rulemaking for a rule governing the operation of the organ procurement and transplantation network. The notice allowed for public comment on the proposed rule until December 7, 1994. The department extended this date until December 13, 1996.

Consistent with the National Organ Transplant Act's language, as well as the practice since the act's passage, the proposed rule recognized the organ procurement and transplantation network's exclusive statutory authority to develop organ allocation policy. It stated:

> (I) The OPTN Board of Directors shall be responsible for developing, with the advice of the OPTN membership and other interested parties:
>
> . . .
>
> (B) medical criteria and related policies for the fair and equitable allocation of human donor organs[.]

The secretary's role under the proposed rule was to oversee "the processes by which the [organ procurement and transplantation network] allocates organs for transplantation" and to "ensur[e] that those processes are fair and equitable, and provide for public participation." The Department of Health and Human Services never adopted the proposed rule.

VIII. FINAL RULE - APRIL 2, 1998

On April 2, 1998, the Health Resources and Services Administration of the Department of Health and Human Services published in the Federal Register a final rule governing the operation of the organ procurement and transplantation network. The final rule was to be codified at 42 C.F.R. pt. 121. The final rule bore no resemblance to the September 1994 proposed rule and was tantamount to a new rule designed and implemented without notice to

the general public and the transplant community and with no opportunity for prior comment. The final rule stated that "[organ procurement organization] areas should not be the primary vehicle for organ allocation" and abandoned the National Organ Transplant Act's stated requirement that organ procurement organizations make organ allocation decisions according to policies of the organ procurement and transplantation network. The new organ allocation policy essentially mandated a single national list of patients with priority to the "sickest patients first." Unlike the proposed rule, the final rule vested ultimate control of organ allocation policy with defendant instead of with the organ procurement and transplantation network. The final rule states that the organ procurement and transplantation network must develop policies that reflect defendant's policies, as expressed in the regulation.

The final rule required the organ procurement and transplantation network to submit all proposed policies (including allocation policies) to defendant thirty days prior to their proposed implementation and provided that the policies would not be enforceable unless approved by defendant. If defendant is dissatisfied with the network's policies, the final rule provided that "the [organ procurement and transplantation network] may be directed to revise the policy consistent with the Secretary's direction." The final rule included a provision permitting the organ procurement and transplantation network, its members or other individuals who objected to policies developed by defendant to submit an appeal to defendant.

An overwhelming majority of leading experts within the transplant community condemned the final rule.

The final rule stated that it would take effect on July 1, 1998. Although the rule was already "final," it provided that the Department of Health and Human Services would accept comments until June 1, 1998. On May 1, 1998, Congress extended the period for submitting comments on the final rule until August 31, 1998, and extended the effective date of the final rule until October 1, 1998. On July 1, 1998, the Department of Health and Human Services published in the Federal Register an "Extension of Comment Period and Delay of Effective Date for the Organ Procurement and Transplantation Network." This document extended the final rule's comment period to August 31, 1998. The document also provided that October 1, 1998, would be the final rule's new effective date.

In October 1998, Congress passed the Omnibus Consolidated and Emergency Supplemental Appropriations Act for 1999. Section 213 of that act provided that the final rule "shall not become effective before the expiration of the 1-year period beginning on the date of the enactment of this Act." Section 213 directed the Institute of Medicine to conduct a review of the current policies of the organ procurement and transplantation network and the final rule and to report the results of its review to the appropriate congressional committee. In addition, § 213 encouraged defendant to "conduct a series of discussions with the [organ

procurement and transplantation network] in order to resolve the issues raised by the final rule" and authorized the use of a mediator to conduct the discussions.

IX. OCTOBER 20, 1999 AMENDMENTS TO APRIL 2, 1998, FINAL RULE

On October 20, 1999, the Health Resources and Services Administration of the Department of Health and Human Services published in the Federal Register amendments to the final rule that purportedly addressed issues raised by the transplant community during the comment period and by the Institute of Medicine report. The amended final rule sought no comments or feedback from affected members of the transplant community and stated that it would take effect on November 19, 1999. The amended final rule strengthens defendant's authority over the organ procurement and transplantation network policymaking process compared to the April 2, 1998 final rule. The amended final rule requires the organ procurement and transplantation network to submit its proposed policies to defendant sixty (rather than the original thirty) days prior to their proposed implementation and gives defendant the power to determine whether the proposed policies are consistent with the National Organ Transplant Act. The amended final rule imposes a tax in the form of a patient registration fee.

The amended final rule purports to give defendant the power to overrule organ

procurement and transplantation policies already in effect when she receives "critical comments" on them and decides there is a "possible risk to the health of patients or to public safety." In such cases, defendant can "[d]irect the [organ procurement and transplantation network] to revise the policies or practices consistent with the Secretary's response to the comments[,]" or "[t]ake such other action as the Secretary determines appropriate." The amended final rule removes the language in the April 2, 1998 final rule that would have permitted the organ procurement and transplantation network, its members or other individuals objecting to defendant's policies to submit an appeal to defendant. By adding substantial additional levels of review before proposed allocation policies can be implemented, the amended final rule impedes the organ procurement and transplantation network's ability to comply with Congress's mandate that proposed organ allocation policies receive public comment and public hearing through the organ procurement and transplantation network prior to adoption.

The amended final rule requires that significant proposed organ procurement and transplantation network policies be referred to defendant's advisory committee on organ transplantation and then published in the Federal Register for public comment. The amended final rule requires defendant to determine whether the proposed policies are consistent with the National Organ Transplant Act and the Department of Health and Human Services'

regulations, taking into account the comments of defendant's advisory committee and the public. The amended final rule allows defendant to provide comments to the organ procurement and transplantation network or to direct the network to revise the policy consistent with her direction. Finally, "[i]f the [organ procurement and transplantation network] does not revise the proposed policy in a timely manner, or if the Secretary concludes that the proposed revision is inconsistent with the National Organ Transplant Act or this part, the Secretary may take such other action as the Secretary determines appropriate, but only after additional consultation with the Advisory Committee [about] the proposed action."

On November 29, 1999, § 210 of the Labor, Health and Human Services Education, and Related Agencies Appropriations Act imposed a 42-day moratorium on the implementation of the amended final rule. On December 17, 1999, President Clinton signed into law the Ticket to Work and Work Incentives Improvements Act of 1999, staying the amended final rule for 90 days upon the date of enactment and requiring defendant to solicit and review comments on the amended final rule. On December 21, 1999, the Department of Health and Human Services announced the establishment of a 60-day comment period on the amended final rule and amended the amended final rule to create an effective date of March 15, 2000. The amended final rule became effective on March 16, 2000.

OPINION

I. MOTION TO DISMISS

A. Standing

Plaintiffs do not challenge any specific policy implemented by defendant but instead contend that she lacks statutory authority under the National Organ Transplant Act to overrule the policies of the organ procurement and transplantation network. The hospital plaintiffs contend that they are injured as members of the organ procurement and transplantation network because defendant has stripped the network of its final policymaking authority. The state plaintiffs argue that they are injured because "the Secretary's usurpation of [the network's] policymaking authority deprives Wisconsin's citizens of the benefits of the federal system of organ allocation policy which [the National Organ Transplant Act] gives solely to [the organ procurement and transplantation network]" and "deprives Wisconsin citizens of their legitimate expectation under the state's Uniform Anatomical Gift Act that donated organs will be allocated to and from the state's citizens through organ procurement organizations in accordance with [the organ procurement and transplantation network]'s procurement and allocation policies." Id. Plts.' Br., dkt. # 13, at 3.

Article III standing is a component of subject matter jurisdiction; without a cognizable Article III injury, this court has no power to hear this case. Plaintiffs bear the burden of

establishing their standing to sue. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992). To establish standing, plaintiffs must show that they have suffered an "injury in fact," meaning an injury that is concrete and particularized and actual or imminent, not conjectural or hypothetical. They must also show a causal connection between their injury and the conduct complained of and that the injury will likely be redressed by a favorable decision. See id. at 560-61.

1. Hospitals

a. Procedural injury

Citing footnote 8 in Lujan, 504 U.S. at 573, the hospital plaintiffs contend that they have suffered a procedural injury from defendant's assertion of final policymaking authority under the National Organ Transplant Act. The hospital plaintiffs do not base their claim of standing on the interests of their transplant patients, but instead assert their own rights as beneficiaries of the policy development system established by the National Organ Transplant Act.

Defendant contends that plaintiffs' argument is analogous to the argument rejected by the Supreme Court in Raines v. Byrd, 521 U.S. 811 (1997). In Raines, the Court held that individual members of Congress did not have standing to challenge the Line Item Veto Act,

which allegedly injured them by altering the effect of their votes on bills containing items subject to separate vetoes, divesting them of their constitutional role in the repeal of legislation and altering the constitutional balance of powers between the legislative and executive branches. See id. at 816. The Court concluded that the members of Congress failed to allege any injury to themselves as individuals; the institutional injury alleged was wholly abstract and widely dispersed; and the members' attempt to litigate the dispute was contrary to the legislative and executive branches' historical practice of resolving such disputes among themselves without involving the judiciary. See id. at 829. The first two reasons for denying standing apply in almost the same way to plaintiffs here. The individual hospital plaintiffs are solely members of the organ procurement and transplantation network and cannot create network policy. In Raines, the Court attached importance to the fact that the members of Congress had not been authorized to represent their respective Houses of Congress, see id.; similarly, plaintiffs are not suing as representatives of the organ procurement and transplantation network. The only entity allegedly injured by the change in ultimate decision making authority implemented by the amended final rule is the organ procurement and implementation network; the hospital plaintiffs have failed to allege any injury to themselves.

Plaintiffs compare their situation to that addressed by the Court of Appeals for the Ninth Circuit in Gorbach v. Reno, 219 F.3d 1087 (9th Cir. 2000). Naturalized citizens who

had been served with notices of intent to revoke their naturalization by the Immigration and Naturalization Service sued the Attorney General, alleging she lacked statutory authority to promulgate a regulation that allowed naturalization to be revoked in an administrative proceeding. In contrast to the naturalized citizen plaintiffs in Gorbach, the hospital plaintiffs are not alleging that their policies are subject to an allegedly unauthorized administrative review. Instead, it is the policies of the organ procurement and transplantation network that are subject to such review. Although the hospital plaintiffs are members of the network, they are not suing on behalf of the network. Thus, they lack standing to challenge defendant's review of the network's policies. Because the hospital plaintiffs do not base their procedural injury on a concrete interest possessed by the hospitals themselves, they lack standing to challenge the amended final rule. See Lujan, 504 U.S. at 573 n.8 ("We do *not* hold that an individual cannot enforce procedural rights; he assuredly can, so long as the procedures in question are designed to protect some threatened concrete interest of his that is the ultimate basis of his standing.").

b. Financial injury

The hospital plaintiffs also contend that the amended final rule injures them financially by requiring them to pay a larger share of the network's operations than they pay currently and

by imposing the additional costs of complying with the administrative procedures required by the amended final rule. They challenge that aspect of the amended final rule that requires network members to pay a registration fee to the network for each transplant candidate they place on the national waiting list. See 42 C.F.R. § 121.5(c). The fee covers "reasonable costs of operating the OPTN and shall be determined by the OPTN with the approval of the Secretary." Id.

Plaintiffs' argument fails for several reasons. First, plaintiffs do not allege that they pay the registration fee themselves. 42 C.F.R. § 121.5(c) requires an organ procurement and transplantation network member to "pay a registration fee to the [network] for each transplant candidate it places on the waiting list." The likelihood is that plaintiffs would pass this fee on to their patients and therefore suffer no extra cost themselves. However, it is impossible to determine from the complaint who pays the fee. Plaintiffs' only allegation regarding the fee in the second amended complaint is part of a legal conclusion asserting, among other things, that the amended final rule "impos[es] an unauthorized tax in the form of a patient registration fee." Second Am. Cpt., dkt. # 18, ¶ 95.

Second, even if plaintiffs had made a sufficient allegation of direct financial injury, they cite no authority that suggests that the imposition of such a fee would constitute an injury-in-fact. My own research found no support for this claim. Plaintiffs do not suggest they have a

right to participate in the network for free; indeed, they were subject to a fee before the promulgation of the amended final rule.

To the extent that plaintiffs' argument depends on the fact that defendant and not the organ procurement and transplantation network sets the fee, plaintiffs lack standing for the same reason they lack standing to challenge defendant's assertion of ultimate policymaking authority. The organ procurement and transplantation network could have raised the fee at any time; its doing so would not have given plaintiffs standing to bring a federal lawsuit in response. The hospital plaintiffs' injury is no greater when the fee is raised by defendant. To illustrate this point, it is helpful to look outside the pleadings to defendant's Notice Concerning Award of OPTN Contract that was filed on October 3, 2000. Although the patient registration fee has increased from $379 a patient to $404 a patient under the amended final rule, defendant did not set that number but merely approved it as reasonable. See Dft.'s Notice, dkt. # 21, at 2. Nothing in the complaint or the briefs suggests that this fee would not have been raised were the amended final rule not in effect. I conclude that plaintiffs have failed to show their injury was caused by the amended final rule or that it would be redressed by an injunction preventing the amended final rule's enforcement.

Finally, plaintiffs contend that being forced to pay the cost of the administrative review imposed by defendant confers standing to sue upon them. In support, plaintiffs point to

language in Hays v. City of Urbana, Illinois, 104 F.3d 102, 104 (7th Cir. 1997) (citing Abbott Laboratories v. Gardner, 387 U.S. 136, 153-54 (1967)), where the court of appeals noted that "businesses potentially affected by a regulation may pursue pre-enforcement challenges to learn whether they must incur the costs of compliance." However, the court's holding does not help plaintiffs. In Hayes, the plaintiff landlords argued that they would be injured if the city ordinance forced them to accept Section 8 tenants, because they would then have to enroll in the Section 8 program, which they claimed was a costly process. See Hayes, 104 F.3d at 104. The court of appeals held that the landlords did not have standing because they did not allege that their housing qualified for the Section 8 program or that the ordinance required them to bear the costs of compliance. Plaintiffs are members of the organ procurement and transplantation network, but their complaint is entirely devoid of any allegation that compliance with the administrative review system set in place by the amended final rule will impose any additional costs on the network, let alone costs that will be passed on to the hospital plaintiffs. I conclude that the hospital plaintiffs lack standing to bring this lawsuit.

2. States

a. Parens patriae capacity

"[A] state may not bring a parens patriae suit against the federal government." Illinois

Dept. of Transportation. v. Hinson, 122 F.3d 370, 373 (7th Cir. 1997) (citing Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez, 458 U.S. 592, 610 n.16 (1982)). In Hinson, the Illinois Department of Transportation sought to challenge the Federal Aviation Administration's interpretation of the Federal Aviation Act, that is, it challenged a federal agency's interpretation of a federal statute. Therefore, it is on point with this case. The Court of Appeals for the Seventh Circuit determined that the state lacked standing to bring the case, noting that "a state does not have standing as the Good Shepherd of its citizens to bring suits in federal court to enforce their purely personal rights." Id. at 373. The United States, and not individual states, represents citizens as parens patriae in the citizens' relations with the federal government. See Massachusetts v. Mellon, 262 U.S. 447, 485-86 (1923) ("[i]t cannot be conceded that a State, as parens patriae, may institute judicial proceedings to protect citizens of the United States from the operation of the statutes thereof."). Plaintiffs State of Wisconsin and State of New Jersey may not bring this action in their capacity as parens patriae.

b. Sovereign capacity in defense of state law

The state plaintiffs are clear in their complaint that they are suing solely in their capacity as parens patriae for the citizens of Wisconsin and New Jersey. See 2d Am. Cpt. at ¶¶ 1, 5. However, in its brief, plaintiff State of Wisconsin argues that it also has standing on

its own behalf to assert its sovereign interest in protecting state law from being frustrated by federal agency regulations. (The briefs were filed before State of New Jersey became a plaintiff in the second amended complaint.) Plaintiff alleges that the public policy of Wisconsin, as demonstrated by its Uniform Anatomical Gift Act, Wis. Stat. § 157.06, is to follow the allocation policies of the organ procurement and transplantation network.

As defendant points out, there is no inconsistency between Wisconsin's Uniform Anatomical Gift Act, Wis. Stat. § 157.06, and federal law. Plaintiffs contend that Wisconsin's public policy that organs harvested in Wisconsin be procured and allocated pursuant to policies developed by the organ procurement and transplantation network is demonstrated by the state's provision for organ procurement organizations to "[o]ffer the vascularized organ for use by an entity that distributes vascularized organs on a regional or national basis under a contract with the federal department of health and human services or a subcontract with a contractor with the federal department of health and human services." Wis. Stat. § 157.06(9)(d)2. Under the amended final rule, such an entity continues to exist, presently the United Network for Organ Sharing, and the quoted provision suggests no state preference as to who determines the network's policies. Plaintiffs do not allege in the second amended complaint that the amended final rule affects any state laws. Any injury to its sovereignty that plaintiff State of Wisconsin may have suffered is not concrete enough to support standing here.

Cf. State of Illinois v. City of Chicago, 137 F.3d 474, 477-78 (7th Cir. 1998). I conclude that plaintiffs State of Wisconsin and State of New Jersey do not have standing to bring this lawsuit.

B. Ripeness

Plaintiffs contend that they have been injured by defendant's assertion (through promulgation of the amended final rule) that she can force the organ procurement and transplantation network to submit its current and future policies to her review. Defendant's action that caused plaintiffs' injury occurred in April 1998 and March 2000. In her reply brief, defendant argued that this case is not ripe because she had not yet exercised her claimed authority under the regulation. However, defendant notified this court on October 3, 2000, that the Department of Health and Human Services had awarded the organ procurement and transplantation network contract to the United Network for Organ Sharing and that the contract incorporates as contractual obligations the requirements that the final rule on organ transplantation imposes on the contractor. The contract took effect on October 1, 2000. See Dft.'s Notice, dkt. # 21. The award of this contract incorporating requirements of the amended final rule may moot plaintiff's argument that the claim is not ripe for adjudication. Because I have already concluded that plaintiffs do not have standing to bring this challenge, it is unnecessary to determine whether the challenge is ripe.

II. MOTION TO INTERVENE

By failing to respond to defendant's brief in opposition to their motion to intervene, the intervenor-plaintiffs failed to show that they should be allowed to intervene in this case. In any event, the motion to intervene is mooted by the decision to dismiss this case for lack of subject matter jurisdiction.

ORDER

IT IS ORDERED that

1. The motion of defendant Donna Shalala, Secretary of the United States Department of Health and Human Services, to dismiss this action pursuant to Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction is GRANTED.

2. The motion to intervene filed by the State of Louisiana, Louisiana Organ Procurement Agency, Louisiana State University School of Medicine at Shreveport through the Board of Supervisors of the Louisiana State University and Agricultural & Mechanical College and Louisiana State University School of Medicine at New Orleans through the Board of Supervisors of the Louisiana State University and Agricultural & Mechanical College is DENIED as moot.

3. The clerk of court is directed to enter judgment for defendant and close this case.

Entered this 22nd day of November, 2000.

BY THE COURT:

BARBARA B. CRABB
District Judge