GAO

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Congressional Requesters

Subject: Organ Procurement and Transplantation Network: Legal Liability and Data Confidentiality

The Organ Procurement and Transplantation Network (OPTN), the statutory program for procuring and allocating organs for transplant candidates, is operated under contract with the Department of Health and Human Services (HHS) by a private nonprofit entity, currently the United Network for Organ Sharing (UNOS). In legislation enacted last year, the Congress posed a series of questions concerning HHS' proposed modifications of the OPTN. As agreed with your staff, this letter responds to the two questions that involve legal determinations, specifically the impact of the modifications on (1) confidentiality of information about the program and (2) the possible legal liability of members of the Network arising from their "peer review" activities.[1]

Medical advances have increased the number of patients who could benefit from an organ transplant, but the supply of organs has not kept pace with the demand. In 1998, according to HHS, about 21,000 organs were transplanted, yet by the end of that year over 62,000 individuals were waiting for transplants.

At present, the OPTN allocates organs largely on a local or regional basis. Transplant centers employ different criteria for determining who needs transplantation, and for determining the greatest medical need among transplant candidates.

HHS believes the current system of regional allocation is inequitable in that organs do not necessarily go to the sickest patients. HHS sought comment in April of last year on a "final rule" that would have changed the allocation of organs by the OPTN to a national approach, with prioritization of transplant candidates to be based on standard medical criteria.[2]

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[1] As provided in the law, the rest of the questions will be addressed in a study conducted by the Institute of Medicine under contract with this Office.

[2] Organ Procurement and Transplantation Network; Final Rule, 63 Fed. Reg. 16,296 (1998) (to be codified at 42 C.F.R. pt. 121).

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HHS' approach generated substantial concern; the current contractor and others believe it would have an adverse effect on the program. In response, the Congress enacted legislation postponing the effective date of the final rule from July 1998 until October 1999, and requiring this Office to contract with the Institute of Medicine for a study of current OPTN policies and the proposed final rule.[3] This report will be completed no later than September 15, 1999.[4]

We agreed with the cognizant congressional committees and the Institute of Medicine that we would respond to the two legal questions posed by the law: the final rule's potential impact on (1) the liability under state peer review laws and procedures of members of the OPTN and (2) the confidential status of information relating to the transplantation of organs.[5]

Both questions relate to the ability of the OPTN and its members to conduct what it calls peer review—evaluations of the competence and performance of members and potential members—without fear of public disclosure or legal liability. If the rule took effect in its present form, it is feared, state laws immunizing peer reviewers from lawsuits based on their evaluations and guaranteeing confidentiality of information used in that process might be preempted by the federal requirements embodied in the final rule, leaving reviewers vulnerable to suit and less willing to participate and be candid in the peer review process.

We conclude that the rule's preemption provision is unlikely to affect the availability of peer review liability protection. Concerns about disclosure of information related to the conduct of peer review are not unfounded, but are not solely the result of the HHS rule. The risk of such disclosure exists now in those states that do not provide statutory immunity for peer reviewers or that define peer review in such a way that their immunity provisions might not protect the peer review activities of the OPTN. Where state law immunizes peer reviewers from suit, it would not be preempted by HHS' rule, but the Secretary could preempt state laws that regulate disclosure of information about peer review if she were to determine, as the rule provides, that disclosure is in the public interest.

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[3] See section 213(a) of the Department of Health and Human Services Appropriations Act, 1999, 112 Stat. 2681-359.

[4] The report will address the impact of the final rule on such issues as: access to transplantation services for low-income populations and for racial and ethnic minority groups; donation rates; waiting times; patient survival rates and organ failure rates; and costs.

[5] See subparagraphs 213(b)(1)(F) and (G) of the Department of Health and Human Services Appropriations Act, 1999, 112 Stat. 2681-359.

Whether or not state law in fact protects them, peer reviewers' perception that their deliberations might be disclosed or that they might be sued because of what they do might affect their performance. For example, they may be less willing to express opinions that reflect poorly on a participant's professional performance if those opinions might become public or if they, an institution with which they are affiliated, or a colleague, might be sued.

It was in part because of such concerns that existing federal law provides that peer review activities conducted under contract with HHS are generally immune from liability, and that information used for such peer review is protected from disclosure. However, it is not clear that this law applies to peer review as conducted by the OPTN.[6]

A more detailed discussion follows.

BACKGROUND

As advances in medical treatment during the 1970s and 1980s made increasing numbers of organ transplants possible, the private sector, with encouragement from federal and state governments, undertook efforts to promote organ donation and organ transplantation and to coordinate these activities on a regional and national level.[7] However, it became apparent that organ donation and procurement procedures were unable to meet the demand and to answer questions about the equity of allocation.[8]

The Congress responded by enacting the National Organ Transplantation Act of 1984 (NOTA). NOTA requires the Secretary of HHS to contract with a private entity to establish and operate the OPTN.[9] The responsibilities of the OPTN include: maintaining lists of individuals requiring organs, facilitating matching of donors with recipients, assisting in the equitable distribution of organs among transplant patients, and adopting quality standards for acquiring and transporting donated organs.[10]

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[6] Authority to determine whether the law in question is applicable to UNOS or to the OPTN's peer review process lies with HHS. Chevron U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837, 843-845 (1984). HHS has not decided this question, and UNOS seems to assume that the law does not protect it.

[7] See S. Rep. No. 98-382, at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3975, 3979-81.

[8] See id. at 4.

[9] 42 U.S.C. § 274(a).

[10] 42 U.S.C. § 274(b).

UNOS has been the OPTN contractor since the inception of the Network in 1986.[11] UNOS was one of the pioneers in organ transplant research and allocation; in fact, before enactment of NOTA and its subsequent contractual responsibility for the OPTN, UNOS had already established a national computer system for patients requiring a kidney transplant.[12]

UNOS organized the OPTN into eleven geographic regions. OPTN members now include: 53 organ procurement organizations (OPOs)[13] that, each within a geographically defined service area, coordinate the identification of potential donors, requests for donation, and the recovery and transport of organs[14]; 272 centers where organ transplants are performed; and 56 independent tissue-typing laboratories.

Under the current OPTN system, organ allocation is weighted toward the local use of organs. When a donor dies, the hospital notifies its designated OPO. The OPO then consults its waiting list in search of a local recipient within its service area. If no suitable recipient is found, the OPO either checks the list for the geographical region in which the OPO is located, or notifies UNOS—which performs the same search. If no suitable recipient is located within the OPO's region, UNOS performs a nationwide search, and selects the most medically urgent candidate as a recipient.[15]

HHS and others have expressed concern that under this approach, organs may not always be allocated to the most critically ill patients or to those whose needs are most medically urgent. For example, the designated recipient in the donor's immediate OPO local area or region may not be as critically ill as a candidate in a distant state. As a result, HHS believes, the chances of the sickest patients being matched to suitable organs are not maximized.[16] HHS has concluded that an organ

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[11] No other contractor has ever competed for this contract.

[12] See S. Rep. No. 98-382, at 3.

[13] There are 62 OPOs in the OPTN; however, 9 of these OPOs are hospital-based, and therefore do not have independent memberships.

[14] For example, the Louisiana OPO performs all organ transplant coordination in the state of Louisiana. However, many of the OPOs are regional, rather than coextensive with a state like the Louisiana organization.

[15] Allocation of thoracic organs—hearts and/or lungs—is subject to somewhat different rules. If the organ cannot be utilized locally, it is then offered in increasing concentric circles based on distance from the donor hospital. See UNOS Policy 3.7, at http://www.unos.org.

[16] See 63 Fed. Reg. at 16,298.

allocation system that functions equitably on a nationwide basis would best serve transplant patients.[17]

On April 2, 1998, the Secretary of HHS invited public comment on a rule, to be effective 3 months later, to eliminate the OPTN's current local-first organ allocation policy. The rule requires the OPTN to establish an organ allocation system that functions, to the extent feasible, on a national basis, allocating organs based on the urgency of patients' medical status rather than on geographic location.

Under the new rule, the OPTN would establish: (1) standardized minimum criteria for including transplant candidates on a national waiting list; (2) "objective medical criteria to be used nationwide" for ranking patients on the waiting list into status groups, from the most to least medically urgent; and (3) donor allocation policies that give priority to patients with the highest medical urgency, with a patient's waiting time in a particular status group used to break ties within those groups.[18] The new rule also requires the OPTN to submit its proposed allocation criteria and policies to the Secretary for evaluation and possible public comment.[19]

In addition, the rule contains a new data release requirement. It provides that HHS may release any collected organ transplant program data that "the Secretary determines will provide information to patients, their families, and their physicians that will assist them in making decisions regarding transplantation."[20]

Finally, the rule contains a "preemption" provision to deal with situations in which state or local governments have requirements that conflict with those of the rule:

> 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, [organ procurement organization], or other party to comply with organ allocation policies of the OPTN or other policies of the OPTN that have been approved by the Secretary under this Part.[21]

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[17] See 63 Fed. Reg. at 16,299. For a discussion of this debate, see Gail L. Daubert, Comment, *Politics, Policies, and Problems with Organ Transplantation: Government Regulation Needed to Ration Organs Equitably,* 50 Administrative L. Rev. 459 (Spring 1998).

[18] See 63 Fed. Reg. at 16,296.

[19] See 63 Fed. Reg. 16,334 (to be codified at 42 C.F.R. § 121.4(b)(2)).

[20] See 63 Fed. Reg. 16,338 (to be codified at 42 C.F.R. § 121.11(c)).

[21] See 63 Fed. Reg. 16,338 (to be codified at 42 C.F.R. § 121.12).

The proposed new rule has been criticized on several grounds. Of relevance to this discussion, UNOS is concerned that the final rule, by preempting state law, strips OPTN members of liability protections under state statutes, subjecting them to potential lawsuits arising out of their service on UNOS' peer review committees. In addition, UNOS believes that the final rule dismantles traditional mechanisms for safeguarding confidential peer review information and the processes under which it is collected, and that the result of disclosure of such information would be to facilitate lawsuits either by the subjects of critical reviews against peer reviewers, or by patients against providers who were criticized by peer reviewers.

STATE PEER REVIEW LIABILITY PROTECTIONS

In general, peer review means the evaluation of a professional by other professionals in the same field.[22] In medicine, the term "peer review" generally refers to the review, by a group or committee of physicians, of practices and procedures of fellow physicians, in an attempt to monitor or discover those whose skills fall below the required standards or who pose a danger to the health of patients.[23] For example, most hospitals have a peer review committee that evaluates whether a particular physician should be given practicing privileges, or alternatively, whether a particular medical procedure was conducted properly.

UNOS characterizes several of its activities as "peer review undertaken by UNOS as the OPTN."[24] These activities are in addition to any peer review conducted by individual OPTN member entities, such as a peer review committee within a transplant center or tissue-typing laboratory.

According to UNOS, any entity applying for membership in the OPTN is subject to a formal review process by UNOS' Membership and Professional Standards Committee (the Committee), which comprises physicians and OPO representatives selected from each of the OPTN's 11 geographic regions.[25] If, for example, a hospital wishes to be

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[22] See Barbara K. Miller, *Defending the System: Application of the Intraenterprise Immunity Doctrine in Physician Peer Review Antitrust Cases,* 75 Tex. L. Rev. 409 (1996).

[23] See 121 A.L.R. Fed. 255 (1998).

[24] Letter from Cindy M. Sommers, Assistant Director for Policy Development, UNOS, to Behn Miller, Office of the General Counsel, GAO (April 8, 1999). See also UNOS' bylaws and policy set out at http://www.unos.org.

[25] The current Committee comprises 17 physicians and 3 OPO representatives.

added to the OPTN as a transplant center, the Committee will review the facility and its physicians.

The Committee also conducts what UNOS characterizes as peer review of each OPTN member's performance and compliance with OPTN policy. For example, an OPTN member that cannot demonstrate compliance with UNOS' organ allocation policies may be asked to explain its actions to the Committee. If deviations are found, the Committee will endeavor to bring the OPTN member into compliance.

Additionally, if the survival rate of transplant patients at an individual transplant center drops below the established OPTN performance goal for a specific organ, the Committee will engage in "peer review" to identify the basis for the low survival rate, and will audit the physicians or programs to discover the reason for the low performance and determine how to resolve the deficiency. UNOS reports that its audit teams typically include a physician or surgeon involved in transplantation of the particular organ, and an individual with experience as a transplant hospital administrator or clinical transplant coordinator.

The OPTN also uses regional review boards to assess "urgent status" patient listings for liver and heart allocation. Each of the 11 OPTN regions has a separate review board for each organ, comprising health care professionals and public representatives from that region.

UNOS explains that the effectiveness of the Committee and the regional review boards depends on the willingness of OPTN members to participate openly and fully and to share patient-identifiable and institution-specific information. This openness, UNOS says, is facilitated through the combination of state laws protecting peer review activities from lawsuits and of policies prohibiting the disclosure of information about the deliberations and conclusions of the reviewers.

Currently, 49 states[26] grant some form of immunity to members of medical peer review committees or organizations.[27] While most state statutes insulate only medical

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[26] Virginia has not enacted medical peer review liability protections.

[27] A federal statute–the Health Care Quality Improvement Act of 1986 (HCQIA), 42 U.S.C. § 11101 et seq.–also extends immunity for some peer review activities. Under that law, "professional review actions" taken by a "professional review body" and meeting certain standards are insulated from damage actions under federal and state law. For a discussion of the HCQIA, see Lu Ann Trevina, Note, *The Health Care Quality Improvement Act: Sword or Shield?*, 22 Thur. Mar. L. Rev. 315 (1997) and Gail N. Friend, Jennifer Rangel, Madison Finch, Brent A. Storm, *The New Rules of Show and Tell: Identifying and Protecting the Peer Review and Medical Committee Privileges*, 49 Baylor L. Rev. 607 (1997).

professionals from peer review liability,[28] the peer review liability laws of some states protect all members conducting peer reviews, including non-physicians, from potential plaintiffs.[29] For example, Louisiana's statute provides:

> No member of any such [peer review] committee ... or any sponsoring entity, organization, or association on whose behalf the committee is conducting its review shall be liable in damages to any person for any action taken or recommendation made within the scope of the functions of such committee if such committee member acts without malice and in the reasonable belief that such action or recommendation is warranted by the facts known to him.[30]

UNOS is concerned that the rule promulgated by HHS will preempt state peer review liability protections, and as a result impair the OPTN peer review process. If OPTN members were subject to liability under state law, they might be unwilling to participate in peer review. UNOS believes that even if willing to serve on the peer review committees, an OPTN member might, without the state liability protections, be more likely to approve an application or a patient's medical status determination in order to avoid the possibility of a lawsuit.

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[28] In such states—e.g., Connecticut (which only exempts "health care providers" from peer review liability, see CONN. GEN. STAT. § 19a-17b (West 1997)) or Colorado (which only extends immunity to physician peer review committees, see COLO. REV. STAT. § 12-36.5-103 (1998))—UNOS and the established OPTN peer review committees do not appear to qualify for peer review immunity because of the narrow scope of coverage.

[29] For example, in Oklahoma, "not-for-profit corporations" are extended "immunity from civil liability," see 76 OKLA. STAT. tit. 63, § 31 (1998); in Washington, peer review immunity is granted to "an entity" that employs at least one Washington-state licensed medical professional, see WASH. REV. CODE § 7.70.020 (1999)). In states with such broad protections, UNOS and the established OPTN peer review committees appear to qualify for immunity.

[30] LA. REV. STAT. ANN. § 13:3715.3.C (West 1998). Louisiana's peer review statute applies to a wide range of health care providers, hospitals, and professional organizations and associations. Other states provide even broader protection. For example, Hawaii's law, unlike Louisiana's, does not specify that immunity is only available if the reviewers' actions are reasonably based on known facts and not motivated by malice. See HAW. REV. STAT. § 624-25.5 (1998).

We conclude that the preemption provision in the final rule is unlikely to affect the availability of state medical peer review liability protection.[31] Generally, preemption takes place only to the extent that a conflict arises between the state and federal provisions. We see no apparent conflict between the final rule and the state laws governing peer review.[32]

The possibility of conflict and preemption does exist with respect to laws in those states—among them Arkansas, Florida, Louisiana, Mississippi, Oklahoma, South Carolina and Tennessee[33]—that give preference in organ allocation to state residents[34] whenever a state resident is not the next designee on the national list.[35] As a result of federal preemption, the OPTN will be required to allocate the organ to the out-of-state recipient. However, none of these states links peer review liability protection to adherence with local allocation of organs. Federal preemption should not reach these states' peer review liability protections recognizing, however, that no one can say with certainty what the ultimate outcome of litigation on this issue might be, or

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[31]It is well established that federal regulations have no less preemptive effect than federal statutes over state law. See Capital Cities Cable Inc. v. Crisp, 467 U.S. 691, 699 (1984); Fidelity Fed'l Sav. & Loan v. De La Cuesta, 458 U.S. 141, 154 (1982).

[32]"[S]tate law is nullified to the extent that it actually conflicts with the federal law. Such a conflict arises when 'compliance with both federal and state regulations is a physical impossibility,' [citation omitted] or when state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress' [citation omitted]." Fidelity Federal Savings & Loan Ass'n v. De La Cuesta, 458 U.S. 141, 153 (1982).

[33] See ARK. CODE ANN. § 20-17-617 (Michie 1997); FLA. STAT. ch. 732.922 (1998); LA. REV. STAT. ANN. § 17:2353 (West 1998); MISS. CODE ANN. § 41-39-15 (1998); OKLA. STAT. tit. 63, § 2204 (1998); S.C. CODE ANN. § 44-43-410 (Law. Co-op. 1998); S.B. 311, 101st G.A. (Tenn. 1999).

[34] We understand that the states of Arizona, Missouri, and Nevada have proposed similar local-preference organ allocation policies for enactment. See H.B. 2269, 44th Leg., 1st Reg. Sess. (Ariz. 1999); H.B. 612, 90th G.A., 1st Reg. Sess. (Mo. 1999); Conc. Res. 19, 70th Reg. Sess. (Nev. 1999). In addition, the states of Kansas and New Jersey have proposed state resolutions urging the United States Congress and the Secretary of HHS to reconsider the new rule's national organ allocation goal because of alleged concerns that the rule will adversely affect potential recipients in those states. See H.C.R. 5013, 78th Leg., 1999 Reg. Sess. (Kan. 1999); S.R. 39, 208th Leg., (N.J. 1998).

[35] The Arkansas statute giving preference to Arkansas patients for all organs and tissues procured in Arkansas probably would not have to be preempted by the federal rule since, by its own terms, it does not apply if it "would be in conflict with federally mandated guidelines." ARK. CODE ANN. § 20-17-617 (Michie 1997).

whether all courts would reach the same conclusion. As discussed below, the behavior of peer reviewers may be influenced by the possibility of preemption removing their protection from liability, however unlikely it may be that such preemption will occur.

CONFIDENTIALITY OF INFORMATION

The concern of UNOS and others about potential liability of OPTN members as a result of their participation in peer review is exacerbated by the treatment of confidentiality in the HHS rule. The rule gives the Secretary broad authority to disclose information about the OPTN:

> The Secretary may release to the public information collected under this section when the Secretary determines that the public interest will be served by such release. The information which may be released includes, but is not limited to, information on the comparative costs and patient outcomes at each transplant program affiliated with the OPTN, transplant program personnel, information regarding instances in which transplant programs refuse offers of organs to their patients, information regarding characteristics of individual transplant programs, information regarding waiting time at individual programs, *and such other data as the Secretary determines will provide information to patients, their families, and their physicians that will assist them in making decisions regarding transplantation* ....[36] (Emphasis added.)

In responding to concerns expressed by some of those commenting on a draft of the rule, HHS acknowledged that protection of confidentiality is important but also pointed out that data collected by the OPTN, a federal contractor using public funds, "generally should be in the public domain." HHS cites the need of bona fide researchers to have access subject to appropriate protections against redisclosure—to detailed data, including personally identifiable medical records, in evaluating how to improve organ transplantation and allocation.[37]

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[36] 63 Fed. Reg. 16,338 (to be codified at 42 C.F.R. § 121.11(c)).

[37] Some are concerned that another pending federal initiative might have an impact on these aspects of the OPTN's operations. The Office of Management and Budget (OMB) recently sought public comment on a proposed revision to its Circular A-110, see 64 Fed. Reg. 5,684 (1999). The revision would require federal agencies to make available to the public any federally-funded research or data underlying published research findings used by the government to develop policy or rules (unless the data are exempted from release by other law).

UNOS' chief objection to the final rule's data release provision is again related to what it perceives as the potential for an adverse effect on the peer review process. Most states,[38] as part of the peer review protection statutes discussed above, have created a privilege for peer review which precludes the disclosure of committee proceedings and records—and, in some cases, the identities of the committee members—to the public.

UNOS is concerned that, relying on her authority in the final rule to disclose data that she determines "will provide information to patients, their families, and their physicians that will assist them in making decisions regarding transplantation," the Secretary could, notwithstanding the state protections, disclose the identities of peer review committee members, records of their meetings, or other information about the peer review process. The availability of that kind of information, it is feared, could make it easier for patients or providers to sue the OPTN peer review committee members. According to UNOS, without the state safeguards that promote candid participation by committee members, the OPTN and its members will be hesitant to participate in the OPTN peer review process or to express candid and objective opinions.

To the extent that the information concerned is proprietary or involves trade secrets of UNOS or anyone else, the Secretary would be prohibited by law from disclosing it, but it is not clear that this prohibition would protect all information concerning OPTN peer review. Under 18 U.S.C. § 1905, the Secretary—and any officer or employee of the United States—is expressly prohibited from disclosing, to any extent not authorized by law, information which "concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses or expenditures of any person, firm, partnership, corporation or association." However, we cannot say that all information about peer review would be considered proprietary.

Thus, with the exception of proprietary information, the Secretary has authority to disclose peer review committee data that would be protected under state statutes, if she decides that the public interest in disclosure outweighs the interest in confidentiality. HHS points out that in creating this authority it was trying to strike a

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[38] For a discussion of the peer review committee privilege, see Charles David Creech, Comment, *The Medical Review Committee Privilege: A Jurisdictional Survey*, 67 North Carolina L. Rev. 179 (November 1998). Typically, state peer review committee protections are quite broad; for example, the state of Alabama's peer review protection, see ALA. CODE § 6-5-333 (1999), provides that "[a]ll information, interviews, reports, statements, or memoranda . . . are privileged [and] "[t]he records and proceedings of any such committees shall be confidential . . . and shall not be public records nor be available for court subpoena or for discovery proceedings."

balance between the interest in confidentiality and its statutory duty to provide information about transplantation, specifically about the resources available nationally and in each State, and the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network.[39] HHS also observes that the disclosure requirement is not a radical departure from prior practice; it has in the past required UNOS to include extensive data in its published reports, such as hospital-specific survival data.[40]

However, (apart from trade secret information which is expressly protected by federal law as described above), it is true that the Secretary could decide to disclose peer review information, and that her decision to do so would preempt state prohibitions against such disclosure. In deciding whether the public interest outweighs the interest in confidentiality, the Secretary would certainly have to consider the impact on peer review of disclosure. We cannot judge the likelihood that she would do so, but the possibility does exist.

UNOS believes that preemption of state confidentiality statutes and regulations, coupled with disclosures by HHS of what institutions regard as confidential business information or specific data or minutes from meetings of the Committee or the regional review boards, will result in a marked increase in litigation against UNOS and OPTN members and may make it difficult to persuade individuals to serve on the Committee and regional review boards. In those states with broadly worded statutes that provide liability protections for peer review committee members, the effect of preemption should be minimal. We agree with UNOS, however, that there could be a heightened risk of litigation in states lacking peer review statutes under which OPTN members serving on UNOS' review boards might qualify for immunity from liability.[41] Moreover, even where state immunity protects peer reviewers from legal liability, the prospect that their deliberations might be disclosed could detract from their willingness to participate with candor and objectivity.

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[39] See 63 Fed. Reg. 16,320.

[40] See 42 U.S.C. § 274c. The purpose of this disclosure is to assist patients, their families, and their physicians "with the costs associated with transplantation." That suggests that disclosure of peer review information may not be required, unless it can be shown to relate in some way to this purpose.

[41] It is not clear that a federal statute which extends immunity for some peer review activities applies to OPTN members serving UNOS' review boards. See also supra notes 5 and 27.

CONCLUSION

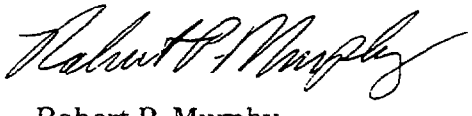
HHS' final rule does not preempt the many state laws that protect peer reviewers from liability arising from the conduct of the peer review. The rule preempts state laws only to the extent it is inconsistent with those laws. State protections against liability for peer review do not appear to be inconsistent with the final rule. However, some states may not provide such protection for the OPTN.

State laws prohibiting disclosure of peer review data could be preempted by the final rule. The Secretary of HHS has authority under the final rule to decide that the public interest in disclosure of information about organ transplants outweighs the interest in confidentiality. It is possible that she would do so with respect to peer review information.

In those states whose laws do not immunize the OPTN peer reviewers, the disclosure of information about peer review activities could make it easier for potential plaintiffs to gather information that would be helpful in a lawsuit. Even in the states that protect them from liability, however, the possibility of disclosure could have some undesirable effects: reviewers might be less candid if they were concerned that their deliberations and opinions about colleagues could become public, and might become the basis for suits against those colleagues.

If you or your staffs have any questions about the information in this letter, please call me at (202) 512-5400 or Barry R. Bedrick, Associate General Counsel, at (202) 512-8203. Other contributors to this letter were Behn Miller and Dayna Shah.

Sincerely yours,



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