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Payers are also directly affected. Their ability to select transplant hospitals for their patients is hampered if listing patients solely at those hospitals forces them to compete with local patients for the limited supply of local organs, even though this listing frees up organs in the areas in which the patient would otherwise be listed. Some large payers have tools at their disposal to ameliorate this problem, such as multiple listing some patients at more than one center, listing some patients at centers with shorter waiting lists, or accelerating hospitalization to put patients in a preferred status. However, most payers do not use such techniques and only a minority of patients benefit from such "gaming."

Perhaps the greatest inequity that the current system of local priority creates is that it particularly disadvantages those who face imminent death through unusually rapid deterioration. The chance that an organ that will match one's physiology will be available in the local area within the next week is very small. Yet, the chance that an appropriate organ will be available somewhere in the country is very high. Except for those few patients (or payers) with the knowledge, will, and ability to engage in a continent-wide search--a search with no guarantee of success--rapid deterioration in a newly listed patient, when combined with local preference allocation, provides only a small chance of survival. In contrast, those whose disease progression is slow, and who have the luck or foresight to list early, often benefit by obtaining organs before death is imminent.

The transplant community is deeply split over the issue of broader sharing primarily because some hospitals reap the benefits of a highly productive OPO and may receive fewer organs under a national system. Local preference draws upon, and reinforces, close bonds among local organ procurement organizations and local hospitals

and physicians. There are logistical and practical reasons why organs cannot be shipped back and forth across the country in response to the daily needs of every individual patient. As noted below in Table 6 there are great disparities among OPOs in the production of donor organs and under the current system the productivity of the local OPO directly impacts on the number of transplant done in the OPO service area.

Table 6

Donors Per Million Population 1995

Donors Per Million Pop.	OPOs (%)
<15.00	19.4
15.00 - 20.00	22.4
20.01 - 25.00	37.3
25.01>	20.9

Note: The range is from 6.4 to 31.6

Source: Calculation by the Division of Transplantation using UNOS Data

Major review agencies including, the Inspector General of this Department and the Congress' General Accounting Office have reviewed allocation issues and issued reports concluding there are major inequities and that major reform is needed to make the allocation system a truly "national" system as intended by the Congress.

The American Medical Association has studied organ allocation through a panel of experts. In its 1996 Code of Medical Ethics it states that: "Organs should be considered a national, rather than a local or regional, resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their

suitability for transplantation." In reaching this conclusion, the AMA panel reviewed the evidence concerning several organ types, and a wide range of alternative formulations. Of particular importance was their finding that current organ allocation policies were, in some cases, seeking to favor patients of lesser urgency but more likely to benefit, but that in actual practice these benefit differences were far too small to justify differential priority.

Taking all of these arguments into account, the Secretary has determined that a performance standard is needed. That standard would reduce geographic inequities by requiring that persons with equal medical urgency (i.e., in the same status as defined under the second performance standard) have essentially equal waiting times regardless of where they live or list. This is a significant departure from current policies not only in making geography less important for allocation purposes but also in its approach to waiting time disparities. The relevant "tie-breaker" will no longer be total waiting time, perhaps years, but will become waiting time within a group of patients with equal medical urgency.

We are mindful that there are practicalities involved, including especially transportation. The problem is not occasional cross-continental shipping from one large city to another, which is relatively straightforward. Instead, however, there can be severe logistical problems with frequent shipping of organs (often preceded by a special team that travels to retrieve the organ and return with it), or with moving organs among relatively transportation-disadvantaged areas, even within the same State. The performance standards are designed to allow (and require) the OPTN to craft policies that are workable, feasible, and avoid organ wastage.

Many commenters urged that the Secretary require national sharing of organs,

without any role for geographic factors. Others urged regional sharing. We prefer the performance standard approach. Achieving the standard will certainly require substantial regional sharing (this does not necessarily mean the current OPTN regions) and will probably require national sharing for some organs and some medical conditions. Indeed, regional sharing is already a prominent feature of heart allocation and national sharing a prominent feature of kidney allocation. However, we believe that any simple formulation would inhibit the ability of the OPTN to craft sensible policies that achieve practical as well as ethical results, and we wish to encourage change over time as medical science and medical criteria improve. Therefore, we are at this time using the performance goal approach, for all organs (with an accelerated schedule for performance standards for liver allocation).

Implicit in the requirement that patients with equal medical urgency and waiting time in status have an equal chance of receiving an organ is reform of policies that allow organs to be diverted from patients of blood type O, the "universal donor", in favor of patients of other blood types, if that would preclude equalization of waiting times in status. One of the inequities of present organ allocation policies is that patients of blood type O wait much longer for organs than other patients. For example, according to recently calculated data from the OPTN, the median waiting time for kidney transplants in 1994 was 854 days overall, but 1,046 days for patients of blood type O. For hearts the median waiting time was 188 days overall, but 319 days for patients of blood type O in 1995. Blood type is not an indicator of medical urgency. However, we do not prohibit taking blood type into account in allocation management if that would not violate our

performance goal.

The Secretary appreciates that there are many factors that can contribute to achieving the geographic equity standard. For example, The Department's organ donation initiative were to achieve a high rate of success, then fewer organs would need to be shared. Improved listing criteria and medical status categories will reduce measured inequities. Nonetheless, within reasonably foreseeable parameters, we see no basis to expect that inequities can be eliminated for any major organ category without very substantially increased organ sharing, on at least a broad regional basis for all patients with high levels of urgency.

We also require the OPTN to take into account key constraints on organ allocation. There are patients with urgent need for whom transplantation is futile. Organs cannot be used without an assessment of the immune system and other physical conditions of patients. Broad geographic sharing should not come at the expense of wasting organs through excessive transportation times. Efficient management of organ allocation will sometimes dictate less transportation when the highest ranking patient can wait a day or two for the next available organ. Sound medical judgment must be exercised before a final decision on whether to transplant a particular organ into a particular patient. Our goals allow for these factors to affect transplantation outcomes (see section 121.8).

[Note to reviewers: this is new and significant. Please consider implications fully.] Finally, we have added a requirement that transition protections (sometimes termed "grandfather" rights) be provided whenever a change in policy significantly disadvantages an identifiable set of patients already waiting on the national list of transplant candidates.

At the public hearing on liver allocation, it became clear that the OPTN had not considered the ethical implications of taking away an existing priority from a person who may have been on a waiting list for many months. To prevent such inequities in the future, we are requiring that as of the effective date of the publication of these regulations that such changes in policy treat each individual on the national list and awaiting transplantation no less favorably than he or she would have been treated had the policies not been changed.

To implement these protections, the OPTN would determine whether a change significantly disadvantaged some patients, and if so develop a transition policy to eliminate that disadvantage. The transition policy would be submitted to the Department for review along with the new policy, together with estimates of the likely effects of each. Only those patients on the list on the date of publication of this regulation would be covered by the grandfathering provision of the transition policy.

A previously listed patient of high medical urgency would not lose under this approach, because this patient would appear high under the old policy. Nor would a newly listed patient of high urgency lose, because a significant fraction of organs (about one-fifth of livers, for example) are already used regionally or nationally. Therefore, even from the first day a substantial fraction of organs, growing rapidly over time, would be available for patients with the highest medical need. However, patients with lower medical urgency but long waiting times would not lose organs to newly listed patients with only slightly higher medical urgency. Thus, patients already listed would be protected from moving from a substantial likelihood of receiving an organ in the near future to a

substantial reduction in priority.

Because a transition policy complicates organ allocation, and because the Secretary wants to preserve OPTN flexibility to develop and implement minor improvements with no consequential effect on existing patients' priorities, the transition provision allows the OPTN some flexibility as to whether, for how long, and for which patients the transition procedure would be developed. Of course, the OPTN would be free to devise particular approaches that would be most efficient and effective for a particular patient population. As with all other allocation policies, the Department would review and approve (or otherwise handle) each proposed transition procedure.

Kidneys pose potential problems because, unlike other organs, a significant fraction of patients have already spent years on the national list and turnover is much lower. On the other hand, transition procedures may be particularly important for kidney patients for the same reason. We request comments on the transition procedure generally and specifically as to its suitability for kidney patients.

8. Indicator Data [Performance Criteria?]

In order to assess performance against the goals previously stated, the Secretary requires the OPTN to collect and report indicator data on outcomes, and to compare alternative policies against estimated or projected outcomes. The Secretary expects the OPTN to develop appropriate indicators, but have specified several of central concern. These are: minimizing disparities in waiting times in status across transplant hospitals; minimizing life-years lost (both pre- and post-transplant); minimizing the number of

patients who die while waiting for a transplant, and minimizing the number of patients misclassified by status or mis-listed. Our requirements for performance indicators are presented in section 121.8(a).

It is primarily against these indicators that the Secretary will determine whether the OPTN's proposed allocation policies will be approved.

Over the past year a great deal of the debate and analysis of alternative allocation policies has benefited from the results of computer-based modeling of liver allocation. While current modeling has substantial limitations, it is nonetheless useful today and holds great promise of assisting the OPTN in devising as well as assessing policies. The Secretary expects the OPTN to develop and use such models for all organs, and present results to the Department along with other information.

9. Deadlines (§121.8(c))

The Secretary expects the achievement of these goals to be an ongoing process. Therefore, we have provided for periodic policy changes over time. However, for all organs other than livers the Secretary is requiring that the OPTN develop revised policies to substantially meet these goals, and to submit these within one year, from the publication date of this rule. For livers, the Secretary is requiring development of policies that will substantially meet these goals, to be submitted by (insert date 90 days from the publication date of this rule).

Shortly after this deadline the Secretary will approve the OPTN liver allocation proposal, approve it with modifications, or directly establish a policy, depending on the

information available to us as to which option best meets the performance goals set out in this rule. The Secretary is committed to using a process allowing for effective comment and presentation of alternatives. The Secretary will follow carefully the OPTN's progress in developing the new liver allocation policy before making a final decision on the best approach. For other organs, we will use a similar review processes in mid- to late-1998.

10. Liver Allocation Policies

Liver allocation policy has been exceptionally controversial. One of the two main purposes of the December hearing was to obtain additional information and views on liver allocation.

UNOS adopted a liver allocation policy in 1986, the first year of OPTN operations. The allocation policy featured a point system assigning relative weights for medical urgency, blood group compatibility and waiting time to patients within distinct distribution units. This initial system allocated organs first among all patients locally (with "local" waiting lists meaning the OPO procurement area, ranging from a single transplant hospital's list to the combined lists of all transplant hospitals in an entire state), then to patients in the OPTN region. At the time this policy was adopted, the country was divided into nine regions. Eventually, the number of regions was expanded to the current eleven to reduce differences in population size among the regions. Major differences still remain, however.

The liver allocation policy also included an informal emergency voluntary sharing practice known as "UNOS STAT" whereby a transplant hospital would notify the UNOS

Organ Center (the 24-hour organ placement operation maintained by UNOS) that a patient was critically ill and expected to die within 24 hours without a transplant. The Organ Center, in turn, would immediately notify all OPOs and transplant programs of the urgent need. Should a liver become available, the OPO could bypass the usual allocation process and the liver could be directed to the UNOS STAT patient's hospital. In effect, UNOS STAT was a system for sharing livers nationally, but only for the neediest patients. Between 1987 and 1990, it is estimated that 15 percent of the patients who received transplants were designated as UNOS STAT.

Objections were raised about the use of UNOS STAT, citing a lack of formal, uniform rules governing its use, and a concern that it was being used excessively or inappropriately. It was abolished by the OPTN in 1991. In addition to eliminating the UNOS STAT category, the liver allocation policy modified in 1991 expanded significantly the definition of the most urgent category by redefining it to mean death within seven days without a transplant (rather than 24 hours as in UNOS STAT). The rationale for the change was to provide greater opportunity within the formal allocation system for transplantation of chronically ill patients as well as those with acute fulminant liver failure.

Waiting time accrual under the liver allocation criteria was also modified to give greater priority to the most urgent patients. Status 1 patients were assigned the highest priority within the same distribution unit by only allowing waiting time accrued by a patient while listed as Status 1 to count for liver allocation. The Status 1 criteria specified until recently that such patients have a life expectancy of less than 7 days without a liver transplant. Patients who are listed as Status 1 automatically revert to Status 2 after 7 days

unless they are relisted as Status 1 by an attending physician. Prior to this policy change, it was possible for a patient who had been waiting a long time in a lower status to accumulate enough waiting time points to give that patient enough total points to be ranked higher than a patient who was a Status 1. The definitions of Status 2 and 3 patients were until recently:

> Status 2: Patients are continuously hospitalized in an acute care bed for at least 5 days, or are in the intensive care unit. Continuous hospitalization is required.
>
> Status 3: Patients require continuous medical care but may be followed at home or near the transplant hospital.

However, because the system allocates organs first locally, and regionally or nationally only if no local patients are a good match for the organ, and because at any time it is likely that the relatively few (or no) local patients in Status 1 will provide such a match, many organs go to Status 2 and 3 patients despite those patients ranking lower as medical priorities than Status 1 patients in nearby areas who are not counted as "local". In 1994, 67.4 percent of liver transplants were received by patients waiting in the "local" area, 19.9 percent by patients in the region and outside of the "local" area, and 12.7 percent by patients outside the region. Therefore, the preference for "local" plays a significant role in determining a patient's likelihood of receiving an organ. Under the current system, there is a wide range among OPOs and the OPTN regions in the number of patients on the waiting list, the number of donor livers available, and the ratio of patients per donor. Consequently, patients in different locations have disproportionate

probabilities of being offered a liver under this arrangement. Further, because fixed boundaries are used in local and regional distribution, some patients nearest the site of the donor who are otherwise highly ranked according to urgency or waiting time continue to wait while less sick patients in the "local" region are transplanted. As a result, some patients with higher medical urgency die waiting for a liver while other patients with less medical urgency receive one.

Between 1990 and 1995, the number of liver transplant hospitals performing at least one liver transplant increased from 75 to 112, and the number of liver transplant programs performing 35 or more liver transplants per year increased from 18 to 40. Thus, patients have more transplant hospitals to choose from, but at the same time competition among liver transplant programs for available livers has increased. During 1994, there were 9,225 registrations for a liver transplant at 110 liver transplant programs. These registrations included patients waiting at the beginning of the year, plus patients added during the year, and include a relatively small percentage of patients listed at more than one hospital.

Some people criticize this policy because livers are allocated "local first" to whoever is highest ranked in the local area of procurement. Thus, less sick patients can be transplanted before sicker patients in other local allocation areas. They believe that the sickest patients should always be transplanted first regardless of their location, because their lives are most at risk and should be saved first. Under the current policy, about 25 percent of liver patients transplanted are Status l and about 35 percent are Status 2. Almost 40 percent of transplanted patients are Status 3, and only 2 percent are Status 4

(the least sick patients)--a category that was eliminated late in 1996.

The counter argument to this criticism is that, if sickest patients are always given preference, there is a less efficient use of the available livers, because the sickest patients (Status l) have lower survival rates than transplant recipients with other statuses. Others say that if less sick patients receive lower preference than under the current policy, more of them will become sicker while waiting and then will have lower survival rates when they are eventually transplanted. Optimally, patients should be transplanted at a time when they are sick enough to benefit from a transplant, but not so sick that the risk of losing the graft is heightened. OPTN data show, however, that at one year there is about an 11 percentage point difference in patient survival rates and 13 percentage point difference in graft survival rates between Status 1 and 2, and some of this difference is due to a side effect of local preference rather than greater risk of graft loss: Status 1 patients often get an inferior organ that was made available only after rejected for use for any patient in the local procurement area.

The following table from page 144 of the 1996 Annual Report of the OPTN shows graft and patient survival rates of liver transplant patients, by status, from October 1987 through December 1994 (the last year for which the OPTN has published data):

Table 7

Three Month and One Year

Graft and Patient Survival Rates of Liver Transplant Patients by Status,

Waiting List Status at Transplant	N	3 Month Survival Rate		One Year Survival Rate	
		Graft	Patient	Graft	Patient
Status 1	1886	67.3 %	76.2 %	60.1 %	69.9%
Status 2	2262	81.8 %	88.1%	73.4 %	81.1%
Status 3	4611	87.2 %	93.3%	80.2 %	89.2%
Status 4	258	89.5 %	93.6%	84.7 %	90.7%
Unknown	1071	n.c. %	n.c.%	n.c. %	n.c.%
Overall	10088	81.0 %	87.6%	73.8 %	82.2%

Another frequent criticism of the current policy is that there is wide variation in waiting times from one geographic area to another. This variation cannot be attributed entirely to the allocation policy, because it may also be a function of patient selection decisions and the number of organs procured locally. However, the allocation policy, particularly as it relates to the size of the initial allocation area, is one determinant of variation in waiting times. The larger the initial allocation area, the more equal waiting times will be throughout the United States. As shown elsewhere in this preamble, waiting times at some transplant hospitals exceed those at others by a factor of 10 to 1 or more.

A third criticism of the "local first" policy is that it effectively eliminates patient choice. If some transplant hospitals do a better job and attract more patients, these patients come to those hospitals only at the price of a reduced chance for a transplant and

compete with each other for the limited supply of organs available locally. Thus, the current system sets up an inherent conflict between scarcity and quality, through its failure to allocate organs where the patients want to receive their transplant.

Consideration of Alternative Policies

At its Board of Directors meeting in June, 1996, the OPTN contractor considered the liver allocation policy in light of the results obtained through computer modeling of several allocation schemes. Following discussions with the Department, which suggested that computer modeling be undertaken, UNOS contracted with the Pritsker Corporation in 1995 to develop a computer simulation model for liver allocation. The model presents the hypothetical outcomes resulting from the application of a number of alternative allocation policies. Among the many outcomes measured were: patients transplanted, percentages of patients transplanted by status, number of pre- and post-transplant deaths, median waiting times, and distance from donor location to transplant location.

Using data masked to conceal identification of the models, the Liver/Intestinal Transplantation Committee of the OPTN considered seven policies that were most representative of all those modeled, including a policy for national sharing proposed by the University of Pittsburgh Medical Center. The Pittsburgh proposal and the other options had also been modeled by the CONSAD Research Corporation under contract with the University. Following its review of the masked data, the Committee eliminated the University of Pittsburgh's proposal for national sharing of organs from further consideration. The Committee's subsequent recommendations were reviewed by the

OPTN Patient Affairs Committee, and by its Allocation Advisory Committee which put forth an alternate proposal. These proposals included a modest component of regional sharing of organs.

At its meeting in June 1996, the Board of Directors considered the policies proposed by the Liver/Intestinal Committee and the Allocation Advisory Committee, as well as the existing liver allocation policy. The Board decided to change the existing policy in several ways, including redefining Status 1 to include only patients with "acute" failure, placing other patients in intensive care into the broader Status 2 group along with other patients of lesser urgency, eliminating Status 4 as an urgency category for prioritizing liver transplant candidates, and mandating regional rather than local sharing for the newly defined Status 1 group (region for Status 1 allocation would be the area encompassing the 20 percent of the total number of Status 1 and 2 candidates on the national list who are nearest to the available organ). The Board of Directors then sent this proposal into an OPTN public hearing process held in the fall. In November, the Board voted to adopt the new Status definitions, but to drop regional sharing. This change was scheduled to take place in January 1997. However, for the reasons described below, the Board suspended the new Status definitions (except for dropping Status 4) and the previous allocation system remained in place with little change.

At the Department's public hearing in December, 1996, these system revisions became a major issue. The de facto effect of the Board's vote, as presented by many witnesses and uncontradicted by any evidence, was to substantially disadvantage the group called "chronic crashers", which had previously had a high priority as the predominant

group within Status 1. In effect, the Board had taken the positive and constructive step of increasing priority for "acute"patients with high medical urgency and little waiting time but the Board had done so at the expense of another group with equally high medical urgency (and equally high likelihood of survival), rather than disadvantage only the much larger group who did not face imminent death without a transplant. According to the 1996 Annual Report of the OPTN (table 31, pages 143 and 144), patients with fulminant liver failure (the "acute" group) have one year patient survival rates of 70.8 percent and three year patient survival rates of 67.6 percent. The corresponding figure for the entire Status 1 group are 69.9 percent and 64.1 percent respectively. The differences between these survival rates are medically and ethically irrelevant. (Graft survival rates between the two groups are also virtually identical).

As a result of the airing of this unanticipated consequence at the HHS hearing, the OPTN Board of Directors rescinded its decision and placed the new policy on hold (while allowing, however, limited experimentation with broader sharing for "acute" patients in two OPTN regions). The net effect was to temporarily restore the prior system. At its meeting of June 25-26, 1997 the OPTN Board approved another policy, which would favor "acute" over "chronic crasher" patients. This revised policy puts the "acute" group first, the "chronic crasher" group second, and less urgent patients lower. It does not require regional or national sharing for any group. This change does not meet or approach the performance goals the Secretary has articulated in this rule.

In light of the extensive deliberative process within the OPTN, the many policies that have been considered, the substantial technical information available, the availability

of two modeling tools that provide approximate quantitative estimates of the differing effects of alternative policies, and above all the demonstrated inequity of the current liver allocation policies, the Department is not providing the OPTN the same period of time to reform liver allocation policy that it is providing for other organs. For all organs other than livers, the OPTN has one year from the publication of these regulations to develop and submit to the Department allocation rules that substantially meet the aforementioned performance standards. For livers, the Secretary is allowing three months from the publication date of these regulations. The Secretary appreciates that this time is far shorter than normal OPTN time frames, which emphasize considerable deliberation. However, such deliberations have already occurred and a great deal of information is available that will facilitate rapid reform.

It is the Secretary's expectation that the OPTN would submit proposed transition procedures at the same time that it submitted the proposed new allocation policy, together with supporting data. The Department would review these materials expeditiously, along with alternative proposals and public comments, and make the final decision.

The Department's plan is to obtain public input immediately following the deadline for the OPTN proposal. Commenters may propose alterations or alternatives. We ask that all proposals, whether from the OPTN or commenters, identify likely effects on inequalities in waiting times for patients of like medical urgency, mortality, life-years, likelihood of organ wastage, and other outcomes of importance. Based on the OPTN submission, and the comments or alternatives we receive in writing, the Secretary will determine whether to approve the OPTN proposal as submitted, approve it with

modifications, accept an alternative proposal or establish an alternative policy that better meets the Department's performance goals. Based on those submission and Departmental review, the Secretary will approve or issue a policy to take effect immediately.

The Secretary anticipates that similar procedures will be followed for other organs in 1998. In assessing these reforms for both livers and other organs, the Secretary will take into account that increased donation, more objective listing standards, and objective medical criteria for status categories all have significant potential for reducing real or perceived geographic inequities. However, the Secretary has seen no evidence suggesting that fundamental inequities can be removed in the near future without substantial geographic sharing of organs, on at least a broad regional basis.

The Secretary has not established by regulation specific quantitative measures that an OPTN liver allocation policy must attain to receive Secretarial approval. However, as a matter of guidance to facilitate the OPTN development process, it is extremely unlikely that the Secretary would approve a policy that did not achieve a significant reduction in the disparity of waiting times. Moreover, it is the Secretary's expectation that the new policy would handle medical urgency and status classifications well enough to result in a reduction in premature deaths and a concomitant increase in life years.

11. Directed Donation (§121.7)

Proposed § 121.7(d) on directed donation elicited several comments. Suggestions were made to delete the section on the basis that it would be misconstrued, and to refine it

to take into account varying State laws. One commenter said that it contradicts the intent of the National Organ Transplant Act, and another said that directed donation should be discouraged but not prohibited. The existing OPTN policy discourages directed donation to designated groups or classes of people, but permits directed donation to named individuals. This policy is consistent with provisions of the Uniform Anatomical Gift Act, a model law that has been adopted by all States. The Department has retained in the final rule the language of proposed § 121.7(d) permitting directed donation of organs to named individuals. See, § 121.8(e). It should be pointed out that the final rule permits directed donation of an organ to named individuals only.

12. § 121.8 (now § 121.9) - Designated Transplant Program Requirements

Section 1138 of the Social Security Act creates an extraordinarily severe sanction for failure to comply with approved OPTN rules and requirements. This, in turn, would make it unfair and impossible to create standards higher than a reasonable minimum that any reasonably competent hospital might attain. In the proposed rule, the Department suggested the idea of "designated transplant programs" as a way around this dilemma. Under this approach, failure to meet certain OPTN standards could result in an inability to receive organs, without necessarily jeopardizing either other transplant programs at the same institution or all Medicare and Medicaid reimbursement. No commenters objected to this approach, and no controversy over this approach surfaced at the public hearing. Accordingly, the Department proposes to retain the proposed approach, while improving it to reflect useful suggestions from commenters.

Most of the commenters on this section of the proposed rule recommended that the standards for the training and experience of transplant surgeons and transplant physicians, required for designation under proposed § 121.8(a)(2), apply also to Medicare-approved transplant programs designated under proposed § 121.8(a)(1). Three commenters suggested that transplant programs be designated on the basis of a minimum volume of transplant procedures and on patient survival standards, criteria now used in approving certain transplant programs for reimbursement under Medicare. Another commenter said that the NPRM was contradictory in admitting as OPTN members all Medicare-approved transplant hospitals, while expressing concern about proliferation of transplant hospitals and emphasizing that the Department did not wish to exclude hospitals from entering the field of transplantation. In the preamble to the proposed rule, the Department stated that the criteria for designation under proposed § 121.8(a)(1) and (2) are complementary, providing designated transplant program status to programs that meet Medicare standards, as well as to non-Medicare-approved programs which meet other requirements established by the OPTN. The Department's concern about the number of transplant hospitals was expressed in the context of "uncontrolled proliferation of transplant facilities," that is, permitting designated status without a method of ensuring the quality of care. See, 59 FR 46488.

The Department sees the merit in having uniform standards for designated transplant programs, but believes that it would be disruptive to impose them unilaterally at this time. Instead, the Secretary will consider this issue in the context of revising the OPTN and Medicare standards. In that light, the Department has asked the OPTN

contractor to consider developing standards regarding risk adjusted graft and patient survival rates, and possibly volume of transplant procedures, if the latest scientific evidence supports such standards. If appropriate, such standards could supplement the requirements for designated transplant programs under § 121.9, following the notice and comment provisions of the Administrative Procedure Act. [we need to make sure there is appropriate conforming language in the HCFA heart/lung/liver Notice.]

The OPTN contractor, UNOS, said that the OPTN would not be able to provide patients with information about key personnel in Medicare-approved transplant programs, because it would have such information only for transplant programs designated under proposed § 121.8(a)(2). In addition, UNOS suggested that the OPTN be given authority to collect, maintain, and distribute data on key personnel for all transplant programs. The Department believes that the OPTN should define such a role through its Board of Directors' policy development process under § 121.4, and has asked the contractor to do so. Thus, explicit regulatory language is not required. In the meantime, to the extent that information is not readily available from the OPTN, we expect individuals to obtain it from the transplant hospitals themselves.

Two commenters suggested that a conflict exists between proposed § 121.8 (c) and proposed § 121.3(d)(2) with respect to designation of transplant programs and membership of transplant hospitals. Under proposed § 121.3(d)(2), the OPTN is directed to accept as members of the OPTN transplant hospitals which meet the requirements of proposed § 121.3(c)(1) or (2). Under proposed § 121.8(c), (now § 121.9(c)), the OPTN may accept or reject applications from transplant programs for designated status. There is

no conflict, because membership under § 121.3 does not confer designated status under § 121.9. One commenter said that proposed § 121.8(a) should indicate that designated transplant programs are also OPTN members. The Department has edited that paragraph in accordance with the suggestion. See, § 121.9(a). We have also added to § 121.9(c) a requirement that the OPTN act "in a reasonable time" on requests for designated status, making it comparable to the change made in § 121.3(d)(2), discussed above.

Another commenter said that proposed § 121.8(a) should limit the requirement to "those OPTN policies, procedures, and issuances which have been approved by the Secretary as mandatory." As clarified above, this final rule and the procedures that it puts in place accomplish that result.

With respect to the disciplines listed in proposed § 121.8(a)(2)(v) as areas for collaborative involvement for designated transplant programs, two commenters suggested adding histocompatibility and immunogenetics. The Department has done so. See, § 121.9(a)(2)(v). The commenters also suggested that the term "tissue typing" in proposed § 121.8(a)(2)(vi) be changed to "histocompatibility testing." The change has been made. See, § 121.9(a)(2)(vi).

13. § 121.10 - Review and Evaluation

Two comments were received on this section of the proposed rule. In response to one comment, an editorial suggestion, the Department has clarified proposed § 121.9(b)(1)(iii) to indicate that compliance by member OPOs and transplant hospitals with OPTN policies, as well as regulations, is covered in reviews and evaluations carried

out by the OPTN. See, § 121.10(b)(1)(iii).

The other comment was an expression of concern about patients listed at transplant programs whose designated status to receive organs for transplantation may be suspended. The Department wishes to assure all who share this concern that the enforcement provisions of § 121.10(c) are constructed to allow for an orderly phase-out and transition period should such a situation occur. Under § 121.10, the OPTN is required to monitor the compliance of individual transplant programs, to report to the Secretary the results of any reviews or evaluations that indicate noncompliance, and to make recommendations for appropriate action by the Secretary. The Secretary expects the OPTN to pay particular attention to programs experiencing difficulty. The rule further permits the Secretary to request more information from the OPTN or from the alleged violator, or both, before accepting or rejecting the OPTN's recommendations, or to take any other action the Secretary deems necessary. We expect that enforcement of these provisions will follow the pattern established by UNOS and member transplant hospitals in seeking voluntary compliance with OPTN policies in the past. That is, through a dialogue between the OPTN (and the Secretary, if necessary) and the transplant hospital alleged to be in violation of the rules, every effort will be made to reach a resolution before a decision is made to suspend a transplant program's designated status. It is the Secretary's intention that the OPTN develop a policy which minimizes disruption and cost to patients, and keeps them informed. The best interests of patient care will be paramount in monitoring and enforcement of compliance with this rule. In this regard, we have also elaborated on the procedures for OPTN reviews of transplant hospitals and OPOs. The

OPTN shall conduct those reviews in accordance with the schedule specified by the Secretary and shall report progress on those reviews to the Secretary. See section 121.10 (b)(3).

14. Proposed § 121.10 - Appeals of OPTN Policies and Procedures

The Department received two comments on this section of the proposed rule. One commenter pointed out that appeals submitted to the Secretary must be sufficiently clear and substantiated. We agree that the Secretary must have appropriate information on which to base a decision, and believe that the language of the proposed rule provides the latitude needed for the Secretary to obtain such information. See, § 121.4(c). The other commenter expressed an opinion that the Secretary's role in approving policies and deciding appeals could lead to arbitrary and capricious actions, and suggested that the Secretary's decisions be published in the Federal Register. Similar points were raised in comments about proposed §§ 121.3 and 121.7 regarding publication of the Secretary's decisions on allocation and other policies of the OPTN, discussed above.

The Secretary's authority under proposed § 121.10(b) is not dependent on appeal and may be exercised at any time. We have moved the language of proposed § 121.10(a) to § 121.4(a)(2). Because proposed § 121.10(b) is redundant in light of § 121.4(a)(2), we have deleted this section from the final rule.

15. Proposed § 121.11 - Record Maintenance and Reporting Requirements

Most of the comments on this section expressed concern that the proposed rule falls short of needed protections of confidentiality, and suggested as a model the

protections delineated in MEDPAR, a Medicare data system used by HCFA. We agree with the need to ensure protection of confidentiality and believe that the protocols in MEDPAR may lend themselves appropriately to the records falling within the purview of § 121.11. We also believe, however, that the design of a system to protect the confidentiality of OPTN records should be left to the OPTN, subject to the Secretary's review and the data release provisions of this final rule. We expect the OPTN to submit for the Secretary's consideration a policy which will protect the confidentiality of OPTN records, but at the same time permit access by researchers to the OPTN and Scientific Registry data bases. Thus, we have amended proposed § 121.11(a) to reflect that records must be maintained and made available subject to policies of the OPTN and this final rule, as well as to applicable limitations based on personal privacy. We have also amended this section from the original proposal to clarify that the OPTN must follow such standard practices as making its information transactions and dissemination electronic to the extent feasible (unless requested in hard copy), and in disseminating information to include manuals and other explanatory materials as necessary to assure that the material is easily and accurately understood and used. We have also emphasized in § 121.11(b) and elsewhere that the OPTN should use rapidly advancing Internet technology to make information swiftly, conveniently, and inexpensively available throughout the nation.

Two commenters suggested adding a requirement that member transplant hospitals submit data to the Scientific Registry, a repository of data on transplant recipients that is operated under contract with the Department. Proposed § 121.11(b)(1) requires that the OPTN submit data to the Scientific Registry. We agree that a parallel requirement for

transplant hospitals and OPOs is also appropriate, and have added it. See, § 121.11(b)(2). Another commenter suggested establishing a 90-day time limit for the submission of data under proposed § 121.11(b)(2). Such an explicit provision is not necessary because proposed § 121.11(b)(2) requires that information be provided on a prescribed schedule. In addition, UNOS suggested requiring the submission of cost data to the OPTN. Although we believe the language of the proposed rule is broad enough to permit the OPTN to request submission of such data, we have added to the final rule the phrase "and other information that the Secretary deems appropriate." We have also corrected omissions in proposed § 121.11(b) by including the Secretary as a recipient of the information.

The OPTN is often asked by researchers, the press, patients, and others for data. Although we appreciate the importance of the OPTN's obligation to maintain the confidentiality of patient-identified data, we also recognize that data collected as a consequence of Federally funded contracts and of official designation as a contractor of the Federal government should generally be in the public domain. Even patient-identified data can be shared with researchers who provide appropriate protections against disclosure. It is vitally important that bona fide researchers and modelers have ready and timely access to detailed OPTN data in order to explore ways to improve organ transplantation and allocation. Therefore, OPTN information should be made available to the public while protecting patient confidentiality. To correct the oversight of omitting this activity from the proposed rule, we have added § 121.11(b) (1) (E) which requires the OPTN to respond promptly (normally within 30 days) and favorably to requests from the

public for data to be used for bona fide research or analysis purposes, to the extent that the OPTN's resources permit, or as directed by the Secretary. The OPTN may impose reasonable charges for responding to such requests. Pursuant to Federal government-wide policy under OMB Circular No. A-130, charges should reflect only the marginal cost of preparing the data for dissemination, not the cost of collecting or maintaining it.

We have also added language in paragraph § 121.11(b) (1) (F) saying that the OPTN must respond similarly to reasonable requests from the press, patients, or others. Of course, patient-identified data would not be provided in these cases. In addition, the OPTN would have to provide ready access to data that it originally received from transplant hospitals and OPOs, to these same institutions.

The Secretary has added language to section 121.11 (b)(2) making clear that hospitals and OPOs must provide data directly to the Department upon request, and must authorize the OPTN to release data to the Department or others as provided in the regulation. The OPTN has informed us of difficulties it has in complying with both instructions from the Department and its perceived obligation to these institutions not to disclose data that might be made public. While we do not believe this to be a serious dilemma we have drafted the final rule to make it unambiguously clear that any hospital or OPO must, as a condition of its OPTN membership make data available without restriction for use by the OPTN, by the Department, and in many circumstances by others, for evaluation, research, patient information, and other important purposes. In this regard, we particularly emphasize that we are requiring that current, institution specific performance data be made available so that patients, payers, referring physicians, the press, and others

can appraise the quality of transplantation programs. The Congress made this an obligation of the OPTN, and the Secretary intends to enforce it.

We have added language in § 121.11(b) stating that the OPTN shall submit to the Secretary information the Secretary deems necessary to prepare the Report to Congress, in order to be absolutely clear about the OPTN's responsibility in this area.

To complete the articulation of this policy, we have added a new paragraph (c) to §121.11, "Public access to data." This paragraph provides that the Secretary may release to the public information upon determining that the release will serve the public interest. For example, data on comparative costs and outcomes at different transplant programs, information on waiting list time, and information on the frequency with which transplant hospitals refuse offers of organs for their listed patients, will assist patients and their families and advisors in deciding where they wish to be transplanted. This release of data is consistent with section 375 of the Act, 42 U.S.C. 274c, which directs the Department to provide information to patients, their families, and their physicians about transplantation resources and about the comparative costs and patient outcomes at each transplant hospital affiliated with the OPTN, in particular. It is also consistent with the Department's practice of having the OPTN contractor include in its published reports extensive data including transplant hospital-specific survival data.

The provisions of §121.11(c) were not included in the NPRM of September 8, 1994. We have decided that the inclusion of this paragraph in the final rule is justified because the delay which public comment would require is contrary to the public interest. The release of data is essential to allow patients, their families, and their physicians to

make the most informed decisions possible about transplantation. To delay the implementation of this paragraph would be contrary to the public interest in that the decision-making of these parties regarding this life-saving procedure should be fully informed as soon as possible. Furthermore, the release of these data is consistent with the above-cited section of law and with the well-established practice of publishing center-specific outcome data, and thus public comment is unnecessary.

The Secretary specifically requests comments on whether the above provisions sufficiently achieve the several important purposes served by provision of information to the OPTN, the Department, and the public, while protecting patient privacy.

16. §121.12 - Preemption

A new section regarding preemption has been added to the final rule. This section does not require notice and comment rulemaking by the agency, as it does not alter the rights and responsibilities of any party. Instead, it simply applies the preemption principles derived from the Supremacy Clause of the United States Constitution. The Secretary is directed by section 372 to oversee a national system for distribution of organs, and the policies of the OPTN presently require organ sharing across State lines, with the performance standards articulated by these rules almost certain to increase the interstate sharing.

At least one State has passed a law that appears to limit the nationwide organ sharing policies that the Secretary has determined are in the public interest. For example,

a national organ sharing system based primarily on medical need, with geographic considerations reduced as allocation criteria, would be thwarted if a State required that, prior to sharing an organ with another State there be a written agreement with that other State or a requirement that the hospital or OPO first attempt to match the organ with an eligible transplant candidate within the State, regardless of status. A national effort for organ procurement and transplantation was seen by the Secretary and by the Congress as the most effective way to protect the public health. It is precisely for this reason that the preemption clause was developed.

Similarly, a State enforcing such a law would almost certainly render impossible the compliance of transplant hospitals and OPOs within that State with rules and requirements of the OPTN, and thus would jeopardize their ability to obtain Medicare and Medicaid reimbursement. This too would thwart the Federal scheme created by Congress.

A further negative effect would flow from the enactment by additional States of such restrictive laws. As more States enact such laws, greater disruption in the allocation of organs under the OPTN's policies would occur. Patients registered for transplants in some States would almost certainly die as a result of the restrictions on organ sharing, while other patients would receive organs even though their transplants would not be approved until later under the OPTN's policies. Accordingly, for policy as well as legal reasons, the Department has added the preemption statement to the regulation.

The preceding discussion constitutes a Federal Assessment, as required by Executive Order 12616, and we certify that this rule was assessed in light of the principles, criteria, and requirements of that Order.

III. Economic and Regulatory Impact

A. Legal Requirements

A number of statutes and executive orders require us to analyze the economic impacts of final rules. Executive Order 12866 requires that all regulations reflect consideration of alternatives, of costs, of benefits, of incentives, of equity, and of available information. Regulations must meet certain standards, such as avoiding unnecessary burden. Regulations which are "significant" because of annual economic effect of $100 million or more; adverse effects on the economy, public health, or other named categories, serious inconsistency with other agency actions; material alteration of the budgetary impact of entitlements and other programs or of the rights and obligations of recipients thereof; or raise novel legal or policy issues, require special analysis.

The Regulatory Flexibility Act requires that we analyze regulations to determine whether they create a significant impact on a substantial number of small entities (for purposes of the Act, all not-for-profit hospitals and all OPOs are categorized as small entities), and if so to prepare a Regulatory Flexibility Analysis exploring ways to mitigate adverse impact.

Executive orders 12875 and 12612 (dealing, respectively, with "Enhancing the Intergovernmental Partnership" and "Federalism") require that we review regulations to determine if they unduly burden States, localities, or Indian tribes, or if they inappropriately infringe upon the powers and responsibilities of States.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that we determine whether regulations may result in the expenditure of $100 million either by

State, local, and tribal governments, or by the private sector.

The Congressional review procedure of Section 801(a)(2)(A) of title 5, United States Code, enacted in 1996 requires that rules with an economic effect of $100 million or more or other comparable effects be classified as "major", and that these rules may not take effect until the Congress has had 60 days to review them.

We have determined that this rule will not have consequential effects on States, local governments, or tribal governments, because it affects primarily the operation of private sector OPTN functions and the allocation of organs among patients based on their medical condition. It will not require an expenditure of $100 million or more by the private sector. Therefore, it does not meet the special consultative requirements of the Unfunded Mandates Reform Act. We have determined that it will not have a significant impact on a substantial number of small entities, and so certify under the provisions of the Regulatory Flexibility Act. However, because there is significant concern over the effects of changes in allocation policies on smaller hospitals, and because we considered as an alternative the possibility of imposing quality standards on transplant hospitals, we have prepared a voluntary Regulatory Flexibility Analysis (RFA). The analysis which follows, together with the remainder of this preamble, constitutes an RFA. We have also determined that this is an economically "significant" rule under EO 12866 and a "major" rule for purposes of Congressional review of agency rulemaking. (This rule is also "significant" under EO 12866 because it "materially alters" the rights of recipients--patients--of entitlement and grant programs). The analysis that follows, together with the remainder of this preamble, constitutes a Regulatory Impact Analysis (RIA) meeting these

requirements.

This combined Regulatory Impact Analysis and Regulatory Flexibility Analysis also serves to analyze the effects of policies that we expect to approve under the procedures put in place under this rule, and that are assessed in this preamble, including all organ allocation policies necessary to implement the performance goals that we establish.

At the time of the proposed rule, we stated that it would be premature to analyze alternatives because of the procedural emphasis of the NPRM. We stated that we would analyze comparatively the range of options that we considered, including the existing OPTN policies, based on the comments and information we later received. Subsequent events explained earlier in this preamble, and the information that we have subsequently received, have made it both desirable and possible to analyze qualitatively, and in part to quantify, the effects of the substantive, non-procedural policies promulgated under this final rule. We are far better able to quantify the effects of changes in liver allocation policy than of changes in allocation policy for other organs. However, we expect those changes to be qualitatively similar, and this analysis covers all allocation policies.

B. Effects of Organ Transplantation

Industry Structure and Size. As indicated in the table below, covering major organs, transplantation services are a very substantial set of medical procedures, although only a very small fraction of the trillion dollar health care sector.

Table 8
Estimated Billed Charges for Transplants, 1996

Major Organ	No. Programs 1996	No. Trans-plants 1996	Average Billed Charges per Transplant 1996 ($K)	Total Program Billed Charges 1996 ($K)	Average Program Billed Charges 1996 ($K)
Kidney	253	11,099	$94	$1,043,306	$4,124
Liver	120	4,058	$290	$1,176,820	$9,807
Pancreas	120	1,022	$110	$112,420	$937
Heart	166	2,342	$228	$533,976	$3,217
Lung	94	805	$241	$194,005	$2,064
TOTAL PROGRAMS	753	19,366		$3,109,751	
TOTAL HOSPITALS	281	19,366		$3,109,751	$11,067

Sources: Data on numbers of programs and hospitals 1996 Annual Report of the OPTN, page 20 and C-2. Data on transplants performed from Facts About Transplantation in the U.S., UNOS, July 23, 1997. Data on billed charges per transplant from "Cost Implications of Human Organ and Tissue Transplantations, an Update: 1996," by Richard H. Hauboldt, F.S.A., of Milliman & Robertson, page 30, excluding OPO changes.

These data show that on average, transplant programs generate revenues in the millions of dollars. Since most transplant hospitals operate several programs, the unduplicated revenue average across the 281 transplant hospitals that are OPTN members exceeds $10 million annually. This includes not just the cost of the transplant procedure itself, but also pre- and post-transplant charges such as time in the hospital waiting for a transplant. Because the source of these data uses billed rather than negotiated charges, actual receipts may be somewhat lower than shown above.

The range of revenues is much broader than these averages convey because the number of transplants performed varies so widely. The following table, taken from OPTN

and Scientific Registry data, shows the dozen highest volume programs for liver transplants performed in 1994 and 1995. These dozen programs performed one fourth of all liver transplants. Taken together, the two dozen lowest volume programs of those that performed transplants in 1995 (about 8 member programs performed zero transplants) only performed about 108 transplants, 3 percent of the total . Among active liver programs, the median program performed about 20 transplants, far lower than the average of about 35.

Table 9

12 Highest Volume Liver Transplant Programs, 1994-1995

Transplant Program	1994 Volume	1995 Volume
UCLA Hospital Center, Los Angeles, CA	245	232
Presbyterian-University Hospital, Pittsburgh, PA	220	212
Mount Sinai Medical Center, New York, NY	175	209
Jackson Memorial Hospital, Miami, FL	116	194
Baylor University Medical Center, Dallas, TX	145	140
University of Chicago Medical Center, Chicago, IL	125	132
University of California, San Francisco, CA	106	106
University of Nebraska Medical Center, Omaha, NE	116	94
Rochester Methodist Hospital, Rochester, MN	76	91
University of Alabama Hospital, Birmingham, AL	63	82
Shands Teaching Hospital & Clinics, Gainesville, FL	36	81
University of Michigan Hospital, Ann Arbor, MI	79	78
TOTAL	1502	1644

Source: 1996 Annual Report of the OPTN, pp. 382-387

Thus transplant volumes, and revenues, are highly skewed, with the average much higher than the median.

The cost data in Table 8 focus primarily on hospitals, and do not include procurement charges, which average approximately $24,000 per major organ in 1996, for a total of approximately one-half billion dollars per year in addition to the $3 billion spent at transplant hospitals. Procurement charges are paid through organ procurement organizations. OPOs are by law given local (in some cases state-wide or even larger) monopolies through a review and designation system administered directly by the Federal

government. Currently, there are 63 of them, averaging some $8 million annually in revenues. Most of the revenues of both transplant programs and OPOs are paid by Federally funded health programs, primarily Medicare and Medicaid, but also FEHPB, CHAMPUS, the Uniform Services and the VA. In total the government is by far the largest single payor of all transplants -- renal and extrarenal.

Included in the data above, but not separately identified, are laboratory costs. These can be very substantial, as a wide range of condition-related tests are necessary to monitor patient urgency, and both donors and recipients must have a broad range of laboratory tests.

The data above also include follow-up charges for one year, but not subsequent follow-up charges for immunosuppressive therapy and other costs. These average, according to Milliman & Robertson, about $7,000 for pancreas, $16,000 for kidneys, and between $21,000 and $29,000 for the other major organs in 1996. Adjusted for survival, Milliman & Roberts estimate the five-year cost of major organ transplants including follow-up costs as follows: heart, $317,000; liver, $394,00; kidney, $172,000; Lung, $312,000; and pancreas, $149,000.

There are other sources of data on these categories of costs, each using somewhat different estimating techniques. Their estimates are generally comparable though sometimes lower. We note that such figures do not generally estimate the marginal cost of transplantation, after subtracting other costs that would be incurred if the patient did not receive an organ. Marginal costs are much lower. In the case of kidneys, a number of studies have estimated that transplantation costs are more than offset by reductions in

other medical costs such as the elimination of dialysis costs.

For purposes of the Regulatory Flexibility Act, an entity is considered "small" if it has revenues below a certain size threshold, or operates as a not-for-profit entity that is not dominant in its field. For health care providers, such as hospitals, the threshold amount is $5 million in annual revenues. Taking into account total hospital revenues and not just transplant revenues, few or no transplant hospitals fall below this threshold. However, the great majority of these institutions are not-for-profit entities, and hence qualify as "small entities" despite their substantial revenues.

Patient Effects. The following table provides dramatic evidence of the importance both of increasing organ donation and of reducing unnecessary deaths while waiting for organs. Unlike growth in the waiting list, which reflects factors such as earlier and more aggressive listing, these data on deaths while waiting for organs provide clear evidence of the need.

Table 10
Reported Deaths on the Waiting List
1988-1996

	Year								
Organ	1988	1989	1990	1991	1992	1993	1994	1995	1996
Kidney	739	759	917	975	1052	1285	1361	1510	1814
Kidney-Pancreas	0	0	0	0	15	61	71	86	91
Pancreas	6	23	21	37	33	3	13	4	5
Liver	195	284	316	435	495	562	657	799	954
Heart	494	518	612	779	780	763	724	769	746
Heart-Lung	61	77	68	45	44	51	48	28	48
Lung	16	38	50	139	219	252	286	340	385
Intestine	0	0	0	0	0	3	15	19	22
Overall	1502	1666	1962	2360	2580	2902	3055	3421	3916

Source: UNOS web site at http://www.UNOS.org/sta_dol.htm, data as of January 13, 1997

The approximately 20,000 annual transplants of major organs fall into two broad groups. More than half are kidneys. In the case of kidneys, dialysis is an alternative to transplantation for extended periods of time. Therefore, for most patients transplantation is not a matter of immediate survival. Instead, the benefits of transplantation fall largely (though not exclusively) in the domain of improved quality of life. These improvements can be very substantial, as physical health while on dialysis is significantly impaired, and dialysis imposes major stresses and substantial inconveniences in carrying out normal activities. In sum, dialysis sustains life but not well-being whereas a transplant can and often does restore well-being. For other organs a transplant is in most cases a matter of survival. There are life-prolonging technologies that work for some patients (e.g., ventricular assist devices for hearts) but for most persons a transplant is literally essential

to survival. Thus, in round numbers the annual benefits of organ transplantation include about twelve thousand lives vastly improved by kidney transplantation, and another eight thousand lives both vastly improved and prolonged by transplantation of other major organs.

It is common, in benefit cost analysis, to use a concept termed "value of a statistical life" to estimate in monetary terms the benefits from lives saved. Estimates of this value can be derived from information on the preferences of individuals for reduction in the risk of death, and their willingness to pay for such reductions. In this case, however, it is important to take into account two major factors that reduce the usefulness of a statistical life as a measure: (a) most organ transplant recipients are much older than average and hence gain fewer years than would average beneficiaries of other life-saving interventions, and (b) an organ transplant carries a substantial probability of either the graft or the patient not surviving. For example, according to historical data from the 1996 Annual Report of the OPTN (page 22), only 59 percent of cadaveric kidney grafts survive 5 years, and only 81 percent of these patients survive 5 years (patient survival is substantially higher because dialysis is usually an option if the organ fails). Five year patient survival rates for livers have been 69 percent, for hearts 68 percent, and for lungs 43 percent. As each year passes, additional patients die, though at lower rates than in the first year or two. Survival rates have improved in recent years, but the statistical expectation of increased longevity and/or graft survival from a transplant is on the order of 10 years (a rough estimate since we do not yet know what the long-term experience will become), not the 40 years (half a lifetime) that underlies most estimates of statistical lives.

Using the more conservative concept of a "statistical life-year" saved, then, the benefit from each year's cohort of approximately ten thousand non-renal transplant recipients approximates one hundred thousand life years. In a recent rule-making on tobacco, HHS estimated the value of a statistical life-year at about $116,000 (see Federal Register of August 28, 1996, at page 44576). This was a conservative estimate that would reasonably apply to organ transplantation (though a figure several times as high could equally reasonably be used). Applying the conservative $116,000 value to statistical life-years saved by non-renal organ transplants, the social benefit from each annual cohort of recipients is on the order of $12 billion. (Additional benefits could be calculated for quality of life improvements for kidney recipients.) Thus, whether one counts lives saved, life-years extended, or improved quality of life, and whether or not monetized, the social benefits of transplantation are enormous and far exceed the admittedly expensive costs of transplantation.

C. Effects of this rule.

This rule creates three major effects. First, it establishes terms of public oversight and accountability for the entire organ transplantation system, and the OPTN in particular. We believe that this reform creates major public benefits in the categories of "good government," preserving public trust and confidence in organ allocation, and assuring the rule of law. The Secretary does not believe that such oversight creates any consequential costs. Its benefits are substantial, but intangible. They may well lie primarily in future problems avoided (e.g., reduction in organ donation if the public were to lose confidence

in the fairness of the OPTN in allocating organs) rather than in specific current problems solved.

Second, this rule requires creation of a system of patient-oriented information on transplant program performance. At present, the fundamentals of such a system exist through the efforts of the OPTN. The OPTN collects, validates, and analyzes a great deal of important information. It publishes, in collaboration with this Department, a "Report of Center Specific Graft and Patient Survival Rates." This report is technically of high quality, but from a patient perspective is not complete. It consists of 9 volumes, and many hundreds of pages. It was last issued in 1994, and the data were current only up to the end of 1991 (a new report is expected in late 1997, but it will contain information only through the end of 1994). The primary limitation of the Report is that the survival rates are for patients transplanted several years earlier and there is no information regarding the waiting list at individual transplant centers. We believe the data should be more current. In addition, we believe center-specific waiting times and numbers and percentages of transplant center organ turndowns of organs for non-medical reasons should be made available to the patients.

This rule will improve equity, by creating performance goals against which the OPTN can reform current allocation policies. Such a reform has important benefits--though benefits virtually impossible to quantify--in their own right. We note that "equity" is an important goal under Executive Order 12866. Unfortunately, improved equity is an extraordinarily difficult concept to quantify. It is a goal, and benefit, to members of society at large, to donor families, to transplant candidates, and to transplant recipients.

We do have some measures of additional benefits arising in part from improved equity, such as life-years saved, but these are a separate category of benefit. We believe that a system that delivers organs to those most in need, without regard to geography , rewarding those who are less sick but happen to have more waiting time, or rewarding "gaming" by patients or physicians, has profound effects quite apart from its live-saving effects.

The table below summarizes a number of measures of the effects of alternative approaches to improved equity in organ allocation, for livers. Comparable data are not readily available for other organs, and for a number of reasons liver transplants are particularly susceptible to improvement (hearts, for example, are already shared regionally and kidney patients have dialysis options). However, these liver data suggest the kinds of improvements that can be made for other organs.

Table 11
Summary of Measures of Alternative Approaches to Liver Allocation

	1996 Policy	Allocation Committee	Inpatient First	National
Percent Transplanted by Hospitalization:				
Inpatient	59%	73%	96%	97%
Outpatient	41%	27%	4%	3%
Share of Organs:				
Local	78%	44%	38%	20%
Regional	18%	28%	31%	6%
National	4%	28%	31%	74%
Number Transplants:				
Initial	10,992	10,998	10,451	10,231
Repeat	1,663	1,659	2,189	2,425
Total	12,655	12,657	12,640	12,656
Number on Waiting List at End:	11,534	11,788	12,729	13,050
One Year Survival Rate:	80%	81%	76%	73%
Deaths:				
Pre-transplant	3,704	3,599	3,168	2,963
Post-transplant	2,539	2,555	2,967	3,144
Total	6,243	6,154	6,135	6,107
Life-years:				
Pre-transplant	26,600	27,193	29,443	29,915
Post-transplant	24,712	24,840	22,759	21,765
Total	51,312	52,033	52,202	51,680

Source: These estimates all come from modeling runs created by the Pritsker Corporation for the OPTN. Most of those results were included in information provided at OPTN Board of Directors meetings. All data cover a three year period, and are not annual estimates.

These data show, in broad outline, the effects of current and several alternative policies for liver allocation. We emphasize that none of the alternatives modeled included the effects of improved listing and status standards, and for that and other reasons discussed below these results cannot be taken as precise predictions of the effects of changes.

These data also omit a large number of alternative policies that have been modeled, in the interest of economy of presentation. Of particular interest are a set of policies modeled by the CONSAD Corporation that deal with a family of options that have been termed "time and distance weighted." This family of options seeks to minimize transportation of organs while achieving equity based on medical urgency and waiting time. In effect, organs are transported long distances only when there is no alternative for patients with high priority. Organs are kept locally when only very small differences in patient benefit could be achieved by regional or national transportation. Depending on the precise weights given to medical status, waiting time, and distance, inequities due to waiting time disparities can be greatly reduced. (See testimony of Dr. John P. Roberts of the University of California, San Francisco, presented at the public hearing and two letters from Dr. Roberts included as Exhibit L in the Liver and Intestinal Organ Transplantation Committee Report presented to the OPTN Board of Directors for its meeting on June 25, 1997).

In the table above, some of the most studied options are presented. These options focus increasingly on broader geographical sharing, and on greater reliance on medical urgency, from left to right. The first column simply presents the predicted results of

current policy. The "Partial Regional" column shows the results of an option reviewed and subsequently rejected by the OPTN Board in 1996, that would have allocated organs to Status 1 (most urgent) patients across regions comprising 20 percent of the eligible patients. Other patients would have received either a slightly improved or no chance at organs from out of the local area. Thus, this represents a very modest change from current policy. The third column, "Inpatient First", shows the results of an option that would have allocated organs nationally to hospitalized patients, and only then to Status 3 patients. The "National" column shows the results of an option proposed by the University of Pittsburgh Medical Center that would have allocated organs by status, primarily on a national basis, from most to least urgent (even the "National" proposal preserved a substantial role for local allocation, by allocating first to a local patient in Status 1, then nationally, then to a local patient in Status 2, then nationally, etc.).

One very striking result is that even a modest change can very substantially change the kinds and places of patients receiving organs. The "Partial Regional" option decreases the share of livers allocated to non-hospitalized patients (Status 3 and 4) from 41 percent to 27 percent, and decreases the number of organs shared locally from 78 percent to 44 percent.

Taking the remainder of the rows in order, broader sharing has no consequential effect on the number of transplants, but raises the number of repeat transplants, thereby reducing the number of individuals transplanted. This is a consequence of transplanting very sick high Status patients who are more likely to reject an organ graft after transplantation. The number on the waiting list rises when organs go first to more urgent

patients. This is both a good and bad outcome--longer waiting is "bad" but not if the alternative for other patients is death. Survival rates decrease with a priority to the most urgent because the most urgent patients tend to have more advanced disease and additional co-morbidities (as discussed below we do not believe that current simulation results accurately measure likely survival rates). However, as shown in the estimate of deaths, the net effect of these changes is to reduce premature death, despite the decrease in survival rates. Of importance is that the net total change in deaths masks a very pronounced difference in direction for deaths pre-transplant (which are substantially reduced), and deaths post-transplant (which in the Pritsker model increase almost enough to offset pre-transplant lives saved--but see discussion below of the CONSAD model). Life-years exhibit a similar pattern to deaths, but are arguably a better measure of real effects. Over a longer period of years, the total number of people dying under all options will approach equality--but only if there is no increase in transplant survival rates through medical progress. But a life-year lived is never "lost" and represents an unambiguous gain for the patients who benefit. Unfortunately, the post-transplant life-years increase very little or decrease under broader sharing (as estimated by Pritsker), whereas the years on the waiting list, not dying but not well, increase dramatically.

As shown both in the Pritsker results and in the CONSAD results presented below, no gains are free. Taking as an example deaths under a National policy, the Pritsker model estimates that over a three year period some 700 fewer people would die pre-transplant, and some 600 more people would die post-transplant. These are changes of one-fifth or more in the number dying in each group. Both costs and benefits are very

high, thus reducing the net benefit substantially.

The CONSAD model produces generally similar results, but shows a distinct difference in the magnitude of deaths and life-years:

Table 12

Numbers of Pre- and Post-Transplant Deaths

Under Alternative Liver Allocation Policies

	1996 Policy	Allocation Committee	Hospital First	National
Deaths:				
Pre-transplant	4,571	4,394	4,060	4,216
Post-transplant	2,468	2,487	2,734	2,527
Total	7,039	6,881	6,794	6,743
Life-years:				
Pre-transplant	15,093	17,837	19,580	18,683
Post-transplant	38,107	38,096	35,537	36,465
Total	51,200	53,933	55,117	55,148

Source: CONSAD model run dated March 24, 1997.

As shown, under the CONSAD model the net life saving and life-year saving effects of broader sharing are much more pronounced, as well as more favorable to post-transplant experience. CONSAD shows National allocation preventing a net of over 300 deaths and saving a net of almost 4,000 life-years, in contrast to Pritsker's estimate of about 140 deaths and about 400 life-years (though 900 life-years for Inpatient First). These are not small differences. Under the Pritsker model, deaths would decrease, and

life-years would rise, only about 2 percent from current levels under the most favorable result for broader sharing. Under the CONSAD model deaths would decrease about 4 percent and life-years would rise about 8 percent. Realistically, in view of the modeling issues discussed below, a 2 percent difference may represent less than the possible error in the model, though an 8 percent difference is much more robust--if the model parameters and assumptions are accurate. But even the CONSAD results, which are more favorable to reform, indicate that improved allocation policies have at best a limited potential to improve outcomes. In contrast, improved organ donation represents an unambiguous gain and potentially a much larger gain.

There are known differences in model assumptions and approaches that illustrate the strengths and weakness of both efforts. The Pritsker model results "throw away" the first four years modeled, to show more clearly the long-term rather than transitional effect of change. In contrast, the CONSAD model cumulates the results of years one, two, and three, rather than two, three, and four. Since many life-years and deaths offer in thee transition year, totals vary for this reason. Second, the Pritsker model assumes that all transplant programs operate at the same effectiveness as in the early 1990's, all through the modeling years. The CONSAD model, in contrast, assumes a slow but steady increase in transplant program performance and patient survival. This assumption naturally results in fewer deaths and more life-years gained in CONSAD runs, differentially in favor of those who would otherwise die for certain but could now expect to survive.

One difficulty shared by both models is that the OPTN has not released current data on transplant outcomes, even to its own contractor. Thus, these modeling results rely

on data centering around 1990 and 1991 (including several years before and after) rather than on current outcome data. Because current graft and patient survival rates are known to be higher, this makes certain outputs, particularly graft survival rates, deaths, and life-years, inaccurate. CONSAD attempts to compensate for recent progress, but this is not a complete substitute for better baseline data.

Neither model completely captures a variety of real world nuances. For example, under current policies survival rates for the sickest patients are probably influenced adversely by the sometimes lower quality of locally rejected organs they receive. But no hard data exist, and neither model attempts to estimate such an effect. Neither model attempts to deal with a hypothetical breakthrough in technology. Neither model deals with the "friction" involved in transporting organs on a substantially increased scale (although they do produce estimates of increased organ travel); both assume no wastage or reduced graft survival results. None of these differences or commonalities imply a fatal weakness in either or both of these models, but simply a recognition that simulation modeling is by its very nature a partial and incomplete representation of reality, with any number of assumptions potentially affecting predicted outcomes in substantial ways.

From the Department's perspective, what is most important about these modeling results is that despite the somewhat different interests of their sponsors and the potential bias that might result, and the infant efforts that they represent, these two independent efforts agree almost completely on the qualitative effects to be expected from changes in allocation policies, and very substantially on the quantitative magnitudes involved.

More complex to display are measures that capture likely effects of improved

policies on disparities in waiting times. As discussed earlier in this preamble, program-specific, area-specific, and region-specific results look very different, because aggregation masks disparities. However, even regional differences are substantial. The table that follows shows the disparities under the current policy and the modest Partial Regional proposal, the Hospital First proposal, and the National (local first, then national) proposal, as measured in average days waiting for a liver transplant:

Table 13

Analysis Average Days Waiting for a Liver Transplant

under Alternative Liver Allocation Polices

OPTN Region	1996 Policy	Allocation Committee	Hospital First	National
Region 1	102	123	110	105
Region 2	126	120	121	124
Region 3	23	70	81	109
Region 4	91	91	100	113
Region 5	121	113	109	119
Region 6	56	107	94	107
Region 7	118	113	105	110
Region 8	110	116	106	122
Region 9	119	99	107	115
Region 10	88	92	93	110
Region 11	70	76	88	123
Standard Deviation	32.24	17.93	11.55	6.81

Source: CONSAD model run dated March 24, 1997.

In this table, the standard deviation entry measures the extent to which regional averages differ. The standard deviation is a statistical measuring tool. In this context, it means that under the current system about two-thirds of the regions are within 32.24 days of the average (both longer and shorter), and the remaining one-third are more than that many days longer or shorter than the average. As these results show, even modest geographic sharing based on a proxy for medical need greatly reduces disparities in

waiting time, from a standard deviation of 32.24 days under current policy to as few as 6.81 days under a National system of distribution. (Of course, as discussed previously, current measures of waiting time disparities are weak because the lack of listing standards do not create uniform, status-related measures that would be truly fair as tie-breaking criteria.)

Another dimension of improved equity arises from reducing the role of ethically irrelevant characteristics such as race or insurance coverage in organ allocation. We already know, from prior studies, that racial minorities--particularly African Americans--benefit disproportionately from organ transplantation, but that they may not benefit to the extent that their medical urgency warrants. In the final rule as noted previously we have levied on the OPTN the task of assessing, and developing policies to reduce, socio-economic inequities. No data from the modeling efforts or other sources enable us to predict precise effects, even if the full potential of such policies were clear. However, to the extent that improved allocation policies reduce the ability of the most affluent patients to "game" the system, it will necessarily benefit the more disadvantaged patients.

The performance goals created by this rule do not directly mandate any of the allocation options just discussed. Instead, we require the OPTN to craft new policies that achieve those goals. To the extent that the modeling results capture our expectations, we expect those reformed policies to show results much more similar to the rightmost two columns in the tables above than to the leftmost two columns. But neither precise policy nor expected results have been modeled yet. And neither modeling effort purports to measure directly equity, except insofar as reduced disparities in waiting time in status

captures this goal.

One final effect of the Department's overall initiative is extremely important, though not attributable to this regulation. Increases in organ donation are an unambiguous benefit. If, as seems possible, the package of initiatives proposed by the Department could increase organ donation by 10 percent, the benefits in lives saved and life-years increased would both dwarf the estimates of these effects as calculated by the simulation models. Increased donation would also reduce waiting times. However, it would not directly improve disparities in waiting times. Only more equitable organ sharing policies can reduce such disparities.

D. Alternatives Considered

Throughout this preamble we have presented and analyzed alternatives that the Department considered. Many of those selected have an importance unrelated to regulatory impact as such, or have little or no economic effect. There were, however, two broad strategic options that we elected not to pursue at this time.

First, we could have required volume or performance standards for transplant programs. The possibility of such standards was presented at the public hearings, even though we had never proposed specific standards for consideration. A great deal of research evidence exists on differences among transplant programs in survival rates (the most common measure), and on how volume correlates with those rates. Nonetheless, we rejected that approach for a number of reasons. There are a number of technical problems with such standards that could have been overcome to varying degrees. For example, a

volume standard would require an exception for new programs during a transition period or it would forever preclude new programs in the many areas of the country that do not have such programs, or to compete with established programs where those now exist. More difficult to solve, a quality standard would have to deal with the variance introduced by small programs. For example, assuming a particular program had a "true" performance rate of 50 percent for a particular procedure, and performed the first four procedures with two successes and two failures, the fifth procedure would result either in a 60 percent or 40 percent cumulative rate, making it look very much better or worse than its true performance. Two or three favorable or unfavorable results in a row would not be statistically unusual. Lucky or unlucky runs that would substantially affect potential error in apparent versus "real" results are inherent in activities at some low volume transplant programs. Further, the need to "case mix adjust" adds significant complexity, and more variance. Yet another problem arises because standards imply "pass-fail" rates which do not necessarily push better programs to even higher performance. And still another arises because a standard set today may be obsolete a year from now as performance generally improves. Not unimportantly, virtually the consensus view of the testimony on this subject at our public hearings opposed volume and even quality standards, and favored more and better information. For these and other reasons, we elected to require instead improved information on transplant hospital performance. We believe that better information can equal or exceed the benefits of "pass-fail" standards without their potentially arbitrary and disruptive effects.

Nothing in this volume/quality position related to minimum volume is intended to discourage large payers and prudent purchasers from setting their own standards. There is a big difference between a single national standard that every program must meet or be terminated, and elective payer standards. We encourage payers to explore and set such standards, which can even focus on levels of excellence that could not reasonably be set as nationally uniform minimum levels. We also expect the OPTN to explore setting voluntary standards of excellence, and to continue both research and modeling on such standards.

A second set of strategic options revolved around the possibility of imposing directly, at this time, specific allocation standards focusing on geographic equity. Such options would have the advantage of reducing known inequities, and could rest substantially on the very competent work already performed both by the OPTN itself and other entities. For example, without any change in medical criteria a "hospital first" allocation policy could be introduced for liver allocation. A "time and distance weighted" allocation policy, with high weight given to health status, could also greatly improve equity without increasing average travel times for donor livers as much as other options:

Table 14
Estimated Average Miles Transported of Donated Livers
Under Alternative Liver Allocation Policies

Option for Liver Allocation	Average Distance in Miles
1996 Policy	161
National Sharing	1072
Time and Distance Proposal (Policy W12)	242

Source: CONSAD Modeling run provided to Dr. John Roberts December 11, 1996. Policy W12 gives only medium weight to health status directly but substantial weight to waiting time, which is correlated.

We have temporarily rejected this family of options because we believe that the performance goal approach we have crafted is likely to produce superior results almost as, or perhaps as, quickly. With the willing cooperation of the OPTN in bringing its expertise to bear, there is no reason why policies better than any yet proposed cannot be developed. In this regard, improved listing criteria and medical status criteria will both reduce the need for broader sharing and increase the professional trust and confidence needed to make that sharing work. As discussed below, improved allocation of organs is not a zero sum game. Not only can most transplant programs expect to gain as many organs for their patients as they lose, but their own most urgent cases will benefit the most.

Nonetheless, this rule does provide for the Secretary to override OPTN proposals, or act if the OPTN is dilatory.

E. Effects on Small Transplant Programs

A great deal of fear and concern was evidenced at the public hearing over effects on transplant programs, particularly smaller programs, if broader sharing were to occur. Many witnesses feared the possibility that patients would select, and organs follow, to the largest programs (some of these witnesses asserted, and others denied, that the largest programs had the best programs). The Department believes that such fears are greatly exaggerated, for many reasons. In the discussion that follows, we note again that the great majority of transplant hospitals are "small entities" under the Regulatory Flexibility Act simply by virtue of their non-profit status, and that there is no known correlation of size of transplant program with size of parent institution (beyond the fact that small

hospitals do not conduct transplant programs at all).

A crucial fact to understand is that for the most part the smaller transplant programs already compete directly with larger programs, even within the "local first" allocation schemes, or have the only program in their metropolitan area. As shown selectively on the table below (covering one-fourth of the states in alphabetical order), and graphically on the map below, the approximately 112 liver transplant programs active in 1995 were concentrated in a far smaller number of cities. In fact, 10 states had no liver allocation program at all.

Table 15

Number of Small, Medium and Large Volume Liver Programs in Selected States

State	City	No. Small (<12)	No. Medium (12-34)	No. Large (35>)	Total
AL	Birmingham	0	0	1	1
AK	None in Alaska	0	0	0	0
AR	None in Arkansas	0	0	0	0
AZ	Phoenix	1	0	0	1
	Tucson	0	1	0	1
CA	Los Angeles area	1	2	2	5
	Sacramento	1	0	0	1
	San Diego area	0	2	0	2
	San Francisco Bay area	0	0	3	3
CO	Denver	2	0	1	3
CT	Hartford	1	0	0	1
	New Haven	0	1	0	1
DC	Washington area	1	0	1	2
FL	Gainesville	0	0	1	1
	Miami	0	0	1	1
GA	Atlanta	1	0	1	2
HI	Honolulu	1	0	0	1
IL	Chicago	0	2	2	4
IN	Indianapolis	0	1	1	2
Total	17 Cities	9	9	14	32

Source: OPTN and Scientific Registry data supplied to the Department, through 1995, dated March 1, 1996.

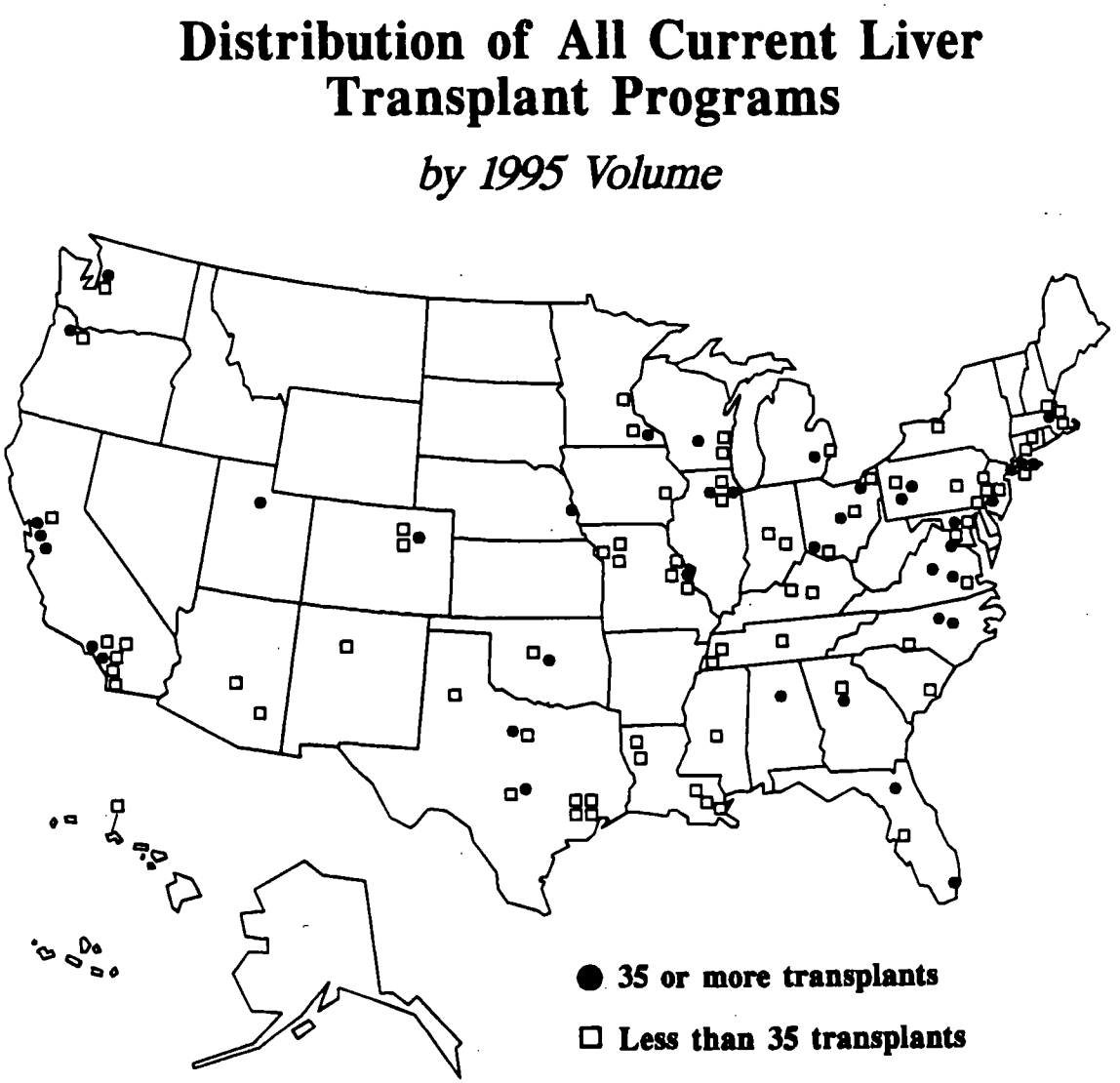
These 13 states and 17 metropolitan areas contain 32 liver transplant programs (the hundreds of remaining metropolitan areas, smaller cities, and rural areas in these states have no local transplant programs--their patients must travel). Of the nine small

(fewer than 12 transplants annually) programs, four have no local competitors. These four have effective local monopolies for patients (undoubtedly a majority) who would prefer local transplantation if given a choice. The five with competitors are already surviving strong competition in their own health market. Thus, with or without changes in allocation policy that favor broader sharing, all of these transplant hospitals have substantial advantages or a demonstrated capacity to withstand competition for patients.

The map below shows the pattern of choice for the entire nation, grouping all transplant hospitals into small and medium (less than 35 transplants) or large (35 or more transplants). It shows that most transplant hospitals already share cities or are located in

closely adjacent cities.

Another potential concern arises from the fact that on average, smaller transplant hospitals serve relatively less sick patients and larger transplant hospitals tend to handle more Status 1 and 2 patients (there are numerous exceptions to these average tendencies). If nothing else changed but the relatively ability of the sickest patients to obtain organs,



smaller transplant hospitals would be expected to lose transplant volume. One of the

modeling firms, CONSAD, addressed this issue. Its modeling shows the following percentage shares of patients transplanted at medium, and large transplant hospitals under the alternative policies modeled, assuming no behavioral responses by the programs.

Liver Transplants	1996 Policy	Allocation Committee	Hospital First	National
Large programs (>35)	40%	45%	51%	52%
Medium programs (12-35)	37%	34%	30%	30%
Smaller programs (<12)	24%	21%	19%	18%

Source: CONSAD modeling run, dated March 24, 1997

This result assumes that programs continue their current policies as to which patients they tend to transplant, e.g., that smaller transplant hospitals do not more aggressively seek to retain the sickest patients. That seems extremely unlikely. Why would a program that is worried about volume not change its practices to improve its volume? But even in this "worst" case for smaller centers, they still perform 18 percent of total liver transplantations, and the medium programs still perform 30 percent of total liver transplantation. Far more likely, "threatened" programs will strengthen their programs and attract as many or more patients as they do at this time.

Finally, all of these computer simulations assume that the number of available organs remains unchanged. We believe that improved use of OPOs in identifying candidates for donation and in contacting families of potential donors to request permission can alone significantly improve organ supply. Early data suggest that organ donation under the Pennsylvania program has increased by 12 percent or more annually. The other actions that the Department will take can also have significant effects in

increasing donation. Thus, it is quite likely that transplant programs of all sizes will see volume increases from the entire package of reforms.

In sum, nothing in the available data nor reasonable expectations as to future business strategies by transplantation programs suggest either that smaller transplant hospitals will be driven out of business or that patients in cities served by smaller centers will be deprived of local service. Nor is there any apparent alternative--short of preserving current inequities that tie patients largely to local organ availability regardless of medical need--that would prevent what little adverse effect on a few local hospitals (not patients) that might occur. Regardless, the purpose of organ allocation policy is not to serve hospital business needs, but to serve patient needs. The benefits to patients from the reforms under this final rule are large.

IV. Paperwork Reduction Act of 1995

This final rule contains information collections which have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 and assigned control number 0915-0184. In addition, there are reporting and disclosure requirements that have not yet been approved (as noted in the table). The title, description, and respondent description of all information collections are shown below with an estimate of the annual reporting and record keeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Organ Procurement and Transplantation Network.

Description: Information will be collected from transplant hospitals, organ procurement organizations, and Histocompatibility laboratories for the purpose of matching donor organs with potential recipients, monitoring compliance of member organizations with system rules, conducting statistical analyses, and developing policies relating to organ procurement and transplantation.

Description of Respondents: Non-profit institutions and small organizations.

ESTIMATED ANNUAL REPORTING AND RECORD KEEPING BURDEN:

Section	Activity	Annual Number	Annual Frequency of Respondents	Average Burden Per Response	Annual Burden Hours
121.4(a)(3) (Reporting)	Submission of Policies	1	4	.5	2
121.4(a)(3)** (Disclosure)	Sending policies to OPOs	1	16	75	1200
121.3(d)(1)	OPTN membership application requirements for OPOs, hospitals, & others	5	1***	2.0	10
121.6(c)** (Reporting)	Submitting criteria for organ accept.	100	1	0.1	10
121.6(c)** (Disclosure)	Sending criteria to OPOs	100	1	0.1	10
121.7(b)(4)	Reasons for refusal	878	13	0.1	1200

121.7(e)*	Transplant to prevent organ wastage	278	4	0.1	111
121.9(b)	Certification application requirements for transplant programs	50	1***	2.0	100
121.11(b)(2)*	Transplant candidate registration	828	43	0.1	3560
121.11(b)(2)*	Donor registration	66	131	0.2	1730
121.11(b)(2)*	Potential Recipient	66	469	0.1	3096
121.11(b)(2)*	Donor Histocompatability	51	206	0.1	1051

121.11(b)(2)*	Transplant Recipient Histocom.	51	369	0.1	1881
121.11(b)(2)*	Transplant Recipient Registration	878	24	0.25	5200
121.11(b)(2)*	Transplant Recipient Follow-up	878	130	0.14	16000
Total		4231			35,161

[Need to insert data on new section 121.11(c) and re-estimate other items.]

* The data collection forms for these activities have been approved by the Office of Management and Budget under the Paperwork Reduction Act (OMB No. 0915-0157).

** These requirements have been submitted for OMB approval. This requirement will not be effective until the Department obtains OMB approval, at which time a notice will be published in the Federal Register to notify the public of such action.

***Current members of the OPTN and currently certified transplant programs will not have to re-apply for membership and certification following promulgation of the new regulation. Only new applicants will be required to apply, one time.

The final rules also require OPOs and transplant hospitals to maintain records, as follows:

Section	Requirement
121.7(b)(4)	Documentation of reason for refusal
121.7(c)(2)	Documentation of suitability tests
121.11(a)(2)	Maintain records on organ donors and recipients

According to staff of OPOs and transplant hospitals, such record keeping is integral to the operation of these facilities. Therefore, these record keeping requirements impose no additional

burden.

List of Subjects in 42 CFR Part 121

Organs-human, Organ procurement and transplantation network, Organ transplantation, Hospitals.

Dated:

Administrator
Health Resources and Services
Administration

Approved:

Secretary