

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FOSTERING EQUITY IN PATIENT
ACCESS TO TRANSPLANTATION:**

Local Access to Liver Transplantation



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Inspector General**

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EXECUTIVE SUMMARY

PURPOSE

The purpose of this inquiry is to clarify the extent to which local access to liver transplants exists.

BACKGROUND

In April, 1998, the Department of Health and Human Services issued a final rule governing the operation of the Organ Procurement and Transplantation Network (OPTN) and providing for greater equity in the distribution of organs. Following publication of that regulation, extensive debate ensued about the effect it might have. In October, 1998, Congress delayed the regulation's implementation for one year, pending a study by the Institute of Medicine. The IOM released that report in July, 1999.

The debate over the regulation accentuated concerns about local access to transplantation. Transplant physicians and patient advocates cited the advantages of receiving a transplant at a local center, including a nearby support system of family and friends, and avoidance of financial costs associated with having to travel to a distant center. Some claimed that the regulation could lead to closure of small transplant centers and deprive patients of local access.

Our purpose in this report is to examine the validity of the perception that widespread local access to a transplant center exists. We provide information on the geographic configuration of the nation's liver transplant centers and the factors that contribute to that configuration.

Our inquiry focuses on liver transplant centers because much of the attention surrounding the regulation has addressed liver transplantation. We use data from the *1998 Annual Report of the U.S. Scientific Registry of Transplant Recipients and the Organ Procurement and Transplantation Network*. We draw on interviews with transplant professionals, a review of literature, and testimony from the Department's 1996 public hearings on liver allocation policy.

FINDINGS

Liver Transplant Centers Are Concentrated Geographically. The 117 liver transplant centers cluster around major metropolitan areas. This pattern leaves large portions of the United States population at considerable distance from a transplant center. This distribution has changed little in recent years.

In 1997, more than 80 percent of liver transplants were performed in just 35 cities; 77 of the 117 liver transplant centers were located in cities with two or more liver transplant centers.

In 1997, 15 States had no liver transplant center within their borders; 45 percent of the U.S. population lived outside of metropolitan areas with liver transplant centers. Most new liver transplant centers have opened in areas where a liver transplant center already operated.

Liver Transplants Are Concentrated Among a Few Centers. A small number of transplant centers account for the great majority of all liver transplants performed. Many smaller transplant centers have been operating for several years at low volume.

In 1997, 20 transplant centers, located in 18 cities, performed more than half of all liver transplants.

Our review of the data found that many of the smaller transplant centers have been operating at a relatively low volume for a number of years. 29 of the 36 centers that performed 12 or fewer transplants in 1997 have been in operation since 1992 or earlier.

Fundamental Factors Constrain Broader Geographic Distribution of Liver Transplant Centers.

Limited Number of Organs for Transplant. The shortfall between the number of livers available and the number of patients seeking a transplant means that the supply of organs, not of centers, determines the number of transplants that can be performed.

Relationship between Volume and Quality. One key criterion that purchasers use in contracting with transplant centers is the number of transplants that a center has successfully performed. For example, to receive Medicare certification a center must perform at least 12 transplants per year.

Costs of a Transplant Center. Establishing a liver transplant center is a costly venture for a hospital, requiring experienced and skilled surgical, medical, and support personnel.

Role of Academic Medical Centers. Liver transplant centers are affiliated with academic medical centers and large teaching hospitals which tend to cluster around urban centers.

CONCLUSION

In the debate over the Department's regulation on organ allocation, concerns were raised that the regulation could hinder local access to liver transplantation. The assumptions underlying this concern are that such local access is of value and that it generally exists. Our study does not draw conclusions about the value of local access to liver transplant centers. Arguments can be made about both the advantages and disadvantages of local, but generally low volume transplant centers, versus high volume centers that draw patients from a broader geographic area.

However, the study does show that the assumption about the availability of local access is flawed. Widespread local access to liver transplant centers is a myth. National policies on organ allocation are not likely to affect the overall distribution of transplant centers one way or the other. Instead, basic factors other than allocation policy affect this access, including the shortage of organs, the relationship between the number of transplants and patient outcomes, the high costs of running a transplant center, and the housing of liver transplant programs in urban academic medical centers. The Institute of Medicine reinforced this point in its recent report, when it noted it “did not find credible evidence that broader sharing or the Final Rule [the Department’s allocation regulation] would result in the closure of smaller transplant centers.”

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INTRODUCTION

Purpose

The purpose of this inquiry is to clarify the extent to which local access to liver transplants exists.

Background

For the past decade, the Office of Inspector General has maintained an active interest in this nation's organ allocation and transplantation system. Our work has been guided by three underlying tenets that the Congress spelled out in the National Organ Transplant Act:

- An equitable system, with each person on a transplant waiting list having an equal opportunity to receive a transplant subject to established medical criteria;
- A national system adhering to uniform policies and standards; and
- A cooperative system based on the best interests of patients waiting for transplantation.

In April, 1998, the Department issued a final rule governing the operation of the Organ Procurement and Transplantation Network (OPTN) and providing for greater equity in the distribution of organs.¹ Following publication of that regulation, extensive debate ensued about the effect it might have. In October, 1998, the Congress delayed the implementation of this regulation for one year,² pending a study by the Institute of Medicine (IOM). The IOM issued that report in July, 1999.³

Local Access to Transplant Services

The debate over the regulation accentuated concerns about local access to transplantation. The significance of local access to transplantation came to light in comments during three days of public hearings that the Department of Health and Human Services held in December, 1996, to examine organ allocation policies.

One transplant surgeon typified these concerns when he said, "We do not want to change allocation in such a way that access is denied to our indigent populations, to our minority populations, and to people who can't afford to travel to large regional transplant centers. There is no need to transport livers and patients long distances for a technology and a procedure that is available to them in their own backyards."

Transplant physicians and patient advocates cite two key benefits to local access. Some claimed that the regulation could lead to closure of small transplant centers and deprive patients of these advantages.

- ▶ Local support. Transplantation requires interaction and participation with a patient's family and loved ones. In its advice to patients on "Which Hospital is Best for You?" the United Network for Organ Sharing (which holds the OPTN contract) urges patients to consider "the support systems you will have in that area (your family, friends)."⁴ Another

speaker at the 1996 hearings, describing her transplant, summarized this concern by saying, “Because I had my transplant at home, my family was able to be with me. They gave me tremendous support and encouragement. They learned my medicines along with me. . . It is not merely that having the transplant regionally was convenient, I don’t believe that I would have lived without the emotional support of my family.”

► Financial impact. Transplantation in a distant city is very costly. Even if a patient’s insurance covers travel and lodging expenses, it still may be insufficient. Another speaker at the hearings noted, “My husband would have been with me regardless of the distance, at a cost of missing almost 7 weeks of work. For many families, the expense and disruption of being far away from home, job, and schools would be too much.”

The UNOS lists the following non-medical costs as items that patients should consider:

- Transportation to and from your transplant center, before and after your transplant;
- Food, lodging, long distance phone calls for you and your family;
 - Child care;
- Lost wages if your employer does not pay for the time you or a family member spends away from work;
- If your transplant center is not near your home, you may need to live near the center before and for a while after your transplant. Some centers offer free or low cost lodging
- You may need to make arrangements for air travel to get to your transplant hospital quickly. You should also make back-up plans to get to your transplant hospital in bad weather, especially in the winter.⁵

This Inquiry

This inquiry examines the validity of the perception that widespread local access to a transplant center exists. Our aim is to contribute to current discussions about desirable organ allocation policies by clarifying the extent to which access to liver transplants is, in fact, localized geographically, both currently and in recent years. We do not speculate as to the allocation rule’s impact on local access. To a large extent, that impact would depend on the details of the allocation rules adopted by the OPTN. Instead, this inquiry provides information on the geographic configuration of the nation’s liver transplant centers and the factors that contribute to that configuration.

We focus on liver transplant centers because liver allocation has been the focus of controversial changes proposed by the OPTN in 1996 and 1997. Consequently, much of the attention and discussion surrounding the rule has focused on livers,⁶ and the regulation included special transition provisions governing liver allocation specifically.

Data Source

Our inquiry utilizes data from the *1998 Annual Report of the U.S. Scientific Registry of Transplant Recipients and the Organ Procurement and Transplantation Network*, published in May 1999. This report provides data on transplant center volume from 1988 through 1997. We

also draw on interviews with professionals in the transplantation field, a review of literature, and a review of testimony from the December, 1996, public hearings on liver allocation policy.

We conducted this inspection in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

Liver transplant centers are concentrated geographically. *The 117 liver transplant centers cluster around major metropolitan areas. This pattern leaves large portions of the United States population at considerable distance from a transplant center. This distribution has changed little in recent years.*

- ▶ *In 1997, more than 80 percent of liver transplants were performed in just 35 cities; 77 of the 117 liver transplant centers were located in cities with two or more liver transplant centers.*

Of the 35 cities that account of 80 percent of liver transplants, 29 contained more than one transplant center. Chicago and Philadelphia house five transplant centers each. As Table 1 shows, in six other cities — Boston, Houston, Los Angeles, New Orleans, New York, and St. Louis — four transplant centers operate.⁷

Table 1			
Number of Liver Transplant Centers by City, 1997			
Number of Transplant Centers	Number of Cities	Number of Transplants Performed	Percent of All Transplants Performed
5	2	415	10 %
4	6	880	21
3	2	296	7
2	19	1,173	28
1	39	1,404	34
Total	68	4,168	100 %

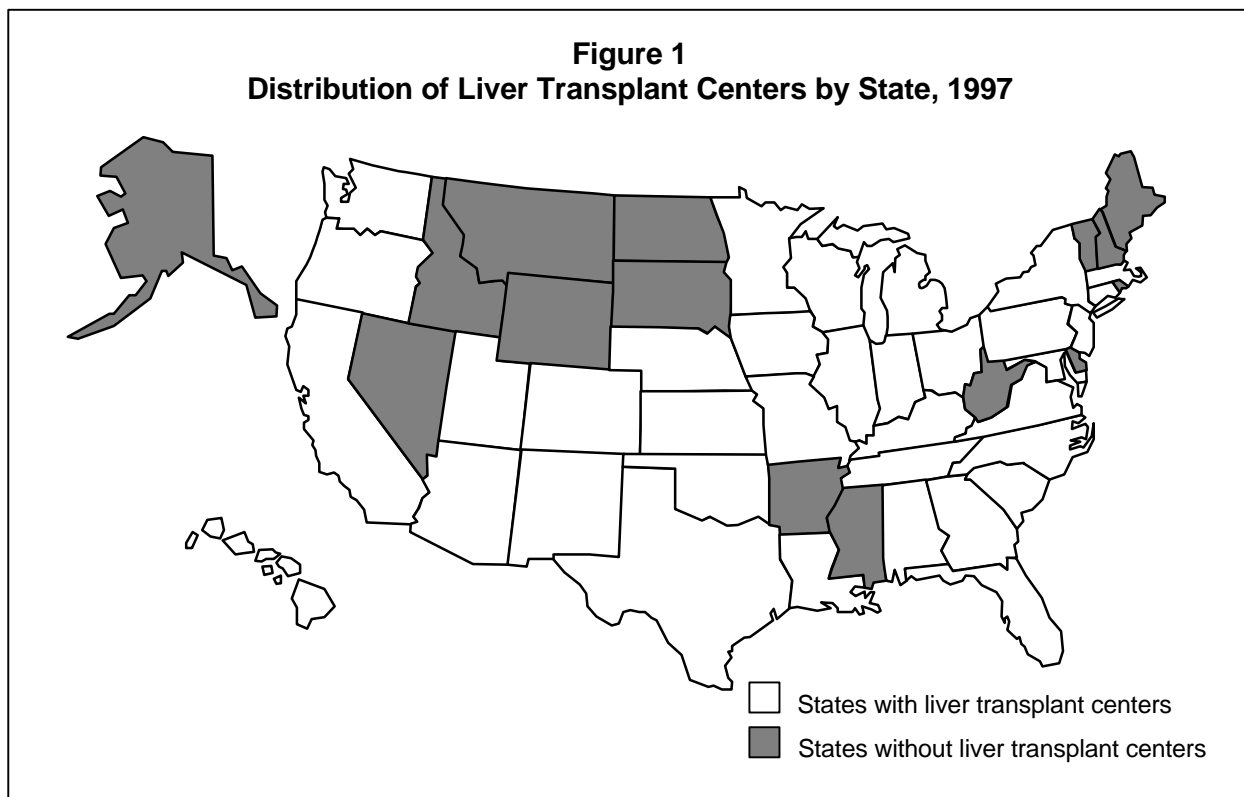
Source: 1998 Annual Report of the U.S. Scientific Registry of Transplant Recipients and the Organ Procurement and Transplantation Network

In addition to the 29 cities with multiple transplant centers, half a dozen other cities — Miami, Omaha, Gainesville, Birmingham, Madison, Palo Alto — have one large transplant center. The centers in these six cities performed 15 percent of the nation’s transplants.

Appendix A presents city-specific information on the number of centers and number of transplants performed in these cities.

- ▶ *In 1997, 15 States had no liver transplant center within their borders.*

In assessing geographic access to transplantation, it is useful to examine areas in which transplant centers are *not* located. The 15 States that had no liver transplant center include the upper Great Plains, as well as the Northern New England States.⁸ Figure 1 shows the geographic distribution



of States with and without a transplant center. Between 20 percent and 28 percent of persons receiving a liver transplant traveled outside of their State of residence to receive the transplant.⁹

- ▶ *45 percent of the U.S. population lived outside of metropolitan areas in which liver transplant centers are located.*

In addition to rural areas, a number of sizeable cities did not have a local transplant center. For example, among the nation's 25 largest cities, Las Vegas, Nevada; Jacksonville, Florida; El Paso, Fort Worth, and Austin, Texas; and Fresno, California, did not have liver transplant centers.¹⁰

- ▶ *Most new liver transplant centers have opened in cities where a liver transplant center already operated.*

Between 1992 and 1997, there was a net increase of 13 liver transplant centers; 15 centers began operation (and two ceased operations). Of the 15 new liver transplant centers, 9 centers opened in cities where at least one liver transplant center was already operating. Three of the new centers opened in New Orleans, where one was in operation; and two of the new centers opened in Los Angeles, where two centers already were operating.¹¹

The remaining six liver transplant centers that opened in 1993 or later are in cities that did not already have a transplant center. In some cases, such as Westchester County, New York, and Irvine, California, these new centers are near cities with existing liver transplant centers. In other cases, such as Albuquerque or Sacramento, the nearest liver transplant center is at some distance.

Thus, although the number of liver transplant centers did increase during these years, clearly the expansion that took place did little to expand geographic access to transplantation.

Liver transplants are concentrated among a few transplant centers. *A small number of transplant centers account for the great majority of all transplants performed. Many smaller transplant centers have been operating for several years at low volume.*

- ▶ *In 1997, 20 of the 117 transplant centers performed more than half of all liver transplants.*

These 20 transplant centers are located in 18 cities. Philadelphia and New York each have 2 centers in this tier of large centers. Of the remaining 16 cities, 6 cities have only one transplant center, and 10 cities have two or more transplant centers.

In almost all of these cities, one dominant center provides the great majority of transplants. Only in Chicago and Philadelphia — each with five transplant centers — does the largest center perform less than 50 percent of all liver transplants in those cities. In the other cities, with the exception of San Francisco, the largest center provides more than 80 percent of all liver transplants performed in those cities.

Table 2 Liver Transplants Performed in 1997, Grouped by Transplant Center Volume			
Number of Liver Transplants Performed by Center	Number of Centers in Group	Total Number of Transplants Performed by Group	
More than 100	6	1,042	25 %
50-99	19	1,315	32
25-49	35	1,249	30
13-24	21	405	10
1-12	26	157	4
0 (inactive)	10	0	0
Total	117	4,168	100 %
<small>Source: 1998 Annual Report of the U.S. Scientific Registry of Transplant Recipients and the Organ Procurement and Transplantation Network</small>			

While a few centers provide the largest share of transplants, also striking is the large number of centers that provide very few transplants (see Table 2). To receive Medicare certification a liver transplant center must perform 12 transplants per year.¹² In 1997, 36 centers did not provide this number and were not Medicare certified.¹³ Another 21 centers provided between 13 and 24 transplants.

Thus, almost half — 57 of 117 liver transplant centers — performed fewer than 25 transplants per year, or no more than two per month.

- ▶ *Our review of the data found that many of the smaller transplant centers have been operating at a relatively low volume for a number of years.*

29 of the 36 centers that performed 12 or fewer transplants in 1997 have been in operation since 1992 or earlier. Transplant centers that perform a low volume of transplants are typically found in cities with more than one transplant center, or in close proximity to a city or cities with a liver transplant center.

It should be noted that some of the small centers are located at children’s hospitals that are affiliated with adult transplant centers at other hospitals and that may share the same staff, even though they are identified as separate transplant centers. However, many of the centers performing a low volume of transplants have been established for many years and are not affiliated with another transplant center.

Fundamental factors constrain a broader geographic distribution of liver transplant centers.

- ▶ *Limited number of organs for transplant. The shortfall between the number of livers available for transplantation and the number of patients seeking a transplant means that the supply of organs, not of centers, determines the number of transplants that can be performed.*

Although over 13,000 registrants are waiting on the liver transplant list, just over 4,400 liver transplants are performed annually.¹⁴ Between 1988 and 1997, the number of cadaveric donors increased by 34 percent, while the number of registrants on the liver transplant list increased by 550 percent. In 1998, the number of organ donors increased 5.6 percent, the largest increase since 1993; yet there were still fewer than 5,800 cadaveric organ donors. Clearly, opportunities exist for increasing the number of donors, both through improved identification of potential donors and increases in the rate of consent for donation.

Recent Departmental efforts may address this constraint and lead to an increase in the number of organ donors. One effort is the National Organ and Tissue Donation Initiative. The goals of this initiative are to increase consent to donation, maximize donation opportunities, and learn more about what works to increase donation and transplantation through carefully designed research efforts.

A second effort is revised Medicare Conditions of Participation governing hospitals. This provision requires hospitals to notify their organ procurement organization (OPO) of all patient deaths. This provision also requires specifically that a representative of the OPO, or someone trained by an OPO-approved course, initiate the request for organ donation, as a way of seeking to improve consent rates for donation.¹⁵

► ***Relationship between volume and quality.*** *One key criterion that purchasers use in contracting with transplant centers is the number of transplants that a center has successfully performed.*

Purchasers typically assess a center's performance using graft and patient survival on a substantial number of patients. Generally speaking, for highly complex procedures such as liver transplantation, a minimum volume is associated with higher quality. As we note above, a center must perform 12 liver transplants per year to receive Medicare certification. In addition, the United Network for Organ Sharing (UNOS), advises patients "to consider many things about the hospital you are considering including the number of transplants the hospital has done."¹⁶

Organ procurement professionals also told us of difficulty that arises in trying to place organs at smaller transplant centers. They indicated that these centers are highly selective about the organs that they will accept for patients. One consequence of this selection process is adding time to the process of finding a recipient which, in turn, can make the organ less viable if it is refused at that center and offered to another patient elsewhere.

Published peer reviewed research on the correlation between volume of transplants performed and outcomes is limited. The Health Care Financing Administration, in issuing a regulation on Medicare coverage of lung transplants, cited a study that found that patient mortality following liver transplantation in the United States is a function of center transplant volume.¹⁷ With respect to heart transplants, research has shown poorer outcomes for very small transplant centers.¹⁸ On the other hand, during the December 1996 hearings, a number of small and medium size transplant centers pointed out that smaller centers also have high quality outcomes.¹⁹

Managed care organizations contract with a limited number of transplant centers, which determines where their enrollees may receive a transplant. We interviewed representatives of national managed care organizations to understand the performance criteria they use to select these centers. The individuals we interviewed indicated that transplant center volume and outcomes are important factors that their plans use in selecting transplant centers. In their assessment, these quality measures outweigh geographic proximity for patients.

► ***Costs of a transplant center.*** *Establishing a liver transplant center is a costly venture for a hospital, requiring experienced and skilled surgical, medical, and support personnel.*

Start-up costs for a liver transplant center are high. In our interviews with transplant professionals, such as staff of OPOs where no liver center exists, they cite the economics of the decision as being the major deterrent.

We did not attempt to calculate the cost to a hospital of opening a transplant center, but per patient charges can provide some indication of the expense of this procedure. Medicare charges for 562 Medicare liver transplant patients in 1997 averaged \$160,000, not including professional fees.²⁰ Total per case billed charges in 1994 averaged \$286,000 including hospital and professional fees,²¹ and \$314,500 in 1996 including the first year of followup care.²²

► ***Role of academic medical centers.*** *Liver transplant centers are affiliated with academic medical centers and large teaching hospitals which tend to cluster around urban centers.*

Liver transplantation is a highly sophisticated procedure. Transplantation began as innovative and experimental procedures in research and academic medical centers; transplant centers continue to be housed at these institutions, where the critical mass of personnel with the necessary skills locate. Transplantation requires cooperation and coordination among medical and surgical staff, as well as transplant management teams.

Because of the complexity of liver transplantation and the resources required to support a transplant center, academic medical centers continue to house liver transplant centers. The nation's 124 medical schools are located in 99 cities and in 45 States; most are located in urban areas. The cities and States with multiple liver transplant centers tend to be those which have more than one medical school, such as Boston, New York, and Los Angeles.

CONCLUSION

In the debate over the Department’s regulation on organ allocation, concerns were raised that the regulation could hinder local access to liver transplantation. The assumptions underlying this concern are that such local access is of value and that it generally exists. Our study does not draw conclusions about the value of local access to liver transplant centers. Arguments can be made about both the advantages and disadvantages of local, but generally low volume transplant centers, versus high volume centers that draw patients from a broader geographic area.

However, the study does show that the assumption about the availability of local access is flawed. Widespread local access to liver transplant centers is a myth. Liver transplant centers are highly concentrated geographically. This concentration existed in the early days of liver transplantation, when there were very few centers. Even as the number of liver transplant centers has increased, they continue to cluster in a relatively few cities. For the most part, new liver transplant centers have not moved into previously underserved geographic areas.

Some basic forces sustain that distribution of transplant centers: The reality of a limited supply of organs; the relationship between volume of transplants performed and patient outcomes; the high cost of starting and running a transplant center; and the tendency for liver transplant programs to be housed in academic medical centers, which are concentrated in urban areas. In fact, these inherent forces suggest that the overall distribution of liver transplant centers is not likely to change much one way or the other, irrespective of the shape of national policies on organ allocation. The Institute of Medicine reinforced this point in its recent report, when it noted it “did not find credible evidence that broader sharing or the Final Rule [the Department’s allocation regulation] would result in the closure of smaller transplant centers.”²³

Our work on organ allocation and donation is continuing.

APPENDIX A

Number of Liver Transplant Centers and Total Number of Transplants Performed by City, 1997

City and State	Number of centers	
Los Angeles, CA	4	322
New York City, NY	4	258
Pittsburgh, PA	3	227
Chicago, IL	5	215
Philadelphia, PA	5	200
Miami, FL	1	197
San Francisco, CA	2	130
Dallas, TX	2	124
Boston, MA	4	112
Rochester, MN	2	105
Omaha, NE	1	101
Cleveland, OH	2	100
Gainesville, FL	1	99
St. Louis, MO	4	90
Atlanta, GA	2	89
Birmingham, AL	1	86
Madison, WI	1	72
Baltimore, MD	2	70
Houston, TX	4	69
Denver, CO	3	69
Palo Alto, CA	1	67
Seattle, WA	2	62
Richmond, VA	2	60
Portland, OR	2	58
Cincinnati, OH	2	55
Ann Arbor, MI	1	55
Indianapolis, IN	2	51
Newark, NJ	1	51
Chapel Hill, NC	1	50
San Antonio	1	48
Nashville, TN	1	45
Oklahoma City, OK	2	42
San Diego, CA	2	42

City and State	Number of centers	
Rochester, NY	1	42
Milwaukee, WI	2	41
Iowa City, IA	1	40
Salt Lake City, UT	2	36
Falls Church, VA	1	36
Memphis, TN	2	32
Durham, NC	1	32
Minneapolis, MN	1	32
Charleston, SC	1	30
New Orleans, LA	4	29
Columbus, OH	2	29
Louisville, KY	2	28
Kansas City, KS	1	28
Tampa, FL	1	28
Lackland AFB, TX	1	26
Detroit, MI	1	25
Charlottesville, VA	1	24
Irvine, CA	1	24
Sacramento, CA	1	24
Tucson, AZ	1	21
Lexington, KY	1	20
Shreveport, LA	2	19
Charlotte, NC	1	19
Valhalla, NY	1	19
Loma Linda, CA	1	11
New Haven, CT	1	11
Albuquerque, NM	1	10
Hartford, CT	1	8
Honolulu, HI	1	7
Kansas City, MO	1	6
Hershey, PA	1	5
Washington, DC	1	5
Galveston, TX	1	0
Lubbock, TX	1	0
Phoenix, AZ	1	0
Total	117	4,168

APPENDIX B

Endnotes

1. 63 Fed. Reg. 16,295-16,338, April 2, 1998.
2. P.L. 105-277, § 213.
3. Institute of Medicine, *Organ Procurement and Transplantation* (Washington D.C.: National Academy Press, 1999).
4. [Http://www.unos.org/patients/101_hospital.htm](http://www.unos.org/patients/101_hospital.htm)
5. [Http://www.unos.org/patients/101_finance_costs.htm](http://www.unos.org/patients/101_finance_costs.htm)
6. “The transplantation community is divided, on allocation policy in general and *specifically on liver allocation.*” (emphasis added). 63 Fed. Reg., 16,311, April 2, 1998.
7. In fact, if one looks more broadly at metropolitan areas, rather than cities, the concentration is even more striking. For example, our analysis lists only one liver transplant center in Washington, D.C., although another center operates at a Inova Fairfax Hospital in Fairfax, Virginia, roughly 12 miles away. Likewise, we do not include Westchester County Medical Center in the analysis for New York City; the Stanford University center in Palo Alto in the San Francisco analysis, nor the centers at University of California at Irvine or Loma Linda University as part of the Los Angeles metropolitan area; nor two centers in New Haven and Hartford, Connecticut.
8. The 15 States without liver transplant centers are Alaska, Arkansas, Delaware, Idaho, Maine, Mississippi, Montana, North Dakota, New Hampshire, Nevada, Rhode Island, South Dakota, Vermont, West Virginia, and Wyoming. In addition to these 15 States, the centers in Hawaii (where the transplant center performed 7 liver transplants in 1997) and New Mexico (where the transplant center performed 10 transplants in 1997) are not Medicare certified.
9. UNOS data supplied by the Division on Transplantation, Health Resources and Services Administration. This data base contains records on 4,084 patients receiving a liver transplant in 1997 (excluding patients from Puerto Rico and Guam). At least 824 (20 percent) of these patients were transplanted outside their State of residence, and the State of residence was not identified for another 342 (8 percent) of patients.
10. U.S. Bureau of the Census, Population Estimates Program, Population Division, Table MA-96-8, “Estimates of the Population of Metropolitan Areas (ranked by 1996 Population),” at <http://www.census.gov/population/estimates/metro-city/ma96-08>.
11. The other cities with new centers that already had centers are Chicago, Baltimore, Salt Lake City, and Louisville.

12. The regulation also requires a 77 percent 1-year survival rate, and a 60 percent 2-year survival rate for patients.
 13. Two of these 36 centers received Medicare certification in 1998.
 14. [Http://www.unos.org/Newsroom/critdata_main.htm](http://www.unos.org/Newsroom/critdata_main.htm). Data are current as of July 14, 1999.
 15. 63 Fed. Reg. 63, p. 33,875, June 16, 1998.
 16. [Http://www.unos.org/patients/101_hospital.htm](http://www.unos.org/patients/101_hospital.htm)
 17. 60 Fed. Reg., 6,540, Feb. 2, 1995. The study, by Erick B. Edwards *et al.*, was presented to the Fifteenth World Congress of the Transplantation Society at Kyoto in 1994. The study is currently under review for publication. This paper is based on data from 1987 through 1991, or relatively early in the life of many liver transplant centers. It is, therefore, possible that the outcomes could be different if more current data were used.
 18. Henry Krakauer *et al.*, "The Relationship of Clinical Outcomes to Status as a Medicare-Approved Heart Transplant Center," *Transplantation*, 58: 6 (March 27, 1995): 840-846. This study used Medicare certification (12 transplants per year) as an independent variable.
- Jeffrey D. Hosenpud *et al.*, "The Effect of Transplant Center Volume on Cardiac Transplant Output, *JAMA* 271:23 (June 15, 1994): 1844-1849. This study found an increased risk of mortality among centers performing fewer than nine transplants per year.
19. Department of Health and Human Services, "Report on December 10-12, 1996 Public Hearings to Examine Allocation Policies for Liver Transplantation."
 20. Health Care Financing Administration, From the 100% Medpar Inpatient Hospital Fiscal Year 1997, "Short Stay Inpatient by State For National DRGs."
 21. Statement of Roger Evans, at December 1996 Public Hearing on Liver Allocation Policies.
 22. Richard H. Haubodlt, "Cost Implications of Human Organ and Tissue Transplantation, an Update: 1996," Milliman and Roberts, Inc., at <http://www2.milliman.com/milliman/publications/reports/hrr16/averagecharges.html>.
 23. Institute of Medicine, p. 42.