DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405 and 486

[BPD–646–FC]

RIN 0938–AE48

Medicare and Medicaid Programs; Conditions of Coverage for Organ Procurement Organizations (OPOs)

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period sets forth changes to the conditions of coverage for organ procurement organizations (OPOs). It provides for exceptions to the OPO qualification and performance standards under certain circumstances, revises the methodology for counting organs, and extends the period for interim OPO designations and notification of termination. It also adds new regulations relating to hospitals that change OPO designations when there is a change in the OPO service area.

This final rule with comment period modifies conditions of coverage previously set forth in an interim final rule. These changes are being made in response to public comments received on that interim rule. New regulations contained in this final rule implement provisions of the Social Security Act Amendments of 1994.

DATES: Effective date: This final rule is effective May 31, 1996.

Comment date: Written comments on the definition of ''donor'' (Section VI of the preamble) or the hospital waiver process (XI of the preamble) will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on July 1, 1996.

ADDRESSES: Mail written comments (One original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–646–FC, P.O. Box 7518, Baltimore, MD 21207–0518.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses: Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC or Room C5–09–26, 7500 Security Boulevard, Baltimore, MD.

Due to staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–646–FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

See section XV of this preamble for special instructions regarding the submission of comments and recommendations regarding the information collection requirements contained in these regulations.

FOR FURTHER INFORMATION CONTACT: Jackie Sheridan, (410) 786–4635.

SUPPLEMENTARY INFORMATION:

I. Background

A. Legislative History

Medicare coverage of services furnished to individuals with end-stage renal disease who require dialysis or kidney transplantation is authorized under section 1881 of the Social Security Act (the Act). Medicare also covers certain other organ transplants that HCFA has determined are ''reasonable and necessary'' under section 1862 of the Act, and pays for those transplants and related organ procurement services.

Under the Medicaid program, payment is made for ''medical assistance'' as defined in section 1905(a) of the Act and in our regulations at 42 CFR Part 440. Each State has a considerable degree of flexibility to supplement Medicaid-required services with optional services the State elects in its State plan. States must pay Medicare coinsurance and deductible amounts for transplant services for ''qualified Medicare beneficiaries,'' and must pay for transplant services to individuals under the age of 21 who receive early and periodic screening, diagnostic, and treatment services. In addition, States may pay for other transplant services based on written standards which provide that similarly situated individuals are treated alike.

Payment may be made under the Medicare and Medicaid programs for organ procurement costs attributable to payments to an organ procurement organization (OPO) only if the organization has been designated by the Secretary as meeting the conditions for coverage as an OPO. OPOs are generally paid indirectly for organ procurement costs. Usually, the transplanting hospital pays those costs to the OPO and claims them on its cost report. An OPO, however, does have to file a cost report with us at the end of its fiscal year. At that time, we settle any overpayments or underpayments with the OPO.

Section 1138(b) of the Act sets forth the statutory qualifications and requirements that an OPO must meet for coverage of the costs of its services in procuring organs for hospitals under the Medicare and Medicaid programs.

Title IV of the Health Omnibus Programs Extension Act of 1988 (Public Law 100–607) contained the Transplant Amendments Act of 1988. This Act contained amendments to section 371 of the Public Health Service Act (PHS Act) (42 U.S.C. 273), which defines OPOs. Specifically, section 402(c)(1)(A) of Public Law 100–607 amended section 371(b)(1)(E) of the PHS Act by revising the definition of ''service area'' that must be encompassed by an OPO. Public Law 101–274, enacted on April 23, 1990, postponed until January 1, 1992, the effective date of section 402(c)(1)(A) of Public Law 100–607. Additional legislation regarding the definition of a service area was included in the Transplant Amendments Act of 1990 (Public Law 101–616). The details of these provisions are discussed under section II ''Service Area'' of this preamble.

Section 201(d)(1) of Public Law 101–616 redesignated section 371(b)(2) of the PHS Act as section 371(b)(3). That section sets forth the functions of an OPO. However, the Congress did not amend two textual references in section 371(b)(1) to the OPO functions formerly specified in paragraph (2). Since that was clearly an oversight and failure to read the section 371(b)(1) text as if those ''paragraph (2)'' references had been changed to ''paragraph (3)'' would make part of the statute meaningless, we are using the corrected references in this document.

Additional legislation regarding OPOs was included in section 155 of the Social Security Amendments of 1994 (Public Law 103–432, enacted on October 31, 1994). This legislation amended section 1138(a)(1) of the Act to require a hospital to have an agreement for notification of potential organ donation only with the OPO designated for the area in which the hospital is located. Because this legislation was passed after our issuance of proposed and interim final rules in 1991 and 1994 respectively to implement statutory provisions, we did not include any revisions regarding this subject in those publications. We are, however, including revisions to the regulations in this final rule to reflect the provisions of Public Law 103–432. These

provisions are discussed under section XI. ''Waiver of Service Area Designations'' of this preamble.

B. Regulations

Regulations regarding organ procurement are currently found at 42 CFR part 486 (''Conditions for Coverage of Specialized Services Furnished by Suppliers'') under subpart G (''Conditions of Coverage: Organ Procurement Organizations''). The existing regulations were recently redesignated from subpart D of 42 CFR Part 485 in a final rule with comment period published in the Federal Register on September 29, 1995 (60 FR 50446). For the benefit of the reader, we are including a redesignation table. All succeeding regulations references will be to the redesignated sections. Throughout this preamble, we generally use the new section numbers in our discussion of specific sections. In some cases, we use both the old and the new section numbers for ease of reference.

Old section (subpart D of part 485	New section (subpart G of part 486
485.301	486.301
485.302	486.302
485.303	486.304
485.304	486.306
485.305	486.308
485.306	486.310
485.307	486.314
485.308	486.316
485.309	486.318
485.311	486.325

On June 21, 1991, we published a Notice of Proposed Rulemaking in the Federal Register (56 FR 28513). In it, we proposed to implement section 402 of Public Law 100–607 and section 201 of Public Law 101–616 by amending certain sections of 42 CFR part 482, which set forth the Medicare conditions of participation for hospitals, and subpart D of 42 CFR part 485, which, at that time, set forth the Medicare and Medicaid conditions of coverage for OPOs.

In addition to the provisions necessary to implement these laws, we proposed some other revisions to the existing regulations. These additional regulations were derived from our experience in administering the OPO program and not related to legislation. The most noteworthy of these latter provisions dealt with change of ownership of an OPO and with termination of participation in the Medicare and Medicaid.

These proposed regulations were updated, revised, and adopted in an interim final rule with comment period issued on September 8, 1994 (59 FR 46513). Provisions in the interim final rule which contained changes based on public comments included:

- Participation in the Organ Procurement and Transplantation Network (OPTN) as one of the Medicare conditions of participation for hospitals.
- Certification requirements for an OPO.
- Requirements for an OPO service area.
- Requirements that an OPO obtain HCFA approval before entering into any change of ownership, merger, consolidation, or change in its service area.
- Medicare payment provisions.
- OPO performance standards.

We have included detailed information regarding the provisions of the proposed and interim final rule with comment period as background in the discussion of individual topics.

We received 33 timely items of correspondence in response to the September 8, 1994, interim final rule with comment period. This final rule with comment period responds to the comments we received on the interim final rule with comment period. It also contains revisions to the regulations to implement provisions of the Social Security Act Amendments of 1994 (Public Law 103–432). These changes to the conditions of coverage for OPOs (42 CFR Part 486) are discussed below.

II. Service Area (§ 486.307)

A. Background

Before enactment of Public Law 100–607, the PHS Act provided that, unless an OPO service area comprised an entire State, it had to be of sufficient size to include ''at least 50 potential organ donors'' each year.

Section 402(c)(1)(A) of Public Law 100–607 amended section 371(b)(1)(E) of the PHS Act to require the service area to be large enough that the OPO ''can reasonably expect to procure organs from not less than 50 donors each year.''

We determined that this change would have resulted in a substantial number of existing OPOs failing to qualify for redesignation, because we interpreted the requirement that the OPO ''can reasonably expect to procure organs from not less than 50 donors'' to be more stringent than the requirement that the service area include ''at least 50 potential organ donors.'' According to a Departmental study cited in the Report of the Committee on Energy and Commerce on a precursor to the 1988 legislative amendments to the Transplant Amendments Act of 1987 (H.R. Rep. No. 383, 100th Cong., 1st Sess. 5–6 (1987)), the average OPO was, at the time of the report, procuring organs from only 44 donors per year. (Because more than one organ may be obtained from a donor, the average number of organs obtained per OPO per year was about 110.) Currently, the average number of donors per OPO is 77, resulting in an average of 279 organs per OPO.

Most of the designated OPOs were scheduled for redesignation beginning in March 1990 and would have been required to meet the new requirement imposed by Public Law 100–607. Information obtained from many representatives of organ procurement organizations (OPOs) revealed that almost one-half of the OPOs would not have been able to meet the new requirement. Some organ procurement and transplantation experts believed that many of the OPOs that did not have a realistic expectation of procuring organs from at least 50 donors were nonetheless effective and efficient entities. Consequently, the Department and other interested parties sought statutory relief to avoid disruption to the nation's organ procurement system.

On April 23, 1990, Public Law 101–274 was passed. It postponed until January 1, 1992, the effective date of section 402(c)(1)(A) of Public Law 100–607, which changed the definition of ''service area.'' Therefore, the ''at least 50 potential donors'' requirement would have remained in full force and effect until that date. However, Public Law 101–616 further amended section 371(b)(1)(E) of the PHS Act to require an OPO to have a defined service area that (1) is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs, and (2) either includes an entire Metropolitan Statistical Area (MSA) or does not include any part of the area. Section 201(d)(2) of Public Law 101–616 required the Secretary to publish a proposed definition of ''service area'' by February 14, 1991, and final regulations defining ''service area'' by November 16, 1991.

In the June, 1991 proposed rule, we specified in § 485.304(d) that an OPO cover a service area ''* * * of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area as specified by the Office of Management and Budget or does not include any part of such area * * * *''.

In the September 1994 interim final rule, we revised proposed § 485.304(d) (now § 486.306(d)) to provide that, for designations in 1996 and thereafter, an

OPO's service area must include an entire State or the OPO must procure organs from an average of at least 24 donors per calendar year in the 2 years before the year of designation. We provided that an OPO operating in a noncontiguous U.S. State, a U.S. Territory, or a U.S. Commonwealth, such as Hawaii or Puerto Rico, was subject to a specified, alternative standard beginning January 1, 1996. We also provided that if an entity has not previously operated as a Medicare-certified OPO, it must demonstrate that it can procure organs from at least 50 potential donors per calendar year.

B. Public Comments and Our Responses

Comment: One commenter suggested that we require that every transplant center have a working relationship with an OPO.

Response: Existing law and regulations already require this relationship. Sections 1138(a)((1)(C) and 1138(a)(3) of the Act require that a hospital have an agreement, as described in section 371(b)(3)(A) of the PHS Act, with its designated OPO if it is to participate in the organ procurement program. Medicare regulations at 42 CFR 405.2163 require that every renal transplant center ''* * * participates in a patient registry program with an OPO designated or redesignated under Part 485, Subpart D * * * ''. (We are changing this reference to Part 486, Subpart G in this final rule with comment period to reflect the redesignation). In addition, we have published in the Federal Register notices containing the Medicare coverage criteria for heart (52 FR 10935, April 6, 1987), liver (56 FR 15006, April 12, 1991), and lung (60 FR 6537, February 2, 1995) transplantations. Each of these notices requires that a hospital submit documentation demonstrating the hospital's agreement with a Medicare-certified OPO as one of the conditions necessary for Medicare approval as a facility for which respective organ transplantation may be covered. We believe that these requirements meet the commenter's suggestion.

Comment: One commenter suggested that more consideration be given to regional MSAs than to State boundaries. The commenter believed the current policy results in poor service to remote areas.

Response: It is not clear to us how the current policy would inappropriately effect organ distribution to remote areas. We believe, however, that the law is clear regarding the MSAs and provides little latitude for alternative interpretation. Section 371(b)(1)(E) of the PHS Act provides that an OPO ''* * * has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs, and that either includes an entire MSA (as specified by the Director of the Office of Management and Budget) or does not include any part of the area.'' Thus, we have no authority to split MSAs in designating OPO service areas. Other than repeating this statutory language, our Medicare regulations do not address MSAs.

As a matter of practice, we designate OPO service areas on a county specific basis. An OPO's service area will include all of the counties within the MSA and as many other counties as it desires and is awarded based on the criteria in § 485.308 (now redesignated as § 486.316). We note that all counties that contain a hospital are assigned to one of the designated OPOs. In addition, in principle, we believe that organ donation is most likely to be enhanced where there is a willing and cooperative arrangement between the hospital and the OPO. Therefore, we believe that it could be potentially deleterious rather than helpful to force hospitals in counties that are not officially part of an MSA to be served by the OPO servicing the MSA. However, if the parties agree that designation of a regional MSA would be helpful, we would not preclude such designations.

Comment: One commenter noted that current terminology used by the Office of Management and Budget (OMB) refers to ''Metropolitan Area'' (MA) rather than MSA as the general term describing urban classifications. Within MAs, there are several categories: MSA, Consolidated MSAs (CMSAs), Primary MSAs (PMSAs), and New England County Metropolitan Areas (NECMAs). The commenter requested clarification as to which MA categories are applicable to the OPO regulations.

Response: For purposes of the OPO regulations, MSAs encompass the current MA categories of MSA, PMSA, and NECMA. A CMSA is comprised of a number of PMSAs that are considered separately for purposes of defining OPO service areas. In New England, we use NECMAs rather than MSAs and PMSAs which are based on townships rather than county areas. Since OPO service areas are defined based on counties, we believe it is more appropriate to use the county equivalent MA designations in New England (that is, NECMAs). The law clearly states that we may not divide an MSA into the service areas of multiple OPOs. If an OPO's service area includes any part of an MSA, PMSA, or NECMA, it must include the entire area.

Comment: One commenter noted that a newly established OPO could qualify based on a determination that it has the potential to procure organs from at least 50 potential donors. The commenter requested clarification as to how the organization would demonstrate this fact. The commenter also noted that currently OPOs convert fewer than 50 percent of the potential donors to actual donors. Therefore, it is unlikely that an organization with only a 50-donor potential can meet the 24-donor criterion.

Response: The current criterion for qualification as an OPO servicing an area of fewer than 2.5 million people is that the organization demonstrate that it has the potential to procure organs from 50 donors. Thus, the criterion we have established for newly functioning OPOs is identical to that currently applied to the existing OPOs. We have historically not prescribed how an OPO must demonstrate this standard is met. Rather, when making such a determination, we have accepted the information submitted by the OPO, evaluated it, and requested clarification if necessary. We believe it is appropriate to hold newly established OPOs to the condition in place for existing OPOs. Thus, we do not intend to specify how such a standard is to be met. We will continue to allow flexibility for the OPO to come forward with reasonable information to demonstrate its position.

We do, however, intend to take a more rigorous look at the information than we have previously. Newly established OPOs need to qualify at the end of a 2-year period based on one of the other criteria. In most cases, this criterion will be an average 24 donors per year over a 2-year period. We believe it would be disruptive to the organ procurement industry to allow OPOs to enter the arena only to exit 2 years later if they cannot meet the qualification criteria. Consequently, we expect OPOs to act responsibly and to have a specific plan for achieving the long-term qualification criteria.

Comment: Several commenters expressed concern about the 24-donor rule. For the most part, these commenters believed that some very small OPOs are performing efficiently as is evidenced by the fact that they meet the performance criteria. The commenters believed that the 24-donor criteria is not an appropriate measure of performance. They recommended that no size limitations be part of the qualification criteria for designation as a Medicare-approved OPO.

One commenter believed that we should continue to permit an OPO that meets the performance criterion to

qualify if it has an alternative local unit (ALU) to address the equitable distribution issue. An ALU is an area developed by the OPO and approved by the OPTN contractor as an alternative area as an aid to equitable distribution. An ALU may be treated as a substitute for the OPO's service area in the allocation scheme. The commenter, from a very small OPO that is one of three OPOs operating in a single medium-size State, believed that HCFA should continue to permit an OPO that meets the performance criterion to qualify if it has an ALU to address the equitable distribution issue. In the commenter's State, the three OPOs share certain matched organs on a broader scale than they would if the ALU were not in place, but the majority of organs are allocated locally. The commenter believed that the regulations should be modified to provide for an exception criterion that would allow this small OPO to continue to qualify.

Response: The qualification criteria are intended to implement section 371 of the PHS Act. Section 371(b)(1)(E) of the PHS Act provides that an OPO must have a defined service area that ''* * * is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs * * *.'' We believe the use of the explicit words ''of sufficient size'' in the statutory language is a clear expression that the Congress intended the Secretary to establish some measures of size in response to this mandate in the law.

Further, when we look at the legislative history, we believe that the Congress intended that the service area size criterion be rigorous. Section 371 initially set the qualification criterion at 50 potential donors. However, the Congress recognized that this criterion was too lax. The Congress subsequently modified section 371(b)(1)(E) in section 402 of Public Law 100–607 to require the service area to be large enough that the OPO ''* * * can reasonably expect to procure organs from not less than 50 donors each year''.

When this legislation was enacted, we recognized that setting the qualification standard at this level at that time would have resulted in decertification of approximately one-half of the OPOs approved by Medicare. Consequently, we sought legislative relief from the statutory standard. The Congress responded to our request with Public Law 101–616.

We acknowledge that the fact that an OPO procures 24 donors per year is not in and of itself assurance of ''maximum effectiveness'' in organ procurement. We believe, however, that this criterion certainly contributes to the retention of OPOs that are more likely to be effective in organ procurement. This is true particularly for OPOs with service areas that have populations under 1.5 million. We do not believe that it is productive and cost effective to continue to retain several OPOs operating within a single, often small, State. In these cases, often too much time and effort are spent in competition with the neighboring OPO rather than in organ outreach. Generally, a merger of a number of small competing OPOs is cost effective because it results in shared overhead, shared optimal practices, and a higher ratio of organs to fixed operating costs.

Our decision to proceed with the 24-donor rule, however, is not solely based on the maximum effectiveness portion of the statutory language. The law also specifically requires that service area designations be sufficiently large to ensure *equitable distribution* of organs. Organs available for transplant are a scarce resource. There are many more people on the transplant waiting list than there are available organs. Both the Congress and this Administration support transplant policies that contribute to the equitable distribution of organs. We believe a proliferation of a large number of very small OPOs does not contribute to this goal. The organ allocation policies give priority, in most cases, to distribution of organs within the service area. Consequently, OPOs must give first priority to keeping organs procured within their service areas for transplant rather than dispersing them to a larger area. The existence of a substantial number of small OPOs could be disruptive to an effective large organ allocation system because each of these OPOs would be keeping organs for transplant within its own small service area.

For example, a small hospital-based OPO may have only a single transplant center (itself) within its service area. In most cases, all the organs procured in the service area are then transplanted to patients on the waiting list at the transplant center instead of being allocated to patients on a regional or national basis. The OPO, in accordance with the national allocation rules, is transplanting the procured organs to the highest-ranking appropriate patients in the local area. These patients may have been on the waiting list a very short time. Equally appropriate patients in the region who have been waiting a much longer period of time would not receive the organs because they are outside the local area. Since the OPO is servicing only itself, it has an incentive to be a high-performing OPO. The patients at this center have a shorter wait time.

However, in a neighboring town that is part of a larger OPO service area, there may be several hospitals that must share the organs procured from an OPO that is as effective in procuring organs as the small OPO. Because this OPO must share organs among several transplant centers, patients in these centers must wait considerably longer for the needed lifesaving organs. As a result, there is significant disparity among the transplant center waiting times. In various hearings on organ transplantation over the years the Congress has expressed concern about the disparity in waiting times for organ transplantation among various geographic areas. Many members of the Congress have expressed a strong desire to move toward a national allocation methodology to mitigate this condition. We believe that the definition of service area in the statute that addresses the idea that an OPO's service area be of sufficient size to assure equitable distribution is direction to the Secretary to not only look at OPO performance or effectiveness but to also consider the impact of service area size on organ distribution since very small OPO service areas tend to result in disproportionately short waits in some areas and disproportionately long waits in other areas. We conclude that a proliferation of very small OPOs may not be consistent with an equitable distribution system as required in the statute.

While we acknowledge the existence of an ALU for the purpose of organ distribution may potentially mitigate some of the concern regarding equitable distribution, we believe that there are other values associated with establishing OPO minimal service area size that cause us to continue to support this position. There are many benefits of the consolidation of OPOs, such as the sharing of best practices, shared overhead, expediency in reacting to emergency situations, consistent procurement and transplant practices, and promotion of equitable treatment. We find no benefit to the program or the American public in retaining very small OPOs under a system of exceptions when there is no potential that these OPOs would ever meet the size criterion.

On the other hand, we have not arbitrarily set up criteria that restrict OPOs to a certain size or population base. We recognize that small OPOs can be very effective in procuring and distributing organs despite serving a small population area in certain circumstances. OPOs may qualify if they service an entire State, regardless of the population or the number of donors

available. Similarly, we have established special qualifying criteria for OPOs servicing areas that are not contiguous to the rest of the nation. OPOs servicing Hawaii, Alaska, and U.S. territories must meet alternative criteria as discussed below.

We also point out that the criterion is applied based on a 2-year average. Thus, if an OPO fails to meet the criterion in one year due to uncontrollable or unforeseen circumstances, it will have an opportunity to make up for lost donors in the following period. Since this is a static number, OPOs will be able to continually monitor themselves against this criterion and take corrective actions as necessary to improve.

In evaluating the impact of this criterion on the existing OPOs using historical data, we are comfortable that the criterion will not have a major adverse impact on the existing OPOs.

Based on 1994/1995 data, three OPOs that would have met the performance criterion if it had existed in that period would not have met the 24-donors per year criterion. However, one of these OPOs would have qualified under the statewide criterion. The remaining two OPOs are small organizations located in States with alternative, OPOs. We believe alternative, high-performing OPOs could service the respective areas adequately, while providing for a broader allocation area that is likely to promote more equity in organ distribution. Consequently, we continue to believe that the 24-donor rule is appropriate as one of the qualification criteria.

In response to the comment that the 24-donor rule is not an appropriate measure of performance, we have reviewed this requirement. We agree that the 24-donor rule is not a measure of performance but a measure of service area size. Furthermore, it is redundant to maintain this requirement as both a performance and a qualification criterion. All OPOs must meet all of the qualification criteria to be recertified. It serves no purpose to place the requirement in two separate sections. Therefore, we are deleting § 486.310(b)(2) (formerly § 485.306(b)(2)) from this final rule with comment period.

Comment: Some commenters noted that this same criterion was both a qualification standard and a performance standard. The performance standard is one that is subject to a corrective action plan. However, it was not clear whether the qualification criterion is subject to corrective action.

Response: As noted above, we are deleting the 24-donor rule as a performance criterion. Nonetheless, we think the commenters' concern that there is no provision for exception to the qualification criteria is important.

The law specifically requires that an OPO be of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs. As discussed above, we do not believe it is in the best interests of the program or the public to establish an exception system for very small OPOs that historically do not possess the base to achieve 24 donors. Even though such a small OPO may be performing adequately based on its population base, we are concerned that the proliferation of extremely small service areas runs counter to the objectives of an equitable national organ allocation system.

However, we recognize that an OPO may experience unforeseen circumstances beyond its control that result in the OPO failing to meet the qualification criterion during a single recertification period. Consequently, we are adding a new § 486.307(d)(3) to provide for an exception process.

This exception process is explicitly limited to those OPOs that have historically met the criteria and that have a specific plan to achieve 24 donors per year in the future. We are also allowing a one-time exception for the transitional period. This exception allows an OPO that meets the performance standards in § 486.310 to continue Medicare and Medicaid participation for 2 years while it puts in place a plan to achieve 24 donors per year in the future. (See Section X of this preamble)

To receive the exception, an OPO must file its request with HCFA at least 15 days before its recertification date. The request must be in narrative form. If the exception is based on unusual circumstances the narrative must explain in detail the unusual circumstances that contributed to the OPOs failure to procure 24 donors per year. The exception request must also include data regarding the number of donors per year for the 5 years immediately preceding the present designation period. For example, if an OPO fails to meet the qualification standard for the 1996 designation period and it requests an exception, it must submit data, by year, for donors procured from 1991 through 1995. The exception request must also detail the specific actions the OPO intends to take to increase organ donors to 24 per year. Detailed instructions concerning the exception process and the corrective action will be included in the manual instructions.

Comment: One commenter wrote encouraging us to view the qualification criteria as bare minimum which should not be weakened for any reason. The commenter was concerned with the discrepancy between the qualification standards for new OPOs and currently existing OPOs.

Response: We appreciate support for the qualification standards adopted. As noted above, we believe it is important to maintain high standards to encourage OPOs to make every effort to procure all available organs. However, we are not aware of any means to avoid a discrepancy in standards between new and existing OPOs. That is, a new OPO will not have actual data on any objective measure of organ recovery or transplant rates. Consequently, we have no alternative than to use a measure of potential procurement for the initial designation.

On the other hand, if an OPO is not recovering the potential organs, despite the fact that the area is large enough to support minimum recovery level, we believe it would be irresponsible to continue to allow that OPO to service the area. Thus, while there may be some discussion as to what exactly is the most appropriate qualification standard for existing OPOs, we believe that there should be no alternative to setting the standard using actual experience measures as opposed to potential. Since it is impossible to use actual data for new OPOs and we are wedded to using actual data for existing OPOs, there appears to be no alternative but to use different standards for new and existing OPOs.

However, from the context of the comment, it appears that the commenter believes the standard for new OPOs, which uses potential recoveries, is more difficult than the standard for existing OPOs. We point out that while the number of potential donors for new OPOs is higher than the number of actual donors for existing OPOs, we do not believe the standard for new OPOs is more rigorous. We have been told by some OPOs that the average conversion rate of potential organs is approaching 3 to 1. This means that to achieve the standard for existing OPOs of 24 donors, a new OPO should have an area big enough to have close to 72 potential donors.

We did not use the 72-donor criterion for several reasons. First, we believe it is inappropriate to hold new OPOs to a different initial standard than that which had to be met by their competitors when they first entered the program. Second, we believe that new OPOs deserve the benefit of the doubt in achieving a conversion rate that is above the national average. That is, a new OPO may have only 50 potential

donors, but because of effective practices is able to achieve a conversion rate of 2 to 1, and thus would continue to meet the qualification criterion at recertification time.

Comment: One commenter noted that not all OPO service areas are contiguous territories. The commenter requested that HCFA prohibit OPOs from developing noncontiguous areas, citing difficulty in organ allocation when service areas are separated.

Response: The commenter did not present any data or examples demonstrating that noncontiguous areas are problematic. Further, the issue of noncontiguous service areas has not presented a significant problem for organ allocation or procurement to the best of our knowledge. Most OPOs that have noncontiguous service areas have established field offices in each territory. Often, they have secured approval for alternative allocation policies for each portion of the service area. While there may be some administrative complexities associated with noncontiguous areas, this concept has appeared to work very well. We find no reason to prohibit the practice in the future.

C. Provisions of This Final Rule With Comment Period

We are making the following changes to the interim final rule.

- We are revising § 486.306(d). We are retaining the general requirements for documentation of service area in paragraph (d) and moving the specific detailed requirements in that paragraph to new § 486.307 *OPO service area requirements and documentation* and including a cross-reference to § 486.307 in § 486.306(d). We are making this change as a technical change to allow for a better organization and readability of the regulations.
- We are adding § 486.307(d)(3) to provide for an exception process when an OPO experiences unforeseen circumstances beyond its control that result in the OPO failing to meet the qualification criterion during a single certification period. To qualify for an exception, the OPO must demonstrate that (1) it failed to meet the 24-donor criterion due to unusual circumstances beyond its control, (2) it has historically maintained a service area sufficient to assure effective procurement and equitable distribution (that is, it has historically achieved 24 donors per year), and (3) it has a specific plan to achieve 24 donors per year in the future.
- We are deleting § 486.310(b)(2) (formerly § 485.306(b)(2)). This paragraph contains the 24-donor rule as a measure of performance. As noted above, we are keeping this measure as a qualification criterion.
- Although we did not receive a comment to this effect, we are redesignating § 486.310(a)(3) (formerly § 485.306(a)(3)), that requires OPOs to enter into a working relationship with any hospital or transplant center in the OPO's service area that requests a working relationship, as § 486.304(b)(8). We believe that this requirement is more appropriately considered as a qualification standard for OPOs rather than as a performance standard.

III. Composition of the Board of Directors of an OPO (§ 486.306(f))

A. Background

Section 485.304(f) (redesignated as § 486.306(f)) requires that as one of the conditions for qualification as an OPO under the Medicare and Medicaid programs, an OPO must have a board of directors or an advisory board that has the authority to recommend policies relating to the donation, procurement, and distribution of organs. That section also specifies that the board must include members with various backgrounds and areas of interest. In the proposed rule, we included a revision to § 485.304(f)(3) (now § 486.306(f)(3)) to allow either a physician or an individual with a doctorate degree in a biological science with knowledge, experience, or skill in the field of histocompatibility to serve on an OPO board of directors or advisory board. In the interim final rule, we changed the requirement from ''a physician with knowledge, experience, or skills in the field of human histocompatibility'' to ''a physician with knowledge, experience or skill in human histocompatibility, or an individual with a doctorate degree in a biological science and with knowledge, experience, or skills in the field of human histocompatibility.''

In addition to this requirement, § 486.306(f) specifies that the board must also consist of:

- Members who represent hospital administrators, tissue banks, voluntary health associations in its service area, or emergency room personnel.
- Members who represent the public residing in that area.
- A neurosurgeon or another physician with knowledge or skills in the field of neurology; and
- A transplant surgeon from each transplant center in its service area with which the OPO has an arrangement to coordinate its activities.

While an OPO may have more than one board, the membership composition specified in § 486.306(f) must exist on a single board.

B. Public Comments and Our Responses

Comment: Several commenters questioned the composition of the policy board. Some commenters expressed concern with the involvement of a transplant surgeon from each transplant center. They interpreted the regulation as requiring that each transplant surgeon from each center be placed on the board. They commented that this provision would produce very large and costly boards and would give transplant surgeons control.

Response: The commenters misinterpreted the regulation. We are not requiring that each transplant surgeon be included on the OPO policy board. Rather, we are including in the regulations the statutory requirement contained in section 371(b)(1)(G)(i)(V) of the PHS Act. This section requires that there be one transplant surgeon from each transplant center within the OPO service area included on the policy board.

We agree with the commenter that to include all transplant surgeons would be inappropriate. Such a situation would give transplant surgeons a disproportionate influence over OPO policies. We did not intend to require the inclusion of every transplant surgeon. In fact, we read the statute as prohibiting this composition. That is, we believe the statute does not provide the OPO an opportunity to alter the composition of the board from that provided in the law. Section 371(b)(1)(G)(i) of the PHS Act states clearly that the board ''is composed of * * * from each transplant center * * * *a* member who is a surgeon * * *.'' We believe the use of the article ''a'' to modify transplant surgeon members, expresses the will of the Congress that the board be composed using only a single transplant surgeon from each transplant center within the service area. The statute does not say that the board must include at least the following members. Rather it clearly states that the board is composed as directed. Thus, OPOs may not add additional members to the policy board other than those specified in § 486.306(f). We are modifying this section to specify that the board must ''be composed of'', rather than say ''include'' to clarify this provision.

Comment: Another commenter recommended that § 486.306(f) be modified to include only a single representative from one of the disciplines from each transplant center on the policy board. The commenter was concerned that the current regulation gives surgeons a disproportionate influence on the board

or requires very large boards to balance their influence.

Response: As noted above, the statute is very clear in describing the composition of the policy board. To alter the composition would require a change in the law. However, we are not convinced that the composition mandated in the law is problematic in most cases.

The law requires both a neurologist and a histocompatibility expert on the board. In addition, it requires an unspecified number of other people that may be included; for example, representatives of hospital administrators, intensive care and emergency room personnel, tissue banks, voluntary health associations, and members of the public. Although the law does not specify the number of these representatives, it is clear that there must be multiple representatives through the use of the plural of the word ''members'' in sections 371(b)(1)(G)(i) (I) and (II) of the PHS Act. In all but a few extremely large urban OPO service areas, using only the minimum representation from these other categories will result in a fairly small and balanced policy board.

We acknowledge that there will be isolated cases where the requirement for a surgeon from each transplant center may be problematic. For example, we are aware of one OPO that services 17 transplant centers. The inclusion of 17 transplant surgeons will result in a very large and potentially difficult policy board. Therefore, we are considering recommending a statutory change to the Congress regarding the law governing OPO board composition. In the meantime, the boards must be composed as directed in the law.

Comment: Other commenters recommended that OPOs be allowed to establish committees, such as a quality of organs recovered committee or a medical committee, in lieu of full representation on the policy board by all surgeons. Still other commenters expressed support for inclusion of one transplant physician from each transplant center on the policy board.

Response: As noted above, the composition of the board is explicit in the statute. We do not have the authority to condone alternative governing strategies. We will consider developing a recommendation for statutory change in this regard. However, we believe that the statute would not prohibit OPOs from establishing the committees that have been suggested. Such committees could advise the board and may be very helpful in developing the OPO's policies and influencing its practices. We strongly encourage OPOs to seek opinions from their customers and others affected by their decisions. The only problem we find with the commenter's recommendation is that such committees cannot be used in lieu of full representation.

Comment: One commenter suggested that § 485.304(f)(3) (now § 486.306(f)(3)) relating to histocompatibility representation on the board be broadened further to include a doctorate level individual in bioethics or a nursing specialty.

Response: We are not certain if the commenter intended that the histocompatibility requirement be met by someone with bioethic or nursing doctorate level education or that such individuals be added in addition to the histocompatibility person. We believe that the histocompatibility requirement is extremely important to the policy board composition. Histocompatibility testing is paramount in discussing policies related to equitable distribution of organs. We believe that the histocompatibility representative on the policy board must be someone with a medical degree or a biological science degree with experience in human histocompatibility.

The requirement included in § 486.306(f)(3) is a reiteration of the requirement in the statute. The current law does not authorize alternative education for this requirement. However, the current regulations do not prohibit an OPO from including someone with a doctorate level education in nursing or bioethics on the board. The statute does not provide specific direction as to the education or number of representatives from hospitals and the public. An OPO could certainly choose to include a person with advanced nursing and bioethics training, or both, as one of these board representatives.

Comment: One commenter recommended that the OPO boards be comprised of not more than 50-percent representation from transplant centers.

Response: As noted above, we have described the composition of the OPO boards in this regulation in accordance with section 371 of the PHS Act. We note that the law does not prescribe the number or skills mix of representatives from hospitals or the public. We expect that, given that the boards must include a transplant surgeon from each transplant center, in most cases the transplant centers will be heavily represented on the boards.

We believe, however, that it is unnecessary and inappropriate to dictate the percentage of transplant center representatives on the board. We believe that each OPO is best equipped to determine the needs of its operation and the community. Given the number of transplant centers in the OPO's service area, such a requirement could result in extremely large boards which could be costly to the OPO and, consequently, the Medicare and Medicaid programs. Further, we do not believe that the statute supports such a requirement because the law was deliberately vague in its use of the term ''representatives'' as opposed to use of limiting article ''a'' in the requirements regarding members of the board.

However, given the rigorous performance standards that OPOs must meet, we expect that each OPO will ensure as broad a representation as practicable in setting up its policy board. We expect that it would want to seek out increased involvement with donor hospitals and public representatives to achieve innovative strategies to increase donation rates. OPOs that fail to modify their boards to achieve a balance in representation from the donor community and the transplant community are likely to feel the consequences in failure to meet performance standards. Thus, although we are not specifying the percentage of representatives, we are holding OPOs accountable for appropriate decisions.

C. Provisions of this Final Rule With Comment Period

We are clarifying § 486.306(f) by revising the language describing the OPO board. The revised language, ''the advisory board must be composed of the following,'' more clearly indicates that there is no discretion to add or remove skills to the mix on the board.

IV. Equitable Distribution of Organs (§ 486.306(i))

A. Background

In a proposed revision to § 485.304(i) (now § 486.306(i)), we specified that an OPO must have a system to allocate donated organs equitably among transplant centers and patients according to established medical criteria. This revision was made to include the word ''equitably'' in the previously existing requirement. In the interim final rule with comment period, we changed the requirement to eliminate the allocation of organs among ''centers'' and to specify the medical criteria that the system must operate under; that is, they must be consistent with Centers for Disease Control and Prevention (CDC) standards and with OPTN rules. We made the former change to be consistent with section 371(b)(3)(E) of the PHS Act.

B. Public Comments and Our Responses

Comment: One commenter believed there was now an absence of a requirement for OPOs to equitably distribute organs. Another commenter recommended that there be a follow-up mechanism to ensure that OPOs use a system to allocate organs according to established medical criteria.

Response: The regulations at § 486.306(i) require OPOs to have a system to equitably allocate donated organs among transplant patients that is consistent with the CDC and the OPTN rules. We made the change in the interim final rule to specifically add the word ''equitably'' to the distribution requirement. Currently, the OPTN develops a national organ allocation system. The system is developed by the membership and is medically based.

Although we are aware of isolated instances of OPOs using allocation systems that do not comport with the national OPTN rules, we do not believe that this situation is widespread. Consequently, we believe it is unnecessary to establish a formal mechanism to evaluate OPO allocation methodologies at this time. However, we invite the public to advise the Department of incidents of organ allocation that fall outside the established system. Incidents should be reported to Judith B. Braslow, Director, Division of Organ Transplantation, Room 7–18, 5600 Fishers Lane, Rockville, MD 20857.

Comment: Two commenters requested clarification regarding the reference to the CDC standards. They noted that the CDC guidelines were published as guidelines, not rules. They inquired if inclusion in § 485.304(i) (now § 486.306(i)) sets these guidelines as standards of practice for the entire transplant community.

Response: Section 486.306(i) requires that an OPO's system of distribution of organs among patients be consistent with the CDC standards. For the most part, these CDC standards relate to screening potential organ donors and organs recovered for Human Immunodeficiency Virus (HIV) infection. We believe that the monitoring for HIV infection is critical and is an essential element for Medicare certification of OPOs. In fact, in section 371(b)(3)(C) of the PHS Act, the Congress has specifically required that OPOs evaluate an organ for HIV infection.

Exclusion of prospective blood donors based on their acknowledged risk factors for HIV infection began in 1983. In 1985, when the test for the HIV antibody became available, screening of prospective donors of blood, tissue and organs began. Both measures have reduced remarkably the transmission of HIV via these routes. A 1991 investigation, however, determined that several recipients had been infected with HIV by an organ/tissue donor who had negative HIV antibodies at the time of the donation. This occurrence raised questions about the need for additional Federal oversight of transplantation of organs and tissues.

A work-group was formed by the Public Health Service (PHS) to address transmission of HIV through transplantation of human tissue. This group produced a set of recommendations that were included in the CDC Guidelines that we have included as an appendix to subpart G of part 486 and referenced in the OPO regulations. OPOs must abide by the CDC guidelines to qualify for Medicare and Medicaid certification.

In developing the recommendations, the PHS sought assistance from public and private health professionals and representatives of the transplant community, public health and other organizations. A total of 37 external consultants and 18 government staff formulated the recommendations. These recommendations address issues such as donor screening; quarantine of tissue from a living donor; inactivation or elimination of infectious organisms in organs and tissues before transplantation; timely detection, reporting, and tracking of potentially infected tissues, organs and recipients; and recall of stored tissues from donors found after donation to have been infected. Factors considered in the development of these guidelines included differences between the screening of living and cadaveric donors; time constraints due to organ/tissue viability that may preclude performing certain screening procedures; differences in the risk of HIV transmission from various organs and tissues; differences between systems for procuring and distributing organs and tissues; the effect of screening practices on the limited availability of organs and some tissues; and the benefit of the transplant recipients.

The CDC guidelines are intended to promote public health and safety. They were not arrived at without appropriate assessment of the risks and benefits for the public health of Americans. We fully support the CDC guidelines and have attempted to assure compliance with them through inclusion in the Medicare conditions of coverage. Thus, the inclusion of the CDC guidelines as a requirement for OPOs does give the CDC guidelines regarding organ allocation the force of regulation. That is, any OPO found to be failing to conduct appropriate screening or distributing organs that are not in compliance with the CDC guidelines for organ allocation can be found out of compliance with the qualifications for becoming a Medicare- or Medicaid-certified OPO and have its certification terminated.

However, we acknowledge that the reference to the CDC guidelines contained in the interim final rule with comment period is not sufficiently clear on this point. Consequently, we are revising § 486.306(i) to specifically incorporate by reference the CDC guidelines. The guidelines were issued as one of the CDC Morbidity and Mortality Weekly Reports, ''Guidelines on Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs,'' Vol. 43, No. RR–8, May 20, 1994.

We did not receive a formal comment on the application of the CDC guidelines during the public comment period for the interim final rule. We understand, however, that OPOs have taken the position that acceptance of recovered organs is a matter of patient choice. Some patients are so dangerously close to death while on the waiting list that they are willing to risk receiving an organ potentially infected with a fatal virus rather than risk the chance of not finding in a timely manner an appropriate healthy organ. Some OPOs support the patient having the opportunity to make this choice for themselves and believe the CDC guidelines prohibit this practice.

The law at section 371(b)(3)(C) of the PHS Act is clear regarding testing for infection with the etiologic agents (HIV–1 and HIV–2) for acquired immune deficiency syndrome and taking steps to prevent exposure to HIV through transplantation of these organs. Regardless of the personal preference of a potential recipient or the opinion of the OPO staff, the law requires that potential donors be tested for viral markers for HIV–1 and HIV–2, and if found to be infected, organs from that donor are not to be transplanted.

The CDC guidelines, however, do permit some measure of judgment for organs tested negative for HIV etiological agents, but procured from donors who have demonstrated high-risk behaviors. The recommendation in the CDC guidelines on donor screening state that ''* * * Regardless of the HIV antibody test results, persons who meet any of the high-risk criteria should be excluded from donation of organs or

tissues unless the risk to the recipient of not performing the transplant is deemed to be greater than the risk of HIV transmission and disease. In such a case, informed consent regarding the possibility of HIV transmission should be obtained from the recipient. * * *''

Thus, while compliance with the CDC guidelines requires OPOs to conduct screening of donors through asking questions about the potential donor's behavior relative to HIV-risk factors, the guidelines do not unilaterally prohibit transplantation of the organs from donors found to have high-risk behavioral criteria who have negative HIV–1 and HIV–2 serologic tests. The OPO may procure the organs from such donors and make the information concerning HIV-risk factors available to the transplant surgeon. The transplant surgeon will then assess the risk factors for HIV against the risk associated with delaying transplantation and together with the potential recipient (and his or her family if appropriate) make a decision to accept or reject the organ. It is imperative, however, that full information regarding the risk factors be disclosed by the appropriate transplant surgeon to the potential recipient.

C. Provisions of this Final Rule With Comment Period

We are including the specific CDC guidelines cited in the interim final rule as appendix A of part 436 subpart G. We are also clarifying the reference to the CDC guidelines in § 486.306(i). As a result of these revisions, we are making the guidelines required standards for OPOs.

V. Testing of Organs (§ 486.306 (q) and (s))

A. Background

In the proposed rule, we added a new § 485.304(r) (now § 486.306(q)) to require OPOs to assure appropriate tests consistent with OPTN standards and CDC guidelines are performed to prevent the acquisition of organs that are infected with the HIV–1 and HIV–2 etiologic agents for acquired immune deficiency syndrome. In the interim final rule, we redesignated the contents of paragraph (r) as paragraph (q) and the contents of paragraph (q) as paragraph (r) and added a new paragraph (s). Revised paragraph (r) required OPOs to assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors. New paragraph (s) required OPOs to ensure that serologic testing for HIV–1 and HIV–2 viral markers is performed on potential donors consistent with OPTN rules and CDC guidelines for solid organ donation.

B. Public Comments and Our Responses

Comment: One commenter recommended that we include standard provisions that are required for all hospital donation protocols. The two provisions the commenter specifically suggested were that (1) hospitals refer all potential donors to the OPO before donation has been mentioned, and (2) a trained professional be involved in all donation requests.

Response: We believe that the suggested protocols are good and are likely to work quite effectively for many OPOs and hospitals. However, it is inappropriate to regulate specific donation protocols at this time. There are many different protocols that can be highly effective in organ donation. We do not wish to stifle the development of innovative means of increasing the procurement rate by regulating specific methodologies or protocols.

Comment: One commenter expressed concern with the requirement in § 485.304(s) (now § 486.306(s)) regarding CDC guidelines for preventing transmission of HIV through transplantation of human tissue and organs. The commenter noted that an OPO has no knowledge of what information the transplant center provided to the potential recipients regarding their informed consent to the risks of transmission of infections. The commenter suggested alternative language describing an OPO's responsibility to make information available to the transplant center. This language would state that an OPO is not responsible for the decision to transplant high-risk organs in life-threatening situations.

Response: Section 485.304(s) (now § 486.306(s)) requires that OPOs ''Ensure that donors are tested for human deficiency viral markers consistent with OPTN rules and CDC guidelines for solid organ donation.'' Similarly, § 485.304(i) (now § 486.306(i)) requires that the OPO allocate organs in accordance with these guidelines. OPOs are responsible for testing and allocating organs in accordance with these guidelines.

If an OPO only allocates organs that comply with the guidelines to a transplant hospital, a transplant center would receive a high-risk organ to transplant to the recipient only on a very rare and carefully selected basis. The OPO is required to ensure that informed consent of the recipient is obtained. Thus, while the commenter is accurate in the statement that an OPO does not formally have direct contact with the recipient, we do not agree that such a situation in any way alters the responsibility of an OPO to follow the CDC guidelines regarding testing and allocation of organs. We expect that in these rare cases the OPO will work closely with the transplant center to impress upon the center the importance of getting informed consent documentation to the OPO timely. We expect hospitals will cooperate with the OPOs in meeting this requirement.

An OPO's responsibility does not stop with testing the donor and making information available to the transplant center. The regulations go beyond this to require the OPOs to allocate organs in accordance with CDC guidelines. We believe it is appropriate to continue to hold OPOs responsible for compliance with the CDC guidelines for allocation as well as testing. Therefore, we are not modifying the regulations as recommended by this commenter. However, as we stated above in discussing § 486.306(i), we believe that the nonspecific reference to the CDC guidelines could be confusing. Thus, we are clarifying the regulations to include a reference to the CDC guidelines in § 486.306(s). The guidelines are also included as an appendix to part 486 subpart G.

Comment: One commenter suggested we also require OPOs to use the guidelines and recommendations of the PHS workgroup on the testing of organ donors for the presence of hepatitis.

Response: Unlike the requirement for testing for HIV viral markers, which is contained in section 371(b)(3)(C) of the PHS Act, there is no express legislative authority to mandate a requirement for hepatitis testing. Although we believe that hepatitis testing is not precluded by the law, there is no clear indication in either the statutory language or the legislative history indicating the Congress intended that the direction provided for HIV testing be expanded to other infectious diseases.

We believe that it would be permissible to issue a regulation requiring hepatitis testing for potential organ donors. However, we believe that it would be imprudent to proceed with such a requirement without the benefit of a prior public comment period to solicit the input of the industry and other interested parties. We recognize that there are significant OPO concerns that must be considered before we proceed with any proposal to require testing for hepatitis. We especially want to consider any cost impact and potential for decline in organ donations before we develop a regulatory change of this nature. Consequently, we are inviting public comment on this issue at

this time. If, after considering any comments we receive, we believe that change in the regulations is appropriate, we will issue a new regulation.

C. Provisions of the Final Rule With Comment Period

We have revised § 486.306 (q) and (s) to include a reference the CDC guidelines as standards in this final rule with comment period. We have also included the CDC guidelines as an appendix to part 486 subpart G.

VI. Qualification Data (§ 486.306(t))

A. Background

In the interim final rule with comment period, we added § 485.304(t) (now § 486.306(t)) to enable us to verify an OPO's compliance with the performance standards. Section 486.306(t) requires an OPO to submit accurate data to us within 15 days following the end of a calendar year (unless otherwise notified), giving information on the—

- Population of designated service areas based on the most recent U.S. Bureau of the Census data;
- Number of actual organ donors;
- Number of kidneys procured;
- Number of kidneys transplanted;
- Number of extrarenal organs by type procured; and
- Number of extrarenal organs transplanted.

B. Public Comments and Our Responses

Comment: One commenter believed that there are multiple interpretations for the terms for ''actual donor'' and ''procured'' that are used in the performance standards. The commenter recommended that HCFA adopt the definitions that have been developed by the OPTN contractor.

Response: Because, in the case of the OPO performance criteria, we are using criteria that are based on the performance of peers, it is important that all OPOs use the same data definitions to report data uniformly. We surveyed the use of various terms within the industry, including the OPTN contractor, and developed the following definitions:

- Kidneys recovered—The number of kidneys recovered is the actual number of kidneys the OPO recovers with the intent to transplant. Kidneys recovered that are intended for research are not to be included in the count. However, if a kidney was recovered with the intent to transplant but was not actually transplanted due to unforeseen circumstances, it may be counted. Kidneys recovered en bloc are counted as two kidneys.
- Kidneys transplanted—The number of kidneys transplanted is the actual number of kidneys that were transplanted into recipients. Kidneys transplanted en bloc are counted as two kidneys. Kidneys transplanted as part of multiple organ transplants, for example, kidney-pancreas transplants, are counted as both a kidney transplant and an extrarenal transplant.
- Extrarenal organs recovered—The number of extrarenal organs recovered is the actual number of hearts, livers, lungs, and pancreas the OPO recovers with the intent to transplant. Each organ is counted individually regardless of the number of organs transplanted into the same recipient.
- Extrarenal organs transplanted—The number of extrarenal organs transplanted into recipients. Each organ is counted individually regardless of the number of organs transplanted into a single recipient.

We had initially collected data from the OPOs using alternative definitions that may have disadvantaged some OPOs serving hospitals that frequently engaged in multiple organ transplants, such as heart-lung transplants, bilateral lung transplants, and kidney-pancreas transplants. We believe these revised definitions treat OPOs fairly. We note that the OPTN contractor has agreed to use these common definitions in its data gathering activities. Consequently, the feedback that the OPTN contractor provides to an OPO throughout the performance period to monitor an OPO's performance against its peers should be consistent with the HCFA performance standards. Moreover, based upon our impact analysis, we believe that changing the definitions from those contained in the interim final rule with comment period will not adversely impact any OPO's ability to meet the performance standards.

We defined ''donors'' in our previous collections as ''the number of cadavers from which the OPO actually recovers at least one viable organ.'' Some OPOs advised us that differences in OPO protocols may result in unintended differences among the OPOs through the use of this definition. They recommended that we alter the definition to count only those cadavers from which at least one organ was ultimately transplanted.

Unlike the changes in other definitions that increase the number of organs counted for nearly all OPOs, this recommendation for the change in the definition of ''donors'' would decrease the count of donors for many OPOs. Further, in conducting an impact analysis, we found at least one OPO that would have met the performance standard under the previously announced definition would not meet the standard under the recommended revision.

We do not want to change the standard without benefit of comment from the full industry, particularly in light of the fact that OPO representatives differ in their views of the most appropriate definition. Similarly, we are concerned that making a change in the definitions that would adversely impact some OPOs at this late time in the performance period without providing those entities an opportunity for comment is not equitable. Consequently, we are retaining the definition of ''donors'' that we used when we initially collected data to calculate performance standards for the 1996 designations. We are, however, open to altering the definitions for the 1998 recertification process. Therefore, we specifically invite the public to comment on this provision. If, after analysis of the comments, we believe that changes are appropriate, we will advise the public, including all OPOs, of these changes on a timely basis.

We advised OPOs of these definitions in our letters to them regarding the collection of data throughout the performance period. Similarly, we intend to include these definitions in the manual instructions being prepared on the OPO conditions of coverage. We believe that this way of proceeding will give us more flexibility in adopting more appropriate definitions that become evident through continued work with the data. We are also soliciting comments on whether changes in the definitions should be made through rulemaking.

Comment: Several commenters objected to our requirement that organs procured and transplanted en bloc, such as a pair of kidneys or lungs, be counted as a single organ. The commenters believed that each organ should be counted separately.

Response: We had intended that the organs be counted in accordance with industry standards. Mistakenly, we utilized the HCFA standard for counting organs that is applied during the cost reporting process. We have now changed our definitions to be consistent with industry usage. Each organ will be counted separately. OPOs are not able to influence the transplantation of multiple organs and therefore should not be penalized for serving centers that engage in this practice at a greater frequency than the national average.

We note that we have already clarified this in our operational instructions to the OPOs in verifying the performance data. Thus, the performance standards

applied for the 1996 recertification process have been calculated based on these revised definitions. Moreover, we are deleting any regulatory reference to how organs are to be counted. We believe that this type of detailed operational instruction is more appropriately placed in a manual where it can be revised more easily as appropriate.

Comment: A few commenters recommended that HCFA use only verified data from the OPTN contractor to monitor performance.

Response: We have analyzed portions of the OPTN data relative to organ recovery and transplantation. We found the donor data reasonably consistent with that reported to HCFA directly. Thus, the idea of using the OPTN data for calculating performance standards is very appealing. This method would reduce the reporting burden on the OPOs and is consistent with the Administration's goal of reducing the Federal regulatory burden. If we make such a change, we will, of course, first notify all OPOs timely.

However, we have two concerns before we can implement such a strategy. First, to make the performance standards as current as possible while still meeting the recertification schedule, we require that the calendar year data be reported as close to the end of the year as possible. Currently, we require the OPOs to report this data to us by January 15 annually. Because of the lag time of hospitals notifying the OPTN of recipient registrations, the OPTN contractor questions if the data reported by the 15th of the following month through routine channels are comprehensive.

Second, we are concerned that OPOs have an avenue to request adjustment of the data or to provide any necessary explanatory material. For example, all of the performance criteria are population based. Due to hospitals dealing with OPOs other than the one designated for the service area or census changes, changes in the actual population data for an area may be necessary. The OPTN data on population is not, to the best of our knowledge, specific to the actual hospitals served by OPOs. Thus, to use the OPTN data without the benefit of adjustment could unfairly penalize some OPOs.

We established a process for collecting data from the OPOs. Each OPO has been asked to submit its data in accordance with our directions defining the variables. OPOs have the opportunity to identify necessary adjustments to the population for its designated service area to take into account hospitals that deal with multiple OPOs or an OPO other than the one designated for the area. When an OPO requests a population adjustment, we will work with the alternative OPO and our regional offices using appropriate census data to accurately apportion the population in question.

National averages and performance criteria are calculated and forwarded to the OPOs, along with our recorded data from that OPO, to provide an opportunity to review the data recorded. The OPO has an opportunity to assure that data entry errors or other mistakes have not been made and provide any necessary corrections to the data base. We believe it is essential to provide OPOs this form of opportunity for input before we use the data for purposes that could potentially result in termination of the OPO from Medicare and Medicaid participation.

Initially, we were concerned that this opportunity for input would not be available if we were to use the OPTN data. However, we anticipate that once the initial population for the OPO service areas has been calculated, future changes or adjustments, or both, will be minor and infrequent. Thus, we may be able to develop a process that is based on calculation of the standards using OPTN data, yet incorporates a process for individual OPO adjustment requests.

Despite these concerns, we are supportive of the concept of using the OPTN data to calculate the performance standards. We, together with the OPTN contractor, will work with the OPOs and the transplant centers throughout the year to obtain the necessary data as timely as possible and develop a process for appropriate adjustments to achieve this goal. We intend to test the 1995 and 1996 OPTN contractor data submissions and analyze differences between the OPTN data and the OPO data. If the OPTN data prove satisfactory, we will begin using them to set the 1998 standards rather than collecting the data individually from the OPOs. We would, however, continue to allow OPOs to review the data and request changes as appropriate. We note that adopting the OPTN data may require revisions to the regulation or paperwork requirements or both. We invite OPOs to participate with us in this process during the ongoing evaluation.

Comment: One commenter believed that the requirement that the data be submitted within 15 days of the end of an calendar year is unreasonable. The commenter recommended that OPOs be given 60 days in which to submit data.

Response: We acknowledge that a 15-day period for submission of data after the end of the year may appear unnecessarily onerous. But, upon closer examination, we believe that the request is quite reasonable. The data are for items routinely collected by nearly all OPOs, there are only six data elements, and the data for the first 11 months may be gathered in advance of the due date with the final month's data added at the end of the year.

In addition, we believe that it is impractical to extend this timeframe because of the work that must be done to determine the performance standards before the recertification process which, for most OPOs, begins in April. Prior to the beginning of April in the years in which the recertification process takes place, we must review the data submitted by the OPOs, make any necessary adjustments, enter the data into a database, and calculate the performance standards. This work must be completed as early in the year as possible so that the OPOs can be notified of the standards, be afforded an opportunity to verify the accuracy of their data, and make any changes to the data prior to the recertification process. Because, the performance standards are based on averages, a change in a single OPO's data can result in a change in the standard that could impact upon other OPOs. We believe that it would be inequitable to OPOs to delay having the performance standards available to them until immediately preceding the recertification.

Additionally, we must also have estimates available as early as possible of those service areas currently served by OPOs that do not appear to meet the standards so that any OPO interested in moving into a service area of a poorly performing OPO has an opportunity to prepare a plan for operating in the service area.

The only alternative we have to collecting data within 15 days of the end of the performance period is to change the base years from which we calculate the standards. That is, we could calculate the performance standards for the 1996 redesignation using data from 1993 and 1994 rather than 1994 and 1995. We find this alternative unsatisfactory. We believe that it is important that the data used to evaluate an OPO's suitability for redesignation reflect the most recent performance of an OPO. The use of old data could result in our terminating the agreement of an OPO that has just completed an outstanding performance year because the OPO did not meet the criteria 2 or 3 years ago.

We note that very few OPOs appear to have difficulty with the data collection process and due date once they have gotten used to the process. For example, only six OPOs did not file their data

timely in response to our 1995 collection effort. Further, none of the OPOs called us to complain that the timeframe was unworkable or unreasonably difficult.

C. Provisions of the Final Rule With Comment Period

We have not made any revisions to § 486.306(t) in this final regulation with comment period. We have, however, removed the introductory paragraph of § 486.310 containing operational instructions regarding the counting of organs. We are removing these instructions from the OPO regulations because they will be more appropriately placed and more easily updated in an operational manual.

VII. Performance Standards (§ 486.310)

A. Background

Section 485.306 (now § 486.310) lists the performance standards for OPOs. In the proposed rule, we proposed revisions to this section to state that we would not ''redesignate'' any OPO that fails to meet the performance standards contained in this section. We also revised § 485.306(b) (now § 486.310(b)) to distinguish between an OPO which has not previously been designated by us for a particular service area and a redesignated OPO with respect to the exemption from meeting the performance standards in § 485.306(a) (1) and (2) (now § 486.310(a) (1) and (2)) for 2 years.

In the interim final rule with comment period, we revised the proposal to add the performance standards that OPOs must meet beginning January 1, 1996. An OPO must meet the primary performance standard by achieving at least 75 percent of the national mean for four of the five performance categories over 2 calendars years before the year of redesignation. The performance categories are:

- Actual donors per million population.
- Kidneys recovered per million population.
- Extrarenal organs recovered per million population.
- Kidneys transplanted per million population.
- Extrarenal organs transplanted per million population.

In addition to the primary performance standard, the interim final rule provided for three additional performance standards. An OPO must:

- Procure organs from an average of at least 24 donors per calendar year in the 2 calendar years before redesignation.
- Maintain an average procurement ratio of three organs per donor.
- Enter into a working relationship with any hospital or transplant center in the OPO's service area that requests a working relationship.

For the purpose of measuring adherence to the performance standards, organs removed en bloc and transplanted en bloc are counted as a single organ.

In addition, § 485.306 (now § 486.310) permits an OPO to submit corrected information if it believes the data used to apply the performance standards were inaccurate. It also allows us to grant an exception from some of the performance standards to OPOs operating outside the contiguous United States.

B. Public Comments and Our Responses

Comment: One commenter suggested that performance measures be reevaluated annually to ensure that the system can incorporate a superior model for assessing underlying donor potential that is under development.

Response: We intend to continually reevaluate the performance standards as new data become available. We believe it is unnecessary to commit to an annual reevaluation because it is unlikely that new measures will surface at a rate that would indicate that the existing standards are antiquated that quickly. Nonetheless, readers can be assured that we will continue to monitor research and experience to further refine and perfect performance standards. Any proposed changes in the standards will be published for public comment before being effectuated.

Comment: One commenter noted that performance standards based on potential would be more accurate and effective than the ones specified in the regulation.

Response: We do not agree with the commenter that standards based on potential performance are superior to standards based on actual performance. We believe it would be inappropriate for us to certify any except a new OPO based on its potential to perform at a certain level, if the OPO is not achieving a certain level of that potential. For example, an OPO could service an area with the potential to produce 100 organ donors and significantly higher than average organs per million population. However, if that OPO does not actually achieve 24 donors and 75 percent of the national average organs per million population, we believe strongly that it would be inappropriate for us to ignore the actual performance and continue to certify the OPO based on its potential performance.

Comment: One commenter expressed concern that the performance criteria disproportionately accentuated recovery over transplantation. That is, the commenter noted that three of the primary performance standards related to recovery (that is, donors per million, kidneys recovered, and extrarenal organs recovered), while only two related to transplantation (that is, kidneys and extrarenal organs transplanted). The commenter believed this emphasis on recovery over transplantation does little to accomplish the primary goal of OPOs—providing transplantable organs for thousands of waiting recipients. The commenter was concerned that such an emphasis may result in increased discard rates.

Response: We believe that both organ recovery and transplantation are critical areas of OPO performance that need to be monitored. We acknowledge that the commenter is accurate in noting that the primary performance criteria do slightly emphasize recovery over transplantation. One of the primary reasons for this is that an OPO can more directly influence the recovery rate than the transplant rate.

While we acknowledge that a small portion of the organs discarded are within the control of the OPO through tasks such as thorough medical history taking, we believe the majority of organ discards occur for reasons that are beyond the OPO's control. For example, surgical nicks, damage to the organ during removal, and diseases that were unknown to the family or not reported in medical records account for many discards.

While we believe it is important to hold OPOs accountable for making every effort to avoid unnecessary discards, we believe it is unnecessary and inappropriate to accentuate the transplantation over recovery. After all, an organ must first be recovered before it can be transplanted. Given that there are but five criteria in the primary performance standard, we continue to believe that it is appropriate to have three recovery-related criteria and two transplant-related criteria. We note that, for the most part, the OPO industry widely supports this division.

Comment: Another commenter expressed concern that the primary performance criteria were antiquated in that they emphasize kidney transplants almost to the exclusion of other tissues and organs.

Response: We do not agree with the commenter that the primary performance standard disproportionately emphasizes kidney transplants ''almost to the exclusion of'' other tissues and organs. Three of the five primary standards are not related to kidney transplants. However, since the

number of kidney transplants significantly outweighs other organ transplants, we believe it is appropriate to establish separate standards that look solely at the kidney recoveries and transplants as part of overall OPO performance. Of the 19017 transplants in 1994, 11,391 or 59 percent were for kidneys. We believe this high incidence of kidney organ transplants justify standards that concentrate exclusively on that organ. We welcome comments on whether this emphasis on kidney transplants is the best course for the future, given the science of transplantation.

Comment: One commenter stated that some OPOs may not meet the extrarenal organ standards for reasons beyond their control, such as geography or availability of transplant surgeons. The commenter stated that there are no pancreas, lung, or heart/lung programs in the commenter's State so the OPO often did not recover these organs due to unavailability of transplant surgeons. The commenter suggested that if an OPO is able to demonstrate that it cannot meet the standard due to such reasons, it be given credit for unrecovered organs.

Response: Although we can sympathize with this OPO's concerns, many OPOs are faced with this situation. Some have developed mechanisms to facilitate procurement of extrarenal organs for transplantation in patients listed at transplant centers outside their States. Many OPOs are meeting these goals by utilizing local surgeons to perform excisions. Other OPOs are developing relationships with extrarenal programs to facilitate placements without impediment from geographic boundaries.

It is an OPO's responsibility to recover all viable organs from all acceptable donors and facilitate their placement in suitable recipients. The performance standards are designed specifically to encourage more effective organ retrieval and transplantation. We believe it would be irresponsible, given the number of persons awaiting organs, to modify the performance standards in any way that would validate the failure to retrieve transplantable organs. Therefore, we are not altering the regulations as suggested by the commenter. We note that in areas where geographical boundaries present real obstacles to placement, such as noncontiguous States and territories, the regulations now located at § 486.310(c)(1) already adequately address this issue through an exception process.

If it is true that viable organs are going unrecovered because there is no transplant program for a specific type of organ in a State, we find a severe problem exists that should certainly be corrected. We do not want to encourage the continuance of the problem by altering the performance standards.

All organs can be transported at least 500 miles without significant chance of damage. With few exceptions, this 500-mile radius goes significantly beyond State and, generally, OPO service area boundaries. Consequently, an organ should be recovered even when the organ cannot be transplanted in the State or within the OPO's service area. We strongly encourage any OPO that has adopted the practice of not recovering organs that it cannot transplant locally to alter that practice immediately.

Comment: One commenter suggested that HCFA include data from all OPOs, including new OPOs, in the calculation of the national mean.

Response: We intend to include all OPOs in the calculation of the national mean, including new OPOs and those in noncontiguous States and territories. However, we believe it is unnecessary to amend the regulations to specify this intention. Since the regulatory language does not restrict the calculation, we believe it already supports our position to include all OPOs in the calculation.

Comment: Several commenters suggested that we substitute deaths per year as the denominator in the primary performance criteria is lieu of population. They believe that logically this denominator is more directly correlated to the potential donor pool and would produce better performance standards.

Response: The objective of the performance standards is to establish an appropriate measure that would enable us to assess how well OPOs are maximizing organ resources and therefore warrant certification by the Medicare/Medicaid program. As such, it is important that the data we use to develop these standards provide an accurate measure of OPO performance. Clearly, the use of hospital deaths versus area population in the denominator from which these standards are derived warrants further investigation. We agree that since OPOs deal with cadaveric donors, deaths per year (particularly hospital deaths per year) is a more targeted measure of an OPO's actual potential donor pool. Therefore, we surveyed the OPOs in an attempt to collect death data from them for 1994 so that we could study the feasibility of using deaths per year as the denominator. In nearly every State, OPOs reported problems obtaining timely data. In at least one State, the data are not available at all. We were able to determine, however, that national death statistics are available from the National Center for Health Statistics (NCHS) and the Social Security Administration (SSA).

Although we have decided to proceed with the use of population as the denominator for a number of reasons discussed below, we are soliciting public comments on which approach—population or death statistics—would best achieve our objectives with respect to measuring OPO performance.

- Population Data:

For purposes of developing the performance standards, we use the latest census data. In addition, adjustments are made in the population data to account for hospitals that deal with OPOs outside the designated OPO service area.

These data are relatively easy to obtain at minimal, if any, cost to the OPOs. We are soliciting comment on the timeliness, cost, and quality of these data and adjustments to these data.

- NCHS Death Data:

NCHS produces a public use data tape that contains deaths by county for all U.S. counties. This tape contains approximately 2.2 million records per year. Although death data are available universally, there are some data elements that may be missing for certain areas. The OPO industry has suggested the use of in-hospital deaths rather than general death data, and while this could be obtained from the NCHS tape, certain areas, such as Oklahoma, do not make fine distinctions in the hospital site. Also, we are not certain about the availability of death data for the United States territories. The NCHS tape may allow some finer analysis based on demographic characteristics that may better reflect the viable organ pool.

In the United States, the collection of these vital statistics data is a State responsibility. Data are gathered by the States, and each State establishes its own definitions for terms and coding rules. Although NCHS conducts a quality review of the data, it uses the individual State guidelines to verify the data were coded appropriately. This approach, especially in terms of the definition of ''hospital'', could affect the OPO performance standards. In addition, there is approximately a two-year delay in the availability of death data from NCHS.

The NCHS public use tape can be purchased for $590 per year. Since performance standards utilize a two-year average to avoid penalizing OPOs for short fluctuations in organ donation, it would cost an OPO approximately $1200 per redesignation cycle to obtain

the tapes. At this time, the data file is only available in mainframe medium. We expect that most OPOs do not employ the staff that would be required to abstract data from the NCHS tapes, although we would welcome comment on this point.

The NCHS data does not identify individual hospitals for any State, and there may be confidentiality issues that preclude States from collecting hospital-specific information. Lack of hospital-specific data would create a problem in adjusting the performance data for those hospitals that deal with OPOs outside of the designated OPO service area. While for most OPOs the impact of hospitals dealing with alternative OPOs is minimal, there are several OPOs where the impact of such hospital choices is very significant.

- SSA Death Data:

Although we may be able to obtain timely death data through the Social Security Administration, we know through experience that there are a small number of deaths that are not reported accurately. Our experience with using these data in our intramural research indicates it is approximately 98 percent accurate. However, we are very concerned with use of data that the OPOs cannot verify. We are further investigating the timeliness, cost and quality of the SSA mortality data. We are interested in receiving public comment on this data source.

- Other Policy Implications:

We are concerned about the impact of using death as the denominator for those OPOs servicing large urban areas. Urban areas may have a higher death rate among apparently suitable donors, however, there is a lower donor consent rate among the minority population and a higher likelihood that a potential donor will be an HIV risk or present a history of substance abuse. Therefore, in these cases, the death rate may not accurately define the potential donor pool and may disproportionately affect OPOs serving large urban areas. We may not want to establish a performance standard that may systematically bias a particular group of OPOs.

We conducted an impact analysis comparing the use of 1991 death data (the most recent data available at the time of our analysis) and population data as denominators in calculating performance standards. We determined that the use of death data would not significantly alter performance outcomes compared to using population data. However, three OPOs servicing major urban areas would not meet the performance standards if death data were substituted for population data, provided that the performance standards is not also changed. We acknowledge that if the denominator used to measure performance were changed, the performance standard itself could in principle be changed, and solicit comments on this issue.

While research is being conducted on determining adjustment factors that would allow for normalization of death or population data to account for demographic factors, we are not aware of a generally accepted adjustment methodology at this time.

In summary, we are soliciting comments on the approaches discussed above with respect to use of population versus death statistics (from either NCHS, SSA or some other national source) as a denominator for measuring performance. Specifically, we are interested in comments concerning the timeliness, cost, and validity of the various data sources. We would also appreciate suggestions concerning possible adjustments to account for varying demographic factors across areas, as well as any other potential changes in the performance measures that could be used in conjunction with death data.

Comment: One commenter suggested that any adopted performance standards include adjustment for demographic risk factors related to the population of the service areas. The commenter suggested historical consent rates and medical suitability rates of potential donors.

Response: We acknowledge that intuitively it would seem to be more difficult to achieve performance standards in some service areas than in others. However, the impact analysis we conducted based on 1994 AOPO data does not support the assumption that the unadjusted population-based performance standards would disproportionately impact on those population bases that have higher demographic risk factors. Rather, it appears that the selected performance standards appropriately identify those OPOs that have not achieved designated performance standards based on factors that are within the OPO's control. For the most part, those OPOs with high demographic risk factors do not appear to have difficulty meeting the standards. For example, the California Transplant Donor Network exceeds the mean of all five of the performance standards while servicing San Francisco, which has one of the largest HIV populations in the country. Similarly, most OPOs servicing populations that have historically had low consent rates also appear to meet the standards.

Finally, the commenter did not propose an empirical value to be used to adjust for these risk factors. Although we are aware of ongoing research in this area, we have not found literature that unequivocally supports a method to calculate exact demographic risk factors that would appropriately adjust the planned performance standards. We are interested in any empirical research in this area. We intend to continue to monitor the research and will consider any significant findings for future refinement of the standards.

We are very interested in the development of alternative performance criteria that would be consistent with our goals of increasing organ donation, setting achievable threshold levels of acceptable performance that are realistic and fair to all the OPOs. Unfortunately, we have not been able to ascertain empirical evidence regarding the correlation between adjustment factors and donation. That is, to the best of our knowledge organ donation is influenced by a myriad of factors. An area that has a high incidence of some factor that would seem to decrease donation may also have a high incidence of another factor that would seem to increase donation. We are not aware of any regression analysis or other statistical studies that would allow us to appropriately adjust performance indicators for idiosyncracies of a geographic area.

Nonetheless, we are very interested in further refining the performance standards. We specifically invite the public to comment on any alternative performance measures that are supportable by empirical evidence.

We should point out, however, that it appears that the rigorous performance standards we have selected are providing the appropriate incentives to increase organ donation. Based on the unverified 1995 performance data reported, there has been an increase of 262 donors in 1995 over 1994, resulting in over 1100 additional organs being procured. We find these statistics very gratifying and may demonstrate that the use of rigorous performance standards significantly benefits the public awaiting transplantation.

Comment: Two commenters noted that many OPOs deal with hospitals outside of the designated service area. They asked if we would calculate the appropriate, actual population served by an OPO in applying the performance standards.

Response: As noted above, we believe that approximately 200 hospitals deal with OPOs outside their service areas. We recognize that this arrangement can contribute to an OPO's failure to meet the performance standards based on servicing a designated area. The

regulations at § 486.310(c)(3) specify an OPO may provide documentation to us to support an adjustment in its population rate if one or more hospitals in its designated service area have agreements with alternative OPOs.

Operationally, we have implemented this provision by soliciting actual population data from each OPO. We asked the OPOs to advise us when a population adjustment is appropriate. We then ascertained appropriate population adjustments through discussions with the alternative OPOs, the hospitals in question, and the HCFA regional offices. We note that effective January 1, 1996, a hospital may deal with only one OPO. We believe this requirement will make it easier to allocate population as the entire hospital service area will be designated to the one OPO with which it has an agreement. As noted above, we calculated the performance standards based on the reported data, asked OPOs to verify the accuracy of their submitted data, and provided OPOs an opportunity to request further adjustments.

We believe that the process we developed provides an opportunity for equitable adjustments to the population data and holds an OPO accountable for all of the hospitals it serves—including hospitals outside of its designated service areas.

Comment: One commenter noted that research currently underway at the Harvard School of Public Health could potentially lead to a more accurate methodology for measuring OPO performance. The commenter requested that the current performance measures be reevaluated annually to ensure that more current research does not produce a superior mechanism for evaluating performance.

Response: We are pleased to see that there is research ongoing in this area. We will be very interested in the results and will consider them fully when the research is complete. While we are always open to improving the mechanism for evaluating OPO performance from any interested source, we believe it is unnecessary and inappropriate to commit to an annual reevaluation in the regulations. OPOs must know in advance to what standards they will be held, so that they can make appropriate plans and changes in their procurement strategies. If the research proves to be superior as the commenter believes, we will issue a proposed notice in the Federal Register for public comment. Changes in the performance standards will only be made after the public has had an opportunity to review and comment on the proposal.

Comment: Two commenters suggested that we develop more appropriate criteria for the noncontiguous States and territories. They noted that Puerto Rico has historically had extremely poor success with organ procurement and would fail to meet the planned standards of 50 percent of the national mean.

Response: We acknowledge the historically small number of organ donations in Puerto Rico. We note, however, that other noncontiguous areas such as Hawaii have had higher donation rates. We feel challenged to develop a standard that would provide an incentive for improvement for Puerto Rico without being so lax as to fail to present any challenge to Hawaii at all. We note that the performance standards for the noncontiguous States and territories are limited exclusively to kidneys procured and transplanted. For this single organ, the standard is 50 percent of the national average.

During 1994, a new OPO assumed responsibility for Puerto Rico. Under the guidance of this new OPO, we are optimistic that Puerto Rico will eventually meet this performance standard. In the meantime, we do not intend to allow a service area that contains a hospital to go unserved. Thus, we have revised the regulations to specify that an OPO that does not meet the performance standards will not be terminated as long as another OPO does not compete for the territory (§ 486.310(c)). Given this change in the regulations, we believe it is acceptable to retain the standards for the noncontiguous States and territories. An OPO may continue to be designated for Puerto Rico even if it does not meet the performance standards as long as no other OPO competes for the service area. If another OPO demonstrates that it can achieve better performance in the area, we believe that it is appropriate to terminate the low performing OPO and give the alternative OPO an opportunity to achieve higher organ donation.

Comment: Several commenters were concerned that the primary performance standard of achieving at least 75 percent of the national mean for four out of the five performance categories is absolutely mandatory. They believed that OPOs should have an opportunity to provide a corrective action plan for the primary performance standards rather than be terminated. Another OPO suggested that OPOs not meeting the primary performance standard be placed on probation for one year.

Response: We, together with staff in the Health Resources and Services Administration, have long believed that there are many more potential organ donors available than are currently being identified by the OPOs. For example, there are nearly 5,000 hospitals in this country that have not identified a single organ donor over a 3-year period. Based on recent research from the Johns Hopkins University, we believe that approximately 850 of these hospitals have donor potential. While there are a myriad of reasons for failure to identify all potential organ donors and to convert all potential donors to actual donors, a major influence on organ donation is unquestionably the OPO.

We believe that the establishment of primary performance standards at 75 percent of the national average is a reasonable standard. We hold no OPO accountable to an arbitrary number but rather look only to its peers. We are not aware of geographical factors that by themselves make it impossible for an OPO to meet the standards in certain service areas. Rather with a 25-percent margin of error off the mean, we believe that the most influential factor to performance is the OPO itself.

We intend these performance standards to serve the people on the transplant waiting lists in all areas of the country by fostering the most efficient OPO service for them. We believe that all Americans, regardless of whether they are Medicare or Medicaid beneficiaries, deserve to be serviced by OPOs that make every effort and use every skill available to procure transplantable organs so that lives may be saved or improved through timely organ transplants.

Consequently, we believe it is important to hold each OPO accountable for meeting the primary performance standard. If the OPO that is assigned to a service area is not achieving appropriate organ donation rates, we would be acting irresponsibly to the Americans on the waiting list to allow that OPO to continue to serve that area rather than replace it with another better-performing OPO.

However, we equally believe we would be acting irresponsibly to allow an area to go unserved rather than to permit an OPO an opportunity for improvement. Therefore, we are altering the regulations to permit an OPO that does not meet the performance standards to retain its certification and submit a corrective action plan, if no other OPO that is performing acceptably is willing to assume the service area.

When an OPO does not meet the primary performance standard, we will solicit interest in assuming the territory from other OPOs. When another higher-

performing OPO wants to assume the service area, we believe that we should make the potentially superior service available in that area. In those cases where no other OPO expresses an interest in assuming the service area, we will allow the poor-performing OPO to submit a corrective action plan and retain its certification for an additional 2-year period.

Comment: Several commenters thought that the performance standard requiring OPOs to maintain an average procurement ratio of three organs per donor should be eliminated. Many of them thought that the standard would discourage innovative practices by OPOs, particularly those related to procuring organs from older donors.

Response: We had originally intended the use of a static number standard, such as the 3 organs per donor and 24 donors per year standards, as part the performance standards to ensure that the standards remained rigorous over time. We wished to safeguard against the industry as a whole becoming lax in performance and driving the national average to artificially low numbers.

Upon further reflection, we believe that the use of static number performance standards is unnecessary and could result in a burden on the OPOs if we required the submission of justification or corrective action plans when these standards are not met. In conducting an impact analysis of these performance standards, we found that all OPOs that did not meet the three organ per donor standard also failed to meet the primary performance standard. Consequently, we anticipate that this standard in and of itself would have no immediate impact.

We also recognize that industry changes that could result in these static number standards not being met may not necessarily be detrimental. For example, innovative practices, such as procuring organs from older donors, can result in a net increase in organs available even though the standard may not be met. We do not wish to discourage aggressive organ procurement practices as long as they promote safe organ acquisition and show respect for the families of potential donors. Our principle goal in the development of performance standards is to increase the total number of organs transplanted. Standards that could potentially deter an OPO from obtaining every viable organ available are contrary to our goal. Consequently, we believe that our goal is best served if we eliminate the static number standards and proceed with the primary performance standards alone.

Comment: One commenter requested that newly merged OPOs and OPOs acquiring significant new territory be granted a grace period for compliance with the performance standards, similar to what we permit for newly formed OPOs. The commenter believed that failure to provide a grace period would deter an OPO from expanding its territory.

Response: The concept of granting a grace period for merging OPOs and OPOs acquiring significant new territory is a difficult one. We recognize that significant changes in OPO management, administration, or new service areas could potentially result in a temporary decline in performance as the organization adjusts to the change.

On the other hand, we are extremely concerned that permitting a grace period could instill a perverse incentive into the program. That is, allowing a grace period could provide an incentive for two poorly performing OPOs to merge merely to avoid termination or for OPOs to enter into bidding wars over service areas to avoid application of performance standards. Policies that promote frequent major changes in the OPO structure could be counter to our goals by resulting in decreased rather than increased organ donations.

After considerable thought, we have decided to retain our current policy of not permitting a grace period for newly merged OPOs or OPOs with significant changes in territory. We believe that this will encourage OPOs to undertake such changes judiciously using careful thought and extensive planning. It is far less likely that big OPOs will overstep their capacity for expansion if they must maintain high performance standards.

We note, however, that the above change in policy, related to the failure to terminate an OPO's provider agreement when there is an absence of interest by another OPO in assuming the service area, would apply in the case of newly merged OPOs. That is, a newly merged OPO will be allowed to continue in the program even if it does not meet the performance standards when no OPO with acceptable performance levels is interested in servicing the area.

We expect that, in most cases, there would be a reluctance on the part of competing OPOs to move into the service area of a newly merged OPO before that OPO has had an extended opportunity to demonstrate its ability to perform. We base our expectation on the realization that repeated changes in OPO personnel and organization practices are disruptive to organ donation and are likely to make it more difficult for the second OPO to meet its performance standards as well.

C. Provisions of this Final Rule With Comment Period

- We have added new § 486.310(c)(2) to provide that an OPO that is performing below standards may be redesignated for a service area if no acceptably performing OPO is willing to accept responsibility for the service area and if the designated OPO submits a corrective action plan.
- We have reorganized § 486.310(c) for clarity.
- We have moved the requirement at § 486.310(b)(4) (formerly § 485.306(b)(4)) that each OPO enter into a working relationship with any hospital or transplant center in the OPO's service area that requests a working relationship to § 486.304(b)(8).
- We have deleted § 486.310(b) (2) through (4) (formerly § 485.306(b) (2) through (4)) relating to the non-primary performance standards for redesignation after January 1, 1996. We are making conforming changes to various other sections to delete references to these sections.

VIII. Definition of an Open Area (§ 486.302)

A. Background

In the proposed rule, we added the definition of ''open area'' to § 485.302 (now § 486.302). We defined ''open area'' as a service area for which we are accepting applications for designation. A service area becomes open for competition once the normal 2-year designation period or brief interim redesignation period has expired, when the designated status of the existing OPO is terminated, or when no OPO previously has been designated for the area. In the interim final rule with comment period, we modified § 485.308(a) (now § 486.316(a)) to clarify that, based upon the language in § 485.302 (now § 486.302), it is the OPO's provider agreement with HCFA (not the OPO itself) that can be terminated.

B. Public Comments and Our Responses

Comment: A few commenters requested clarification of the concept of an open area. The commenters believed that, if an OPO meets the performance criteria, no other OPO should be allowed to compete for its service area.

Response: It is the intent of the law to encourage the most effective organ procurement and allocation system. During various Congressional hearings on transplant issues, the Congress has made it clear that it supports as

equitable a system as possible. We believe it is the Congress' expectation that we establish conditions in the Medicare and Medicaid program that provide incentives for OPOs to operate as efficiently and effectively as possible in procuring lifesaving organs.

Consequently, we believe that the law does not in any way intend to assure OPOs a monopoly simply because they barely meet the Medicare performance criteria. The structure of the statute, which allows only a single OPO to be designated in any given area, sets up an inherently competitive system. Thus, it is appropriate and in keeping with the principles of our national economy to permit competition regardless of the fact that an OPO is meeting the performance criteria.

We intend to designate the best performing OPO for each service area. We believe it is inappropriate to designate a marginally performing OPO for a service area simply because it has operated in that area previously if a peak-performing OPO is also competing for the area and has the support of the hospital community. However, we recognize that organ donation is a voluntary action. Therefore, to perform well in an area, any OPO must have the support and cooperation of the community. The ''tie-breaking'' criteria we will use to adjudicate the competition are specified at § 485.308(a) (1) through (6) (now § 486.316(a) (1) through (6)). These criteria emphasize the relationship between the OPO and the hospitals in the service area, the proximity of the OPO to the area, and past performance.

With regard to the explicit request for clarification of the open area designations, every county in the country is open for competition at redesignation time. Currently, most OPOs are in two-year designation periods that end April through June 1996 and every two years thereafter. Thus, an OPO may compete for any county, or all counties in an MSA, that it believes it can serve better than the existing, designated OPO at that time. To bid on an open area, the OPO must notify the HCFA regional office of its intention. The regional office will advise the existing, designated OPO of the competition and request the necessary information to evaluate the proposals.

In addition to the open area competition that may occur at redesignation time, an area will be declared open if the provider agreement with the OPO serving the area is terminated or if no OPO has been designated for the area. There are a number of counties that do not contain hospitals. Consequently, no OPO had been designated for these counties in prior designation periods. We believe that every county should have a designated OPO to work within the community. Therefore, we instructed our regional offices to designate these counties based on the affiliation of the hospital from which the majority of the residents seek care. That is, we asked the Regional Offices to designate these counties to the OPO servicing the hospital that is used routinely by the majority of the residents.

We had considered designating the county to the hospital furnishing trauma care to the locality. However, we decided to designate the OPO of the local hospital because the nearest trauma facility may be located very far away. We believe that designating the area to an OPO that is a great distance away is likely to be a deterrent to the OPO's ability to serve the community.

Finally, we point out that the final regulation states explicitly a policy HCFA has applied administratively in implementing the OPO redesignation process. We have historically allowed competition for OPO service areas designations at time of redesignation. Further, we would accept a bid for a service area for undesignated counties or the service area of a terminated OPO at any time should an entity apply. Such competition has been minimal. We do not expect this to change with the inclusion of this policy in the regulations. It is generally accepted that OPO-hospital relationships may make procurement more difficult during the transition. Since OPOs acquiring new service areas will continue to be held to rigorous performance standards, we do not believe OPOs will seek expansion without considerable thought and planning.

Comment: Another commenter noted that the interim final rule did not list the factors that would be used to adjudicate the designation of a service area that is being contested. The commenter suggested the following factors: procurement rate, satisfaction of transplant centers with service provided by the OPO, organ procurement costs, response time to donor referrals, extent and effectiveness of professional and public education, established patterns of organ donor referrals, organ discard rate, and donor hospital satisfaction.

Response: We did not reprint the factors that would be considered in adjudicating contested service area designation because we did not intend to change the regulations. As noted above, the factors are listed at § 486.316(a) (1) through (6). Many of the factors noted by the commenter are included in these regulations. These factors follow.

(1) Prior performance, including the previous year's experience in terms of the number of organs retrieved and wasted and the average cost per organ;

(2) Actual number of donors compared to the number of potential donors;

(3) The nature of relationships and degree of involvement with hospitals in the organization's service area;

(4) Bed capacity associated with the hospitals with which the organization has working relationships;

(5) Willingness and ability to place organs within the service area; and

(6) Proximity of the organization to the donor hospitals.

As noted above, we have not heretofore experienced a significant amount of competition among the OPOs. Thus, we have only limited experience with these criteria. If competition increases among the OPOs as a result of this final rule with comment period, we will consider revising the factors in the future. In that regard, we will give consideration to the factors noted by the commenter. We will also publish a proposed notice of these changes in the Federal Register and invite public comment on the proposal.

C. Provisions of This Final Rule With Comment Period

As we stated above, we are making no revisions in the definition of ''open area'' at this time.

IX. Termination of an OPO's Provider Agreement (§ 486.325(b))

A. Background

In the interim final rule, we added § 485.311 (now § 486.325(b)) to specify the conditions for both voluntary and involuntary termination of an OPO's provider agreement. For a voluntary termination, we required that the OPO provide us with a written notice of its intention with a proposed termination date. We will take action to approve the request as submitted or take other action to ensure that there is no disruption in services in the affected service area.

For an involuntary termination, we may terminate an agreement if we find that an OPO no longer meets the conditions of coverage. Under § 485.311(b) (now § 486.325(b)), we indicated we would give 15 days notice of termination. We also set forth an OPO's appeal rights, the requirement that an OPO give prompt public notice regarding the voluntary termination, and reinstatement provisions.

We made editorial changes to this section as part of the interim final rule

with comment period but we did not make any significant changes in the substance.

B. Public Comments and Our Responses

Comment: One commenter believed that a 15-day notice of termination, if used, could lead to serious disruption of organ procurement efforts. The commenter urged a minimum notice requirement of 90 days.

Response: The added the 15-day termination notice is included in the OPO regulations to be consistent with the treatment of providers under the Medicare program. It is common practice in the Medicare program to give providers a 15-day notice of termination of their agreement to participate in the Medicare program for failure to comply with the conditions of coverage.

However, upon further reflection, we can see some significant differences between certification of Medicare participating providers and certification/designation of an OPO that may warrant an alternative policy for OPO termination. Most notably, providers are generally terminated for serious and imminent health and safety reasons, while OPOs are most likely to be terminated for failure to meet performance standards. While it is possible for an OPO to be terminated for a health and safety reason, such as procuring organs from HIV-infected donors, such a termination has not occurred to date. Consequently, we expect that such an occurrence would occur very rarely, if at all. Thus, in the case of serious health and safety issues, it is important to protect the health and safety of our beneficiaries by proceeding with termination expeditiously. However, we believe that because no serious harm is likely to befall anyone if we move more cautiously with termination of an OPO's provider agreement, we can consider an extended termination notification period.

In addition, Medicare beneficiaries generally have easier access to alternative health care when a provider of health care services is terminated. That is, while a Medicare beneficiary is no doubt inconvenienced somewhat when the provider of choice is terminated from the program, 15 days is generally enough notice for the beneficiary to locate an alternative source of care within the area. In the case of an OPO, however, the situation is significantly different. That is, an OPO does not furnish health care services directly to the beneficiary, and there are no generally available alternative OPOs within easy access. Thus, in the case of OPOs, expeditious termination of the entity could present a significant problem to the providers who have an agreement with the OPO.

We note that we are changing the process for termination somewhat from that in the interim final rule with comment period. That is, we have concluded that we will not necessarily terminate an OPO that does not meet the primary performance standard if no other OPO is willing to assume the territory. Rather, we will solicit interest from other OPOs in assuming the service area. Thus, it seems only practical to allow for a period in which to solicit such interest from competing OPOs before terminating the OPO that does not meet the performance standard. To do otherwise would place an OPO in the anomalous position of being terminated 15 days after notification of failure to meet the performance standards only to be reinstated within a month or two when we discover no alternative OPO is willing to assume the territory. Consequently, we have modified § 485.311 (now § 486.325) to provide that termination of OPOs will occur 90 days after the notification by the Secretary that the OPO does not meet the standards.

C. Provisions of this Final Rule With Comment Period

We have revised § 486.325(b) (formerly § 485.311(b)) to provide for a 90-day advance notification before a termination of an OPO's provider agreement becomes effective. Similarly, we have revised § 486.304(e)(3)(ii) (formerly § 485.303(e)(3)), relating to interim designation periods, to extend the length of such designations to 180 days to take into account the longer advance notification period to effectuate terminations.

X. Effective Dates

A. Background

In the September 1994 interim final rule, we noted that, although the regulations were effective 30 days after publication, we would apply the new qualification and performance standards for the first time with the recertification of OPOs that takes place in the spring of 1996 (for most OPOs, June 1, 1996). For purposes of the recertification, we would use data from calendar years 1994 and 1995.

B. Public Comments and Our Responses

Comment: Several commenters suggested that we delay the effective date of the regulations to provide for 2 full years of advance notice before we apply the standards.

Response: Although the actual regulations were not issued until 9 months into the 24-month performance period (1994 and 1995), we believe that OPOs have had adequate advance notice of the intent to improve performance through both the law and the notice of proposed rulemaking that was issued in June 1991. That is, since 1991, revisions in the statute relating to OPOs that were discussed in the interim final rule have expressed the intent of the Congress that OPOs be held to rigorous performance standards. Moreover, while the 1991 notice of proposed rulemaking did not specify detailed qualification and performance standards, it included a discussion of the exact standards we included in the September 1994 interim final rule.

We believe that OPOs have had adequate advance notice that performance would be monitored and should have taken appropriate steps to ensure that they are performing to the best of their ability. In addition, the interim final rule was issued only 9 months into the performance period. Thus, even if an OPO had not been planning for the rigorous performance standards, it still has approximately 63 percent of the performance period remaining to make up for any past performance problems.

Finally, we note that the primary performance criteria are based on national averages. All of the data that are used to set the actual performance standards numbers come from actual performance of OPOs. Since the content of the interim final rule was not released until publication, all of the OPOs are treated equally with regard to knowledge of the standards. Thus, it is reasonable to assume that no OPO is unfairly treated by reliance on standards that are based on the performance of its peers. We collected the 1994 performance data from the OPOs. National averages were calculated and distributed to the OPOs in 1995. Thus, each OPO had an indication of what the performance standards would be and if it needed to significantly alter its performance to achieve performance equivalent to its peers. In addition, the AOPO has published peer performance data for OPOs to review and monitor their own performances throughout the performance period.

We are anxious to implement meaningful performance standards for OPOs. We believe that implementation of these standards will promote organ availability and result in additional lifesaving transplants for not only Medicare and Medicaid beneficiaries, but for all Americans in need of organ transplants. The 1996 recertifications are for a 2 year period. Thus, if we delay implementation of the standards beyond

the 1996 recertification, the standards will not be fully effective until June 1998.

Nonetheless, we recognize that the move to a system of performance and qualification standards that are objectively measured and strictly enforced is a major transition for the OPO community. Consequently, we are providing for a transition mechanism for OPOs that do not meet the standards for the 1996 redesignation period but are making progress towards meeting them. Therefore, we are providing transitional standards for both the service area size designation qualification standard and the performance standards for the 1996 redesignation period.

We will grant an exception to the 24-donor service area size criterion during the 1996 redesignation process for those qualified OPOs that meet the performance standards in § 486.310. To qualify for the exception, an OPO must submit a written request to HCFA that includes a narrative description of its plans for meeting the standard by the 1998 redesignation period. We emphasize that this is a one-time exception opportunity that will not be repeated for any OPO after the 1996 redesignation process.

We are also providing a one-time exception process for OPOs that do not meet four of the five performance standards at the time of redesignation. This exception is limited to those qualified OPOs that meet three out of the five performance criteria in § 486.310(b) (1) through (5). Similar to the exception process for the qualification standard, an OPO must submit a written request to HCFA accompanied by a detailed, narrative description of the OPO's plans for ensuring that it will meet the performance standards by the 1998 redesignation.

C. Provisions of This Final Rule With Comment Period

We are not making any changes in the effective dates of the provisions of the interim final rule with comment period. We are, however, as explained above, adding two one-time exceptions for the 1996 redesignation process only.

- We are adding § 486.307(d)(4) stating that HCFA may grant an exception to the 24-donor criterion in paragraph § 486.307(d)(2)(ii) to an OPO that can demonstrate that (1) it meets the performance criteria in § 486.310(b), and (2) it has a specific plan to meet the service area size criterion in paragraph § 486.307(d)(2)(ii) by the 1998 redesignation period.
- We are adding § 486.310(c)(3) to provide that for the 1996 designation period only, HCFA may continue to designate for a service area an OPO that does not meet the standards under paragraph (b) of this section if the OPO (1) meets three of the five criteria in § 486.310(b)(1) through (b)(5); and (2) submits an acceptable corrective action plan in accordance with § 486.310(d).

XI. Waiver of Service Area Designations

A. Background

Section 1138(a)(1)(A)(iii) of the Act had required hospitals participating in the Medicare program to notify an OPO of potential organ donors. The use of the article ''an'' indicated that a hospital need not have an agreement with the OPO whose designated service area includes the county in which the hospital is located. Thus, a significant number of hospitals, for various reasons, have chosen to have agreements with a Medicare/Medicaid-certified OPO other than the OPO designated for their areas. In fact, several hospitals have agreements with multiple OPOs.

Sections 155 (a)(1)(A) and (a)(1)(B) of Public Law 103–432 amended sections 1138 (a)(1)(A)(iii) and (a)(1)(C) of the Act to add requirements that a hospital have an agreement for notification of potential organ donation only with the OPO designated for the area in which the hospital is located. Public Law 103–432 also provided for waiver of the requirements under certain circumstances. Section 155(a)(1)(C) added new section 1138(a)(2)(A) to the Act. Specifically, the Secretary must approve waiver requests if (1) the waiver is expected to increase organ donations and (2) the waiver will assure equitable treatment of both those patients within the service area served by the hospital's designated OPO and those patients within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver.

The law is quite specific in identifying the factors that HCFA may consider in adjudicating waiver requests. That is, section 1138(a)(2)(B) provides that in making a determination on a waiver request the Secretary may consider the factors that would include, but not be limited to (1) cost effectiveness; (2) improvements in quality; (3) any change in a hospital's designated organ procurement agency due to a change made on or after December 28, 1992, in the definitions for MSAs (as established by the Office of Management and Budget); and (4) the length and continuity of a hospital's relationship with an organ procurement agency.

Sections 1138 (a)(2)(C) and (a)(2)(D) of the Act are quite specific in detailing the process for the waiver requests. Effective January 1, 1996, any hospital seeking a waiver must submit an application to the Secretary. Within 30 days of receipt of a waiver request, the Secretary will publish a public notice of the request offering interested parties a 60-day period to comment on the request. Allowing HCFA only 30 days to evaluate the comments and render a decision would result in a minimum time period of 120 days for processing a waiver request.

Section 155(a)(2) of Public Law 103–432 contains a grandfathering provision for hospitals which on October 31, 1994, the date of enactment of Public Law 103–432, have existing agreements with OPOs other than the OPO designated for their service areas. Any hospital that has an agreement with an OPO other than the OPO designated for its area on October 31, 1994, may continue the agreement until HCFA has adjudicated its waiver request, provided the hospital has filed a waiver request by January 1, 1996. This provision was included because it would be disruptive to a hospital to force it into an agreement with the OPO designated for its area while a waiver request is being processed.

We believe the provisions of section 155 are self-implementing. Thus, we proceeded with implementation prior to modification of the regulations or prior public comment. In October 1995, we issued Program Memorandum A–95–11 to our intermediaries outlining the process for making a waiver request. We instructed each intermediary to notify every hospital that it serviced of the opportunity to request a waiver to deal with an OPO other than the OPO designated for the area. We advised the hospitals that we intended to adjudicate the requests using the criteria set forth in the law. We advised the hospitals that, to retain their existing out-of-area OPO agreements that were in effect as of October 31, 1994, their waiver requests must be received by January 1, 1996.

The law did not address the impact of changes in OPO service areas on future waiver requests. That is, we note that changes in OPO service areas are ongoing events. We anticipate that, with the implementation of the provisions contained in the September 8, 1994, final rule with comment period, such changes may become somewhat more frequent. Often these changes occur through mergers or cooperative means. Some changes, however, are the result of competitive actions among the OPOs with HCFA awarding the service areas

based on the criteria in § 485.308 (now § 486.316). When these changes in service areas occur, the hospitals in the affected counties must enter into agreements with the newly designated OPO or request a waiver to deal with an alternative designated OPO.

As noted above, the minimum period of time necessary to process a waiver request is 120 days. We believe it is unproductive and contrary to the goal of increasing national organ donation to force the hospitals in affected areas into new working relationships with a OPO and then to approve a waiver request and allow an alternative agreement a few months later. Such a system would be disruptive to the hospital and to effective organ procurement nationally.

Consequently, we are adding a new provision to the regulations at § 486.316 to permit the grandfathering of existing agreements between an OPO and a hospital when changes in a service area occur pending resolution of the hospital's waiver request.

To be eligible for the grandfathering, a hospital must have had an agreement with the OPO prior to the changes in service area and the hospital must have requested waiver from the provisions of section 1138 (a)(1)(A)(iii) and (c) of the Act within 30 days of the effective date of the change in service area. Of course, if HCFA denies the waiver request on its merits (the request does not demonstrate that it is expected to increase organ donation and assure equitable treatment of patients), the hospital must enter into an agreement with the new OPO for the area. The regulations provide that such new agreements must be executed within 30 days of notification of the determination on the waiver request.

We recognize that this grandfathering provision is not explicitly stated in the law. Nonetheless, we believe the provision is authorized under section 1138(a)(2)(A) of the Act which vests broad authority to HCFA to waive the new requirements of sections 1138(a)(1)(A)(iii) and 1138(a)(1)(C) of the Act. The provision is also complementary to the grandfathering provision specified in section 155 of the Social Security Act Amendments of 1994. We believe that allowing such a grandfathering policy during the processing of the waiver request is the only means to ensure a smooth transition and promote organ donation. Nonetheless, we are providing an opportunity for public comment in this final rule with comment period.

B. Provisions of This Final Rule With Comment Period

We have revised § 486.316 (formerly § 485.308) by adding new paragraphs (c) through (f) to implement section 1138 (a)(2) of the Act and the grandfathering provisions of section 155(a)(2) of Public Law 103–432. These revisions permit grandfathering of a hospital to the OPO with which it has an historical working relationship while the hospital's request for waiver is being considered when changes in the OPO designated for the service area in which the hospital is located occur beginning January 1, 1996. We are soliciting comments on this provision of the final rule with comment period.

XII. Technical Revisions

We have made the following technical revisions to the regulations for the purposes of clarifying and reorganizing the OPO regulations.

- We amended § 405.2163 by removing the reference to part 485, subpart D and replacing it with a reference to part 486, subpart G to reflect the earlier published redesignation of the OPO regulations.
- We revised § 486.301 to add section 1138(a) and (b) of the Act and section 371(b) of the PHS Act as the statutory bases of the OPO regulations.
- We reorganized § 486.310 to include the exceptions and exemptions to the OPO standard requirements under paragraph (c).
- We deleted § 486.310(e) (previously designated as § 485.306(e)) as it is unnecessary and has created confusion among the OPO industry. This provision provides that an OPO that has not previously been designated by HCFA for a particular service area is exempt from meeting the performance standards for its first 2 years of designation as the OPO for that area. However, the performance standards are used to measure the OPO's qualifications to be redesignated beginning 2 years after the OPO has been first designated for any portion of a service area.

Since there is no data on the OPO's performance in the area when it is newly designated, it would be impossible to apply the performance standards at the time of initial designation. Thus, we believe it is unnecessary to maintain an exemption of this nature. The remaining portion of the provision merely states that we will apply the normal performance standards at the time of redesignation. Therefore, this portion of the regulation is also unnecessary since, without it, we would have no alternative but to apply the normal performance standards.

- We revised the cross-reference in § 486.314 (formerly § 485.307) to reflect the reorganization of the material.

XIII. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the Federal Register and invite public comment before issuing a final document. Most of the provisions of this rule were open for public comment through both the June 21, 1991, proposed rule and the September 8, 1994, interim final rule. We are now publishing these provisions as final rules. Because they have previously been open for comment, we are not inviting further public comment on these provisions.

The Social Security Act Amendments of 1994 were enacted subsequent to the September 8, 1994, interim final rule with comment period. Section 155 of these amendments, relating to OPO hospital relationships, are inextricably linked to this final rule. The provisions of section 155 are self-implementing and do not require rulemaking.

XIV. Regulatory Impact Statement

We generally prepare a regulatory impact statement that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless we certify that a rule will not have a significant economic impact on a substantial number of small entities.

For purposes of the RFA, we consider all providers and suppliers of health care as small entities. Individuals and States are not included in the definition of a small entity. Also, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a MSA and has fewer than 50 beds.

This final rule with comment period sets forth changes required by Public Law 100–607, Public Law 101–616, and Public Law 103–432. In the September 1994 interim final rule with comment period, we provided an impact analysis on the provisions of Public Law 100–607 and Public Law 101–616. In that analysis, we stated that we expected that, while OPOs may incur some additional costs, those costs would be minimal. We invited public comment on the impact statement in the interim final rule with comment period. We did not receive any public comments.

The provisions of section 155 of Public Law 103–432 included in this final rule with comment period conform to section 1138(a)(2) of the Act to provide for a waiver of section

1138(a)(1)(A)(iii) and (c) of the Act under certain circumstances. Section 1138(a)(1) requires that a hospital have an agreement for potential organ donations only with the OPO designated for the area in which the hospital is located. We expect any additional costs related to this provision to be minimal. Any hospital wishing a waiver must file a request with us. We believe, however, that any additional costs are minimal compared to the improvement these provisions will have on the quality of health care for organ recipients.

We have determined and we certify that this final rule with comment period will not have a significant economic effect on a substantial number of providers and suppliers. Also, OPOs (independent and hospital-based) are not considered small rural hospitals since OPOs generally service large geographical areas. Therefore, a regulatory flexibility analysis under the RFA and a rural impact analysis under section 1102(b) of the Act are not required.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

XV. Information Collection Requirements

Under the Paperwork Reduction Act of 1995, agencies are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. This final rule with comment period contains information collections that are subject to review by OMB under the Paperwork Reduction Act of 1995. The title, description, and respondent description of the information collections are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and collecting and reviewing the collection of information.

We are, however, requesting an emergency review of these regulations. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirement for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR. Part 1320 to permit recertification of OPO's as required by statute. Failure to issue these rules in time for the 1996 redesignation process may result in the termination of OPO agreements. As a consequence, persons in need of organ transplants may not receive them. The agency cannot reasonably comply with the normal clearance procedures because public harm is likely to result if normal clearance procedures are followed. Without this information, we could not ensure compliance with this Congressional mandate.

We are requesting that OMB provide a 21-day public comment period with a 7-day OMB review period and a 90-day approval. We will publish a separate Federal Register notice for an emergency request for the OPO manual requirements.

Type of Information Collection Request: New Collection.

Type of Information Collection: Conditions of Coverage for Organ Procurement Organizations.

Form No.: HCFA–R–13.

USE: Organ Procurement Organizations are required to submit accurate data to HCFA concerning population and information on donors and organs on an annual basis in order to ensure maximum effectiveness in the procurement and distribution of organs.

Frequency: Annually.

Affected public: Not-for-profit institutions.

Number of Respondents: 66.

Total Annual Responses: 66.

Total Annual Hours Requested: 4,096.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786–1326.

The sections in these final regulations with comment period that contain information collection requirements are:

- Sections 486.304 (c)(2), (c)(4), (c)(7), and (c)(8) require that an OPO submit documentation to HCFA as part of the conditions for payment. These requirements include cost reporting, cost projection, and data to show the number of organs procured and transplanted. The OPO must maintain data in a format that can readily be continued by a successor OPO.
- Section 486.306(d) requires that an OPO document that it meets the service area requirements at § 486.307.
- Section 486.306(t) requires that an OPO submit to HCFA within 15 days following the end of the calendar year information on the service area population, number of donors, number of organs procured, and the number of organs transplanted.
- Section 486.307(a) requires that an OPO make documentation available to HCFA to verify that it meets the requirements for boundary designation, service area location, and service area size.
- Section 486.307(d) requires that, for the 1996 transitional redesignation period only, an OPO that does not meet the qualification standards in § 486.307(d)(2)(ii) may submit a request to HCFA for a one-time exception to the standard if it can demonstrate that it meets the performance criteria in § 486.310(b) and has a specific plan to meet the 24-donor standard by the 1998 redesignation period.
- Section 486.310(c)(3) requires that, for the 1996 transitional redesignation period only, HCFA may continue to designate for a service area an OPO that does not meet the standards of § 486.310(b) if the OPO can demonstrate that it meets three of the criteria in § 486.310(b)(1) through § 486.310(b)(5) and if the OPO submits an acceptable correction plan in accordance with § 486.310(d).
- Section 486.310(d) requires that an OPO that does not meet the performance standards may continue to be designated for a service area if no acceptably performing OPO is willing to accept responsibility for the service area and if the OPO submits a corrective action plan that is acceptable to HCFA.
- Section 486.316 requires that an OPO submit an application to HCFA if it wishes to be designated as the OPO for a service area. Applications are only accepted if the area is an open area.
- Section 486.318 requires that a designated OPO notify HCFA if it is considering a change in ownership or service area. It must submit the same information that it supplied at the time of designation.
- Section 486.325(a)(1) requires that an OPO that wishes to terminate its agreement with HCFA send written notice of its intention with the proposed termination date to HCFA.

The information collection requirements concern quantifiable data for submission to us that document an OPO's performance. The respondents for the information collection requirements are the 66 OPOs participating in the Medicare program. The OPOs are required to keep performance data on an ongoing basis and submit a yearly report. The reporting burden for the collection of all of this information is estimated to be 1,000 hours per submission.

Other reporting requirements for special circumstances such as termination of agreements and requests for exceptions and exemptions rely on the same information that an OPO must submit in its annual report. Consequently, no extra collection of

information is required. Since these submissions depend on special circumstances, we cannot give the exact number of submissions. However, since there are only 66 OPOs participating in the Medicare program, we expect the number of these submissions will be extremely small.

These information collection and recordkeeping requirements are not effective until they have been approved by OMB. The agency has submitted a copy of this final rule with comment period to OMB for its review of these information collections. A notice will be published in the Federal Register when approval is obtained. Interested persons are invited to send comments regarding this burden or any other aspect of these collections of information, including any of the following subjects: (1) The necessity and utility of the information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. Comments should be sent to HCFA, OFHR, MPAS, C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

XVI. Response to Comments

Because of the large number of items of correspondence we normally receive on a final rule with comment period, we are not able to acknowledge or respond to them individually. However, we will consider all comments that we receive related to the waiver process discussed in section XI of this preamble, § 486.316, and the definition of ''donor'' by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a final rule, we will respond to the comments in the preamble of that rule.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 486

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Chapter IV is amended as set forth below:

A. Part 405, subpart U is amended as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart U—Conditions of Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

1. The authority citation for part 405, subpart U continues to read as follows:

Authority: Secs. 1102, 1138, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b–8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

2. Section 405.2163(f) is amended by removing the reference to ''part 485, subpart D'' and replacing it with a reference to ''part 486, subpart G.''

B. Part 486 is amended as follows:

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY PROVIDERS AND SUPPLIERS

Subpart G—Conditions for Coverage: Organ Procurement Organizations

1. The authority citation for part 486 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Section 486.301 is revised to read as follows:

§ 486.301 Basis and scope.

(a) *Statutory Basis.* (1) Section 1138(b) of the Act sets forth the requirements that an organ procurement organization must meet to have its organ procurement services to hospitals covered under Medicare and Medicaid. These include certification as a ''qualified'' organ procurement organization (OPO) and designation as the OPO for a particular service area.

(2) Section 371(b) of the PHS Act sets forth the requirements for certification and the functions that a qualified OPO is expected to perform.

(b) *Scope.* This subpart sets forth—

(1) The conditions and requirements that an OPO must meet;

(2) The procedures for certification and designation of OPOs; and

(3) The terms of the agreement with HCFA, and the basis for, and the effect of, termination of the agreement.

3. In § 486.304, the introductory text of paragraph (b) is republished, new paragraph (b)(8) is added, and paragraph (e)(3)(ii) is revised to read as follows:

§ 486.304 General requirements.

* * * * *

(b) *Requirements for designated status.* To be the designated OPO for a service area, an entity must do the following:

* * * * *

(8) Enter into a working relationship with any hospitals, including transplant centers, in the OPO's service area that request a working relationship.

* * * * *

(e) *Designation periods*

* * * * *

(3) *Interim designation.* * * *

(ii) The interim designation period does not exceed 180 days after the normal designation period has expired.

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4. In § 486.306, the introductory text and paragraphs (d), (f) introductory text, (i), (q), and (s) are revised to read as follows:

§ 486.306 Qualifications for designation as an OPO.

To be designated as the OPO for a service area, an organization must, at the time of application and throughout the period of its designation, meet the following requirements:

* * * * *

(d) Document that it has a defined service area that meets the requirements of § 486.307.

* * * * *

(f) Have a board of directors or an advisory board that has the authority to recommend policies relating to the donation, procurement, and distribution of organs. While an OPO may have more than one board, the members specified in paragraphs (f)(1) through (f)(5) of this section must be members of a single board. The board of directors or advisory board must be composed of the following:

* * * * *

(i) Have a system to equitably allocate donated organs among transplant patients that is consistent with—

(1) ''Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs'' issued by the Centers for Disease Control and Prevention (CDC) that are appended to this subpart; and

(2) Rules of the Organ Procurement and Transplantation Network (OPTN), see § 486.308.

* * * * *

(q) Ensure that appropriate donor screening and infection tests, consistent with OPTN standards and the CDC guidelines that are appended to this subpart, are performed by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter, including tests to prevent the

acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome.

* * * * *

(s) Ensure that donors are tested for human immunodeficiency viral markers consistent with OPTN rules and the CDC guidelines appended to this subpart for solid organ donation.

* * * * *

5. A new § 486.307 is added to read as follows:

§ 486.307 OPO service area size designation and documentation requirements

(a) *General documentation requirement.* An OPO must make available to HCFA documentation verifying that the OPO meets the requirements of paragraphs (b) through (d) of this section at the time of application and throughout the period of its designation.

(b) *Boundary designation.* The defined service area either includes an entire Metropolitan Statistical Area or a New England County Metropolitan Area as specified by the Director of the Office of Management and Budget or does not include any part of such an area.

(c) *Service area location and characteristics.* An OPO must precisely define and document a proposed service area's location through the following information:

(1) The names of counties (or parishes in Louisiana) served or, if the service area includes an entire State, the name of the State.

(2) Geographic boundaries of the service area for which U.S. population statistics are available.

(3) Total population in service area.

(4) The number of and the names of acute care hospitals in the service area with an operating room and the equipment and personnel to retrieve organs.

(d) *Sufficient size requirements.* (1) Before January 1, 1996, an OPO must demonstrate that it can procure organs from at least 50 potential donors per calendar year or that its service area comprises an entire State.

(2) Beginning January 1, 1996, an OPO must meet at least one of the following requirements:

(i) Its service area must include an entire State or official U.S. territory.

(ii) It must either procure organs from an average of at least 24 donors per calendar year in the 2 years before the year of redesignation or request and be granted an exception to this requirement under paragraph (d)(3) or (d)(4) of this section.

(iii) In the case of an OPO operating exclusively in a noncontiguous U.S. State, a U.S. territory, or a U.S. commonwealth, such as Hawaii or Puerto Rico, it must procure organs at the rate of 50 percent of the national average of all OPOs for kidney procurement per million population and for kidney transplantation per million population.

(iv) If it is an entity that has not been previously designated as an OPO, it must demonstrate that it can procure organs from at least 50 potential donors per calendar year.

(3) HCFA may grant an OPO an exception to paragraph (d)(2)(ii) of this section if the OPO can demonstrate that—

(i) It failed to meet the requirement because of unusual circumstances beyond its control;

(ii) It has historically maintained a service area of sufficient size to meet the criterion in paragraph (d)(2)(ii) of this section; and

(iii) It has a specific plan to meet the size criterion in paragraph (d)(2)(ii) of this section in the future.

(4) During the 1996 redesignation process only, HCFA may grant an exception to paragraph (d)(2)(ii) of this section to an OPO that can demonstrate that—

(i) It meets the performance criteria in § 486.310(b); and

(ii) It has a specific plan to meet the service area size criterion in paragraph (d)(2)(ii) of this section by the 1998 redesignation period.

6. Section 486.310 is amended by removing the introductory text, adding a heading for paragraph (a); removing paragraphs (a)(3) and (e); and revising paragraphs (b), (c), and (d) to read as follows:

§ 486.310 Condition: Adherence to performance standards.

(a) *Standards before January 1, 1996.*

* * * * *

(b) *Standards beginning on January 1, 1996.* Except as specified in paragraph (c) of this section, each OPO must achieve at least 75 percent of the national mean for four of the following five performance categories, averaged over the 2 calendar years before the year of redesignation:

(1) Number of actual donors per million population.

(2) Number of kidneys recovered per million population.

(3) Number of extrarenal organs recovered per million population.

(4) Number of kidneys transplanted per million population.

(5) Number of extrarenal organs transplanted per million population.

(c) *Exceptions and exemptions.*

(1) *Exception based on location.* OPOs operating exclusively in a noncontiguous U.S. State, a U.S. territory, or a U.S. commonwealth, such as Hawaii or Puerto Rico, may be granted an exception from the performance standards of paragraph (b) of this section because of special geographically related characteristics, such as difficulty in transporting organs to the mainland, that impede satisfaction of the national rate of organ procurement. They must meet a standard of 50 percent of the national average of all OPOs for kidneys recovered and transplanted per million population.

(2) *Exception because of lack of competition for a service area.* HCFA may continue to designate an OPO that does not meet the standards under paragraph (b) of this section for a service area if no OPO that meets the performance and qualification requirements is willing to accept responsibility for the service area and if the designated OPO submits an acceptable corrective action plan in accordance with paragraph (d) of this section.

(3) *Exception for 1996 transition period.* During the 1996 designation period only, HCFA may continue to designate for a service area an OPO that does not meet the standards under paragraph (b) of this section if the OPO:

(i) Meets three of the criteria in paragraphs (b)(1) through (b)(5) of this section; and

(ii) Submits an acceptable corrective action plan in accordance with paragraph (d) of this section.

(d) *Corrective action plans and corrected information.*

(1) *Corrective action plans.* (i) If a designated OPO does not meet the standards of paragraph (a) of this section, it may submit to the appropriate HCFA regional office a corrective action plan explaining why it failed to meet them and specifying the actions it will take to ensure it meets those standards in the future.

(ii) HCFA will not accept corrective action plans from an OPO for failure to meet the standards specified in paragraph (b) of this section unless the OPO continues to be designated under paragraph (c)(2) or (c)(3) of this section.

(2) *Corrected information.* An OPO may request correction of the information required by § 486.306(e) from HCFA throughout the two-year designation period. HCFA will evaluate the OPO's request and may seek input from other sources, such as hospital personnel, neighboring OPOs, the OPTN contractor, and the Census Bureau as necessary to verify the OPO's information before making the changes requested by the OPO. In addition,

HCFA will notify an OPO if it does not meet the performance standards based on the information reported. Any OPO so notified may provide corrected information for consideration within 30 days of receipt of a notice of failure to meet the standards.

(e) [Removed]

§ 486.314 [Amended]

7. Section 486.314 is amended by removing the reference to ''§ 485.310 (a) and (b)'' and replacing it with a reference to ''§ 486.310''.

8. Section 486.316 is amended by adding new paragraphs (c), (d), (e), (f), and (g) to read as follows:

§ 486.316 Designation of one OPO for each service area.

* * * * *

(c) After January 1, 1996, a hospital must enter into an agreement only with the OPO designated to serve the area in which the hospital is located unless HCFA has granted the hospital a waiver under paragraphs (d) through (g) of this section to be serviced by another OPO.

(d) If HCFA changes the OPO designated for an area, hospitals located in that area must enter into agreements with the newly designated OPO or submit a request for a waiver in accordance with paragraph (e) of this section within 30 days of notice of the change in designation.

(e) A hospital may request and HCFA may grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. To qualify for a waiver, the hospital must submit data to HCFA establishing that—

(1) The waiver is expected to increase organ donations; and

(2) The waiver will ensure equitable treatment of patients referred for transplants within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement.

(f) In making a determination on waiver requests, HCFA considers:

(1) Cost effectiveness;

(2) Improvements in quality;

(3) Changes in a hospital's designated OPO due to changes in the metropolitan service area designations, if applicable; and

(4) The length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO.

(g) A hospital may continue to operate under its existing agreement with an out-of-area OPO while HCFA is processing the waiver request. If a waiver request is denied, a hospital must enter into an agreement with the designated OPO within 30 days of notification of the final determination.

§ 486.325 [Amended]

9. In § 486.325, in paragraph (b), ''15 days'' is removed and ''90 days'' is added in its place.

10. Appendix A is added to subpart G to read as follows:

Appendix A to Subpart G of Part 486—Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs

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Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs

Summary

Although previous recommendations for preventing transmission of human immunodeficiency virus (HIV) through transplantation of human tissue and organs have markedly reduced the risk for this type of transmission, a case of HIV transmission from a screened, antibody-negative donor to several recipients raised questions about the need for additional federal oversight of transplantation of organs and tissues. A working group formed by the Public Health Service (PHS) in 1991 to address these issues concluded that further recommendations should be made to reduce the already low risk of HIV transmission by transplantation of organs and tissues. In revising these recommendations, the PHS sought assistance from public and private health professionals and representatives of transplant, public health, and other organizations. The revised guidelines address issues such as donor screening, testing, and exclusionary criteria; quarantine of tissue from living donors; inactivation or elimination of infectious organisms in organs and tissues before transplantation; timely detection, reporting, and tracking of potentially infected tissues, organs, and recipients; and recall of stored tissues from donors found after donation to have been infected. Factors considered in the development of these guidelines include differences between the screening of living and cadaveric donors; time constraints due to organ/tissue viability that may preclude performing certain screening procedures; differences in the risk of HIV transmission from various organs and tissues; differences between systems for procuring and distributing organs and tissues; the effect of screening practices on the limited availability of organs and some tissues; and the benefit of the transplant to the recipient.

INTRODUCTION

Exclusion of prospective blood donors based on their acknowledged risk behaviors for human immunodeficiency virus (HIV) infection began in 1983 (*1*). In 1985, when tests for HIV antibody became available, screening prospective donors of blood, organs, and other tissues also began (*2,3*). Both measures have reduced markedly the transmission of HIV via these routes.

A 1991 investigation determined that several recipients had been infected with HIV by an organ/tissue donor who had tested negative for HIV antibody at the time of donation (*4*). This occurrence raised questions about the need for additional federal oversight of transplantation of organs and tissues. To address these questions, the Public Health Service (PHS) formed a working group comprising representatives from several federal agencies. The working group concluded that, although existing recommendations are largely sufficient, revisions should be made to reduce the already low risk of HIV transmission via transplantation of organs and tissues. Adequate federal

regulations, recommendations, and guidelines for blood and plasma are already established and are not addressed in this document.

Those developing guidelines for other organs and tissues should consider donor screening and testing; quarantine of tissue from living donors; inactivation or elimination of infectious organisms in organs and tissues before transplantation; timely detection, reporting, and tracking of potentially infected organs, tissues, and recipients; and recall of stored tissue from donors found after donation to have been infected.

These guidelines apply largely to donation and transplantation of organs and solid tissues. Although they also apply generally to donation of human milk and semen, some modifications may be needed because donors of human milk and semen are living and often donate repeatedly. Additionally, donor milk should be pasteurized (a heating procedure that inactivates HIV) before dispensing. This document can serve as a general guide to facilities that bank breast milk or semen and should be followed where feasible.

In revising these recommendations for transplantation of organs and tissues, PHS sought assistance from public and private health professionals and representatives of transplant, public health, and other organizations (see pages iii-v). These guidelines do not supersede existing state laws but are to be implemented in accordance with existing statutes.

BACKGROUND

Epidemiology of HIV Infection in Recipients of Organs and Tissues

Most transmission of HIV to organ/tissue recipients occurred before 1985, before the implementation of donor screening. In addition to HIV transmission through blood and blood products, reports of HIV infection following transplantation have implicated the kidney, liver, heart, pancreas, bone, and possibly skin as sources of infection (*4*). HIV has also been transmitted from infected semen during artificial insemination (*5*). Several studies and case reports indicate that HIV can be transmitted through breast milk from HIV-infected women to their children (*6,7*); these investigations include several prospective studies indicating that breast-fed infants are at greater risk of acquiring HIV from their infected mothers than are bottle-fed infants (*8,9*).

Reports of transmission from screened, HIV-antibody–negative donors of organs or tissues have been rare. In one instance, hemodilution from multiple transfusions given to the organ/tissue donor before collection of the blood sample resulted in an HIV-antibody test result that was initially false negative (*10*). Serum samples taken on admission, before the transfusions, and 2 days after the transfusions later tested positive for antibody to HIV. In another instance, a kidney donor tested HIV-antibody negative 8 months before donation but seroconverted between the time of testing and donation (*11*). The donor was not retested at the time of donation. In a third instance, an organ from an HIV-infected donor was transplanted under emergency conditions before results of the HIV-antibody test were known (*12*).

A fourth case involved transmission from an organ/tissue donor whose HIV-antibody test was negative at the time of donation (*4*). Most likely, the donation occurred sometime between infection and antibody seroconversion, which, for most

infected persons, ranges from 4 weeks to 6 months (*13*). Six years after the donor's death and ensuing donation, HIV infection in the stored donor material was confirmed by virus culture and polymerase chain reaction (PCR) of stored donor lymphocytes (*4*). Among the 41 recipients identified and tested, those who received the solid organs and unprocessed, fresh-frozen bone acquired HIV infection from the allografts (one recipient of a heart, two recipients of kidneys, one recipient of a liver, and three recipients of fresh-frozen bone). The recipients of other processed bone and relatively avascular soft tissue (fascia lata, tendons, ligaments, dura mater, and corneas) did not become HIV infected (*4*).

Current Use of Organ and Tissue Transplants

The number of transplants has grown considerably over the last several years, a phenomenon attributable to many factors, including the availability of improved immunosuppressant drugs. Approximately 66 Organ Procurement Organizations (OPOs) and 260 organ transplant centers are members of the Organ Procurement and Transplantation Network (OPTN). In 1990 these centers recovered approximately 15,000 organs (e.g., kidney, liver, heart, lung, and pancreas) from 4,500 donors.

OPOs and tissue banks also recovered tissues (other than the organs listed above) from an estimated 7,500–10,000 donors in 1990. These tissues were used in approximately 250,000–300,000 (mostly bone) allografts.

In 1990, member banks of the Eye Bank Association of America (EBAA) retrieved ocular tissue from more than 40,000 donors. These tissues are used for corneal transplantation and are also processed into epikeratophakia lenticules (EBAA Statistical Report, 1990).

More than 400 establishments either bank or commercially process one or more human tissues. Approximately 100 eye banks and 125 bone banks operate in the United States (although the number of hospitals that store bone for future transplantation is difficult to estimate). Also, several hospitals may retrieve and store bone from living donors. Seven human milk banks operating in the United States process donor breast milk.

The American Fertility Society is aware of approximately 100 semen banks in the United States. Slightly fewer than half of artificial inseminations performed in the United States involve unrelated-donor semen used to inseminate approximately 75,000 women per year. In addition to these 100 semen banks, an undetermined number of smaller banks are hospital based or located in the offices of individual physicians.

The National Heart, Lung, and Blood Institute (NHLBI) within the National Institutes of Health (NIH) is aware of 99 bone marrow transplant centers, of which 41 participate in programs involving bone marrow transplants from unrelated donors. Many additional facilities are equipped to obtain marrow from donors. About 2,200 bone marrow transplants involving allogeneic marrow took place in the United States in 1991. Of those, approximately 435 were provided by donors who were not related to the recipients. Peripheral blood stem cells are being used for autologous transplantation and, in the future, may be useful for allogeneic use. Furthermore, cord blood stem cells are being used for both related- and unrelated-donor allogeneic transplantation.

Current Guidelines and Recommendations

Procedures for procurement and transplantation of organs and tissues are addressed by a) federal laws, regulations, and guidelines; b) state laws and regulations; and c) voluntary industry standards. Several federal agencies either directly or indirectly regulate procurement and transplantation of organs and tissues. These activities range from the publication of guidelines that address the transmission of communicable diseases through transplantation to regulatory requirements for registration and premarket product licensure or approval (blood and certain other tissue products).

The Health Resources and Services Administration (HRSA), through the United Network for Organ Sharing (UNOS), administers the contract for OPTN as required by Section 372 of the Public Health Service Act and as amended [42 USC 274]. The contract covers specified solid organs (kidney, liver, heart, lung, and pancreas) but does not cover corneas, eyes, or other tissues. Technically, all UNOS policies are voluntary; however, HRSA is currently developing regulations dealing with OPTN membership and operation.

Under a separate contract with HRSA, UNOS maintains a Scientific Registry for Transplant Recipients that includes information on all solid-organ transplant recipients (since October 1, 1987) from the date of transplantation until failure of the graft or death of the patient. In addition, HRSA informally conveys recommendations to organizations involved in procurement and transplantation of organs. Through OPTN and the Scientific Registry for Transplant Recipients, HRSA has the capacity to link organ donors and their recipients.

FDA regulates a limited number of specific tissues as either "biological products" or "medical devices." Examples of tissues include blood, dura mater, corneal lenticules, umbilical veins, nonautologous cultured skin, and heart valves. In addition, FDA has recently published regulations regarding behavioral screening and infectious-disease testing (HIV-1, HIV-2, hepatitis B virus, and hepatitis C virus) for donors of human tissue for transplantation (*14*). FDA also regulates certain agents and devices for processing bone marrow, although bone marrow transplants from unrelated donors are under the auspices of NHLBI.

NHLBI manages the federal contract for the National Marrow Donor Program. Two bone marrow donor registries currently exist: one independent registry and one registry managed through the NHLBI contractor. Each registry group has voluntary guidelines/standards that resemble blood-banking standards. Although federal regulations have not yet been promulgated, the current practice of bone marrow acquisition and transplantation includes procedures to reduce the risk of HIV transmission. NHLBI is preparing regulations that will set forth criteria, standards, and procedures for entities involved in bone marrow collection, processing, and transplantation. These entities include the National Marrow Donor Registry, individual donor centers, donor registries, marrow-collection centers, and marrow-transplant centers. The regulations will include donor-selection criteria to prevent the transmission of infectious diseases, including HIV infection.

Donor Screening

PHS has made recommendations for preventing HIV transmission through organ/tissue transplantation and artificial insemination (*1–3,15,16*). These

recommendations include screening for behaviors that are associated with acquisition of HIV infection, a physical examination for signs and symptoms related to HIV infection, and laboratory screening for antibody to HIV.

PHS has made no specific recommendations for donation and banking of human milk, although HIV-infected women in the United States are advised to avoid breast feeding their infants because of the risk of HIV transmission through breast milk (*17*). The Human Milk Banking Association of North America has issued guidelines for the establishment and operation of human milk banks (*18*). These guidelines state that all human milk donors should be screened according to the American Association of Blood Banks' standards for screening blood donors. All milk accepted for donation should be pasteurized unless the recipient's condition requires fresh-frozen milk, in which case the milk bank director should consult with the medical director and advisory board to approve the dispensing of microbiologically screened, fresh-frozen milk from suitable donors.

Since March 1985, the FDA has licensed a number of screening and supplemental tests for detection and confirmation of HIV antibody. All these tests are intended for use on either fresh or freezer-stored samples of serum or plasma. The FDA has not required manufacturers to submit data showing that HIV-1 antigen and antibody-detection kits produce accurate results when applied to postmortem blood samples. Postmortem blood samples are often hemolyzed, which may affect the specificity of screening assays for HIV antibody (*19,20*).

The screening tests include enzyme immunoassays (EIAs), several of which are also approved for testing blood spots dried onto a specific filter paper, which may provide a method for storing samples. Rapid screening assays for HIV antibody that use a latex-agglutination or EIA (microparticle-based) format have also been approved for screening serum, plasma, or whole blood. A licensed EIA for detecting antibodies to HIV-2 is also commercially available, as are "combination tests" that simultaneously detect antibodies to HIV-1 and HIV-2 (*21*). FDA has also licensed one manufacturer to make and distribute a test for detection of HIV-1 p24 antigen for patient diagnosis and prognosis of HIV infection but not for screening blood donors.

Western blot tests and an immunofluorescence assay for HIV-1 are approved for supplemental, more specific testing of serum, plasma, and whole-blood samples found reactive by HIV-1 antibody screening tests. No additional, more specific test is approved that confirms either antibodies to HIV-2 (*21*) or eluted, dried blood-spot results. The licensed p24-antigen test includes a neutralization procedure that is to be used for specific testing of samples with repeatedly reactive test results.

Federal regulations already require that all donations of blood, blood components, and plasma intended for further processing into injectable products ("source plasma") be screened with a licensed test that detects HIV antibody. Since June 1992, PHS has also required that all blood and plasma donations be screened for HIV-2 antibody.

PHS has not recommended the use of the licensed HIV-1 p24-antigen assay for screening donated blood or source plasma, nor has the kit been approved for use in donor screening. This position is based on findings from several studies indicating that a blood donor with a positive test for antigen and a negative test for antibody is rare (*22,23*). Such rarity is probably attributable to the effectiveness of the donor-qualification procedures, including donor education, voluntary exclusion, and

antibody testing that together operate to prevent donation by persons at increased risk for HIV infection.

Limited studies have been conducted to examine the use of the p24-antigen assay to screen organ/tissue donors (*19,20,24*). Among approximately 1,000 samples from HIV-1 antibody-negative donors, no donors had detectable HIV-1 p24 antigen.

Recipient Screening

Until recently, PHS had made no recommendations regarding routine testing of recipients of organs, tissues, semen, or donated human milk. However, in response to the July 18, 1991, report of the PHS Workgroup on Organ and Tissue Transplantation, HRSA asked UNOS to request that transplant centers implement an interim voluntary HIV-testing policy for organ recipients. HRSA has requested that recipients be tested for HIV-1 antibody immediately before transplantation and at 3, 6, and 12 months after transplantation. If HIV infection is diagnosed in an organ recipient, the results of the HIV test are reported by the transplant center to the Scientific Registry for Transplant Recipients and to the procuring OPO, in accordance with existing state laws. No comparable registry exists for recipients of tissues, semen, or donated human milk. However, the National Marrow Donor Program routinely tracks both donors and recipients of bone marrow for unrelated-donor transplants. This program reports no known seroconversions among either donors or recipients, although recipients are not routinely screened for HIV.

Routine testing of recipients after transplantation has several potential benefits. First, early identification of HIV infection in a recipient allows for early intervention before signs and symptoms develop. Both antiviral therapy to prevent progression to acquired immunodeficiency syndrome (AIDS) (*25*) and prophylactic therapy to prevent opportunistic infections (*26,27*) have been recommended for HIV-infected patients, based on CD4+ T-lymphocyte levels. Second, early identification of HIV infection in a transplant recipient allows for early intervention to prevent further transmission from the recipient to sex or needle-sharing partners and to future offspring (through vertical transmission from mother to infant). Third, early identification of HIV infection in a recipient potentially identifies an infectious donor. Should further investigation indicate that the donor is the source of the HIV infection in the recipient, other recipients of tissue from that same donor can be notified and stored tissue can be retrieved, preventing further transmission through transplantation.

Concern has been expressed that linking HIV infection in a transplant recipient to the transplantation may be difficult because many recipients may have also received blood or blood products or have other risk factors. However, identification of multiple HIV-infected recipients of tissue from the same donor strongly implicates the donor as the source of the HIV infection in the recipients. In addition, stored blood or lymphoid samples from the donor (when available) can be tested for the presence of virus to confirm the HIV-infection status of the donor (*4*).

Questions have been raised about whether transplant recipients who may be receiving immunosuppressive therapy to prevent rejection are capable of producing antibody against HIV if transmission occurs. Several reports now indicate that the HIV-antibody response is not delayed in transplant recipients receiving antirejection therapy, which primarily affects cellular immunity (*4*).

The additional costs of routine screening for HIV in recipients must be considered as well. The Institute of Medicine has estimated that laboratory costs are approximately $4 for a patient who tests negative and $35 for a patient who tests positive. (The latter cost includes the added expense of repeat EIAs and Western blot or other supplemental tests.) These costs may be underestimates, however. The time required for pretest and posttest counseling was estimated to be approximately 0.5–1.0 hour for an HIV-seronegative patient and 1.5–2.0 hours for an HIV-seropositive patient (*28*).

Inactivation of HIV in Tissues

Thorough donor screening is considered the most effective method for preventing HIV transmission through transplantation; however, the use of chemical or physical inactivating or sterilizing agents to reduce further the already low risk of transmission has been considered. If such agents are to be useful, they must either inactivate or eliminate the virus while maintaining the functional integrity of the tissue or organ.

No mechanism for inactivating virus in whole organs currently exists. However, several agents have been suggested as possible disinfectants for tissues such as bone fragments (*4*). Pasteurization has been shown to inactivate HIV in human milk without substantially compromising nutritional and immunologic characteristics (*29*).

Although some physical and chemical agents have been shown to reduce the likelihood of isolating virus from treated solid tissues, conclusive evidence that those processes render solid tissue completely safe yet structurally intact is lacking. In the recent case of an HIV-infected donor who was antibody negative (*4*), tissues that had been processed in a variety of ways did not transmit HIV. These tissues included a) lyophilized fascia lata, tendons, or ligaments; b) dura mater that was lyophilized and irradiated with 3.0–3.4 Mrad of gamma radiation through a cobalt-60 source; c) bone fragments that were treated with ethanol and lyophilized; and d) one sample of fresh-frozen long bone with the marrow elements evacuated (*4*). However, because most of these tissues were relatively avascular, it is unclear whether the absence of HIV transmission was due to processing, avascularity, or both.

General Considerations

In developing guidelines for preventing HIV transmission from organ/tissue donors to recipients, several factors were considered: a) differences between the screening of living, brain-dead, and cadaveric donors; b) time constraints due to organ/tissue viability that may preclude performing certain screening procedures; c) differences in the risk for HIV transmission from various organs and tissues; d) differences between systems in place for procuring and distributing organs and tissues; e) the effect of screening practices on the limited availability of organs and some tissues; and f) the benefit of the transplant to the recipient (i.e., some transplants are lifesaving, whereas others are life enhancing).

Living donors can be interviewed about potential high-risk behavior, whereas deceased donors cannot. In the case of brain-dead or cadaveric donors, family members and others may be unable to provide an accurate risk history. Therefore, exclusion of potentially infected brain-dead or cadaveric donors relies even more heavily on laboratory screening and physical examinations than on interviews regarding high-risk behavior.

Screening procedures that require more than 24 hours to complete may not be feasible for brain-dead or cadaveric donors of organs and certain tissues. Most tissues must be recovered and most organs must be recovered and transplanted shortly after cessation of circulatory function of the donor. Whereas some tissues can be stored for months, others must be transplanted within a few days after procurement. These time constraints may limit the ability to interview certain family members or significant life partners who are not nearby and may preclude the use of certain laboratory screening tests that cannot be performed within these time constraints.

The precise risk of HIV transmission from various tissues is not known, yet some organs and tissues clearly present a higher risk for HIV transmission than others (*4*). For example, studies indicate that the risk for transmission from an organ of an HIV-infected donor is nearly 100%. Fresh-frozen, unprocessed bone also appears to carry a high risk for transmission, particularly if marrow elements and adherent tissue are not removed. Relatively avascular solid tissue, some of which is also processed by using techniques that might inactivate HIV, appears to carry a lower risk for HIV transmission.

As noted earlier in these guidelines, there is considerable variability in the role of federal agencies regarding transplantation of organs and tissues and the procurement and distribution systems. Oversight for, existence of, and compliance with recommendations also vary between these systems. When organs and tissues are procured from a single donor, tracking systems must involve multiple distribution systems that may be difficult to link.

Donor-screening practices must also consider the already inadequate supply of most organs and tissues needed for transplantation. However, even though attempts should be made to ensure the highest level of safety, donor-screening practices should not unnecessarily exclude acceptable potential donors.

Those involved in developing guidelines should consider that some transplants are lifesaving (e.g., a heart transplant), whereas others are life enhancing. Some physicians may be willing to offer the patient a transplant of a lifesaving organ from a donor whose HIV risk status is questionable but would not use life-enhancing tissue from such a donor.

RECOMMENDATIONS

Donor Screening

1. All prospective living donors or next of kin or significant life partners accompanying brain-dead or cadaveric donors should be informed of the general nature of the donor-evaluation process, including a review of medical and behavioral history, physical examination, and blood tests to exclude infectious agents that might be transmitted by organ or tissue transplant.

2. Prospective living donors or next of kin or significant life partners accompanying brain-dead or cadaveric donors should be informed about modes of transmission and risk factors for HIV infection, emphasizing that HIV can be transmitted via transplanted organs and tissues. They should be told that a negative test for HIV antibody does not guarantee that the donor is free of HIV infection because of the

rare situation of donation after infection but before seroconversion. Therefore, organs and tissue must not be transplanted from persons who may have engaged in activities that placed them at increased risk for HIV infection. This information should be presented in simple language to ensure that the donor, next of kin, or significant life partner understands what is considered high-risk behavior and the importance of excluding persons who have engaged in this behavior. Persons soliciting the donation should not place undue pressure to donate on potential living donors and those persons providing permission for potential brain-dead or cadaveric donors who might otherwise decline to donate or give permission because of high-risk behavior.

3. To ascertain risk factors, all prospective living donors should be interviewed in a confidential and sensitive manner by a health-care professional competent to elicit information about behaviors that place persons at risk for HIV infection. Interviewers should ask direct questions about high-risk behavior.

4. For potential pediatric donors for whom maternal transmission of HIV is a consideration, the mother and, if possible, the father should be interviewed about behaviors that may have placed them at risk for acquiring HIV infection that could have been transmitted to their child.

5. Except where retrieval occurs by legal authorization, the next of kin or significant life partner of brain-dead or cadaveric donors should be interviewed in a confidential and sensitive manner by a health-care professional regarding potential HIV risk factors in the donor. Other family members, friends, and sex partners may also need to be interviewed, if available. When consent for removal of organs/tissue is required, at least the person signing the consent form should be interviewed. Other possible sources of information about behavioral risk factors may include hospital, police, and coroner's records, if available. When an interview is not performed, as allowed by legal authorization, the transplant surgeon should be fully informed that the donation was accepted, even though a direct interview with the next of kin or significant life partner was not performed.

6. If available, the medical records, including autopsy reports of all donors, should be reviewed for signs and symptoms associated with HIV infection and for evidence of high-risk behavior (e.g., male-to-male sexual contact, acquisition of sexually transmitted diseases, exchange of sex for money or drugs, injecting-drug use, or birth to a mother either at risk for or infected with HIV).

7. All prospective donors of organs, solid tissue, and semen should undergo a physical examination as close as possible before donation, with special attention to physical signs of HIV disease and injecting-drug use. The extent of the physical examination should be determined by the responsible medical officials according to the context of organ/tissue donation. Human milk banks should obtain a release from the primary health-care provider certifying that the prospective donor is in good health and does not constitute a risk to potential recipients.

8. As with donors of blood and plasma, prospective living organ, tissue, semen, and milk donors found after careful screening to be acceptable donors should sign

a consent statement indicating that they have reviewed and understand the information provided regarding the spread of HIV and have agreed not to donate should they be at potential risk for spreading HIV. The statement should also indicate that prospective donors understand that they must be tested for HIV as part of the donor-screening process and will be notified of positive results as specified by any existing state statutes, regulations, or guidelines. For acceptable brain-dead or cadaveric donors, procurement personnel should document that a careful attempt has been made to eliminate persons at high risk through available information, including interview of family members or significant life partners, physical examination, review of medical records, autopsy findings, and any other records that might provide information about high-risk behavior or possible HIV infection. For either type of donor, the statement should be included as part of a general checklist or donor evaluation form covering all important aspects of the donor evaluation and should be included in the transplant records or record of the procuring agency. All records generated by the interview should be kept confidential.

Donor Testing

1. For all prospective donors, a blood sample obtained before any transfusions were administered (during the current hospital admission for inpatients) should be collected as close to the time of retrieval of tissue as possible. Bone marrow donors must provide blood samples far enough in advance of marrow harvest to permit the tests to be performed and results reported before the recipient's preparative regimen (marrow ablatement) is begun. Samples should be tested for antibodies to both HIV-1 and HIV-2 by using FDA-licensed tests. Separate tests or a combination test for HIV-1 and HIV-2 may be used. All antibody-screening tests should be performed by EIA unless the condition of the recipient or donor dictates the use of a more rapid screening assay.

2. Transfusions and infusion of other fluids to the prospective donor might produce false-negative results because of hemodilution. Efforts should be made to perform HIV-antibody testing on the most recent pretransfusion/infusion specimen for which identity and quality can be ensured. Specimens should not be drawn immediately downstream from an intravenous site to prevent dilution with intravenous fluids.

   Posttransfusion/infusion specimens may be considered for testing after efforts to obtain a pretransfusion/infusion sample have been exhausted and posttransfusion/infusion samples have been assessed for evidence of dilution. The suitability of posttransfusion/infusion samples must consider a) the volume of the material transfused as a percentage of the patient's total blood volume and b) the amount of time between the last transfusion/infusion and the collection of the sample to be tested. An exchange of one total blood volume will reduce the concentration of an intravascular substance such as IgG to 35% of initial levels if there is no replacement from the extravascular space. More than 50% of total body IgG is extravascular, and reequilibration to normal levels of IgG should be nearly complete within 24 hours of a total blood volume exchange of albumin (*30*).

3. The HIV p24-antigen assay may identify a few of the rare donors who are HIV-infected, yet antibody-negative; however, studies examining the utility of this assay for screening organ/tissue donors are limited and currently do not allow a definitive recommendation on the use of this test (*19,24*). The utility of other assays such as PCR, which are currently experimental, should be considered for evaluation as they become available for clinical use. Those institutions choosing to use the HIV-1 p24-antigen assay should be aware that in populations with low prevalence (e.g., organ/tissue donors), a large percentage of persons who test repeatedly reactive (without confirmation with the neutralization assay) will be false positive. Consideration should also be given to the potential problems with decreased specificity when the assay is used to test postmortem samples (*19*).

4. The testing algorithm for HIV-antibody assays should be performed as described in the package insert with an initial test and, if reactive, a retest on the same specimen. However, the time constraints of some situations may not accommodate the delay of repeat testing by EIA as described in the package insert. In such extreme cases of lifesaving organ transplantation, the sample should be set up in triplicate in the initial EIA. A repeatedly reactive result (positive screening test) is defined as reactivity above the test cutoff in two or more of the three assays. When testing by EIA is impractical, a more rapid licensed test should be performed in triplicate. Testing by the conventional algorithm should be performed as early as possible, even if it follows the procurement and/or transplant of the organs or tissues.

5. Results of HIV testing for organ/tissue donors should be handled confidentially, in accordance with general medical practices and applicable federal and state statutes, regulations, and guidelines.

6. Prospective living donors should be notified if they are found through the screening process to be HIV infected. Because of the possibility of sexual or parenteral transmission, the spouse or known sex partners of brain-dead or cadaveric donors should be notified in accordance with state law. All notifications should be handled in a manner congruent with current recommendations regarding counseling, testing, and partner notification (*31,32*). Before the notification of these persons, transplant and procurement organizations should consult with their state health department concerning local notification policies.

   Also before notification, the repeatedly reactive screening assay should be confirmed with more specific supplemental tests. An aliquot of the original sample should be analyzed by using the following, more specific tests. For repeatedly reactive HIV-1 antibody EIAs, an HIV-1 Western blot or immunofluorescence assay should be performed. For repeatedly reactive HIV-1 antigen assays (if performed), a neutralization procedure must be performed. For HIV-2, no licensed supplemental test is available; however, consideration may be given to the use of research assays such as Western blot, immunofluorescence, radioimmune precipitation, and synthetic peptide-based EIA. Arrangements for HIV-2 supplemental testing may need to be made with either the state or local health department. For repeatedly reactive combination HIV-1 and HIV-2 assays, the published testing algorithm should be followed (*21*). When the results of any supplemental tests are unclear, the use of research assays should be considered.

Notification of HIV-infected prospective living donors or spouses/known sex partners of cadaveric donors should be done in accordance with state law and in a confidential and sensitive manner by staff competent in counseling and discussing positive HIV results and their implications. If such staff are not available in the organ/tissue procurement organization, arrangements should be made with other organizations such as health departments or clinics to provide appropriate notification.

7. When it is possible to properly obtain and store samples, one or more of the following samples from the donor should be saved for at least 5 years after the expiration date of the tissue: dried blood spots, a frozen buffy coat, spleen cells, lymph node cells, bone marrow, and an aliquot of serum. These samples can be examined if subsequent information indicates that the donor may have donated during the period after infection but before antibody seroconversion.

8. Confirmed positive HIV test results in a prospective organ/tissue donor should be reported to state health agencies if required by state law or regulation.

Donor Exclusion Criteria

Regardless of their HIV antibody test results, persons who meet any of the criteria listed below should be excluded from donation of organs or tissues unless the risk to the recipient of not performing the transplant is deemed to be greater than the risk of HIV transmission and disease (e.g., emergent, life-threatening illness requiring transplantation when no other organs/tissues are available and no other lifesaving therapies exist). In such a case, informed consent regarding the possibility of HIV transmission should be obtained from the recipient.

Behavior/History Exclusionary Criteria

1. Men who have had sex with another man in the preceding 5 years.

2. Persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 5 years.

3. Persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrates

4. Men and women who have engaged in sex in exchange for money or drugs in the preceding 5 years.

5. Persons who have had sex in the preceding 12 months with any person described in items 1–4 above or with a person known or suspected to have HIV infection.

6. Persons who have been exposed in the preceding 12 months to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane.

7. Inmates of correctional systems. (This exclusion is to address issues such as difficulties with informed consent and increased prevalence of HIV in this population.)

Specific Exclusionary Criteria for Pediatric Donors

1. Children meeting any of the exclusionary criteria listed above for adults should not be accepted as donors.

2. Children born to mothers with HIV infection or mothers who meet the behavioral or laboratory exclusionary criteria for adult donors (regardless of their HIV status) should not be accepted as donors unless HIV infection can be definitely excluded in the child as follows:

   Children >18 months of age who are born to mothers with or at risk for HIV infection, who have not been breast fed within the last 12 months, and whose HIV antibody tests, physical examination, and review of medical records do not indicate evidence of HIV infection can be accepted as donors.

3. Children ≤18 months of age who are born to mothers with or at risk for HIV infection or who have been breast fed within the past 12 months should not be accepted as donors regardless of their HIV test results.

Laboratory and Other Medical Exclusionary Criteria

1. Persons who cannot be tested for HIV infection because of refusal, inadequate blood samples (e.g., hemodilution that could result in false-negative tests), or any other reasons.

2. Persons with a repeatedly reactive screening assay for HIV-1 or HIV-2 antibody regardless of the results of supplemental assays.

3. Persons whose history, physical examination, medical records, or autopsy reports reveal other evidence of HIV infection or high-risk behavior, such as a diagnosis of AIDS, unexplained weight loss, night sweats, blue or purple spots on the skin or mucous membranes typical of Kaposi's sarcoma, unexplained lymphadenopathy lasting >1 month, unexplained temperature >100.5 F (38.6 C) for >10 days, unexplained persistent cough and shortness of breath, opportunistic infections, unexplained persistent diarrhea, male-to-male sexual contact, sexually transmitted diseases, or needle tracks or other signs of parenteral drug abuse.

Inactivation of HIV in Organs/Tissues

Definitive recommendations cannot yet be made regarding inactivation of HIV in organs and tissues because of lack of information about potentially effective inactivation measures. Research should continue in this area. Efforts to evaluate the effect of certain processing techniques on tissue sterility and quality should be expanded to include virologic studies for HIV. Thus, until more is known, it is prudent to process bone and bone fragments and carefully evacuate all marrow components from whole bone whenever feasible.

Quarantine

For semen donations and, when possible, for tissue donations from living donors, the collection should be placed in frozen quarantine and the donor retested for

antibodies to HIV-1 and HIV-2 after 6 months (*15*). The quarantined material should be released only if the follow-up test results have been obtained and are negative.

Record Keeping for Tracking of Recipients and Tissues

1. Each establishment involved in the acquisition, processing, distribution, or storage of organs or tissues should have a graft identification system that allows the tracking of organs and tissues from the donor source to the recipient institution and vice versa. Furthermore, each establishment involved in the acquisition of organs or tissues from a single donor should have mechanisms in place to facilitate the communication between establishments for the purposes of tracking organs and tissues to recipients who should be notified if HIV transmission from donor source material is confirmed. Procurement, processing, distribution, and storage centers should keep accurate records of the distribution of each organ/tissue according to the donor identification number, tissue type and identifying number, and identifying information for the receiving center, along with dates of procurement and distribution. Records should be kept a minimum of 10 years after expiration of tissue.

2. The transplantation center, hospital, physician, or dentist should keep accurate records of all organs/tissues received and the disposition of each. These records must be separate from patients' medical records (e.g., in a log book) so that this information is easily obtainable should tracking be necessary. Recorded information should include the organ/tissue type; donor identification number; name of procurement or distribution center supplying the organ/tissue; recipient-identifying information; name of recipient's physician or dentist; and dates of a) receipt by the center and b) either transplantation to the recipient or further distribution.

3. The donor identification number and organ or tissue type should be recorded in the recipient's transplant/medical/dental record.

Testing and Reporting of Recipients

1. Health-care providers for transplant recipients and the recipients themselves should be aware of the small but potential risk of infections, including HIV, from transplanted organs and tissues. The recipient's informed consent to the transplant should include acknowledgment of the risks, including transmission of HIV and other infections.

2. Until the risk for HIV transmission from screened donors has been clarified, recipients of solid organs should be routinely advised to be tested for HIV immediately before transplantation and at 3 months following the transplant. Testing of recipients should be done with consent of the recipient and should not be mandatory. Recipients of tissues other than solid organs do not require routine testing for HIV following receipt of the tissue from appropriately screened donors. Results of HIV testing of organ recipients should be collected and analyzed by the Scientific Registry for Transplant Recipients. (If data indicate no benefit from recipient testing, then this recommendation for recipient testing may be omitted in a revision of these guidelines.)

3. If a transplant recipient is found to be infected with HIV, the transplant center or health-care provider should, consistent with state law, immediately notify the state health department and the organization from which the tissue was obtained. HIV infection in a solid-organ recipient should also be reported to the Scientific Registry for Transplant Recipients.

Recall of Stored Tissue and Tracking of Recipients of Organs/Tissue from HIV-Infected Donors

1. Upon being notified that an organ/tissue recipient is infected with HIV, the organ/tissue collection center, in collaboration with the state or local health department and with assistance from CDC, is responsible for determining as soon as possible whether the donor was HIV-infected. This is done by determining the HIV-infection status of other recipients of organs/tissues (particularly those recipients of organs and fresh-frozen bone) and by laboratory testing of stored donor material. Experimental diagnostic laboratory assays such as PCR may be useful in these situations and should be used when they become available.

2. If evidence suggests HIV infection in the donor either from testing of stored donor specimens or by finding HIV infection in other recipients, all other recipients of that donor's tissue or organs should be notified through their transplanting physician and informed of the likelihood of HIV exposure and advised to undergo HIV testing.

3. HIV-infected recipients should be counseled about their need for medical evaluation and about prevention of HIV transmission to others. They should also be advised to inform their sex or needle-sharing partners of their potential risk and need for HIV counseling and testing. HIV-infected women should be informed of the risk of transmission of HIV to their children born after the transplant and be advised to have these children evaluated and to avoid breast-feeding. Pregnant women should receive pregnancy counseling about HIV.

4. All stored organs/tissues from a donor found to be HIV-infected should be retrieved and quarantined immediately and either used only for research purposes or destroyed, except when the transplantation of an indispensable organ/tissue is necessary to save the patient's life.

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Dated: April 15, 1996.

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Administrator, Health Care Financing Administration.

Dated: April 25, 1996.

Donna E. Shalala,

Secretary.

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