part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended. EPA and the Florida Department of Environmental Protection (FDEP) have determined that the Site poses no significant threat to public health or the environment and therefore, further response measures pursuant to CERCLA are not appropriate.

DATES: Effective June 22, 1998.

ADDRESSES: Comprehensive information on this Site is available through the EPA Region 4 public docket, which is available for viewing at the information repositories at two locations. Locations, contacts, phone numbers and viewing hours are:

Record Center, U.S. EPA Region 4, 61 Forsyth Street, Atlanta, Georgia 30303–8909, Phone: (404) 562–9530, Hours: 8:00 a.m. to 4:00 p.m., Monday through Friday—By Appointment Only; and

Media Center, George Stone Vocational School, 2400 Longleaf Drive, Pensacola, Florida 32526–8922, Phone: (850) 944–1424, Hours: 8:00 a.m. to 9:00 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Randa Chichakli, U.S. EPA Region 4, Waste Management Division, 61 Forsyth Street, Atlanta, Georgia 30303–8909, (404) 562–8928.

SUPPLEMENTARY INFORMATION: EPA announces the deletion of the Beulah Landfill Superfund Site in Pensacola, Escambia County, Florida from the NPL, which constitutes Appendix B of the NCP, 40 CFR part 300. EPA identifies sites on the NPL that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substances Superfund Response Trust Fund (Fund). Pursuant to section 300.425(e)(3) of the NCP, any site deleted from the NPL remains eligible for Fund-financed Remedial Actions if conditions at the site warrant such action. EPA published a Notice of Intent to Delete the Beulah Landfill Superfund Site from the NPL on April 24, 1998 in the **Federal Register**, (63 FR 20361–20362). EPA received no comments on the proposed deletion; therefore, no responsiveness summary is necessary for attachment to this Notice of Deletion. Deletion of a site from the NPL does not affect the responsible party liability or impede agency efforts to recover costs associated with response efforts.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, penalties, superfund, Water pollution control, Water supply.

Dated: June 10, 1998.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Appendix B [Amended]

2. Table 1 of Appendix B to part 300 is amended by removing the site ''Beulah Landfill, Pensacola, FL.''

[FR Doc. 98–16252 Filed 6–19–98; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 482

[HCFA–3005–F]

RIN: 0938–AI95

Medicare and Medicaid Programs; Hospital Conditions of Participation; Identification of Potential Organ, Tissue, and Eye Donors and Transplant Hospitals' Provision of Transplant-Related Data

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

ACTION: Final rule.

SUMMARY: This final rule addresses only provisions relating to organ donation and transplantation. It imposes several requirements a hospital must meet that are designed to increase organ donation. One of these requirements is that a hospital must have an agreement with the Organ Procurement Organization (OPO) designated by the Secretary, under which the hospital will contact the OPO in a timely manner about individuals who die or whose death is imminent in the hospital. The OPO will then determine the individual's medical suitability for donation. As well, the hospital must have an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage, and distribution of tissues and eyes, as long as the agreement does not interfere with organ donation. The final rule requires a hospital to ensure, in collaboration with the OPO with which it has an agreement, that the family of every potential donor is informed of its option to donate organs or tissues or not to donate. Under the final rule, hospitals must work with the OPO and at least one tissue bank and one eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of organs and tissues take place. In addition, transplant hospitals must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide, if requested, such data directly to the Department.

DATES: These regulations are effective on August 21, 1998.

FOR FURTHER INFORMATION CONTACT: Marcia Newton, (410) 786–5265.

SUPPLEMENTARY INFORMATION: *Copies:* To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 37194, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Deposit Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

I. Background

A. Key Statutory Provisions

Sections 1861(e) (1) through (8) of the Social Security Act (the Act) provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act specifies that a hospital must also meet such other requirements as the Secretary finds necessary in the interest of the health and safety of the hospital's patients.

Under this authority, the Secretary has established in regulations the requirements that a hospital must meet to participate in Medicare (42 CFR Part 482, Conditions of Participation for Hospitals).

Section 1905(a) of the Act provides that Medicaid payments must be applied to hospital services. Under regulations at 42 CFR 440.10(a)(3)(iii), hospitals generally are required to meet the Medicare Conditions of Participation in order to participate in Medicaid.

Section 1138 of the Act provides that a hospital participating in Medicare must establish written protocols for the identification of potential organ donors that (1) ensure that families of potential organ donors are made aware of the option of organ or tissue donation and their option to decline donation, (2) encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of those families, and (3) require that an organ procurement agency designated by the Secretary be notified of potential organ donors.

B. Why the Hospital/OPO Relationship Must Improve

An estimated 12,000 to 15,000 deaths occurring in the United States every year could yield suitable donor organs. [Gortmaker SL, Beasley CL, et al. ''Organ donor potential and performance: Size and nature of the organ donor shortfall.'' *Critical Care Medicine* (1996); 24 432–39] However, in 1997, only 5,475 of these deaths resulted in the donation of an organ.

As progress has been made in the science of transplantation, the gap has widened considerably between the number of individuals who could benefit from transplants and the number of organs available for transplantation. In the twelve years since the enactment of Section 1138 of the Act, the number of organ donors has increased by only 33 percent, while the transplant waiting list has grown by 250 percent. As of June 3, 1998, 56,222 individuals were on the waiting list for a transplant, but the number of organs transplanted from cadaveric donors in 1997 numbered only 17,032. Preliminary 1997 data compiled by the Organ Procurement and Transplantation Network contractor indicates that the number of donors (5,475 donors in 1997) increased by only 54 donors or by less than one percent over the 5,421 donors in 1996.

A 1993 Gallup poll showed that 85 percent of Americans support the general concept of organ donation and 69 percent would be somewhat or very likely to donate their own organs. [The Gallup Organization, Inc. ''The American Public's Attitudes Toward Organ Donation and Transplantation,'' A survey prepared by the Gallup Organization, Inc. for The Partnership for Organ Donation, Boston, Massachusetts, (February 1993)] Information from a number of recent studies and from States that have passed organ donor legislation has given us a clearer understanding of the reasons for the disparity between the strong public support for the concept of organ donation and the apparent failure of the current system to convert potential donors to actual donors. We have used this information to guide us in promulgating the final rule.

II. Notice of Proposed Rulemaking

On December 19, 1997, a proposed rule, ''Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval'' [HCFA–3745–P] was published in the **Federal Register** [62 FR 66726]. The proposed rule extensively revised the current conditions of participation for hospitals. Among the proposed changes were provisions designed to increase the number of organs available for transplantation.

The proposed rule was developed in response to issues raised during public hearings held by the Department on December 11 through 13, 1996, to examine the allocation policies for liver transplantation and to receive comments regarding methods to increase organ donation. The comments we received at the public hearings highlighted that there is a critical shortage of organs available for transplantation and some of the options available to alleviate the shortage.

Every day an estimated 10 individuals in the United States die because organs are not available to save their lives. This fact gave particular urgency to publication of a final rule covering the provisions of the proposed rule designed to increase donation and transplantation. Therefore, we have extracted those provisions from the proposed rule and are publishing them here, with some modifications, as a final rule. We will be publishing other provisions of the proposed rule as a final rule at a later date.

III. Analysis of and Responses to Public Comments

We received a total of 150 comments on these provisions from hospitals, OPOs, tissue and eye banks, professional organizations, transplant organizations, medical practitioners, donor family organizations, and other organizations and individuals. A summary of the major issues and our responses follow:

Impact on Tissue and Eye Donation

Comment: Several commenters said the regulation should not require that hospitals contact OPOs exclusively about potential donors, including potential tissue and eye donors. Commenters voiced concern that calls about potential tissue donors would not be handled by the OPOs satisfactorily.

Response: The proposed rule did not include a requirement that all calls be referred exclusively to an OPO. However, the final rule does include a requirement that all deaths must be referred to the OPO or a third party designated by the OPO, using protocols developed by the OPO. In the absence of separate arrangements between the hospital and a tissue bank and an eye bank, the OPO will identify and refer potential tissue and eye donors using protocols developed in consultation with the tissue bank and eye bank. The final rule also authorizes a hospital to notify a tissue or eye bank directly about potential tissue or eye donors. We believe these requirements will assure that the interests of the tissue and eye banks are considered and will encourage all parties to reach a consensus that will honor the hospital's need for a referral process that is not burdensome for hospital staff.

Comment: One commenter stated that the proposed rule does not address ways to effectively ensure OPO and hospital cooperation with the eye and tissue banks in their communities. Many commenters questioned why the OPOs should be the ''gatekeepers'' for all donations and predicted this would adversely impact tissue and eye donations. One commenter suggested all language referring to tissues or eyes be removed from the text of the regulation, so that the rule applies only to organ donation. The commenter expressed the belief that expecting OPOs to serve as the focal point for both organ and tissue donation places too great a burden on OPOs.

Response: In promulgating a rule designed to increase organ donation, we wish to avoid the possibility that the rule will have an adverse impact on tissue and eye donation and retrieval. In the proposed rule, we stated our expectation that hospitals, OPOs, eye and tissue banks would work cooperatively and effectively to facilitate and enhance organ, tissue, and eye donation. However, we noted the considerable local variation in arrangements and how they might be modified under the proposed changes. We specifically requested comments on

how the proposed rule might impact tissue donation and suggestions for measures we can take to maximize donation of organs, tissues, and eyes.

We received many comments from tissue and eye banks, their professional organizations, and individuals active in this area. Some of these commenters stated that in communities where the relationship among the hospitals, OPOs, and the tissue and eye banks is collaborative in nature, the system works well. Many described communities where a single, toll-free telephone number has been established for hospitals to call for referrals of potential organ, tissue, and eye donors. The entity taking the call (whether the OPO or, in some cases, a commercial entity under contract) screens the calls and refers them appropriately and expeditiously. However, other commenters described communities where some hospitals have never referred a single potential donor and where the relationship between the OPO and the tissue and eye banks is acrimonious and antagonistic.

The final rule preserves the flexibility of hospitals, tissue banks, and eye banks to enter into arrangements that do not involve the OPO. However, the final rule makes OPOs the default ''gatekeepers'' for referral of potential tissue and eye donors in the absence of other arrangements. Therefore, we have included in the final rule a requirement that the OPO consult with the tissue and eye bank(s) in establishing protocols for the identification and referral of potential tissue and eye donors. We have also added language to ensure that hospitals work cooperatively with a tissue bank and an eye bank, as well as the OPO, in educating hospital staff, reviewing death records, and maintaining potential donors. We will be monitoring the progress of the cooperative relationships envisioned by this rule to ensure that the gatekeeper role described does not harm tissue and eye donation.

Comment: Many commenters suggested expanding the regulation so that tissues and eyes are included. One commenter pointed out that there is a critical shortage of tissues for transplant in the United States. For example, patients who await a long bone allograft for treatment of cancer must often wait months for a transplant or resort to amputation. Several commenters said that only 8 percent of needed tissue is currently obtained. Other commenters added that we should include in the final regulation definitions for tissues and eyes.

Response: We agree there is a critical need for tissues and corneas as well as solid organs. We have, therefore, modified the text of this regulation to ensure that tissue and eye banks participate in the local decision-making process. We believe that the addition of these references will increase donations for tissues and eyes as well as solid organs. The procurement and transplantation of tissues and eyes, however, is not regulated by HCFA; therefore, we are not including definitions of these terms in the final rule. The regulation requires OPOs to consult with the designated tissue and eye bank in defining tissue and eye donor and we will rely upon the OPOs, tissue banks, and eye banks to define tissues and eyes as well.

Comment: Some commenters suggested that the rule discourage excessive fees charged by OPOs for referral of tissue donations to tissue and eye banks. Some commenters said that some OPOs may begin referring their donor calls to the highest cost reimburser, with eye and tissue banks forced to try to outbid each other for tissues. One commenter was concerned about donor family and public perceptions that might negatively affect willingness to donate. Other commenters expressed concern that high referral fees would put eye banks out of business.

Response: Our policies defining reimbursement for OPOs extend only to those activities in which the OPO engages on behalf of an eligible Medicare or Medicaid beneficiary, and are limited to reasonable costs. Therefore, any expenses incurred by an OPO, or any charges which may be made to payers other than HCFA, will not be addressed here. We have, however, expressly preserved hospitals' rights to enter into agreements with tissue and eye banks so long as those arrangements do not interfere with an OPO's efforts to recover solid organs. We would anticipate that tissue and eye banks that encounter fees they consider excessive would have the opportunity to address this issue during the establishment of donor and referral protocols.

Comment: One commenter stated we should clarify that our intent is not to disrupt existing contracts between hospitals and tissue banks.

Response: It is certainly not our intent to disrupt contracts between hospitals and tissue banks or hospitals and eye banks. We believe the regulation's requirement which authorizes agreements between the hospital and a tissue bank and an eye bank and its emphasis on collaboration among hospitals, OPOs, and tissue and eye banks will increase tissue and eye donation without disrupting contracts.

Referral Systems

Comment: Some commenters expressed concern that the proposed rule would mean elimination of current, successful community systems for referral of organ, tissue, and eye donors.

Response: Our intent in promulgating this rule is certainly not to disturb successful community referral systems, and we would urge hospitals and OPOs not to abandon them. Therefore, we have revised the rule to clarify that it does not preclude such systems. The final rule permits the hospital to refer potential donors to a third party designated by the OPO and to continue successful arrangements with tissue banks and eye banks. In addition, we encourage OPOs and hospitals, in consultation with tissue and eye banks, to use this opportunity to improve upon current referral systems to maximize not only organ donation but tissue and eye donation as well.

Comment: Many commenters suggested a system whereby all referral calls go to a single non-proprietary answering service or a referral system operated by one of the organ or tissue agencies and supported by all. They pointed out that the process is more successful when hospitals are required to make a single phone call, rather than contacting multiple agencies about a potential donor. One commenter added that hospitals and grieving families should not be burdened with two distinct but parallel operating communications regarding donations. One large, nationwide tissue bank suggested that all referrals be made either to the OPO or a non-proprietary service. One eye bank commented that eye banks in areas with a non-proprietary phone number experience an increase in donations. In contrast, another tissue bank suggested a two-call system which is used in its State. In this State, hospitals are required to contact the OPO on all brain deaths. All other deaths are reported to a referral agency, based on a plan agreed to by the hospital and all other agencies.

Response: Before responding to the comment, we want to clarify that this rule requires hospitals to notify OPOs or a third party designated by the OPO, of individuals whose death is imminent of who have died in the hospital. Some commenters make reference to ''brain death'' donors, meaning heart beating donors who have been declared brain dead. This regulation does not exclude the reporting of non-heartbeating deaths. Hospitals must report both brain dead and cadaveric potential donors.

We have added language to the text of the regulation to clarify that referral of phone calls to a third party entity designated by the OPO is not precluded. Anecdotal evidence indicates that a one-phone-call referral process may increase organ donations, as well as tissue and eye donations. Logically, it would seem that a system that makes it possible for a hospital to refer potential donors with a single phone call would make hospital compliance easier and, therefore, more likely. We would urge communities to explore this option.

However, regardless of how the referral by the hospital is accomplished, we would also urge that protocols ensure that families of potential donors are approached about donation by a single agency (either the OPO, a tissue bank, or an eye bank) in collaboration with hospital staff. For example, Florida donation legislation provides that the OPO must be given the opportunity to approach the families of suitable vascular organ donors. OPOs may represent the tissue and eye bank. Under the Florida law, the tissue bank must be given the opportunity to approach the family of suitable tissue donors if the OPO has not already approached the family. Eye banks must be given the opportunity to approach the family of suitable eye donors if the OPO or a tissue bank has not already approached the family.

Comment: Several commenters suggested we strengthen the regulation by adopting a routine referral approach which requires referral of all patient deaths to OPOs. Commenters pointed to the success of the Pennsylvania routine referral law and predicted similar increases in donation rates if a nationwide routine referral approach were to be adopted. Commenters gave the following reasons for supporting routine referral: (1) A clear standard is established for hospitals regarding when referrals must be made to the OPO; (2) allows early intervention by the OPO to guide the organ and tissue process to ensure a successful outcome; (3) ensures that the hospital will not erroneously assume that a potential donor is too old or has a medical condition that precludes donation; (4) removes from hospitals the burden of keeping abreast of changing standards for donor screening and suitability criteria; (5) minimizes regional differences in organ procurement and transplant waiting times, and (6) facilitates compliance by hospital systems whose member hospitals are served by more than one OPO. However, many commenters who supported routine referral suggested some flexibility be built into the regulation in consideration of resource limitations or local circumstances. For example, commenters suggested that deaths of individuals above a certain age be excluded from routine referral.

Response: We agree with the commenters who support routine referral of all deaths and have adopted their recommendation in this regulation. We believe that the experiences of States with routine referral legislation have demonstrated that referral of all deaths is the single most critical factor in increasing organ donation rates. Referral of all deaths assures that determination of medical suitability is made by the OPOs, because OPOs are the entities with knowledge of transplant hospitals' donor suitability criteria.

However, we have not adopted the recommendations of those who advised us to give OPOs the discretion to exclude certain categories of deaths from the requirement for routine referral. Referral of all deaths, with no exclusions, eliminates the need for OPOs and hospitals to rewrite referral protocols and reeducate hospital staff whenever transplant hospitals' donor suitability criteria change. It is also less difficult for HCFA to monitor hospital compliance if there are no exclusions. Finally, it is important to note that many OPOs will be screening donors for tissue and eye donation, and tissue and eye banks often have criteria for donation that differ significantly from the criteria for organ donation. For example, in 1997, only 6.4 percent of organ donors were over the age of 65. The Eye Bank Association of America reports however, that more than 28 percent of all eye donors in 1997 were over the age of 70.

Comment: Some commenters urged us not to adopt a routine referral approach. Commenters stated that routine referral will not work where relationships between OPOs and hospitals are, at best, uncooperative. Other commenters cited the burden and cost to hospitals and OPOs of making or receiving many unproductive calls.

Response: We believe routine referral is workable and will increase organ donation. We hope that all OPOs and hospitals will be encouraged by this regulation to develop relationships that increase organ and tissue donation. If they are not able to develop such relationships, however, a hospital may choose to seek waiver to associate with another OPO, or the original OPO may find itself unable to meet HCFA certification standards and be replaced by an OPO better able to develop the kind of relationships that lead to greater organ and tissue recovery.

A 1988 commentary published in the *Journal of the American Medical Association* states that the cooperation of the medical professions is the primary factor limiting the supply of transplantable organs. The author suggests that routine referral ''would not solve all the problems of professional cooperation, but it would ameliorate a key one and open the bottleneck that presently constrains the supply of organs.'' [Prottas, J. ''Shifting Responsibilities in Organ Procurement: A Plan for Routine Referral.'' *Journal of the American Medical Association*. 1988;260:6]

We do not expect the cost to hospitals of referring all deaths to be significant. As discussed in the Regulatory Impact Statement, the average hospital should require no more than four person days per year to report every death that occurs in the hospital to the OPO. This time is in lieu of time hospitals' spend complying with existing requirements. If tissue and eye referrals are made by the hospital to either the OPO or a third party entity, rather than to tissue and eye banks, calls made to tissue and eye banks about medically unsuitable donors should not increase, as the calls will be screened by the OPO or third party entity. However, we expect that OPOs will find that the increased number of donations resulting from routine referral will enable them to meet the additional expenses without a significant increase to their current standard organ acquisition costs. Further information about the expected economic impact of routine referral on OPOs can be found in the Regulatory Impact Analysis.

Best Practices

Comment: Some commenters suggested that HCFA is abdicating its policy-making and regulatory authority to the OPOs. The commenters urged us to identify the best practices by which organ donation can be increased and use those practices as the basis for a regulatory definition of potential donor. The commenters pointed out that the proposed rule indicates that approximately 12,000 to 15,000 of the one million patients who die in hospitals annually are likely to be potential organ donors but that the proposed rule does not establish criteria by which hospitals would be required to identify those patients.

Response: We have not specifically defined potential donor in the final rule because the definition is continually changing, particularly as to the upper age. Instead, we have included the requirement that hospitals routinely refer all deaths and all individuals for

whom death is imminent to the OPO, with the assumption that this requirement will, in most communities, lead to better identification of the medical suitability of the potential donor based on the most recent medical research in transplantation. Contrary to the commenter's statement that one million patients die annually in hospitals, it is estimated that there are approximately 2,080,000 hospital deaths per year. The final rule also requires that the hospital and OPO collaborate in advising the family of potential donors of their option to donate. We have chosen not to dictate best practices for other aspects of organ donation, such as education and death records review, as we believe that each hospital and OPO, working together, can identify practices that will be most useful in their specific situation.

Following is a synopsis of the most recent research in organ donation and best practices for organ donation. We encourage hospitals and OPOs to use these studies and the many other studies that have been done on best practices for organ donation to guide their development of protocols that will work to increase organ donation in their communities. The estimate of 12,000 to 15,000 potential organ donors annually is based on the results of retrospective reviews of 1,990 medical records in 69 acute care hospitals in 4 geographic regions in the United States and a stratified random sample of 89 hospitals in 3 of the same areas (33 of the same hospitals) in 1993. The study found that only one third of the potential organ donors became organ donors. By extrapolating the 1990 findings to the entire United States, researchers postulated a pool of 13,700 medically suitable donors per year. [Gortmaker SL, Beasley CL, et al. ''Organ donor potential and performance: Size and nature of the organ donor shortfall,'' *Critical Care Medicine* (1996); 24:432–39]

The study also showed that potential donors were correctly identified 90 percent of the time, and families were advised of their donation options only 71 percent of the time. The study's authors concluded that prospective identification and requesting donation in all suitable potential donor cases could lead to 1,800 additional donors per year.

An earlier study based on 1988 and 1989 data estimated the pool of potential organ donors to be between 6900 and 10,700 annually. [Evans RW, Orians CE, Ascher NL. ''The Potential Supply of Organ Donors: An Assessment of the Efficiency of Organ Procurement Efforts in the United States,'' *Journal of the American Medical Association* (1992); 267:239–246.] The study was based on a review of multiple cause of death data from death certificates. The researchers excluded non-traumatic causes of death and, therefore, may have underestimated the potential donor pool by as much as 50 percent. However, the study demonstrated that there are many more potential than actual donors. The study's authors concluded that it may be possible to increase the number of actual donors by 80 percent.

These studies and several other recent studies are defining the best practices for increasing organ donation. As research continues in the field of organ donation, best practices will continue to evolve. Therefore, we are hesitant to use current best practices as the sole basis for promulgating a regulation that cannot be changed quickly enough to keep pace with the results of future research in the field of organ donation. However, we firmly believe there has been sufficient research upon which OPOs and hospitals can develop protocols that will lead to a significant increase in organ donation rates.

Through this final rule and related activities in the National Organ and Tissue Donation Initiative, we are encouraging hospitals and OPOs to incorporate other best practices into protocols for increasing donation rates. For example, recent studies have indicated that organ donation rates can be increased using a variety of best practices related to (1) advising families of potential donors of their rights regarding donation; (2) medical record reviews for evaluating performance and identifying opportunities for education; and (3) education of hospital staff.

The study cited above [Gortmaker SL, Beasley CL, et al. ''Organ donor potential and performance: Size and nature of the organ donor shortfall,'' *Critical Care Medicine* (1996); 24:432–39] found that approximately half of the families asked to donate a relative's organs decline to give consent. Likewise, a stratified random sample of 23 acute-care general hospitals in two metropolitan areas found that only 46.5 percent of families of potential organ donors agreed to donate organs, and 22 percent of those who agreed to donate placed conditions on the donation. [Siminoff LA, Arnold RM, Caplan, AL, Virnig BA, Seltzer DL. ''Public Policy Governing Organ and Tissue Procurement in the United States.'' *Annals of Internal Medicine.* 1995; 123:10–17] The study's authors concluded that ''problems with the ways in which families are asked about donation rather than the failure of . . . altruism, may account for the high refusal rate.''

An interview study of donor and nondonor families [DeJong W, Franz HG. ''Requesting Organ Donation: An Interview Study of Donor and Nondonor Families,'' *American Journal of Critical Care* (1998);7: 13–23] identified the factors identified with consent for organ donation. The study cites unpublished data [Gortmaker SL, Beasley CL, Sheehy E, et al] that demonstrate a significant increase in the consent rate when three elements are in place when the family is advised of its right to consent to or to decline donation. First, family members must be given time to understand and accept their relative's death before the donation request is made. This means that the hospital staff's notification of the family about the patient's death and the explanation of brain death must be ''decoupled'' from the request for donation. An earlier study of the consent process also found the timing of the request to be critical. The study indicated a 60 percent consent rate when the subject of organ donation was discussed with the family before notification of death, a 68 percent consent rate when organ donation was discussed simultaneously with notification of death, and a 78 percent consent rate when organ donation was discussed after notification of death. [Cutler JA, et al. ''Increasing the Availability of Cadaveric Organs for Transplantation: Maximizing the Consent Rate,'' *Transplantation* (1993); 56(1)225–28]

Second, consent rates are higher when the request is made by the OPO in conjunction with the hospital staff. A retrospective review of all medically suitable potential donors referred to a single OPO in a one-year period found a 67 percent consent rate when the OPO coordinator approached the family alone, a 9 percent consent rate when the hospital staff approached the family alone, and a 75 percent consent rate when the approach was made by the OPO coordinator and hospital staff together. [Klieger J, Nelson K, Davis R, er al. Analysis of Factors Influencing Organ Donation Consent Rates. *Journal of Transplant Coordination* (1994); 4:132–34] A 1995 article [Dejong, W, Drachman, et al. ''Options for Increasing Organ Donation: The Potential Role of Financial Incentives, Standardized Hospital Procedures, and Public Education to Promote Family Discussion,'' *The Milbank Quarterly* (1995);73: 463–79] suggested that the donation option should first be mentioned to the family by a hospital-based health professional, but the

formal request should be made by the OPO coordinator.

The third critical element in the consent process is the setting in which the request for donation is made to the family. The request should be made in a quiet, private setting, such as a conference room or family meeting room, rather than in a hallway or waiting room. When all of these methods are used in conjunction, consent rates are 47 percent higher than when none of these methods is used.

The study's authors note that in general there is currently no widely accepted protocol with regard to the process for requesting donation. They suggest that hospitals' protocols should include (1) communicating often and honestly with the family about the patient's prognosis, (2) making sure the family understands brain death, (3) decoupling the request for donation from the explanation of brain death, (4) using a quiet, private setting for discussion of donation options, and (5) defining clear roles and responsibilities for the hospital staff and the OPO coordinator.

Another recent study [McNamara P, Franz HG, Fowler RA, et al. ''Medical Record Review as a Measure of the Effectiveness of Organ Procurement Practices in the Hospital,'' *Joint Commission Journal on Quality Improvement* (1997);23:321–33] makes several recommendations for quality improvement initiatives based on medical records review. The study's authors suggest that OPO staff provide feedback from medical records review to key hospital staff concerning practice improvements. They suggest hospitals use information from medical records review to assess the hospitals' performance in the organ donation process, identify areas where performance can be improved, and monitor the effectiveness of the implemented changes. They also suggest that medical records review should be conducted annually at large hospitals.

As referenced earlier, research in education of hospital critical care staff [Evanisko MJ, Beasley, CL, Brigham, LE. ''Readiness of Critical Care Physicians and Nurses to Handle Requests for Organ Donation,'' *American Journal of Critical Care* (1998); 7:4–12] found that training of critical care physicians and nurses in effective procedures for requesting organ donation is significantly associated with higher rates of organ donation. However, two thirds of critical care staff reported no relevant training. A 1986 United Network for Organ Sharing survey found a surprising lack of knowledge among the transplant hospital staff regarding knowledge of organ donation and transplantation. [Ettner BJ, Youngstein KP, Ames JE. ''Professional Attitudes and Knowledge About Organ Donation and Organ Transplantation,'' *Dialysis and Transplantation,* (1988); 17:72–76] Eighteen percent of the respondents were physicians, and 68 percent were nurses. Thirty-four percent of the respondents were unsure if their hospital had written protocols for organ recovery, and nearly half of the respondents answered no to the statement that the organ donor protocols provided adequate guidelines and protection for the donor and for hospital staff. The final rule ensures that only OPO representatives or trained individuals will approach families to explain their donation options and make the actual request for donation.

Our review of these and other studies has convinced us that there has been sufficient research upon which OPOs and hospitals can base protocols that will take advantage of best practices for advising families of their right to consent to or to decline donation, evaluate hospital and OPO staff performance through medical records reviews, and educate hospital staff.

Necessity for Change

Comment: Several commenters suggested that we make no change in the hospital conditions of participation for organ procurement responsibilities. They pointed out that the current regulations, which allow hospitals to establish their own organ donation policies, often result in good donation rates. They suggested that in lieu of a regulation, HCFA continue to evaluate what works to increase donation rates and encourage hospitals and others to make changes.

Response: The current hospital conditions of participation have not produced the results which were anticipated. Therefore, in our response to the previous comment, we outlined research studies that show several approaches that work to increase donation rates. We believe that all hospitals, including those that are currently successful, should consider whether these approaches, in addition to routine referral, could further increase organ donation. A study of 1,990 death records from 69 hospitals in four geographic regions found a wide variation in hospital performance with a hospital donation rate (i.e., actual donors as a percentage of potential donors) ranging from 0 percent to 68 percent. Note that this was not a random sample of hospitals; the hospitals tended to be larger institutions with either a history of donor activity or suspected potential for donation. The average organ donor potential in the hospitals was 13.3; average actual organ donors were 4.3. [Sheehy E, Poretsky A, Gortmaker, SL. ''Relationship of Hospital Characteristics to Organ Donation Performance,'' *Transplantation Proceedings* (1996); 28:139–141]

These data demonstrate that, some hospitals need more than encouragement to meet the requirements of section 1138 of the Act, which mandates that hospitals identify potential organ donors and assure that families of organ donors are informed of their donation options. In view of the critical and growing shortage of donated organs in this country, we would be abdicating our responsibility as a Federal agency if our only response to this crisis were merely to be encouragement. We believe that a less burdensome approach for hospitals, requiring only a phone call to the OPO, will be more successful in providing opportunities for families to consider donation. Therefore, we are not accepting this comment.

Comment: One commenter suggested a delay in publishing the final rule until the Department can convene a workshop to come up with a different proposal. The same commenter also suggested allowing hospitals at least three years to develop an action plan to increase donation rates.

Response: We believe the need to substantially increase organ donation immediately outweighs any potential benefits from adopting the commenter's suggestion. As noted above, 10 people die every day waiting for an organ transplant. In addition, the Department sought public comments on the issue of increasing organ donation as part of its development of a related rule regarding the Organ Procurement and Transplantation Network, including a three-day public hearing in December 1996. It also conducted a conference in April 1998 to identify methods to evaluate and identify successful mechanisms to increase donating consent. In view of the every-widening gap between the number of people waiting for organ transplants and the number of organs available, further delay in passing a regulation to alleviate this crisis is unacceptable.

Regulatory Flexibility

Comment: Many commenters warned against promulgating a final regulation that is too prescriptive. They emphasized that what is needed, above all, is flexibility to design protocols to meet needs of local communities, rather than a ''one-size-fits-all'' regulation

which defines potential donor and the protocols for notification and referral for the entire country. One commenter pointed out that such flexibility allows for look-back data and new research to be incorporated into hospitals' policies.

Response: We agree with these commenters and have used this viewpoint to guide our development of the final rule. For example, it allows the OPO to determine medical suitability in light of the most recent transplantation research and the needs of transplant recipients, surgeons, and hospitals. The final rule requires collaboration between the hospital and the OPO in informing families of potential donors of their donation options because the evidence is overwhelming that involvement of the OPO in the consent process is critical. We believe however, it is best for hospitals and OPOs to have the flexibility to design a protocol for informing families that takes into account circumstances in each community. Finally, the final rule allows hospitals, OPOs, and tissue and eye banks the flexibility to adapt best practices in the areas of death record reviews and education of hospital staff to suit the circumstances in their local communities.

Medical Suitability

Comment: One commenter suggested there should be Federal baseline criteria for defining potential donors, with HCFA setting minimum standards, including tests, required for an individual to donate an organ. Hospitals and OPOs could be more exacting, but could not fall below the Federal standard. Another commenter called for a national conference to determine the broadest possible definition based on national need and the varying acceptance criteria of transplant surgeons and institutions. For example, commenters suggested variously that ''potential donor'' should be defined as a patient who is brain dead and heart beating or any patient on a ventilator.

Response: We believe these commenters are seeking a Federal definition for medically suitable donors, rather than a Federal definition for potential donors. Generally, a definition for potential donors is designed to cast a wide net by defining potential donors, for example, as all hospital deaths or all patients on ventilators. By making the pool of potential donors so large, OPOs ensure that no medically suitable donors are missed. However, many, if not most, of the potential donors in this large pool will not be medically suitable to be actual donors.

We are reluctant to impose a Federal standard for medically suitable donors. Some OPOs, for example, the Louisiana Organ Procurement Agency, have experimented with expanded criteria for determining medically suitable donors, with good results. However, transplant hospitals vary in their willingness and ability to transplant organs from potential donors with particular medical conditions or from donors who are past a certain age. At one time, most organ donors were age 45 or younger; now some transplant hospitals are transplanting livers from 80-year-old donors. According to the Organ Procurement and Transplantation Network contractor, the 33 percent increase in cadaveric donors between 1988 and 1996 is primarily due to the increase in donors ages 50 and over. Cadaveric donors age 50 and over increased from 12 percent in 1988 of all cadaveric donors to 27 percent in 1996. [*United Network for Organ Sharing 1997 Scientific Registry and Organ Procurement and Transplantation Network Annual Report*] Some transplant hospitals will consider organs from donors with any medical condition other than metastatic cancer or HIV; other transplant hospitals are more restrictive.

It is likely that as transplantation research continues, the ability of medical professionals to obtain and transplant organs from patients once considered medically unsuitable will grow. Therefore, since the definition of medically suitable donor will likely be broadened in the future, we believe it would be inappropriate to impose a regulatory definition.

Comment: One commenter stated that in order to determine if a potential donor is medically suitable to be a donor, it may be necessary for the OPO to examine the body, conduct tests, review medical records, and obtain medical information from the family and physician. The commenter said that hospitals have expressed concern that this violates laws governing patient privacy and confidentiality of medical records and asked us to emphasize that the authority to do so is implicit in the law.

Response: We agree with the commenter that the OPO may examine the body of the potential donor and his or her medical records and conduct the tests, inquiries, and investigations that are necessary to determine if the potential donor would be medically suitable to be a donor. The Public Health Service Act section 371, 42 U.S.C. 274 specifies that OPOs must arrange for the acquisition and preservation of donated organs and provide quality standards for the acquisition of organs which are consistent with the standards adopted by the OPTN under section 372(b)(2)(E), including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome. Section 371 of the Act also specifies that OPOs must arrange for the appropriate tissue typing of donated organs. Certainly, after receipt of consent for donation from the potential donor's family, it would be necessary for the OPO to examine the body of the potential donor, conduct tests, review medical records, and obtain medical information from the family and physician in order to accomplish the requirements of section 371 of the Act. Therefore, after receipt of consent, we believe the authority to conduct testing, review medical records, and gather other medical information needed to determine the medical suitability of the potential donor is implicit in the law.

OPO Conditions of Coverage

Comment: Some commenters had suggestions for changes in the OPO procedural standards in the regulations governing OPOs, such as requiring OPOs to refer potential tissue donors to eye banks and/or tissue banks.

Response: We are not making changes to the OPO conditions of coverage here, as the OPO conditions of coverage are not within the purview of this regulation. However, we will retain the comments for reference and continue to review the OPO requirements with a view toward improving their effectiveness. In addition, we would point out that the OPO conditions of coverage do require OPOs to ''have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all usable tissues are obtained from potential donors.'' [42 CFR 486.306(l)] Because this final rule does establish OPOs as the default gatekeepers for referral of tissues and eyes, we will regard very seriously the failure of any OPO to refer promptly all potential tissue and eye donors to the tissue and eye bank(s) specified by the hospital.

Comment: One commenter cited ''anecdotal evidence'' that managed care organizations, hospitals, and other providers are reluctant to provide services for patients with non-survivable brain injuries. The commenter recommended changing HCFA reimbursement rules for OPOs to allow costs related to donor clinical assessment prior to declaration of death. The commenter suggested this would eliminate a barrier to OPOs' early

involvement with the potential donor and address hospital concerns regarding donation-related charges incurred prior to brain death.

Response: Although reimbursement is not within the scope of this regulation, HCFA will be looking into this matter with a view to determining what steps appropriately can be taken to ensure that providers' difficulties in obtaining reimbursement for services to patients with non-survivable brain injuries does not become a barrier to organ donation.

Comment: A few commenters responded to our request for suggestions about how to design or implement the most cost-effective outcome standard for OPOs related to organ recovery. The commenters called for a more precise way to measure potential donors for comparison with actual donors so that each OPO is evaluated in light of its true potential. Some commenters said that if HCFA adopts an outcome standard based on conversion of potential to actual donors, the current performance standards should be reviewed with a view to changing or eliminating them.

Response: We agree that the current method of using population to define potential donors may not reflect regional differences in number and cause of deaths. A recent GAO report [U.S. General Accounting Office, ''Alternatives Being Developed to More Accurately Assess Performance (GAO/HEHs–98–26),'' (November 1997)] noted that unless OPO performance is measured according to the number of potential donors, HCFA cannot determine OPOs' effectiveness in acquiring organs. We agree with the conclusions of the GAO report and will be evaluating two methods suggested by the GAO for more accurately identifying the number of potential donors in an OPO's service area: death record review and modeling. We also will be evaluating the results of the study of death record reviews being conducted by the Association of Organ Procurement Organizations in conjunction with the American Congress for Organ Recovery and Donation (ACORD) and a methodology for estimating potential donors, which is being developed by Harvard Medical School, the Harvard School of Public Health, and the Partnership for Organ Donation. If the current method of using population to estimate the number of potential donors in an OPO's service area is changed, we will review all OPO conditions of coverage to determine their appropriateness in view of that change.

Comment: One commenter suggested hospitals should be allowed to set minimum credentials for OPO personnel working in their hospitals. The commenter said surveys of donor family satisfaction and satisfaction of hospital personnel with OPO personnel should be permitted, and hospitals should have the option of terminating their contract with the OPO if a workable solution is not found.

Response: There is nothing in the regulation that precludes a hospital from surveying donor families or hospital personnel to determine their level of satisfaction with the OPO. However, standards for OPO personnel are a HCFA responsibility. [42 CFR 486.306] A hospital dissatisfied with its designated OPO has the option of requesting a waiver from HCFA permitting an agreement with an 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 showing that the waiver is expected to increase organ donations and 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.

Resolution of Disputes

Comment: Several commenters suggested there should be a mechanism for ''due process'' if there are disagreements between OPOs and hospitals or between OPOs and tissue and eye banks. One commenter suggested that the rule should require an agreement as to the content of the protocols signed by both the OPO and the hospital. The commenter suggested that the Department should set up a system for mediating and, if necessary, arbitrating disputes. In the case of arbitration, the decision of the Secretary would be final.

Response: We have tried to structure a final rule that will encourage hospitals and OPOs to work together to alleviate the critical shortage of organs for transplant. We have included a requirement that hospitals and OPOs work ''collaboratively'' in advising families of potential donors of their donation options. We have included a requirement that hospitals work ''cooperatively'' with OPOs and tissue and eye banks in reviewing death records, educating hospital staff about donation issues, and maintaining potential donors. We have included a requirement that the OPO consult with a tissue and an eye bank in developing protocols for identification and referral of tissues and eyes. We believe these requirements will obviate the need for dispute resolution mechanisms, such as mediation or arbitration. However, based on the correspondence we have received, we understand that, in some communities, relationships between hospitals and OPOs and between OPOs and tissue and eye banks are contentious and that collaboration may prove to be difficult.

We know that hospitals, OPOs, and tissue and eye banks share our view that organs and tissues are a precious national resource and that only through the collaborative efforts of all parties can lives be saved. As one commenter wrote, ''at risk in * * * this issue are patient lives that could either be saved or be unnecessarily lost by the success—or failure—of hospitals and OPOs working together.''

We will monitor donation rates and OPO and hospital performance after this rule becomes effective. In those instances where tensions among the actors in the donation process are hindering improvements in organ donation, we will explore ways in which we might play a constructive role in encouraging and facilitating a successful local solution.

Family Consent to Donation

Comment: One commenter expressed concern that strengthening the role of the OPOs in the donation process will encourage OPOs to apply too much pressure on bereaved families in order to meet HCFA performance standards. The commenter suggested the final rule should address the need for sensitivity toward families and their religious views and the need for education of hospital staff in sensitivity to families' grief. Another commenter cited OPO ''quotas'' and hospitals' concerns about lack of control as reasons why the OPO should not be involved with the potential donor's family until the family has agreed to donation or requested additional information about donation.

Response: We have no evidence that families of potential donors are being pressured by OPO or hospital staff and no reason to believe that this change in the hospital conditions of participation would lead to such a problem. We note however, that the final rule requires collaboration between the hospital and OPO in informing families of potential donors of their donation options and also requires hospitals to encourage discretion and sensitivity with respect to the circumstances, views and beliefs of families of potential donors. In addition, the final rule both permits the hospital to choose the individual who will initiate the request for donation to the family and ensures that the

individual initiating the request has been educated in the consent process.

Although our earlier references to research on the family consent process emphasize that best practices lead to improved consent rates, such improvement is achieved in large part through greater sensitivity to families and their beliefs, their backgrounds, and their grief. For example, the interview study cited earlier [DeJong W, Franz HG. ''Requesting Organ Donation: An Interview Study of Donor and Nondonor Families,'' *American Journal of Critical Care* (1998);7:13–23] discusses family demographic characteristics, such as race, ethnicity, and education and concludes, ''This information should be used to remind the health care team to be especially attentive to concerns that certain families might have and to take special care to meet the families' informational and emotional needs. Healthcare providers should approach the family with the belief that a donation is possible and should take steps to ensure the family is treated with respect and care.''

The services provided by Nebraska Health Systems are an example of what hospitals and OPOs can do to increase family consent to donation while providing emotional support and counseling to grieving families. This transplantation facility offers a program called Acute Bereavement Services, staffed by organ recovery personnel, nurse resource coordinators, and pastoral care staff. These individuals are available at any time to guide discussions with survivors concerning potential organ and tissue donation; act as a resource for family questions about funeral arrangements, coroner notification, autopsy consent, grief resources, hospital leave-taking, religious resources, and ritual; act as a resource for staff questions about notification of organ recovery staff; and act as advocates for the immediate grief needs of survivors. Nebraska Health Systems instituted their Acute Bereavement Services because ''we wanted to have a positive impact on the grieving process even after our medical responsibilities to the patient and family ended.'' In 1996, the Nebraska Health Systems family consent rate was 75 percent. Hospitals interested in obtaining more information about Acute Bereavement Services can contact Nebraska Health Systems at Box 984075, 600 South 42nd St., Omaha, NE 68198–4075, Attention: Marsha Morien.

Comment: Some commenters voiced concern about the use of the word ''discretion'' in the text of the regulation. The regulation requires that hospitals ''encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors.'' Commenters suggested there is a risk that in some circumstances the term ''discretion'' might be used as a justification to avoid advising eligible families about organ donation because of a presumption on the part of hospital staff that the family would not be receptive because of their intense grief, socioeconomic status, race, or religion. The commenter cited a study that found minority families, particularly African Americans, were less likely to be asked about the option of donation. The commenter suggested this might be due to hospital staff perception that ethnic minorities are opposed to donation, despite ample evidence that minorities donate in significant numbers. One OPO commented that the greatest impediment to donation is a hospital's conclusion that consent cannot be obtained. The OPO stated, ''In such a situation, the OPO has lost a potential donor without ever being afforded the opportunity to act.''

Response: Our use of the term ''discretion'' in the text of the regulation reflects the statute's use of that term in section 1138(a)(1)(A)(ii) of the Act. However, we are grateful for an opportunity to point out that our use of the term ''discretion'' in the text of the regulation should not be construed to mean that hospital staff should, under any circumstances, make a judgment that certain families should not be approached about donation. The hospital staff's perception that a family's grief, race, ethnicity, religion, or socioeconomic background would prove a barrier to donation should never be used as a reason not to approach the family. We cannot emphasize too strongly that all families of potential donors must be advised about their donation options.

Comment: Many commenters strongly supported our language regarding notification of donor families. Many mentioned the research that shows that highest family consent rates are obtained when OPOs and hospitals collaborate. One OPO reported an 87 percent consent rate when OPO staff and hospital staff collaborate in the request to the family and a 38 percent consent rate when the hospital staff approach the family alone. Some commenters emphasized that hospital staff should be free to continue to participate in advising families of their donation options. However, one commenter suggested that if hospital staff consent rates differ markedly from OPO staff consent rates, the hospital should be required to return consent responsibility to the OPO or provide training to hospital staff. Some commenters recommended that the regulation specify that only trained personnel (whether OPO or hospital staff) are permitted to advise families of potential donors of their donation options. One commenter pointed out that in Pennsylvania, which has a routine referral law, hospital personnel can become designated requestors only after undergoing training by the OPO.

Response: We appreciate the commenters' support for the final rule's emphasis on collaboration in notifying families of potential donors of their options for donation. Research has shown best practices include participation of both OPO personnel and hospital staff in the process, with the actual request for donation made by OPO personnel. We encourage hospitals and OPOs to consider these best practices when determining how this process will occur. We agree with the commenters who suggested that only personnel trained in the consent process be permitted to approach families with a request for donation, and we have included that provision in the final regulation. We have also modified the text of the regulation to make it clear that hospitals have discretion in determining who will initiate the request for donation.

Comment: Some commenters suggested further strengthening the rule by giving the OPOs even more control over the process. For example, one commenter suggested the rule be strengthened to give OPOs the sole responsibility for initiation of the request for organs or tissues. The commenter mentioned that currently OPOs are being held accountable by the Federal government but have not been given the tools to increase donation rates. Several commenters urged us to eliminate the requirement for collaboration between the OPOs and the hospital in the consent process and make it clear that only OPO staff should be permitted to approach the family about donation.

Response: We are sympathetic to the commenters' point of view. OPOs have been in the difficult position of having to meet specific performance standards for organs donated and transplanted, while at the same time having less than total control over the donation and transplantation processes. However, we disagree that only OPOs should be permitted to advise families of potential donors of their donation options. As stated elsewhere in this preamble, studies show that the highest family consent rates are a result of collaboration between OPOs and

hospitals. The participation of hospital staff is critical both to ensure that a family understands and accepts the brain death of the potential donor and to provide compassionate support to the family. A 1987 study of donor family perspectives concluded that the hospital nursing staff are in the best position to have a positive effect on donor families' attitudes toward their donation experiences and, ultimately, as families share their experiences with family and friends, in the future availability of organs for transplant. [Bartucci, MR. ''Organ Donation: A Study of the Donor Family Perspective.'' *Journal of Neuroscience Nursing.* 1987; 19:305–309] The final rule gives OPOs considerably more control over the donation process while at the same time encouraging collaborative relationships between OPOs and hospitals.

Death Record Reviews

Comment: Many commenters strongly supported the requirement for death record reviews. One commenter, a hospital association from a State with a routine referral law, suggested that death record reviews be performed only by licensed OPOs. Another commenter encouraged us to take the next step by providing support and resources to allow compilation of medical records review data in a centralized database, and by accelerating the development and application of methods to accurately estimate underlying donor potential in hospitals and OPOs.

Response: We agree that death record reviews are an essential component of this final rule. We expect that requiring hospitals to cooperate with OPOs, tissue banks and eye banks in reviewing death records will allow the OPOs, tissue banks and eye banks the opportunity to review death records to determine donor potential, monitor hospital compliance, and identify areas where education in a hospital's organ donation procedures is needed. The final rule will permit the hospital, OPO, tissue bank, and eye bank to determine who will perform the death record reviews. Providing resources for compilation of medical records review data is beyond the scope of this regulation. However, we are interested in a further exploration of how such a database could be useful in increasing organ donation. We are currently considering various methods for estimating donor potential and are also awaiting the outcome of a review of hospital death records being conducted by the Association of Organ Procurement Organizations in conjunction with the ACORD.

Comment: A few commenters were concerned that giving outside agencies access to death records would be disruptive or would jeopardize patient confidentiality.

Response: In requiring hospitals to work cooperatively with OPOs, tissue, and eye banks in performing death record reviews, we are confident that a system can be worked out among all parties to minimize disruptions. Likewise, we would expect that all parties can come to an agreement on the protocols that will be used both to perform death record reviews and analyses. We also expect all parties involved to use the resulting data in a manner that ensures patient confidentiality is not threatened. Note that both hospital and OPO regulations require hospitals and OPOs to have procedures for ensuring the confidentiality of patient records. Hospitals and OPOs must ensure that unauthorized individuals cannot gain access to or alter patient records. Hospitals and OPOs must also ensure that original medical records are released only in accordance with Federal or State laws, court orders, or subpoenas. [See 42 CFR 482.24(b)(3) and 42 CFR 486.306(o).] We believe that sufficient safeguards exist in Federal and State law to protect the confidentiality of hospital death records.

Comment: One commenter asked that HCFA provide explicit authority for OPOs to conduct audits of hospital organ and tissue donation performance to be provided upon request to HCFA or the Joint Commission on Accreditation of Health Care Organizations. Confidentiality would be assured as a condition of OPO designation.

Response: Although this regulation does not give OPOs specific authority to conduct death record reviews, it does require that hospitals work cooperatively with their OPOs in reviewing death records. This means that a hospital must develop a protocol which permits the OPO access to death record information that will allow the OPO to assess the hospital's donor potential, assure that all deaths or imminent deaths are being referred to the OPO in a timely manner, and identify areas where both OPO and hospital staff performance might be improved.

General Comments

Comment: One commenter cited ''concerns in the medical community'' about the broad language of the proposed rule and the possibility that unintended and unanticipated actions could be taken. The commenter suggested that we hold meetings with interested parties to assess their understanding of the language and request suggestions for clarifying the proposed rule.

Response: We carefully considered all comments we received from hospital and medical associations; tissue and eye banks and their professional organizations; transplant and donor organizations; OPOs; and other organizations and individuals. In addition, we have tried to be quite specific in this preamble in our discussions of the meaning of the regulation text and in our suggestions for implementation.

Comment: Some hospital associations expressed concern that OPOs would establish policies that are unworkable because the proposed rule provides no guidance to OPOs about the policies they should establish. The hospital associations gave as an example, the proposed requirement that the hospital assure that the family of each potential donor knows of its option to donate or decline to donate organs or tissues. They suggested that if an OPO defined potential organ donor as any patient who dies, the hospital would be required to inform the families of all deceased patients of their donation options even if it knew the patients were not medically suitable to be donors.

Response: We believe the final rule's emphasis on cooperation and collaboration between hospitals and OPOs will ensure protocols are developed and implemented that will function efficiently for both hospitals and OPOs. In addition, since OPOs must meet regulatory performance standards, it certainly is in their best interests to establish policies that are workable.

Comment: One commenter stated that the key to success of protocols for defining and referring donors will be ensuring that the burden on hospitals to carry out the protocols is not unduly heavy. The commenter suggested there should be some latitude in local protocols but that all protocols should strive to meet three criteria: (1) Ensuring that no medically suitable potential organ donor is missed; (2) minimizing the number of non-eligible cases that are referred; and (3) ensuring referral well before discontinuation of ventilation and cardiac arrest. Others echoed the third criterion in asking us to clarify that, whenever possible, referrals should be made when death is imminent to ensure that brain-dead or near brain-dead patients are maintained until a referral is made and are not referred to the OPO after mechanical support has been discontinued.

Response: We agree with the commenters' first and third criteria and believe the final rule will achieve these goals. OPOs are the entities familiar with the parameters for transplantable organs used by transplant hospitals and surgeons. Routine referral coupled with the OPO's determination of medical suitability increases the likelihood that no medically suitable potential donors are missed.

The requirement for timely referral at death or when death is imminent means that hospitals must make referrals both before a potential donor is removed from ventilator and while the potential donor's organs are still viable. Timely referral also means that the hospital must notify the OPO about potential donors early enough in the process to allow sufficient time for the family of the potential donor to make an informed decision about donation. We added these requirements to the final rule to minimize the possibility that organs will be lost to medical complications. One recent study noted that without aggressive support, cardiac arrest occurs in 20 percent of potential donors within 6 hours after the declaration of brain death and in 50 percent of donors within 24 hours. The authors conclude that delays in referrals may reduce the availability of organs since hemodynamic instability and cardiac arrest can develop relatively soon after brain death and emphasize that early identification and intervention are crucial for the successful recovery of organs. [Hauptman PJ, O'Connor KJ. ''Medical Progress: Procurement and Allocation of Solid Organs for Transplantation,'' *New England Journal of Medicine;* 336:422–431]

With respect to the commenters' second suggested criterion, we would prefer also to minimize the referrals of potential donors later determined not to be medically suitable. We believe such an approach is implicit in our current regulation which permits hospitals to develop protocols for potential donors and refer only those cases to OPOs. However, as discussed previously, this approach has resulted in a significant percentage of potential donors not being identified.

Comment: Some commenters suggested we include provisions and funding for public education, which could be a cooperative effort by the OPOs and hospitals. One commenter questioned the need for any of the provisions in the proposed rule and implied the best way to increase the donation rate is to educate the public.

Response: We agree with the commenters that public education about organ donation is important and a variety of efforts have been and will be needed to enhance public awareness of the benefits of organ donation. The Department of Health and Human Services launched the National Organ and Tissue Donation Initiative with dozens of partners in December 1997. One of the three goals of the initiative is to build public awareness about the essential role of families in consenting to donation. The initiative features the Coalition on Donation's message, ''Organ and Tissue Donation: Share your life. Share your decision'' to underscore the need for family discussion about donation. The Department also has a new site on the Internet at http://www.organdonor.gov to provide up-to-date information to the public about organ and tissue donation and transplantation.

However, we do not believe we should rely exclusively on that as a strategy to increase donation. If hospitals do not identify potential donors, if families of potential donors are not asked to donate, or if those families are asked in a way that is unlikely to lead to their consent for donation, then public support for organ donation is immaterial.

Comment: Several commenters suggested we expand the definition of organ to include small bowel or intestine.

Response: We will not expand the definition of organ at this time. Before moving forward, we will need to assess fully the policy considerations of expanding the definition of organ to include small bowel or intestine. However, we will retain these comments with a view toward consideration of expanding the definition of organ in a future regulation.

Comment: A rural hospital suggested we take into account rural frontier areas when finalizing the regulation. They pointed out that their closest tertiary facility is 300 miles away. Another commenter recommended an exemption from the regulation for hospitals without potential donors, such as those facilities that lack ventilator support capabilities, do not have ICUs and do not provide trauma, neurology or neurosurgery services.

Response: We do not intend to establish exemptions for particular types of hospitals at this time. We do not believe routine referral will be burdensome to these small hospitals, and we believe that the information provided to the OPOs through the referral calls made by these hospitals may prove to be useful for organ, tissue, or eye donation.

Comment: A commenter pointed out that studies have shown that transplant hospitals as a group are no more effective in organ donation than non-transplant hospitals. The commenter recommended an extra level of donation accountability for transplant hospitals.

Response: We believe the requirements contained in the final rule will maximize the number of transplantable organs yielded by every hospital, making it unnecessary to have a different level of accountability for transplant hospitals. We agree that transplant hospitals should be especially active in identifying potential donors. However, we intend to hold all hospitals to the same level of accountability, that is, to use their best efforts to respond to the critical organ shortage.

Comment: Three commenters described proposed regulations or existing laws in their States that require hospitals to develop their own protocols for organ donation. The commenters expressed concern that the proposed rule is in conflict with those State laws because it would remove a hospital's authority under State law to determine a potential donor's medical suitability.

Response: We do not believe the final rule is in conflict with the spirit of the State legislation described by the commenters, which appears to have been written for the purpose of increasing organ donation. We note that in the 1980s, 44 States and the District of Columbia passed legislation designed to increase organ donation by requiring hospitals to develop protocols for identifying potential organ donors and informing families of their option to donate, and it is clear from the research on potential donors that have not been identified by hospitals that the laws have been inadequate. In response, States have begun to pass routine referral laws. We would also point out that the Federal regulation would supersede both State law and State regulations to the extent that it presents otherwise irreconcilable conflicts with State policies.

Comment: One commenter had several questions related to how various issues should be handled in cases where two or more OPOs are operating in the same area, such as whether hospitals would be responsible for two or more sets of criteria from these OPOs.

Response: The regulations at 42 CFR Part 486, Conditions for Coverage for Organ Procurement Organizations, specifically § 486.316, states that HCFA designates only one OPO per service area. 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. Thus, a hospital would never be permitted nor required to have an agreement with more than one OPO at a time.

Hospitals' Provision of Transplant Data and Hospital Accountability

Comment: Several commenters urged us not to add outcome standards to the regulation because they would be too prescriptive. One commenter suggested individual hospitals should decide whether they need to monitor their outcomes.

Response: This regulation does not include numerical organ donation goals for hospitals.

Comment: An OPO pointed out that a hospital cannot (except with HHS approval) choose its OPO and is at the mercy of how well the OPO performs. The commenter suggested that to ensure hospitals' cooperation and to ensure they are not evaluated on the basis of their OPOs' performance, a provision be added to the final rule that states a hospital has met its obligations under section 1138 of the Act if it has entered into an agreement with an OPO designated by HCFA, the OPO certifies that the hospital has complied with the agreement and protocols, and the hospital has authorized the OPO to determine medical suitability and to make requests for donation.

Response: We see no need to include this specific language in the regulation. However, we would agree that if a hospital has met the requirements in the regulation, then it is likely the hospital has met its obligations under section 1138 of the Act, regardless of whether the OPO's performance has been satisfactory or unsatisfactory. Meeting the requirements of the regulation include, but are not limited to, referring all deaths to the OPO and ensuring that the family of every potential donor determined by the OPO to be medically suitable for donation has been advised of its donation options by an OPO representative or a designated requestor.

Comment: One commenter suggested oversight of the hospitals' actual participation in the process, which could be assured through death record reviews, audit results, or other record keeping to demonstrate the hospitals' level of compliance. The commenter added that this should be enforced by Medicare surveyors, and a second commenter urged us to discuss our plans for educating surveyors to ensure that hospitals will work assiduously to meet organ donor identification, referral and other related requirements. Another commenter suggested that hospitals be required to maintain records of a quality improvement process that supports its protocols. One commenter stated that they would support the inclusion of an assessment of organ donation procedures as part of a hospital's overall quality assessment and performance improvement process. The commenter added that such a provision would establish a hospital's accountability for actions it can control. Some commenters recommended including performance standards for hospitals to measure the variance between the number of potential donors, referrals, and actual donations. The commenters added that OPOs should participate in developing performance indicators based on documented best practices.

Response: Surveyors and HCFA regional offices will oversee compliance with the requirements of this regulation. However, surveyor procedures are beyond the scope of this regulation. The proposed rule for the hospital conditions of participation does not propose a specific set of quality indicators or objective performance measures be used. Instead, each hospital would be allowed flexibility to identify its own measures of performance for the activities it identifies as priorities in its quality assessment and performance improvement strategy. We recommend that every hospital make organ donation one of its priorities for quality assessment and performance improvement. Death record reviews are a powerful tool hospitals can use in their quality assessment and performance improvement strategies. In addition, we strongly recommend that OPOs perform death record reviews and advise hospitals of any failure to identify or refer potential donors or to advise families of potential donors of their donation options.

Comment: Many commenters suggested that the proposed rule must be strengthened to hold hospitals accountable if they do not cooperate with OPOs. Several commenters stated that the language of the proposed rule falls short of requiring hospital staff to cooperate with the OPO. One commenter suggested that we strengthen the language related to termination of participation in Medicare and Medicaid if a hospital does not cooperate. Another commenter added, ''We do not see how these proposed regulations will make a hospital with a ''lukewarm'' interest in donation become more actively involved in the process.''

Response: We believe the language of the final rule is unequivocal in requiring a hospital to refer all deaths to the OPO or a third party designated by the OPO, collaborate with the OPO in assuring that families of potential donors are advised of their donation options, and cooperate with the OPO and tissue and eye banks in reviewing death records and educating hospital staff in donation issues. This regulation is part of the conditions for hospital participation in the Medicare and Medicaid programs. Therefore, a hospital will jeopardize its Medicare and Medicaid certification should it fail to meet the requirements listed in the regulation.

Hospital Transplant Data

Comment: We received many comments about the requirement in the proposed rule for transplant hospitals to provide transplant-related data. Several commenters pointed out that the text of the proposed rule specifies that the data must be provided to the Organ Procurement and Transplantation Network, the Scientific Registry, the OPOs, and the Department of Health and Human Services, whereas the preamble language specifies that the data must be provided to the Organ Procurement and Transplantation Network, the Scientific Registry, the OPOs, or the Department of Health and Human Services. Commenters added that requiring hospitals to report data to all entities would be duplicative, burdensome, and would increase administrative costs.

Response: The information provided in the preamble was correct. The text of the final rule has been changed to state that the data must be provided as requested to the OPTN, the Scientific Registry, or the OPOs. The hospital must also provide data directly to the Department when requested by the Secretary. However, our intent is not to require hospitals routinely to report identical data to more than one entity, but rather to authorize direct requests by each of these entities.

Comment: Several commenters asked whether the intent of this provision is to require hospitals to provide tissue transplant data as well as organ transplant data. They pointed out that approximately 500,000 tissue transplants are performed annually in the U.S., and providing tissue transplant data would be a significant burden for hospitals.

Response: This requirement applies only to organ transplant data. The text of the regulation has been changed to clarify that hospitals must provide organ-transplant-related data.

Comment: Many commenters pointed out that the proposed rule was too vague regarding the type of data hospitals would be required to provide and how often they would be required to provide it. Commenters asked for reassurance that data requests will be reasonable.

One commenter suggested that we specify what data will be requested and allow time for meaningful comment. The commenter added, ''In the absence of this specificity, the claim on page 66754 of the **Federal Register** that these requirements are usual and customary in the conduct of hospital business are without foundation.'' Another commenter asked that we specify the branch of the Department that will receive the data.

Response: At this time, we have not determined the type of organ transplant data that may be requested by the Department. We included this provision to give the Department the flexibility to request data from transplant hospitals in the event that needed data cannot be obtained expeditiously from the OPOs, the OPTN, or the Scientific Registry. Data may be needed by HCFA, the Health Resources and Services Administration (HRSA), or the Office of the Secretary, but, under this regulation, data could be requested by any agency within the Department. Note that a similar provision regarding the mandatory reporting of data by transplant hospitals also is contained in a related regulation. [See final rule with comment period, Organ Procurement and Transplantation Network [98–HRSA–01, 63 FR 16295] published April 2, 1998, effective October 1, 1998.] In accordance with 42 CFR 121.11(a)(2)(record maintenance requirements for OPOs and transplant programs) and 121.11(b)(2) (reporting requirements for OPOs and transplant hospitals) these programs are required to maintain and report to the OPTN, the Scientific Registry, and the Secretary data concerning, among other things, each potential donor identified. Therefore, the requirement in this (HCFA) rule, when considered with the requirements in the OPTN rule, will enable the Department to obtain information routinely from all transplant hospitals and OPOs in support of donation programs under this authority.

Comment: Several commenters expressed concern about the confidentiality of the data and pointed out the extremely sensitive nature of transplant patient data. One commenter stressed that because the patient population is relatively small, it is difficult to protect patient confidentiality, even when patient identifiers are removed from the data.

Response: HCFA's primary intent is to use requested data internally to assess whether a transplant hospital is qualified to participate (or continue to participate) in the Medicare program and monitor organ donation. We agree that the confidentiality of donor and transplant recipient records must be protected and are confident that Federal and State laws provide adequate safeguards. No additional specific provisions to protect confidentiality are required in this regulation.

Comment: One commenter suggested that the public have access to all data provided by the transplant hospitals. However, several commenters warned that release of data without proper analysis and verification can result in dissemination of inaccurate or misleading information. One commenter noted that release of such data may harm individuals or have a negative impact on organ donation.

Response: Section 121.11(b)(1)(v) of the recent OPTN regulation [98–HRSA–01, 63 FR 16295] requires the OPTN and the Scientific Registry to provide data which is to be used for *bona fide* research or analysis purposes, to the extent that resources permit, or as directed by the Secretary. Section 121.11(b)(1)(vi) requires the OPTN and the Scientific Registry to provide data to the public. Section 121.11(b)(2) requires that hospitals and OPOs provide data directly to the Department upon request and that they may not impose restrictions on subsequent redisclosure. The Secretary has requested comments on whether the provisions ''sufficiently achieve the several important purposes served by providing information to the OPTN, the Department, and the public, while protecting patient privacy.''

Another related provision § 121.11, ''Public access to data'' provides that the Secretary may release to the public information that will serve the public interest. This information would include data on comparative costs and outcomes at different transplant programs, information on waiting list time, and information on the frequency with which transplant hospitals refuse offers of organs for their listed patients. The preamble to the OPTN regulation notes that release of this data is consistent with section 375 of the Public Health Service Act, 42 U.S.C. 274c, which directs the Department to provide information to patients, their families, and their physicians about transplantation resources and about the comparative costs and patient outcomes at each transplant hospital affiliated with the OPTN.

IV. Provisions of the Final Rule

We are adding § 482.45 in regulations to add the new requirements concerning organ procurement organizations and transplant hospitals. The final rule strengthens the role of OPOs in the donation process, encourages the use of best practices, and provides a framework for better collaboration among organizations involved in organ, tissue, and eye donation with the goal of making transplants more readily available to the many patients who need them. We are confident these revisions to the current hospital conditions of participation will narrow the gap between the number of deaths of patients on the waiting list and the number of organs available for transplant.

The final rule will enable hospitals and OPOs to take advantage of the most recent research in organ donation by using protocols that have proved successful for referring potential donors, obtaining family consent for donation, educating OPO and hospital staff, and reviewing death records. We have written the provisions of this final rule to enable hospitals and OPOs to take advantage of these best practices in order to increase organ donation rates nationwide.

In view of the research that has been done in the field of organ donation, the demonstrated increase in organ donation rates in States that have passed routine referral laws, and the comments we have received, we believe that routine referral of all deaths is the most effective way to increase organ donation rates substantially.

However, the final rule does not mandate how best practices are to be applied at the local level. It is designed to maximize organ donation while allowing local communities a certain amount of flexibility in applying the rule to their local situation. The rule takes this approach in order to encourage innovation at the local level and to assure that successful alternative approaches are not disrupted. For example, although the final rule specifies that the individual requesting donation from the family of a potential donor must be trained in the family consent process, it allows the hospital to decide whether that individual will be an OPO representative, a tissue bank or eye bank representative, or a hospital employee and encourages OPOs and hospitals to collaborate in defining how the process will occur [§ 482.45(a)(3)].

There are a number of sources of information and guidance about the most recent research in organ donation for OPOs and hospitals that want to ensure their protocols reflect best practices. One of these is The Partnership for Organ Donation, Inc., Two Oliver St., Boston, MA 02109–4901. The Partnership is an independent, nonprofit organization that sponsors research in organ donation and has worked with hospitals and

OPOs across the United States to improve organ donation.

The current regulations require the governing board of a hospital to have a written protocol to identify potential organ donors and carry out the other requirements of section 1138 of the Act. We have revised how these requirements are articulated, in keeping with the way in which we are generally transforming these conditions of participation for hospitals. The final rule requires that the hospital actually carry out specified responsibilities. For example, the hospital must contact the OPO or its designee about every death or imminent death that occurs in the hospital. This requirement will relieve the hospital of the responsibility for keeping current with changing potential donor criteria and determining the medical suitability of potential organ donors (unless the hospital has an alternative arrangement with its tissue and eye banks in which the hospital determines the medical suitability of tissue and eye donors) and will ensure that no potential donors are missed.

The Commonwealth of Pennsylvania passed legislation effective in March 1995, requiring that hospitals report all deaths to the OPO. The OPO for southeastern Pennsylvania, Delaware and southern New Jersey (Delaware Valley Transplant Program) has seen a 40 percent increase in organ donation since enactment of the law. In contrast, since 1990, the organ donation rate nationwide has increased an average of less than 3 percent per year and, as noted above, remained essentially unchanged in 1997. Other OPOs that have instituted routine referral within some hospitals in their service areas have seen similar, substantial increases in those hospitals. One OPO reported that two of their hospitals had their first organ donors in 1997, yielding five organs for transplantation. Another OPO that uses routine referral has seen their consent rate for organ donation among African Americans rise from 32.7 percent in 1991 to 68.9 percent in 1997.

The final rule specifies that the hospital must ensure, in collaboration with the OPO, that the family of each medically suitable potential donor identified by the OPO is advised of the right to donate or decline to donate. This provision is based on research that indicates that consent to organ donation is highest when the formal request is made by OPO staff or by OPO and hospital staff together rather than by hospital staff alone. While we require collaboration, we also recognize that hospital staff may wish to perform this function and may do so when properly trained. Under this final rule, the hospital may choose to have OPO staff contact potential donor families, have hospital and OPO staff jointly perform this function, or rely exclusively on hospital staff. If hospital staff, rather than organ procurement coordinators, initiate the request for donation to the family, it is important that they be trained in best practices for advising the family of their options and initiating the request for donation. Therefore, the rule requires that hospital staff who initiate the request for donation must be designated requestors. A designated requestor is defined in the regulation as an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology of approaching potential donor families and requesting organ or tissue donation. The Pennsylvania routine referral legislation also requires that hospital employees complete a course in how to approach families and explain their donation options.

One recent study demonstrated a 47 percent increase in consent rates when best practices are used. [Gortmaker SL, Beasley CL, Sheey E, et al, unpublished data] Another recent study demonstrated that training of hospital staff about protocols for organ donation is significantly associated with superior rates of organ donation. However, the study also demonstrated that current levels of training about organ donation are inadequate. [Evanisko MJ, Beasley, CL, Brigham, LE ''Readiness of Critical Care Physicians and Nurses to Handle Requests for Organ Donation.'' *American Journal of Critical Care* (1998; 7:4–12]

The final rule requires a hospital to ensure that it works cooperatively with the OPO, a tissue bank, and an eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors during necessary testing and placement of donated organs and tissues [§ 482.45(a)(5)]. Review of death records is the key method an OPO uses to determine a hospital's donor potential. It allows the hospital to develop strategies for improving donation and allocating resources to educate hospital staff. Review of death records also enables hospitals to recognize missed opportunities for organ donation and to identify hospital, OPO, and recovery staff who may need additional education.

The final rule mandates that a hospital have an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage, and distribution of tissues and eyes [§ 482.45(a)(2)]. This agreement can be used to spell out whether the OPO will determine medical suitability for tissue and eye donation and handle the referral process for tissue and eye donors or whether an alternative referral process will be used. If the OPO determines medical suitability and refers tissue and eye donors, it must do so using the definition of potential tissue and eye donor and a notification protocol developed in consultation with the tissue bank and eye bank designated by the hospital. An alternative arrangement might, for example, specify that the hospital will refer potential tissue and eye donors directly to the tissue bank and eye bank. We added these requirements in the final rule to ensure that tissue and eye banks have potential tissue and eye donors referred to them appropriately and expeditiously. It is important to note when discussing agreements between hospitals, tissue banks and eye banks, that some OPOs are also tissue and/or eye banks. This regulation does not preclude a hospital from having a single agreement with such an OPO which encompasses the services the OPO will provide in regard to organs, tissues, and eyes, in lieu of separate agreements with an OPO, a tissue bank, and an eye bank.

The final rule stresses cooperation and collaboration between all parties. It is our expectation that in communities where hospitals, OPOs, and tissue and eye banks have not yet developed cooperative relationships, these requirements will encourage all parties to work together with the best interests of their communities in mind to establish protocols that will increase organ, tissue, and eye donation rates.

The final rule requires transplant centers to provide requested organ-transplant-related data to the OPTN, the Scientific Registry, the OPO, or the Department, as requested by the Secretary [§ 482.45(b)(3)]. Currently, transplant centers report data to the OPTN, the OPO, and the Scientific Registry regarding the disposition of organs made available for transplant. These data include information regarding why a center declines the offer of a donated organ, information regarding patients waiting for transplants, information on those who have received a transplant, follow-up data on patients who have received a transplant, and information on those offered an organ for transplant but declining to use the organ at the time. At the time the proposed rule was published, submission of these data by transplant centers to the OPTN was voluntary.

However, a final rule with comment period, Organ Procurement and Transplantation Network [98–HRSA–01, 63 F.R. 16295, published April 2, 1998, effective October 1, 1998] has made reporting by transplant centers mandatory. In accordance with 42 CFR 121.11(a)(2) (record maintenance requirements for OPOs and transplant programs) and 121.11(b)(2) (reporting requirements for OPOs and transplant hospitals) these programs are required to maintain and report data to the OPTN, the Scientific Registry, and the Secretary. Therefore, the requirement in this HCFA final rule, when considered with the requirements in the OPTN rule, will ensure that data will be available to implement section 1138 of the Act to operate the OPTN and to obtain information from the Scientific Registry, and to provide information to the Secretary, patients, their families, physicians, and the public.

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety effects, distributive impacts, and equity.

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) requires agencies to analyze options for regulatory relief for small entities. Consistent with the RFA, we prepare a regulatory flexibility analysis 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 treat most hospitals and most other providers, physicians, health care suppliers, carriers, and intermediaries as small entities, either by nonprofit status or by having revenues of $5 million or less annually. 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. That analysis must conform to the provisions of section 603 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 Metropolitan Statistical Area and has fewer than 50 beds.

The Unfunded Mandate Reform Act of 1995 requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits for any rule that may result in an annual mandated expenditure by State, local, and tribal governments, in the aggregate, or by both the private sector, of $100 million. The notice has no mandated consequential effect on State, local, tribal governments, or the private sector and will not create an unfunded mandate.

We have determined that this regulation is economically significant under E.O. 12866 and a major rule for purposes of Congressional review of agency rulemaking.

We do not anticipate that the provisions in this final rule will have a substantial economic impact on most hospitals, including small rural hospitals. However, we believe it is desirable to inform the public of our projections of the likely effects of the final rule on hospitals, small rural hospitals, OPOs, tissue banks, and eye banks.

There are several provisions in this regulation that will impact hospitals to a greater or lesser degree. Specifically, hospitals will be required to have written protocols; have agreements with an OPO, a tissue bank, and an eye bank; refer all deaths that occur in the hospital to the OPO; ensure that hospital employees who initiate a request for donation to the family of a potential donor have been trained as ''designated requestors''; and work cooperatively with the OPO, tissue bank, and eye bank in educating hospital staff, reviewing death records, and maintaining potential donors. It is important to note that because of the inherent flexibility of this regulation, the extent of the economic impact of most of these requirements is dependent upon decisions which will be made either by the hospital or by the hospital in conjunction with the OPO and/or the tissue and eye banks. Thus, the impact on individual hospitals will vary and is subject in large part to their decision making. The impact will also vary according to each hospital's current organ donation protocols and level of compliance with existing law and regulation. For example, eight States already have routine referral legislation, and in several other States, OPOs and hospitals have routine referral agreements.

The first requirement in the regulation is that hospitals have and implement written protocols that reflect the various provisions of the regulation. Currently, under section 1138 of the Act and the existing regulation, hospitals must have written protocols for organ donation. Most hospitals will need to rewrite their existing protocols to conform with this regulation; however, this is clearly not a requirement that imposes a significant economic burden.

In addition, a hospital must have an agreement with its designated OPO and with at least one tissue bank and at least one eye bank. Although the current regulation does not specifically require an agreement with an OPO, hospitals are required under section 1138 of the Act and the existing regulation to refer all potential donors to an OPO. Also, the OPO regulation at 42 CFR 486.306 requires, as a qualification for designation as an OPO, that the OPO have a ''working relationship'' with at least 75 percent of the hospitals in its service area that participate in the Medicare and Medicaid programs and that have an operating room and the equipment and personnel for retrieving organs. Therefore, presumably most hospitals already have some type of agreement with their designated OPO. Although hospitals may need to modify those existing agreements, the need to make modifications would not impose a significant economic burden. The current regulation does not require hospitals to have agreements with tissue and eye banks. However, we must assume most hospitals have agreements with tissue and eye banks, since hospitals are the source for virtually all tissues and eyes.

The provision of the regulation that will have the most impact on hospitals is the requirement to notify the OPO about every death that occurs in the hospital. Approximately 400 deaths per year occur in the average hospital in the U.S. If the average notification telephone call to the OPO takes five minutes, the hospital will need approximately four person days per year to make the calls. We believe this is a generous estimate. One OPO has reported that the referral calls hospitals make to the vendor that handles their referral calls average one minute, 20 seconds. An OPO in a State with routine referral estimates the calls they receive from hospitals, on average, last no more than three to five minutes. (A call about a ventilator dependent patient might last an hour, but, of course, these calls are infrequent.)

Most likely, additional time would be needed by the hospital staff person to annotate the patient record or fill out a form regarding the disposition of the call. This paperwork should take no more than five minutes. Therefore, paperwork associated with the call might add approximately four person days per year.

In summary, the impact of referring all deaths to the OPO should be limited to approximately eight person days per year. Thus, the economic impact for a hospital of referring all deaths will be small. Although small rural hospitals have fewer staff than the average hospital, there are also fewer deaths to report. Therefore, the impact on small rural hospitals of notifying OPOs of all deaths would be commensurately small.

Under the regulation, a hospital may agree to have the OPO determine medical suitability for tissue and eye donation or may have alternative arrangements with a tissue bank and an eye bank. These alternative arrangements could include the hospital's direct notification of the tissue and eye bank of potential tissue and eye donors or direct notification of all deaths. If a hospital chose to contact both a tissue bank and an eye bank directly on all deaths, it would need a total of 16 person days per year (i.e., five minutes per call (four person days) and five minutes for paperwork (four person days) in order to call both the tissue and eye bank directly). Again, the impact is small, and the regulation permits the hospital to decide how this process will take place. Note that many communities already have a one-phone-call system in place, and this regulation does not preclude, and in fact encourages, these local systems. Also, some OPOs are also tissue banks and/or eye banks. A hospital that chose to use the OPO's tissue and eye bank services in these localities would need to make only one telephone call on every death.

This regulation requires that the individual who initiates a request for donation to the family of a potential donor must be an OPO representative or a ''designated requestor.'' A designated requestor is an individual who has taken a course offered or approved by the OPO in the methodology for approaching families of potential donors and requesting donation. It is difficult to estimate how much hospital staff time will be needed for designated requestor training, as it is dependent both upon the length of the course and the number of employees the hospital wishes to have trained. An OPO in a State with similar legislation has a one-day training course for its designated requestors. The Partnership for Organ Donation, an independent, nonprofit organization that sponsors research in organ donation and work with hospitals and OPOs to improve organ donation, offers intensive two-day training for hospital donation teams. Even if the OPO requires a two-day training course and the hospital wants to have a sufficient number of designated requestors to ensure that all shifts are covered, this provision of the regulation would not have a significant economic impact on hospitals. In addition, the hospital may choose to have donation requests initiated by the OPO staff rather than hospital staff, in which case there is no economic impact.

The regulation requires a hospital to work cooperatively with the OPO, a tissue bank, and an eye bank in educating hospital staff. We do not believe education of hospital staff will demand a significant amount of staff time. For example, the Pacific Northwest Transplant Bank recently worked with the Oregon Health Sciences University to educate all 400 nurses and all staff physicians, chaplains, social workers, and medical interpreters. The OPO transplant coordinator gave a 15-minute presentation highlighting staff responsibilities and changes in the hospital protocol, with an emphasis on a more sensitive family approach. Presentations were given at times convenient for the staff, such as at regular staff meetings and before and after shift reports. Clearly, such brief educational presentations, even if given once a year or more often, would not have a significant impact on hospitals. Also, most OPOs currently have educational programs for their hospitals. For example, one OPO has one full-time and eight part-time staff devoted to hospital staff training for the hospitals in their service area.

The regulation requires a hospital to work cooperatively with the OPO, a tissue bank, and an eye bank in reviewing death records. Most OPOs currently conduct extensive hospital death record reviews. The hospital's assistance is required only to provide lists of hospital deaths and facilitate access to records.

Finally, the regulation requires a hospital to work cooperatively with the OPO, a tissue bank, and an eye bank in maintaining potential donors while necessary testing and placement of potential donated organs and tissues take place. If this regulation is successful in increasing organ donation, hospitals will have more brain dead potential donors to maintain until family consent is obtained and the donors' organs are removed. As referenced earlier, The OPO for southeastern Pennsylvania, Delaware and southern New Jersey (Delaware Valley Transplant Program) has seen a 40 percent increase in organ donation since enactment of routine referral legislation in Pennsylvania in 1995. In contrast, since 1990, the organ donation rate nationwide has increased an average of less than 3 percent per year. Of course, we must take into account the fact that eight States have some type of routine referral legislation, although most of it is quite recent. Therefore, if we assume that this regulation will result in a more modest increase of 20 percent (10 percent or 548 additional donors per year) in the two years following the effective date, there will be approximately 1,096 additional donors in that two-year period (based on the 5,475 organ donors in 1997). (Note that the goal of the Organ and Tissue Donation Initiative is an increase in the organ donation rate of 20 percent in two years.) However, since there are approximately 5,200 short stay hospitals in the U.S., the additional number of donors per hospital would be quite small.

It is possible that because of the final rule, some small rural hospitals may have their first organ donors. Therefore, we considered the impact on a rural hospital of maintaining a brain dead potential donor on a ventilator until the organs can be placed. Small rural hospitals with full ventilator capability should have no trouble maintaining a potential donor until the organs are placed. However, some small rural hospitals have ventilator capability only so that a patient can be maintained until he or she is transferred to a larger facility for treatment. These hospitals would have the equipment and staffing to maintain a potential donor until transfer to another facility occurs. Many small rural hospitals do not have ventilator capability and would be unable to maintain a potential donor however, small rural hospitals without ventilator capability will still be obligated to notify the OPO, or a third party designated by the OPO, of all individuals whose death is imminent or who have died in the hospital. We do not believe there will be a significant impact on small rural hospitals no matter what their situation—full ventilator capability, ventilator capability only for patients who are to be transferred to a larger facility, or no ventilator capability.

It is important to estimate the costs to OPOs of screening the significant number of additional calls they will receive. There are 63 OPOs that will receive the referral calls generated by the approximately 2,080,000 hospital deaths per year. This means that the average OPO will receive 33,016 referral calls per year (90 referral calls per day). An OPO may choose to hire a third party vendor to triage the phone calls or may hire staff to handle the calls in-house. Currently, some OPOs use a combination of systems, with OPO staff

handling calls received during business hours and a vendor handling calls received during non-business hours. One OPO that uses a vendor pays $1,200 per month for the first 300 calls and $3.20 per call for each additional call. The vendor's staff enters all necessary information into a database that can be accessed by the OPO and also contacts the tissue and eye banks on every call. One vendor that triages calls for a number of OPOs charges $5 to $10 per call, depending upon the type of services desired.

An OPO that chooses to have calls handled by OPO staff will have costs for staff training, additional telephone lines and computers, and computer software upgrades. One OPO in a State with routine referral legislation, has 70 percent of the 32,000 calls it receives every year handled by a vendor and the remainder handled by OPO staff. An OPO representative estimated their start-up costs to be approximately $40,000. The OPO pays the vendor $180,000 per year and spends $220,000 per year on salary and benefits for the additional staff that is needed for routine referral. The OPO has also seen their telephone charges increase by about 50 percent. However, in spite of these costs, the OPO has maintained its organ acquisition costs below the national average. A representative from an OPO in a State that recently passed routine referral legislation called its start-up costs ''significant.'' However, in the seven-month period since the legislation went into effect, the OPO's organ donors have increased by 70 percent (when compared to the nine-month period prior to the legislation), while its organ acquisition cost has risen just 3 percent.

It is clear that set-up costs for OPOs to handle the increased calls resulting from routine referral are significant. They include costs for improving communications and computer systems and hiring and training staff. Likewise, ongoing costs for OPOs of handling the increased calls are significant. The OPO that pays its vendor $1,200 per month for the first 300 calls and $3.20 per call for each additional call would spend approximately $105,280 to screen 32,000 calls per year. An OPO that uses a vendor that charges $10 per call would spend $320,000 per year to screen 32,000 calls. An OPO that uses both a vendor and OPO staff might spend more than $400,000 per year to screen 32,000 calls. However, the critical issue is whether the acquisition cost per organ will increase significantly. The acquisition cost per organ is a function not only of the cost per call, but the number of calls required for each organ, given the system set up by the OPO. Based on the experience of some OPOs in States with routine referral, these costs are likely to remain the same or increase only slightly.

We received many comments about the proposed rule which expressed concern that the regulation would have a negative impact on tissue and eye banks. A few commenters even predicted that some eye banks would be forced out of business. However, the final rule contains safeguards to ensure that OPOs consult with tissue and eye banks in establishing protocols for identifying and referring tissue and eye donors to the tissue banks and eye banks chosen by the hospital. Therefore, we do not believe there will be a significant impact on a substantial number of tissue and eye banks.

We expect that this regulation will increase tissue and eye donations as well as organ donations. A study of the impact of the Pennsylvania routine referral legislation on tissue and eye donations was presented at the Fourth International Society for Organ Sharing Congress and Transplant Congress in July 1997. [Nathan, HM, Abrams, J, Sparkman BA, et al. ''Comprehensive State Legislation Increases Organ and Tissue Donations'] This study used data from the Delaware Valley Transplant Program, the OPO for southeastern Pennsylvania, and found that although the maximum donor age was lowered from <66 to <60, tissue donations increased 14 percent from 1994 through 1996. The study also showed that eye donations increased 28 percent during the same period, despite more restrictive donor criteria. This virtually eliminated the waiting list for suitable corneas. North Carolina's routine referral legislation became effective in October 1997. The Carolina Organ Procurement Agency (one of three North Carolina OPOs) has seen heart valve donations increase by 109 percent and other tissue donations increase 114 percent through May 1998.

As discussed earlier, we expect this regulation will result in an additional 1,096 donors in the first two years after it goes into effect. In 1997, there were 3.11 organs transplanted for every organ donor (17,032 cadaveric transplants from 5,475 organ donors). Therefore, an additional 1,096 donors could result in an additional 3,409 transplants, that is, an additional 3,409 lives being improved or saved in the first two years of the regulation.

Transplants are performed both to save lives and to improve the quality of recipients' lives. In the case of kidneys, dialysis is an alternative to transplantation for extended periods of time. Therefore, for most patients, kidney transplantation is not necessary for survival, but it does significantly improve the quality of the transplant recipient's life. Physical health while on dialysis is significantly impaired, and dialysis imposes major stresses and substantial inconveniences in carrying out normal activities. Of the 17,032 transplants from cadaveric donors performed in 1997, slightly more than half (50.4 percent), or 8,584, were kidney transplants.

For all other organs, a transplant is, in most cases, necessary for survival. In the first two years, this regulation will result in approximately 1,718 (50.4 percent of 3,409) lives vastly improved by kidney transplants and 1,691 (49.6 percent of 3,409) lives both vastly improved and prolonged by transplantation of other major organs.

The following reasoning was used to construct a benefit cost analysis in the OPTN regulation. It is common, in benefit cost analysis, to use a concept termed ''value of a statistical life'' to estimate in monetary terms the benefits from lives saved. Estimates of this value can be derived from information on the preferences of individuals for reduction in the risk of death, and their willingness to pay for such reductions. In this case, however, it is important to take into account two major factors that reduce the usefulness of a statistical life as a measure: (a) most organ transplant recipients are much older than average and hence gain fewer years than would average beneficiaries of other lifesaving interventions, and (b) an organ transplant carries a substantial risk of either the graft or the patient not surviving. For example, according to historical data from the 1997 Annual Report of the OPTN (page 23), only 62 percent of cadaveric kidney grafts survive 5 years, and only 81 percent of these patients survive 5 years (patient survival is substantially higher because dialysis is usually an option if the organ fails). Five year patient survival rates for livers are 72 percent, for hearts 67 percent, and for lungs 43 percent. As each year passes, additional patients die, though at lower rates than in the first year or two. Survival rates have improved in recent years, but the statistical expectation of increased longevity and/or graft survival from a transplant is on the order of a dozen years (a rough estimate since we do not yet know what the long-term experience will become), not the 40 years (half a lifetime) that underlies most estimates of statistical lives. Using the more conservative concept of a ''statistical life-year'' saved, then, the benefit from 1,691 non-renal transplant recipients

approximates 20,292 life years in the first two years of the regulation.

In a recent rulemaking on tobacco, HHS estimated the value of a statistical life-year at about $116,000 (see **Federal Register** of August 28, 1996, at page 44576). This was a conservative estimate that would reasonably apply to organ procurement and transplantation (though a figure several times as high could equally reasonably be used). Applying the conservative $116,000 value to statistical life-years saved by non-renal organ transplants, the social benefit from 1,687 non-renal transplants is approximately $2,353,872,000 in the first two years of the regulation.

In order to calculate the transplantation costs that will occur because of this regulation, we have used five-year costs, which include follow-up costs. The OPTN regulation uses Milliman and Robertson's estimates for the five-year cost of major organ transplants (adjusted for survival). They are as follows: liver, $394,000; heart, $317,000; lung, $312,000; heart-lung, $351,000; pancreas, $149,000; and kidney $172,000. According to HCFA actuaries, kidney transplantation costs are offset by reductions in other medical costs over time, such as dialysis costs.

In 1997, 24 percent of transplants performed were liver transplants, 13 percent were heart transplants, 5 percent were lung transplants, 6 percent were pancreas transplants, and 1/3 of one percent were heart-lung transplants. Slightly more than half of all major organ transplants in 1997 were kidney transplants. (Figures are approximate.)

Earlier we postulated a 20 percent increase in organ donation in a two-year period, resulting in an additional 1,096 donations and 3,409 organs transplanted in the first two years after the effective date of the legislation. If we assume that all the gains from the regulation occur in the first two years (that is, the number of additional donors remains at 1,096 in every two-year period) or 584 per year, the number of additional donors due to this regulation would stand at approximately 2,740 (5 years X 548 donors per year) in a five-year period, and the number of additional transplants would stand at 8,521.

Using 1997 percentages, we would expect that during the five year period following the effective date of this regulation, there would be an additional 2,045 liver transplants, 1,108 heart transplants, 426 lung transplants, 28 heart-lung transplants, and 511 pancreas transplants. Therefore, the approximate overall five-year cost of the additional non-renal organ transplants would be as follows: liver, $805,730,000; heart, $351,236,000; lung, $132,912,000; heart-lung, $9,828,000 and pancreas, $76,139,000, for a total greater than $1,375,845,000. As stated earlier, kidney transplant costs are offset overtime by reductions in other medical costs, such as kidney dialysis. Therefore, we did not include the costs of kidney transplants in the calculation of the overall five year transplantation costs. Some offsetting reductions in medical costs for other types of transplants are also likely, but are not as readily quantifiable.

We also calculated the statistical and social benefits from the 4,118 non-renal transplants during a five-year period. Using our earlier methodology, the five year statistical and social benefits would be as follows: 49,416 additional life-years and $5,732,256,000 additional social benefit.

Below, provided by HCFA actuaries, are estimated costs to the Medicare program resulting from additional organ transplants.

ESTIMATED COSTS TO THE MEDICARE PROGRAM

Fiscal year	Cost (millions)
1999	35
2000	75
2001	115
2002	160
2003	200
2004	240

These estimates include both the cost of the transplants and follow-up medical care, adjusted for patient survival. Costs increase every year because each year's cost includes transplants performed in that year plus medical care for those transplant recipients who received transplants in previous years. Thus, the impact in each year was calculated as the sum of the number of transplants in that year plus the cost of patient graft survivals. Our analysis indicates that administrative costs to the Medicare budget are minimal.

Cost estimates were adjusted for:

- Normal annual percentage increase in organ donation and transplantation that would occur independent of the impact of this regulation;
- The fact that the Medicare population tends to be sicker than the general transplant population;
- The fact that approximately ⅓ of kidney transplant recipients leave Medicare end stage renal disease (ESRD) rolls after three years if the transplant is successful; and
- Reduced costs to the Medicare program for kidney transplant recipients because they no longer need dialysis.

HCFA actuaries also estimated the cost to the Medicare program of transplants and follow-up medical care for transplant recipients in FY 2004 *without* the regulation to be $1,630,000,000. Total costs to the Medicare program in FY 2004 *with* this regulation total $1,870,000,000 ($1,630,000,000 + $240,000,000). Thus, the regulation will increase the cost to the Medicare program and associated medical care by approximately 15 percent in FY 2004.

Note the cost estimate for 1999 does not include the first three months of FY 1999. Although the regulation's effective date will be in August 1998, it is not expected that there will be an impact on the Medicare budget until January 1, 1999.

We attempted to compare the costs to hospitals and OPOs of the proposed regulation and the final regulation. The proposed regulation would have permitted OPOs to define both ''potential donor'' and the notification protocol hospitals would use to refer potential donors. We cannot quantify the costs of implementing the proposed regulation because we have no way of knowing with any certainty, what the individual OPOs would decide to do if given the responsibility of deciding which deaths would be referred by their hospitals. Some OPOs might exclude individuals by age; other OPOs might exclude individuals by clinical category (e.g., HIV positive or metastatic cancer). However, even absent a comparison of costs, we believe the final regulation is a more effective mechanism to increasing organ donation. Referring all deaths is a better approach because it creates a clear standard for hospitals to follow, it ensures that hospitals will not erroneously assume that a potential donor should be excluded, it allows early intervention by the OPO to guide the organ and tissue procurement process to ensure a successful outcome, and will make it easier to standardize transplantation waiting time.

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

VI. Collection of Information 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. In order to fairly evaluate whether an information collection should be approved, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements summarized and discussed below.

Section 482.45(a) Standard: Organ Procurement Responsibilities

The burden associated with the requirements of this section include; (1) the requirement to maintain protocol documentation demonstrating that the five requirements of this section have been met, (2) the requirement for a hospital to notify an OPO and/or tissue bank of a death, and (3) the time required for a hospital to document and maintain OPO referral information.

We estimate that, on average, the requirement to maintain protocol documentation demonstrating that the requirements of this section have been met will impose one hour of burden per hospital (on 5,200 hospitals) on an annual basis (a total of 5,200 annual burden hours).

The burden associated with the requirement for a hospital to notify an OPO of every death that occurs in the hospital is estimated to be approximately 400 calls per year in an average hospital, multiplied by five minutes per call, for a total annual burden of 34 hours per hospital (a total of 176,800 annual burden hours). We believe this is a generous estimate. One OPO has reported that the referral calls hospitals make to the vendor that handles their referral calls average one minute, 20 seconds. An OPO in a State with routine referral estimates the calls they receive from hospitals, on average, last no more than three to five minutes. (A call about a ventilator dependent patient might last an hour, but, of course, these calls are infrequent.)

In addition, time would be needed by the hospital staff person to annotate the patient record or fill out a form regarding the disposition of the call. The burden associated with this activity is estimated that be five minutes per call, multiplied by 400 calls, for an annual burden of 34 burden hours per hospital (a total of 176,800 annual burden hours).

Under the regulation, a hospital may agree to have the OPO determine medical suitability for tissue and eye donation or may have alternative arrangements with a tissue bank and an eye bank. These alternative arrangements could include the hospital's direct notification of the tissue and eye bank of potential tissue and eye donors or direct notification of all deaths. If a hospital chose to contact both a tissue bank and an eye bank directly on all deaths, it would need an additional 68 annual hours of burden per hospital (a total of 353,600 annual burden hours), (i.e., five minutes per call and five minutes for paperwork in order to call both the tissue and eye bank directly). Again, the impact is presumed to be small, since the regulation permits the hospital to decide how this process will take place. It should be noted that many communities already have a one-phone-call system in place, and this regulation does not preclude, and in fact encourages, these local systems. Also, some OPOs are also tissue banks and/or eye banks. A hospital that chose to use the OPO's tissue and eye bank services in these localities would need to make only one telephone call on every death.

Section 482.45(b) Standard: Organ Transplantation Responsibilities

If a hospital performs any type of transplants, it must provide organ-transplant-related data as requested by the Organ Procurement and Transplantation Network (OPTN), the Scientific Registry (SR), or the organ procurement organizations (OPOs). The hospital must also provide such data directly to the Department of Health and Human Services when requested by the Secretary.

The new reporting requirement imposed with this section, which is subject to the PRA, is the requirement on an estimated 300 transplant hospitals to provide data to 63 OPOs. Based upon discussions with industry representatives the data that will be requested by the OPO's is data currently requested and supplied by transplant hospitals to the OPOs. Therefore, we are assigning one token-hour for the burden associated with this requirement.

The burden related to the requirement for a hospital to provide data to the OPTN and SR is currently imposed by the Health Resources and Services Administration and is approved under OMB number 0915–0157, with an expiration date of 10/31/99. The burden associated with these requirements ranges from .1 hour to .4 hours per submission, depending on donor type. On an annual basis the total number of submissions is 285,600 for a total burden of 39,970 hours. The remaining requirement that data may be requested by the Secretary, would be collected on an individual basis and/or during the pursuit of an administrative action, audit, or investigation, and is therefore not subject to the requirements of the PRA as defined under 5 CFR 1320.3 (h)(6) and 1320.4.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements in *§§ 482.45(a) and 482.45(b).* These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850. Attn.: John Burke HCFA–3005–P

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503. Attn.: Allison Herron Eydt, HCFA Desk Officer

List of Subjects in 42 CFR Part 482

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

For reasons set forth in the preamble, 42 CFR chapter IV is amended as follows:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

1. The authority citation for part 482 continues to read as follows:

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

Subpart B—Administration

§ 482.12 [Amended]

2. In § 482.12, paragraph (c)(5) is removed.

Subpart C—Basic Hospital Functions

3. A new § 482.45 is added to subpart C to read as follows:

§ 482.45 Condition of participation: Organ, tissue, and eye procurement

(a) *Standard: Organ procurement responsibilities.* The hospital must have and implement written protocols that:

(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;

(2) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(b) *Standard: Organ transplantation responsibilities.* (1) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term ''rules of the OPTN'' means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(2) For purposes of these standards, the term ''organ'' means a human kidney, liver, heart, lung, or pancreas.

(3) If a hospital performs any type of transplants, it must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the Department when requested by the Secretary.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare Hospital Insurance; Program No. 93.778, Medical Assistance Program)

Dated: June 15, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: June 16, 1998.

Donna E. Shalala,

Secretary.

[FR Doc. 98–16490 Filed 6–17–98; 10:12 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73 and 74

[MM Docket No. 98–93; FCC 98–117]

1998 Biennial Regulatory Review—Streamlining of Radio Technical Rules

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: On June 15, 1998, the Commission released a Notice of Proposed Rule Making and Order. The Commission adopted a number of changes in this proceeding to promote greater technical flexibility in the FM service and to streamline and expedite the processing of applications in several services.

EFFECTIVE DATE: July 22, 1998.

FOR FURTHER INFORMATION CONTACT: Peter Doyle, Dale Bickel or William Scher, Audio Services Division, Mass Media Bureau (202) 418–2780.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rule Making and Order* (*Order*) in MM Docket No. 98–93 and FCC No. 98–117, adopted June 11, 1998 and released June 15, 1998. The complete text of this *Order* is available for inspection and copying during regular business hours in the FCC Reference Center (Room 239), 1919 M St., N.W., Washington, D.C. 20554 and may also be purchased from the Commission's copy contractor, International Transcription Service, (202) 857–3800 (phone), (202) 857–3805 (facsimile), 1231 20th St., N.W., Washington, D.C. 20036.

Synopsis of Order

1. The Commission is making a number of amendments to the FM technical rules in order to clarify existing rules. Because these amendments are non-controversial and will have no adverse effect on any party, we find that notice and comment procedures are unnecessary and need not be followed prior to their adoption.

Ordering Clauses

2. *Accordingly, it is ordered,* that these minor rule changes shall become effective July 22, 1998.

List of Subjects

47 CFR Part 73

Radio, reporting and recordkeeping requirements.

47 CFR Part 74

Radio, reporting and recordkeeping requirements.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

Rule Changes

Accordingly, Parts 73 and 74 of Title 47 of the Code of Federal Regulations are amended as follows:

PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

2. Amend § 73.45 by revising paragraph (c) introductory text and paragraph (c)(2) to read as follows:

§ 73.45 AM antenna systems.

* * * * *

(c) Should any changes be made or otherwise occur which would possibly alter the resistance of the antenna system, the licensee must commence the determination of the operating power by