Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Medicare Conditions of Participation for Organ Donation:

An Early Assessment of the New Donation Rule

JUNE GIBBS BROWN
Inspector General

AUGUST 2000
OEI-01-99-00020

OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, is to protect the integrity of the Department of Health and Human Services programs as well as the health and welfare of beneficiaries served by them. This statutory mission is carried out through a nationwide program of audits, investigations, inspections, sanctions, and fraud alerts. The Inspector General informs the Secretary of program and management problems and recommends legislative, regulatory, and operational approaches to correct them.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) is one of several components of the Office of Inspector General. It conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The inspection reports provide findings and recommendations on the efficiency, vulnerability, and effectiveness of departmental programs.

OEI's Boston Office prepared this report under the direction of Mark R. Yessian, Ph.D., Regional Inspector General. Principal OEI staff included:

REGION

Russell W. Hereford, Ph.D., *Project Leader*
Maria E. Maddaloni, M.A., *Program Analyst*

HEADQUARTERS

Alan Levine, *Program Specialist*
Barbara Tedesco, *Mathematical Statistician*
Linda Moscoe, *Program Analyst*

To obtain copies of this report, please call the Boston Regional Office at 617-565-1050.
Reports are also available on the World Wide Web at our home page address:

http://www.hhs.gov/oig/oei

EXECUTIVE SUMMARY

PURPOSE

To provide an early assessment of hospitals' and organ procurement organizations' responses to Medicare conditions of participation designed to increase organ donation.

BACKGROUND

More than 71,000 Americans are waiting for organ transplants, yet only 22,000 received organ transplants last year. More than 6,000 people died while awaiting a transplant.

As many as 15,000 deaths occur annually that could yield suitable donor organs. Yet fewer than 6,000 of those deaths result in the donation of an organ.

In June 1998, the Health Care Financing Administration (HCFA) changed the Medicare conditions of participation to spur an increase in donation. In this report, we refer to this new condition as the "donation rule." The donation rule contains two key provisions:

- Hospitals must contact their organ procurement organization (OPO) in a timely manner about individuals whose death is imminent or who die in the hospital.
- Only OPO staff or trained hospital staff — referred to as designated requestors — may approach families about organ donation.

This report focuses on hospitals' and OPOs' early experiences with the donation rule. We base our findings on a survey of all 61 OPOs; responses from 353 hospitals representing a stratified sample of Medicare-certified hospitals; site visits to 2 OPO service areas, where we interviewed hospital clinicians and administrators, OPO staff, and staff from tissue banks; and interviews with staff at 8 other OPOs.

FINDINGS

Hospitals and organ procurement organizations have made progress in implementing the donation rule.

Hospitals are showing some improvement in their referral of potential organ donors. Two-thirds of OPOs reported an increase in the number of potential organ donors referred by hospitals. Based on our survey, we estimate that 40 percent of hospitals nationally have seen an increase in the number of potential donors that they have referred to OPOs.

OPOs are using the rule to increase the prominence given to organ donation within hospitals. Nationally, 65 percent of hospitals are seeing an increase in their overall interaction with OPOs.

OPOs are collecting data and providing feedback to hospitals on their performance in referring potential donors. Most OPOs are performing routine death record reviews, which serve as the basis for feedback to hospital administrative, quality assurance, and clinical staff.

However, OPOs and hospitals have not taken full advantage of the donation rule.

OPOs resist using hospital staff to discuss organ donation with families. Research shows that a collaborative approach between OPO staff and hospital staff yields the highest consent rates. However, in our survey and site visits we found:

- Limited training of designated requestors. Only 22 of the 61 OPOs had trained designated requestors in more than 10 percent of their hospitals; 23 OPOs had trained none at all.
- Tensions between physicians and OPOs. Many physicians believe that the designated requestor provision intrudes on their right to practice medicine, because it requires that they must be trained by the OPO in order to discuss organ donation with their patients' families.
- Limited involvement of hospital staff. Many hospital staff feel untrained or uneasy in approaching families to discuss donation.

Hospitals are not consistently notifying their OPO of all deaths or imminent deaths. Our survey of OPOs and our site visits found that many hospitals are failing to notify their OPO of potential donors. Only 2 OPOs responded that all hospitals are reporting all imminent deaths; 9 OPOs said that fewer than 25 percent of hospitals are reporting all imminent deaths.

OPOs consider their relationship with hospitals to be collegial. They resist taking forceful actions to ensure that hospitals notify them of all deaths or potential donors. OPOs stress professional education and internal hospital improvement. They rarely use other strategies, such as publicizing hospital-specific performance data on donation and referral. Even when hospitals fail to notify them of potential donors, OPOs indicated that they would not inform HCFA.

Despite projections of a 10 percent increase, the number of organ donors rose by less than 1 percent in the first year of the donation rule. The number of organ donors increased by only 44 — from 5,807 in 1998 to 5,851 in 1999. In 28 OPOs, the number of donors decreased in 1999. Several factors may explain the shortfall between expectation and achievement. One explanation may be that implementing a change such as this takes

longer than originally anticipated. A second factor may be the 1-year grace period that HCFA gave hospitals before enforcing the donation rule. In addition, many OPOs already had voluntary referral programs with some hospitals in their service areas.

HCFA does not obtain routine data to assess how well the donation rule is working.

HCFA lacks a mechanism to assess the rule's impact on organ donation. Although OPOs collect data and provide feedback to hospitals on their performance, the organizations are not required to share these data with HCFA.

HCFA lacks a proactive way to assess hospital compliance with the rule. The agency does not require OPOs to submit either aggregate or hospital-specific data that it could use to assess the extent to which hospitals are complying. Nor does it obtain routine information about OPOs' efforts to collaborate with hospitals to implement the rule.

HCFA relies on State certification agencies and the Joint Commission on Accreditation of Health Care Organizations to ensure hospitals' compliance with the rule. These surveys take place every 3 years, and donation activities encompass only a minor part of that review.

RECOMMENDATIONS

HCFA should revise the Medicare conditions for coverage for OPOs to make them more accountable for implementation of the donation rule.

Because the donation rule is a Medicare condition of participation for hospitals, it places the obligation for compliance solely on hospitals, with no requirements for OPOs. Effective implementation of the rule requires accountability on behalf of OPOs as well as hospitals.

HCFA should require OPOs to provide hospital-specific data on referrals and on organ recovery. HCFA could utilize these data to assess hospital compliance with the donation rule, identify hospitals which are out of compliance with the conditions and, if appropriate, initiate corrective action. These data should include relevant medical indicators and information on consent.

HCFA should require OPOs to make hospital-specific data on donation publicly available. Public information could encourage hospitals to work to maximize their participation in donation activities and would foster public discussion and education on donation.

HRSA should require that OPOs, as members of the Organ Procurement and Transplantation Network, submit hospital-specific data on referrals and on organ recovery.

Our recommendation to HCFA specifies the types of data elements which should be included. In fact, in a proposed new contract to operate the OPTN, the Health Resources and Services Administration has proposed that the OPTN maintain such data. Our recommendation is consistent with the proposed language in the renewal contract.

HRSA, in its funding initiatives, should support demonstration projects on how to effectively train and make use of designated requestors.

In 1999, HRSA funded $13 million in grant programs to OPOs and community groups. None of these programs addresses the role of designated requestors in the donation rule. In future funding solicitations, HRSA could give strong consideration to proposals to develop innovative programs for training designated requestors. Such programs might include use of distance learning and computer-based training strategies.

HRSA should develop an award that recognizes hospitals that demonstrate exemplary performance in donation.

HRSA could work with HCFA and other agencies to develop criteria for this award, which would be an incentive for hospitals. It could be based on the data submission we describe above, as well as other efforts, such as community education programs. HRSA could issue the award during National Organ and Tissue Donor Awareness Week.

COMMENTS ON THE DRAFT REPORT

We received comments on our draft report both from within the Department and from external organizations. We present the full text of the written comments in Appendix B. In the body of the report, we respond in full to all written comments. Here, we describe the key points made in the comments. For the external organizations, we also provide, in italics, a summary of our response.

Comments from within the Department

HCFA and HRSA provided written comments on our draft report, and the Office of the Assistant Secretary for Planning and Evaluation provided verbal comments. These agencies responded positively to our report and recommendations.

Comments from the Association of Organ Procurement Organizations

Overall, AOPO disagrees with many of our findings and recommendations. The

association raises a number of points, but places particular emphasis on our findings and discussion about limited training and use of designated requestors.

We base our finding about designated requestors on surveys of and discussions with the OPO and hospital communities. We believe that these data sources provide balanced evidence. We acknowledge the expertise of OPO staff in working with families. However, at an organizational level, we found a number of practices that indicate OPO resistance to training and using hospital staff as designated requestors. It is because of the concerns we identified that we recommend that HRSA support projects on how to effectively train and use designated requestors.

Comments from the American Hospital Association

Overall, AHA raises concerns about our recommendations related to increased reporting of hospital-specific data on donation. The association believes that "the full freight of increasing organ donation nationwide cannot and should not rest on a regulatory solution."

Our recommendations proceed from the underlying assumption that data measurement forms the basis for performance improvement. In our efforts to determine the extent to which hospitals are complying with this Medicare condition of participation, and the extent to which organ donation has changed in response to it, it was readily apparent to us that timely data are not available on a voluntary basis. It is for this reason that we recommend that HCFA require the submission of such data.

TABLE OF CONTENTS

INTRODUCTION

PURPOSE

To provide an early assessment of hospitals' and organ procurement organizations' responses to Medicare conditions of participation designed to increase organ donation.

BACKGROUND

More than 71,000 Americans are waiting for organ transplants, yet only about 22,000 received organ transplants last year. More than 6,000 people died while awaiting an organ transplant. An estimated 12,000 to 15,000 deaths occurring in the United States every year could yield suitable donor organs. However, fewer than 6,000 of those deaths result in the donation of an organ.[1]

Organ donation requires close coordination and support among organ procurement professionals, hospital and medical personnel, and grieving families. On page 11, we present a primer that provides an overview of organ donation.

The Department's Role in Organ Donation

Health Care Financing Administration (HCFA). HCFA carries out several important responsibilities with respect to organ procurement. The agency specifies organ procurement service areas and certifies organ procurement organizations (OPOs) for participation in Medicare. HCFA, through the Medicare program, provides funding for organ procurement organizations.

Medicare covers organ transplantation for Medicare beneficiaries. Of special note is Medicare coverage for kidney transplantation. End Stage Renal Disease is unique, in that it is the only disease-specific condition that qualifies someone for Medicare coverage, regardless of age. That coverage includes kidney transplantation.

HCFA also determines the conditions of participation for hospitals, including their interactions with OPOs.

Health Resources and Services Administration (HRSA). HRSA's Division of Transplantation provides Federal oversight and support for the organ procurement, allocation, and transplantation system. HRSA funds the Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR). The contract for both of these operations is currently held by the United

Network for Organ Sharing, a nonprofit organization based in Richmond, Virginia.

The OPTN is charged with operating and monitoring an equitable system for allocating organs, maintaining a waiting list of potential recipients, matching potential recipients with organ donors, and increasing organ donation. All organ procurement organizations and transplant programs are members of the OPTN. The SRTR is a database on recipients of solid organ transplants; the database supports ongoing evaluation of the scientific and clinical status of transplantation.

HRSA also is responsible for national coordination of organ donation activities, the funding of grants and special initiatives to learn more about what works to increase donation, and technical assistance to OPOs and other transplant-related entities. For example, HRSA conducts national technical assistance workshops that bring together staff from OPOs and hospitals to address implementation of the donation rule, and to identify and share effective practices in collaboration.

The National Organ and Tissue Donation Initiative. In response to the need for organ donors, the Secretary launched this initiative in December 1997. The goals of the initiative are to increase consent to donation, maximize donation opportunities, and learn more about what works to increase donation and transplantation through carefully designed research efforts.[2]

Organ Procurement Organizations

Each OPO serves a defined geographic area. The population in an OPO's service area ranges from just over 1 million people to more than 11 million people. At the end of 1999, 61 OPOs were in operation.[3] HCFA certifies OPOs for two years. HCFA measures OPO performance on five standards related to organ procurement.[4]

Every hospital has an agreement with one OPO. OPOs work with medical professionals and the public to encourage organ donation. They provide the services necessary to coordinate the identification of potential organ donors, requests for donation, and recovery and transport of organs.

The Donation Rule: Medicare Conditions of Participation for Organ, Tissue, and Eye Donation

HCFA published the final rule on Medicare conditions of participation for organ, tissue, and eye donation as part of the National Organ and Tissue Donation Initiative. The rule became effective August 21, 1998.[5] The donation rule was based on a 1994 Pennsylvania law requiring hospitals to report all deaths to the OPO. The OPO in eastern Pennsylvania saw a 40 percent increase in organ donation in the first two years of operation, compared to an average increase of 3 percent nationally.

In this report, we refer to these conditions of participation as the "donation rule." The rule imposes several requirements that are designed to increase organ donation.[6] The donation rule mandates that each hospital must contact its OPO in a timely manner about individuals whose death is imminent or who die in the hospital. The OPO then determines the individual's medical suitability for organ donation. Because the hospital notifies the OPO of each death or imminent death, the rule is intended to ensure that the family of every potential donor is informed of its option to donate organs, tissues, or eyes.

The donation rule also strengthens the role of OPOs in the donation process. It requires that families be advised of their donation options by an OPO representative or a "designated requestor" trained by the OPO. A designated requestor is defined in the donation rule as an individual who has completed a course offered or approved by the OPO in the methodology of approaching potential donor families and requesting organ donation.

The designated requestor requirement is based on research showing that consent for organ donation is highest when the following practices are observed:

- The family members are given time to understand and accept their relative's death before the organ donation request is made;
- The request is made by the OPO coordinator and a member of the hospital staff together;
- The request is made in a quiet, private setting.[7]

Importance of Collaboration between Hospitals and OPOs

The critical piece to making these provisions work is collaboration and cooperation between hospitals and OPOs in identifying and managing potential donors and in obtaining consent from donor families. Hospitals and OPOs both have important roles to play in increasing donation. Hospitals must refer and manage donors; OPOs must train hospital staff on how to identifying and manage potential donors, and on how to request consent. The donation rule encourages the use of best practices, based on research that indicates that consent to organ donation is highest when the formal request is made by OPO and hospital staff together.

This Inquiry

This report focuses on hospitals' and OPOs' early experience with the donation rule. We evaluate the progress OPOs and hospitals are making in implementing the donation rule, as well as obstacles encountered in implementation. This report focuses on the provisions of the rule relating to organ donation, not tissue and eye donation.

METHODOLOGY

We surveyed the executive directors of the 61 organ procurement organizations in October 1999, with a 100 percent response rate. We also visited two OPO service areas. In each service area, we met with OPO staff, hospital staff (nurse managers, administrators, physicians, nurses, and quality assurance personnel), and tissue bank staff. In addition, we conducted in-depth interviews with staff from 8 OPOs to learn more about their experiences with the donation rule.

We surveyed a stratified sample of Medicare-certified hospitals in February 2000, to learn more about their early experiences in implementing the donation rule. We stratified the sample by size: small hospitals (100 beds or fewer), medium (101 to 299 beds), and large (300 beds or more). We received usable responses from 353 hospitals, 78 percent of the total surveyed. Appendix A contains confidence intervals for the estimates derived from this survey.

We also spoke with staff from other organizations with interest in the donation rule, such as the Association of Organ Procurement Organizations and the American Hospital Association. Appendix A contains a detailed description of our methodology.

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

PRIMER ON ORGAN DONATION

The Process of Donation

1. Identifying a Potential Organ Donor. Organ donors appear at unpredictable times, most often from tragic circumstances, such as an automobile accident, gunshot wound, or other trauma that causes irreversible damage to the central nervous system. Upon admission to a hospital, the individual may be maintained for up to several days on a ventilator, a machine that provides artificial life support for breathing and respiratory function.

2. Notifying the Organ Procurement Organization (OPO). The hospital notifies its OPO about the individual who has died or whose death is imminent. OPO staff obtain information needed for a preliminary assessment of that individual's medical suitability as an organ donor.

3. Managing the Donor's Care. Medical, hospital, and OPO personnel monitor the individual's progress and maintain vascular organ function through medical treatment.

4. Determining and Declaring Brain Death. Physicians conduct tests to determine whether the individual is brain dead. If brain death is confirmed, a physician declares death. Brain death is the complete and irreversible loss of all brain function. Brain death can be determined through tests that include an electroencephalogram (EEG) to determine the absence of electrical activity in the brain, blood flow studies to determine the absence of blood flowing to the brain, or clinical assessment (no movement, no response to stimulation, no breathing, no brain reflexes) to determine the absence of function in all parts of the brain.

5. Requesting Consent. A trained OPO staff member or a hospital's designated requestor asks the individual's family members for consent to donate their relative's organs. Even if the individual had indicated willingness to donate organs (*e.g.*, on the driver's license), it is practice in this country to obtain consent from the next-of-kin. A family may refuse to give consent, or it may give consent for donation of all or only some organs.

6. Recovering Organs. If the family consents to donation, the organs are removed in an operating room in a sterile surgical procedure.

7. Transporting Organs for Transplantation. The organs are shipped immediately to the transplant hospital(s) where patient(s) awaiting a transplant receive them.

Key Terms in Organ Donation

Organ. Transplantable organs include the heart, liver, lungs, kidneys, pancreas, and intestines.

Imminent Death. Imminent death is defined under hospital policies devised in conjunction with its OPO. Imminent death generally includes a severely brain-injured individual on a ventilator.

Designated Requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO in the methodology for approaching potential donor families and requesting organ donation.

FINDINGS

Hospitals and organ procurement organizations have made progress in implementing the donation rule.

Hospitals are showing some improvement in their referral of potential organ donors.

In response to our survey, 40 of the 61 OPOs reported an increase in the number of potential organ donors referred by hospitals since the rule took effect; 38 OPOs noted that the timeliness of hospital referrals had improved. Hospitals' responses support those of the OPOs. Based on the results from our survey of hospitals, we estimate that 40 percent[8] of hospitals nationally have seen an increase in the number of imminent deaths they referred to OPOs. The impact of these changes was exemplified by donation coordinators we met with at one OPO. They told us that prior to the rule, they received 40-50 calls per month about potential donors, but now they were receiving over 100 calls per month.

In addition to the overall increase in referrals, it is noteworthy that there is improvement among hospitals with little prior involvement in organ donation. According to 26 OPOs, organ donation occurred in hospitals that had not provided organ donors previously; 23 OPOs reported an increase among those hospitals that had provided organ donors only occasionally.

We found that fewer small hospitals — those with 100 or fewer beds — had an increase in the number of imminent deaths referred to the OPO ($p<.01$). Among the small hospitals, 28 percent saw an increase in referral of imminent deaths, compared with 51 percent of mid-size hospitals (101- 299 beds), and 57 percent of hospitals with 300 or more beds.

OPOs are using the rule to increase the prominence given to organ donation within hospitals.

OPOs are taking advantage of the donation rule to increase their presence in hospitals. Nationally, we estimate that 65 percent of hospitals are seeing an increase in their overall interaction with the OPO since the rule went into effect. In 36 percent of hospitals the presence of OPO staff in the hospital has increased, and in 47 percent the OPO is more responsive to their concerns.

This increased leverage results from linking referral of organ donors to the Medicare conditions of participation. Previously, a hospital's involvement in donation depended to a large extent on the persuasiveness of OPO staff and the comitment of key clinicians and

administrators. With the advent of the donation rule, hospitals face review of their participation in organ donation by the Joint Commission on Accreditation of Health Care Organizations and State survey agencies. One OPO staff member summarized this impact when she said that "Prior to the rule we came in at the hospital's invitation. Now we have serious clout; we can encourage dialogue and collaboration."

The increased interaction with the OPO also has led to increased awareness among hospital staff about donation. We found this to be the case among smaller hospitals in particular. In their qualitative responses to our survey, many cited this increased knowledge among their staff as a benefit of the donation rule.

OPOs are collecting data and providing feedback to hospitals on their performance in referring potential donors.

Feedback is a key tool that the OPO staff use to work with hospitals on increasing donation. In response to our survey, 57 OPOs reported that they conduct death record reviews to verify hospitals' reporting of deaths and imminent deaths. 52 OPOs reported that they also reviewed hospitals' death logs. These reviews serve as the basis for the feedback that OPO staff give to hospital administration and quality assurance committees about a hospital's compliance with the rule.

In addition to this formal reporting structure, OPO staff provide feedback to the key units in the hospital, such as the intensive care unit, the emergency department, and other areas in which ventilator-dependent patients receive care. A good portion of OPO staff time is devoted to working with key nurses and physicians on these units. For example, staff at one hospital we visited told us that its quality assurance committee holds a conference after each referral for organ donation. These meetings, held with OPO staff, are used to determine what worked well, and where future improvements could be made.

OPO feedback emphasizes two points that help guide OPOs' education and training agenda for hospital staff. The first point relates to "missed potential donors," *i.e.*, those who were never identified or about whom the OPO never received notification. In these cases, educational efforts focus on identifying and referring potential donors.

The second point relates to potential donors who were identified, but for whom the family did not give consent. For example, the hospital staff may have approached the family without involving the OPO at the appropriate time. Feedback to the hospital staff in this type of situation would focus on the need for timely OPO involvement in approaching families about donation.

However, OPOs and hospitals have not yet taken full advantage of the donation rule.

OPOs resist using hospital staff to discuss organ donation with families.

Research shows that a collaborative approach between OPO staff and hospital staff yields the highest consent rates. However, in our survey and site visits we found:

Limited designated requestor training. Our survey found that 23 of the 61 OPOs had trained no designated requestors at all; only 22 OPOs had trained designated requestors in more than 10 percent of the hospitals in their service area. Based on our survey of hospitals, we estimate that 70 percent of hospitals had been offered designated requestor training by their OPO. But staff in only 44 percent of hospitals had, in fact, been trained.

We heard of situations in which training programs were not marketed widely to hospitals, and situations in which the OPO made it difficult for hospital staff to attend — for example, holding a 3-day training program in a city that is several hundred miles away from some hospitals. In some cases, OPOs have established only a standard, one-size-fits-all program, lacking the flexibility to respond to the varying needs of hospitals or different types of providers, such as physicians and nurses.

Tensions between physicians and OPOs. Many physicians believe that the designated requestor provision intrudes on their right to practice medicine. Undoubtedly, tensions existed between OPOs and physicians prior to the rule. But stipulating that physicians cannot discuss organ donation with families unless they have received designated requestor training from the OPO exacerbates these tensions.

During our site visits we met with a number of physicians from hospital units in which there are potential organ donors, such as pediatric and adult intensive care units and trauma services. All were vehement about this provision, telling us that it puts them in a very awkward position with the family of a potential donor. One physician exemplified these feelings when he told us, "It is distasteful to call the OPO to meet with the family. This hospital has an open policy of working closely with families, and parents are involved in the care of their children. I hold nothing back from them; they are there at *all* procedures. Why am I not good enough to speak to them about organ donation?"

Limited involvement of hospital staff. Among hospital staff, the designated requestor requirement may be leading to an unintended result. Rather than moving toward a collaborative approach to requesting consent, this provision runs the very real risk of turning consent into an OPO function, with little involvement from hospital staff. Our survey responses from hospitals and our visits with them supported this finding. Several of the qualitative responses to our hospital survey indicated that their staff were happy to

turn requesting donation over to the OPO, because the hospital staff felt untrained and uncomfortable in approaching families.

Controlling the consent process. OPOs have little incentive to train hospital-based designated requestors. OPOs cite their training and experience, as well as the time their staff are able to spend with the family as reasons for a higher consent rate. They can focus solely on donation and family concerns (whereas hospital staff must care for other patients on the unit). As one OPO staff member explained, "Gaining a family's consent is a process, not a one-time thing. It takes a long time to discuss options, answer all their questions, answer questions that the family hasn't even asked." OPO staff cite their continuing experience and practice in approaching families, something that a trained designated requestor would not possess, even in a hospital with a large number of donors.

At an organizational level, OPOs have a pragmatic reason for maintaining control. The OPOs feel that they — not hospitals — are responsible for meeting the minimum standards required to maintain their Medicare certification.[9] Therefore, they believe that it is in their best interests to be in complete control of the process of obtaining consent.

Implications. The implications of OPO reluctance to train designated requestors are multiple. First, if the requirements really do lead to separation of the OPO and hospital in obtaining consent, the positive impact of a collaborative approach to the family will be lost. Second, in hospitals that are geographically distant from the OPO, no one may be available with any knowledge about donation when the time comes to speak with a family. Even if the hospital contacts the OPO early in the process, distance may prevent the staff from getting to the hospital on time. In these cases, the opportunity to request consent may be lost, simply because no one is able to raise the issue.

The lack of OPO training for designated requestors raises a fundamental conflict: It is up to the hospital to determine who may approach a family to request. The rule requires that "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."[10] However, if the OPOs are not training hospital staff to become designated requestors, then the hospital has no option but to use the OPO staff. This directly contradicts research showing that a collaborative effort between hospitals and OPOs is the most effective way of obtaining family consent to donation.

An even more far-reaching problem may be the gradual disenfranchisement of hospital staff from involvement in organ donation. To the extent that nursing and other hospital staff see organ donation as "the OPO's job," one in which the hospital staff should have no involvement, there is likely to be little true collaboration or interest in organ donation.

Hospitals are not consistently notifying their OPO of all deaths or imminent deaths.

Many hospitals are moving forward to implement the donation rule; however, OPOs have not had complete success in working with hospitals toward implementation. Successful implementation is not something that the OPO can do on its own. After all, the rule is a *hospital* condition of participation, and it requires a great deal of commitment, initiative, and cooperation among the various parties involved.

According to the OPOs, hospitals are not notifying them of all imminent deaths. In our survey, only 2 OPOs responded that all hospitals are reporting all imminent deaths; 9 OPOs said that fewer than 25 percent of hospitals are reporting all imminent deaths. During our site visits, we reviewed detailed data from 1999 on imminent death reporting in three hospitals. These hospitals failed to report 43 percent, 29 percent, and 14 percent of the imminent deaths.

From our observations, we identified three key challenges that hospitals face in taking full advantage of these provisions.

Internal Hospital Leadership. In many hospitals, organ donation may be relatively low on the priority scale; it is just one of many things for which hospitals are responsible.

Where donation is working well, there tends to be a champion who has taken the donation cause under his or her wing and who is leading the charge within the hospital. This leadership may come from administrative, nursing, or medical personnel (or, preferably, all three). Comments from two hospital administrators exemplify this point. In a hospital that had been struggling with organ donation, the administrator told us, "No one is really willing to wrap their arms around organ procurement." In a hospital that was encountering success with donation, the executive said, "You really need an individual in the hospital to be committed to this. You need an avid supporter."

Physician Resistance. Above, we discussed the difficulty that the designated requestor provision poses for some physicians. Other concerns of physicians affect how the donation rule is implemented. In some hospitals, administrators may be reluctant to challenge medical staff who resist implementing the rule and have adopted a hands-off attitude toward these physicians.

We heard consistently about the need for creative ways to inform the OPO of donor candidates by "going around the back" of the physicians to call the OPO. At one hospital (which had more than 20 organ donors — a relatively large number — in 1999), a nurse on the intensive care unit told us that "Physicians resent nurses notifying the OPO, so often we do it behind the scene." Elsewhere, a nurse told us, "Most of the staff wait for the doctor to code the patient [declare the patient brain dead] before calling the OPO."

These instances of reluctance to contact the OPO early in the process occurred in hospitals with a large number of donors; undoubtedly, the problem is more severe in hospitals with fewer donors.

Cumbersome Operational Procedures. In some hospitals it is not clear who will call the OPO in the case of a patient whose death is imminent. Some hospitals have interpreted these provisions to mean that only a nursing supervisor can phone the OPO. Other hospitals have interpreted the provisions to mean that only someone who has gone through the OPO-sponsored designated requestor training may notify the OPO.

OPOs consider their relationship with hospitals to be collegial. They resist taking forceful actions to ensure that hospitals notify them of all deaths or potential donors.

In our work on external quality oversight of health care providers, we have found it helpful to consider oversight efforts in terms of a continuum, characterized by a collegial approach on one side and a regulatory approach on the other. External reviewers in the collegial mode focus on educating and improving performance; those in a regulatory mode focus on investigating and enforcing minimum requirements.[11]

This continuum also is a useful way of viewing the relationship between OPOs and hospitals. As they currently operate, OPOs fall on the collegial, rather than regulatory, side of this continuum. OPO staff note that they are invited into a hospital at the hospital's request, that they approach the hospital staff and physicians as professionals for peer education, and that their work with hospitals focuses on continuous process improvements, not on enforcement of minimum standards. Staff from OPOs we interviewed emphasized that it is HCFA's job — not the OPOs' — to enforce any noncompliance by hospitals.

However, the OPOs do not facilitate HCFA's ability to ensure compliance with the rule's provisions. Only two OPOs indicated that they would inform HCFA about poor compliance by hospitals with the rule's notification requirements. The OPOs strongly reject any enforcement role. In their qualitative responses to our survey, typical comments from OPOs included "concern of OPOs acting as a policemen — should not put OPOs in that position," and "threat of HCFA punishment puts OPO in the position of tattling which impacts our working relationships negatively."

Rather, OPOs stress collegiality. When we asked OPOs about how they respond to a hospital that failed to notify them of all deaths or imminent deaths, 59 responded that they conduct additional training, 55 that they meet with hospital administration, and 47 that they provide feedback to the hospital quality assurance department. OPOs cited educating hospital staff, meeting with physicians, establishing donor awareness teams, and working with the hospital liaisons as their preferred strategies.

Although OPOs have data and provide detailed feedback to hospital units, as we showed above, we found them extremely reluctant to provide hospitals with comparative data on their performance in organ donation. Staff we spoke with from hospitals that had increased donation took great pride in that fact. Most OPOs, however, do not release these data or share them with other institutions. However, at least one OPO — apparently the exception — does release these data, which include total referrals, organ referrals, organ donors, tissue referrals, and tissue donors.[12]

HCFA does not obtain routine data to assess how well the donation rule is working.

HCFA lacks a mechanism to assess the rule's impact on organ donation.

OPOs gather data that could be used to help determine the rule's impact on organ donation. These data could provide information to determine the success of efforts to increase donation and guide future initiatives. OPOs gather data on the number of hospital deaths, number of imminent deaths, potential candidates for donation, families approached for consent, and outcome of requests for consent. Indeed, these data form the basis of feedback that OPOs give to the hospitals in their service areas.

OPOs, however, consider these data to be confidential information. They do not share the data with HCFA either at a hospital-specific level, or even at an aggregate OPO level. The only data that HCFA currently receives from OPOs are in an annual report on the total number of organ donors, number of kidneys procured and transplanted, and number of extra renal organs procured and transplanted. HCFA uses these data in its biennial OPO certification process to assess OPO performance in obtaining donors.

HCFA lacks a proactive way to assess hospital compliance with the rule in a timely manner.

OPOs collect data on the number of notification calls that hospitals make and how many they fail to make, based on the results of death record reviews. They also collect data on the rate of consent for donation. Again, however, HCFA does not require OPOs to share these data with the agency in a way that could be used to assess hospital compliance with the rule on an ongoing basis.

The primary mechanism that HCFA uses to gather ongoing, timely information is its staff in the field. When the donation rule was promulgated, HCFA named four regional coordinators to work on implementing the regulation. These coordinators have been responsible for responding to calls and questions from OPOs and hospitals regarding implementation of the rule, and for training State surveyors.[13]

Hospitals and OPOs may contact the coordinators when conflicts or problems develop. By its very nature, however, this arrangement is reactive. Furthermore, the coordinators are caught in a conflict between their efforts to provide technical assistance to hospitals and OPOs, versus the hospitals' and OPOs' perception of their role as regulators.

HCFA relies on State certification agencies and the Joint Commission on Accreditation of Health Care Organizations to ensure hospitals' compliance with the rule.

The Joint Commission and State survey and certification agencies assess compliance with all Medicare conditions of participation through their survey process. However, the interval between these surveys is lengthy. Hospitals accredited by the Joint Commission are surveyed every 3 years.[14] State agencies conduct certification surveys even less frequently; as of late 1997, fully half of the nonaccredited hospitals had not had a survey within three years.[15]

Furthermore, standards assessing the donation rule comprise a small part of accreditation and certification surveys.[16] Several hospitals we visited had been surveyed by the Joint Commission prior to our visit. Staff at some of these hospitals told us that they had been asked only to show surveyors their policies and procedures governing organ donation. One hospital, which was not scheduled to have a Joint Commission visit for another year and a half, still did not have its policies and procedures in place.

Despite the reported increase in referrals, the number of organ donors increased by less than one percent in the first year of the donation rule.

Nationally, the number of organ donors increased by only 44, from 5,807 in 1998 to 5,851 in 1999.

The Department projected that the donation rule would lead to a 20 percent increase in donation over a 2-year period, 10 percent in each of the first two years.[17] This projection was based on the results of the Pennsylvania law, under which the OPO in eastern Pennsylvania saw a 40 percent increase in the first two years of operation. However, the results of the first full calendar year[18] of HCFA's donation rule fell far short of that expected progress.

Not only did the total number of donors increase only marginally, but 28 OPOs also had fewer donors in 1999 than in 1998. In 19 of these 28 OPOs, the decrease was greater than 10 percent, and greater than 20 percent in 4 of them. In 31 OPOs, there was an increase in the number of donors procured in 1999.

There may be some plausible explanations for the small increase in the first year of operation of the donation rule. One explanation may simply be that the time required to implement a change such as this is longer than originally anticipated.

A second explanation may lie in the 1-year grace period that HCFA gave hospitals. HCFA informed hospitals that they would not be held to compliance with the rule for the first year. However, hospitals were expected to be working with their OPOs to achieve full implementation of the rule. It is likely that some hospitals were not moving towards implementation. In fact, we saw evidence of this slow progress during our site visits.

Third, many OPOs already had voluntary routine referral programs with at least some hospitals in their service areas, and others operated in States with laws requiring referrals of deaths and imminent deaths. Consequently, these OPOs may already have achieved some of the increase that HCFA had projected. These laws and arrangements, however, do not contain any provisions analogous to the designated requestor requirement in the HCFA rule.

Responses to our survey showed that 48 out of 61 OPOs had voluntary referral arrangements with at least some hospitals in their service areas. Under these arrangements, a hospital notified the OPO of deaths that occurred in the hospital. These arrangements varied; in some cases hospitals reported all deaths, in others they excluded deaths over a certain age or with certain diseases. We estimate that 51 percent of hospitals nationally had voluntary arrangements with their OPO prior to the donation rule.

Some States, such as Pennsylvania, had enacted laws requiring hospitals to refer donors to the OPO. The OPOs responding to our survey indicated that 16 States have these required referral laws.[19] Like the voluntary arrangements (but unlike the HCFA rule), these laws often exclude from the reporting requirements deaths of patients with certain diagnoses or above a minimum age. Significantly, though, the two OPOs in Pennsylvania — where the State law serves as the model for the HCFA rule — reported large increases in 1999; one OPO had 38 more donors (26 percent increase) and the other OPO had 33 more donors (11 percent increase).

RECOMMENDATIONS

Increasing organ donation is a high-priority national objective. More than 71,000 seriously ill Americans are waiting for an organ; in 1999, more than 6,000 died while awaiting an organ. The need for organs for transplantation is reflected in national policies, such as the National Organ Transplant Act, Medicare coverage for renal failure, and broad-based educational efforts. These efforts are clear evidence that enhancing donation cannot be left to the vagaries of local performance.

HCFA's new Medicare conditions of participation for organ, tissue, and eye donation are such an initiative. This donation rule, promulgated in 1998, aims to give OPOs better access to hospitals and to potential organ donors therein. Our analysis is an early implementation study of that donation rule.

Although we found some early signs of progress in improving referrals, we also found signs that difficulties lie ahead in realizing the donation rule's potential. In particular, we found problems in the rule's provision to improve the methods for obtaining family consent through designated requestors; the lack of data available to HCFA to assess the effects of the regulation and how hospitals and OPOs are responding to it; and the disappointing increase in organ donation during the first year of implementation.

We offer the following recommendations as ways of increasing organ donation by helping to enhance the operations of the new donation rule. Both HCFA and HRSA have critical roles to play in maximizing the impact of the donation rule. HCFA sets the conditions under which both OPOs and hospitals participate in the Medicare program; HRSA oversees the OPTN contract and supports education to increase organ donation.

HCFA should revise the Medicare conditions for coverage for OPOs to make them more accountable for implementation of the donation rule.

Our guiding principle underlying this recommendation is straightforward: Maximizing organ donation requires coordination and collaboration between hospitals and OPOs. The donation rule, however, is contained in the Medicare conditions of participation for *hospitals*. While it provides OPOs with significant leverage that they can use to work with hospitals on donation, the rule places the obligation for compliance solely on hospitals; it sets no requirements for the OPOs. Effective implementation of the donation rule requires accountability on behalf of both OPOs and hospitals.

- **HCFA should require OPOs to provide hospital-specific data on referrals and on organ recovery.**

We found that HCFA lacks a mechanism to assess the rule's effect on donation and that

the agency lacks a proactive way to assess hospitals' compliance with it. The most effective and efficient way of reaching these goals is to obtain data through the OPOs. The rule requires that hospitals notify their OPO of all patient deaths and patients whose deaths are imminent. Therefore, the OPOs have the necessary data readily available. We do not envision the need for data beyond what OPOs currently collect.

OPOs should submit these data for all deaths or patients whose deaths are imminent in a hospital. One way in which the data could be collected and aggregated would be via OPO submission to the Organ Procurement and Transplantation Network.

At a minimum, these data should include:

- Demographic information, such as hospital name, age of patient, and date of call;
- Relevant medical indicators, such as whether the patient was on a ventilator, the causes/ circumstances of death, and diagnoses that preclude organ donation;
- Consent information, such as whether a request for organ donation was made, whether the request was made by OPO or hospital staff, whether consent was given, and whether organs were recovered; and
- The total number of deaths and imminent deaths in each hospital, and the number for which the OPO never received notification, or received notification after the ventilator had been disconnected.

To make these data useful, HCFA should require that OPOs submit timely and accurate information. In fact, we believe that these data are sufficiently important for HCFA to include their timely and accurate submission in its OPO performance measures. In our site visits, we found that OPOs have these data readily available; in some cases, the data are shared with hospitals on a weekly basis. We believe that OPOs could reasonably, inexpensively, and easily provide current data on a quarterly basis.

HCFA could use these data for three purposes. First, the data would provide a basis upon which HCFA and the Department could assess the effectiveness and impact of efforts to increase organ donation.

Second, HCFA could use these data in the OPO certification process. The OPO community has raised concerns that current performance standards fail to reflect variation among OPOs in the potential donor pool. Some OPOs argue that their true potential donor pool is smaller than that in other service areas, due to local factors such as differences in the cause of death and population mix. We believe these data could be used to shed light on these differences and to begin to identify regional variation in the potential donor pool.

Third, HCFA could use these data to assess hospital compliance with the conditions of participation. Having these data available would enable HCFA to identify and deal with

noncompliant hospitals, rather than place that burden on the OPOs.

- **HCFA should require OPOs to make hospital-specific data on donation publicly available.**

  The data that an OPO has about hospitals' performance on organ donation could be made available for publication in local newspapers or on the Internet. As we note above, at least one OPO already publishes these data in its annual report.

  One important goal in making such data publicly available is to hold hospitals more accountable for their performance in referring organ donors. We also know, however, that some parties may raise concerns that the data would be misinterpreted. We have heard concerns that patients might avoid a hospital that provides a large number of donors, out of fear that the hospital would be more interested in procuring their organs than in saving their lives. Contrary to those concerns, we believe that making these data publicly available would foster public discussion and education about the need for organs and could, indeed, spur donation.

HRSA should require that OPOs, as members of the Organ Procurement and Transplantation Network, submit hospital-specific data on referrals and on organ recovery.

Organ procurement organizations are members of the OPTN, the private entity responsible for day-to-day operation of the national system for distributing organs. HRSA should require that the OPOs submit to the OPTN, and that the OPTN maintain, data on deaths and imminent deaths in hospitals.

Our recommendation to HCFA specifies the types of data elements which should be included. In fact, in a proposed new contract to operate the OPTN, HRSA has proposed that the OPTN maintain such data. Our recommendation is consistent with the proposed language in the renewal contract.

HRSA, in its funding initiatives, should support demonstration projects on how to effectively train and make use of designated requestors.

In 1999, HRSA awarded $13 million in grant programs to OPOs and community groups. None of these programs addresses the role of designated requestors in the donation rule. In future funding solicitations, HRSA could give strong consideration to proposals to develop innovative programs for training designated requestors. For example, to address issues of long distance access to training programs, HRSA might encourage the use of innovative technologies, such as computer-based training strategies.

It will be particularly important to pay attention to the role of physicians in discussing

organ donation with families. The designated requestor provision has brought concerns about that role to the forefront. In a hospital setting, physicians are major influences in medical decisions, such as those surrounding organ donation. Many physicians believe that they are in the best position to discuss donation with, and obtain consent from, family members; OPO staff cite their own expertise, knowledge, and approach as more effective.

We believe that it is important to encourage approaches to collaboration that effectively involve all the parties involved in requesting consent for donation.

HRSA should develop an award that recognizes hospitals that demonstrate exemplary performance in organ donation.

HRSA could work with HCFA and other agencies within the Department to develop criteria for this award. Such an award would serve as a positive incentive to hospitals to enhance their commitment and efforts in encouraging organ donation. It could be based on the data submission we describe above, as well as other efforts, such as community education programs. We suggest that it may be appropriate for HRSA to issue the award during National Organ and Tissue Donor Awareness Week.

COMMENTS ON THE DRAFT REPORT

Within the Department, the Health Care Financing Administration (HCFA) and the Health Resources and Services Administration (HRSA) provided written comments to our draft report. We also received verbal comments from the Office of the Assistant Secretary for Planning and Evaluation.

We solicited comments on the draft report from the Association of Organ Procurement Organizations (AOPO) and the American Hospital Association (AHA). Here, we present a synopsis of the written comments from each agency and association, and, in italics, our response. We also made some editorial and technical changes in the report, based on these comments. Appendix B contains the full text of all written comments.

Health Care Financing Administration

HCFA responded positively to our report and recommendations. The agency intends to explore ways in which additional data can be used to assess OPO effectiveness and hospital compliance with the donation rule. HCFA comments that our recommendation about making organ donation data publicly available should be considered, taking into account the potential for misinterpretation of these data.

We support HCFA's initiative to use data to assess OPO accountability. In response to HCFA's concerns about public release of hospital-specific data on organ donation, we encourage the agency to review the experience of LifeGift, the Houston-based OPO, which has made such data publicly available in its annual report. The OPO has reported no adverse consequences from that effort.

We appreciate the additional information that the agency provided about the work underway to estimate organ donation potential by OPO service area.

Health Resources and Services Administration

HRSA responded positively to our report. The agency concurred in our recommendations to it. HRSA asks if the report could highlight examples of effective collaborative practices between OPOs and hospitals.

We opted not to highlight any particular practices that we observed. Although we did find examples where things appeared to be working well, a full assessment of such practices is beyond the scope of this inquiry. We applaud HRSA's ongoing efforts to identify and publicize effective practices, such as the two technical assistance workshops that the agency has led on "The Challenge of Collaboration." These workshops have included presentations by OPO and hospital staff on successes and efforts to implement

the donation rule.

HRSA asks if unique circumstances surrounded the large increase in donation at the OPO in Eastern Pennsylvania after that State enacted its required referral legislation.

Undoubtedly, there were some unique circumstances. We did not, however, conduct an independent analysis of that OPO's performance, or the reasons underlying that success.

HRSA recommends that we recommend to HCFA that it require hospitals to submit data on referrals and organ recovery directly to HCFA.

We considered having hospitals, not OPOs, report these data directly to HCFA and the OPTN, but rejected that idea for two reasons. First, OPOs already collect these data in their ongoing collaboration and death record review in hospitals. Second, our suggested approach minimizes the reporting burden on hospitals. It seems much simpler to have the 59 OPOs (as of August, 2000) provide these data to HCFA and the OPTN, rather than to require each of 5,000 hospitals to submit the data.

Association of Organ Procurement Agencies

Overall, AOPO disagrees with many of our findings and recommendations. The association raises a number of points, but places particular emphasis on our findings and discussion about limited training and use of designated requestors.

AOPO's General Comments:

- AOPO states that an underlying presumption of our report is that full compliance with the donation rule will lead to an substantial and immediate increase in organ donation. The association notes that trends in donation are also affected by attitudes of the public and health professionals, as well as by causes and rates of death.

  We do not claim that the donation rule is, by itself, the "answer" to the shortage of organs. However, the donation rule clearly gives OPOs the opportunity to be notified about more potential organ donors. And, as we heard consistently from OPO staff, the rule gives OPOs greater clout and influence with hospitals to address donation. Our report cites evidence of the progress that has been made.

  Despite this progress, almost half of the OPOs had fewer donors in 1999 than in 1998; in almost one-third of OPOs this decrease was greater than 10 percent. By any measure, a national increase of less than one percent in organ donation must be considered a disappointment.

- AOPO supports our view that both OPOs and hospitals are accountable for organ

donation. However, the association notes that effective collaboration must extend beyond merely meeting the requirements of the donation rule.

We agree. We recommend hospital-specific data submissions to HCFA as one way of increasing hospital accountability for organ donation. We also recommend that HRSA develop an award recognizing hospitals that show exemplary performance in organ donation. Both recommendations encourage joint ownership of organ procurement. As AOPO notes, our report focused solely on implementing the donation rule, not on additional activities that OPOs perform in their ongoing interactions with hospitals.

- AOPO recommends that we review "important, recent empirical work" by Siminoff, *et al.*, on organ donation. According to AOPO, this research found that consent for donation was highest when the request was made by an OPO coordinator.

  We appreciate AOPO's pointing out this important research on organ donation. Data from the second study (completed in December 1999) have not yet been published, but we obtained copies of the final report on both studies submitted to the Agency for Healthcare Research and Quality, and we have reviewed that research carefully.

  We disagree with AOPO's characterization of the findings from that research. The research does indicate that families who raised the issue of donation were more likely to donate, and it notes the importance of OPO staff spending time with families. On the central point that AOPO raises, however, the investigators report, "Donor rates were equivalent when doctors, nurses, social workers, or OPO staff raised the issue."

- AOPO claims that the report did not fully develop the role physicians play in the donation process. The association asks for further recommendations directed at physicians and the medical community.

  We address the role that physicians play and their concerns about the donation rule at two distinct places. No one concerned about donation would disagree that additional steps could be taken to educate physicians and other health care professionals about organ donation. We urge AOPO to play a leadership role in developing approaches to working with medical and specialty groups to address these issues.

- AOPO believes that the Department of Health and Human Services, not individual OPOs, should have responsibility for any public reporting of hospital-specific compliance and other data about organ donation and recovery.

  We believe that OPOs should take on this responsibility for two reasons. First, OPOs are the local resource providing information to the public about organ donation. We view providing these data to the local area as part of that resource role. Second, as we note in our response to HCFA's comments, the experience from at least one OPO indicates no

adverse consequences from that effort.

- AOPO states that there is some evidence to suggest that hospital staff may be taking advantage of designated requestors to exclude OPOs from the donation process.

  We base our finding about designated requestors on survey data from both OPO directors and hospital staff. We believe that this provides balanced evidence on this question. We have added language in the report, based on our survey of hospitals. We found that about 70 percent of hospitals had been offered designated requestor training by the OPO, but that staff in only 44 percent of hospitals had, in fact, been trained.

- AOPO commented that the report did not include an assessment of the workload impact of the donation rule on OPOs, hospitals, and tissue banks.

  We examined that issue to a limited degree but did not report the data because it did not appear to impact implementation adversely. While 65 percent cited an increase in the number of deaths referred to the OPO, only 2 percent responded that the amount of time it takes staff to notify the OPO about a patient's death posed a major obstacle; and only 2 percent responded that the amount of record keeping required was a major obstacle.

- AOPO indicates that our report lends weight to conclusions of other research about the inadequacy of population-based performance measures.

  *We did not assess the adequacy or inadequacy of population-based performance measures, but we are aware of the concerns that the OPO community has raised about such measures. We believe, and we state in our recommendations, that the data we call for OPOs to submit to HCFA and to HRSA (through the OPTN) could be useful in shedding light on the population mix and causes of death among service area*s.

AOPO's Specific Comments:

- AOPO claims that it is disingenuous to blame the donation rule for not achieving projected increases in organ donation, and it states that the projection is more of a challenge than a realistic projection.

  Nowhere do we blame the donation rule for not achieving the stated numerical goal. The simple fact of the matter, however, is that the actual increase in donation fell far short of the increase that the Department projected when promulgating this regulation.

- At several places the association disagrees with our findings and discussion about how OPOs resist using hospital staff to discuss donation.

  As we note above, we base these findings on surveys of and discussions with both the

OPO and hospital communities. We acknowledge the expertise and training of OPO staff, their interaction with families, and their ongoing involvement with and knowledge of donation. However, at an organizational level, we found a number of practices that indicate OPO resistance to training and using hospital staff as designated requestors.

- The association states that OPOs were required to assist hospitals in implementing the donation rule, but did not receive additional funding to do so.

  We recognize that OPOs did not receive additional funding to implement the donation rule. However, an OPO would be able to recover the appropriate portion of those costs through its Medicare cost recovery process. In addition, to the extent that an OPO increased organ procurement, it would realize revenue by placing additional organs.

- AOPO cautions that a careful definition of the term "imminent death" is required for data collection statistics.

  We recognize that defining "imminent death" requires medical judgement, and that such a definition may differ among physicians, OPOs, and hospitals. We are not proposing that a national definition of imminent death be developed. We would expect an OPO to submit data to HCFA in accordance with the criteria and definition that the OPO uses.

American Hospital Association

- Overall, AHA raises concerns about our recommendations related to increased reporting of hospital-specific data on donation. The association believes that "the full freight of increasing organ donation nationwide cannot and should not rest on a regulatory solution."

  Our recommendations proceed from the underlying assumption that data measurement forms the basis for performance improvement. In our efforts to determine the extent to which hospitals are complying with this Medicare condition of participation, and the extent to which organ donation has changed in response to it, it was readily apparent to us that timely data are not available on a voluntary basis. It is for this reason that we recommend that HCFA require the submission of such data.

- The association stresses the importance of maintaining collaborative relationships between hospitals and OPOs.

  We agree with the importance of collaborative relationships and cite a number of areas in which they are working well. But we also found areas in which improvements could be made. These areas include expanding the availability of designated requestor training for hospital staff and improving cumbersome operational procedures within hospitals. We hope that AHA will establish its own initiatives to deal with these shortcomings.

- AHA expresses concern about our recommendation that OPOs provide hospital-specific data to the Department on referrals and on organ recovery.

  As we note in our response to HRSA's comments, OPOs already collect these data. We also felt strongly that our suggested approach would minimize the reporting and regulatory burden on hospitals. It seems much simpler (and, indeed, more amenable to the hospital community) to have the 59 OPOs provide these data to the Department, rather than to require each of 5,000 hospitals to submit the data.

- AHA notes that our report does not address the OPOs' infrastructure capacity to deal with the requirements of the donation rule.

  As we note in our response to AOPO, we examined that issue to a limited degree but did not report the data because it did not appear to impact implementation adversely.

- AHA raises concerns that our recommendations would place OPOs in the position of ensuring compliance with a hospital condition of participation.

  Our recommendations do not call on the OPOs to perform a compliance function. Compliance monitoring would continue to be the responsibility of HCFA, the State surveyors, and the Joint Commission. Our recommendation would merely have the OPOs transmit data that they already collect to HCFA. HCFA could then use those data to assess if and where hospitals are not meeting their obligations.

- AHA disagrees with our recommendations that OPOs should make hospital-specific data on donation public. The Association raises concerns that the public might misconstrue these data and the performance of a particular hospital in this regard.

  As we note in our response to HCFA's comments, the experience from at least one OPO indicates no adverse consequences from that effort.

- AHA agrees with our recommendation that HRSA support demonstration projects on training and using designated requestors. AHA urges the Department to establish projects to further the research on successful models of securing consent and encouraging donation.

  We welcome the AHA's support of this recommendation. We believe that there are many opportunities to review and publicize effective practices on donation.

APPENDIX A

Methodology

Data Collection from Organ Procurement Organizations

We mailed a survey to the executive directors of the 61 organ procurement organizations in October 1999, with a follow-up mailing to those that had not responded in November. We received responses from all 61 OPOs in operation at that time. Since then, two OPOs no longer operate, and their service areas have been subsumed by other OPOs. We use 61 OPOs in reporting our results because that was the number operating at the time of the survey.

Data Collection from Hospitals

We mailed a survey to the chief executive officer of a stratified random sample of Medicare-certified hospitals in February 2000, with a follow-up mailing to those that had not responded in March.

Our original sample comprised 450 hospitals, selected using HCFA's OSCAR database. We stratified the universe into three groups, based on number of certified beds: hospitals with 100 or fewer beds, hospitals with 101 to 299 beds, and hospitals with 300 or more beds. When compared with the national distribution of Medicare hospitals, this strategy undersamples the smallest hospitals and oversamples the largest hospitals. We chose this sampling scheme because larger hospitals are more likely to see potential organ donors than are smaller hospitals. Because the donation rule applies to all Medicare-certified hospitals, we wanted to have adequate representation among all 3 categories of hospitals.

Therefore, in presenting estimates from our hospital survey, we have weighted the responses to reflect their proportions in the national population. On the following pages, we present the confidence intervals for the variables used in this report, and a non-respondent analysis. We found no difference between the sample and the population on two key variables: type of hospital and hospital control.

We deleted 3 hospitals from the original sample after internal consultations with other components of the Office of Inspector General, reducing our sample size to 447. We then found that another 8 hospitals had ceased operation, even though they still appeared in the OSCAR database, reducing our sample size to 439. We then found that 5 hospitals were "critical access hospitals," for which the Medicare conditions of participation do not apply and which, therefore, were not subject to the donation rule. This reduced our final sample size to 434 hospitals.

APPENDIX A

We received responses from 357 hospitals, yielding a response rate of 79 percent of the total sample. Deleting the responses from the 4 critical access hospitals yielded a total of 353 responses, or 81 percent of the reduced sample of 434 hospitals.

Characteristics of Hospital Sample

Certified Beds	Population	Sample Size	Number of Responses	Response Rate
< =100	3,236	150	117	78.0 %
101-299	1,882	150	125	83.3 %
>= 300	1,010	150	111	74.0 %
TOTALS	6,128	450	353	78.4 %

Non-Respondent Analysis

Item: Hospital Type	Respondents	Non-Respondents	Total	Percent
General Hospitals	303 (85.8 %)	77 (79.4 %)	380	79.7 %
Other Hospitals	50 (14.2 %)	20 (20.6 %)	70	71.4 %
Total	353	97	450	78.4 %
Chi - square statistic = 0.5201			Degrees of freedom = 1	

Item: Hospital Control	Respondents	Non-Respondents	Total	Percent
Voluntary non-profit	190 (53.8 %)	55 (56.7 %)	245	77.6 %
Proprietary	65 (18.4 %)	17 (17.5 %)	82	79.3 %
Public	98 (27.8 %)	25 (25.8 %)	123	79.7 %
Total	353	97	450	78.4 %
Chi - square statistic = 0.0558			Degrees of freedom = 2	

APPENDIX A

Confidence intervals for key questions

Description	Raw Value (%)	Weighted Estimate (%)	
Hospital had voluntary arrangement to report deaths	54.5 %	51.3 %	+/- 5.8 %
Increase in deaths referred to OPO	66. 9%	64.7	+/- 5.6 %
Increase in imminent deaths referred to OPO	45.2 %	39.8 %	+/- 5.4 %
Time needed to notify OPO about a patient's death	2.6 %	1.9 %	+/- 1.3 %
Responsiveness of OPO to phone calls	3.2 %	2.3 %	+/- 1.5 %
OPO offered to train hospital staff as designated requestor	72.3 %	70.3 %	+/- 5.4 %
Hospital staff trained as designated requestor by OPO	44.3 %	43.7 %	+/- 5.7 %
Increase in hospital's overall interaction with OPO	66.4 %	65.3 %	+/- 5.5 %
Increase in presence of OPO staff in hospital	40.7 %	35.6 %	+/- 5.2 %
Increase in responsiveness of OPO to hospital's concerns	49.1 %	47.1 %	+/- 5.8 %
Increase in referral of donors - hospitals <= 100 beds	28.1 %	—	+/- 8.2%
Increase in referral of donors - hospitals 101-299 beds	50.8 %	—	+/- 9.2%
Increase in referral of donors - hospitals > = 300 beds	56.8 %	—	+/- 9.2%

APPENDIX A

Site Visits

We conducted site visits to the service areas of two OPOs: Southern California Organ Procurement Center (Los Angeles) and Southwest Transplant Alliance (Dallas). During our visits we interviewed staff from the OPO; hospital personnel, including nurses, social workers, administrators, and clergy; hospital-based physicians; and tissue bank staff.

Interviews with OPO Staff and External Stakeholders

We interviewed, either in person or by telephone, staff from eight additional OPOs. We also interviewed staff from the Association of Organ Procurement Organizations, the American Hospital Association, the American Association of Tissue Banks, and the Eye Bank Association of America.

APPENDIX B

Comments on the Draft Report

In this appendix we present the full text of comments of the parties that responded to our draft report. We present them in the following order:

- Health Care Financing Administration
- Health Resources and Services Administration
- Association of Organ Procurement Organizations
- American Hospital Association

APPENDIX B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE: JUL 31 2000

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: AMedicare Conditions of Participation for Organ Donation: An Early Assessment of the New Donation Rule," (OEI-01-99-00020)

Thank you for the opportunity to review the subject draft report. We appreciate the effort the OIG has made in assessing the implementation of the Health Care Financing Administration's (HCFA) Medicare Conditions of Participation (COP) for organ donation. I am pleased that your findings show that hospitals and organ procurement organizations (OPOs) have made progress in implementing the organ donation rule.

It is of the utmost importance that the organizations that receive and distribute organs for human transplantation be able to do that job well. The patients who need organ transplantation must come first. To assure high quality in this vital area, HCFA applies performance standards to all OPOs. The OPOs must meet those standards, which are set by statute and regulation, in order to remain a part of the Medicare program. There are 59 OPOs nationwide that play a critical role in identifying and supplying organs for people who need transplants. An important part of their job is making the public aware of the need for donations and encouraging donors. It is important that standards be maintained if there is to be an adequate supply of donated organs for those who need transplants. Very few OPOs fail to meet these standards, but where they do fall short of participation standards, HCFA has procedures it follows to assure that service continues and an adequate supply of organs is available.

Each year, in the U.S., 12,000 to 15,000 deaths occur that could yield suitable donor organs. However, only approximately 6,000 of these deaths result in donations. HCFA has identified two major problems. First, many potential donors were not identified, and, secondly, no one determined whether a declaration for donation had been made, or offered the donation option to the family. To help combat these problems, HCFA, in June 1998, established through a public rulemaking process, the Hospital Conditions of Participation for organ donation. This final rule created several steps designed to increase organ donations. One requirement is that a hospital must have an agreement with the OPO designated by the Secretary, under which the hospital will provide the OPO with timely notification about individuals who die or whose death is imminent

in the hospital. The hospital must also have an agreement with at least one tissue bank and one eye bank to cooperate in the retrieval, processing, preservation, storage, and distribution of tissue and eyes, as long as the agreement does not interfere with organ donation. The final rule also 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. In addition, transplant hospitals must provide organ-transplant data, when requested by the Organ Procurement and Transplantation Network, the Scientific Registry, OPOs and the Department of Health and Human Services. The organ donation provisions are intended to ensure that hospitals identify those deaths, that might result in organ donation, and ensure that families are given the opportunity to donate.

This final rule is the centerpiece of the National Organ and Tissue Donation Initiative launched by the Clinton Administration. Although the expected 20 percent increase in organ donation in the first two years of the regulation has not taken place, HCFA will continue to work to make sure we reach the 20 percent goal as quickly as possible.

Attachment

Our specific comments on OIG recommendations are as follows:

OIG Recommendation

HCFA should revise the Medicare conditions of coverage for OPOs to make them more accountable for implementation of the donation rule.

- HCFA should require OPOs to provide hospital-specific data on referrals and on organ recovery.
- HCFA should require OPOs to make hospital-specific data on donation publicly available.

HCFA Response

We agree that effective implementation of the Medicare hospital conditions of participation for organ, tissue, and eye procurement requires accountability by OPOs as well as hospitals. We welcome the OIG's recommendation that HCFA change the OPO conditions for coverage to increase OPOs' accountability. As we develop new conditions for OPOs, we will explore ways in which additional data, including demographic data, medical indicators, consent information, and hospital death and referral data, can be obtained by HCFA and used to assess OPO effectiveness and hospital compliance. In addition, we will consider whether such data would be useful in the OPO certification process.

As a first step in developing new conditions of coverage for OPOs, HCFA has contracted with the Harvard School of Public Health to further study a model for estimating organ donation potential by OPO service area. The model was developed by Harvard and the Partnership for Organ Donation and published in the *American Journal of Public Health* in November 1998. It uses publicly available hospital data, such as Medicare case-mix index to estimate the number of potential donors.

Current HCFA regulations require each OPO to meet four out of five performance standards, based on the population in each OPO's service area (for example, number of donors per million population). In its November 1997 report, the General Accounting Office urged HCFA to investigate methods for estimating donor potential that could be used as alternatives to population. Under the current contract, Harvard is applying their model nationwide to produce an estimate of organ donor potential for each of the 59 OPO service areas. Results are expected by September 2000. If the Harvard model appears to be a reasonable option, HCFA will consider it as one of a number of alternatives to be considered in a notice of proposed rulemaking.

We believe the OIG's recommendation that HCFA should require OPOs to make hospital-specific data on donation publicly available has merit and should be considered. In doing this, HCFA will weigh the value of making such data public against the possibility that the data could be misinterpreted and fuel the fears of individuals who believe a hospital's success in organ donation means that the need for transplantable organs takes precedence over saving patients in that facility.

Technical Comments:

Page 7, 4th paragraph (1st. par. under the heading Organ Procurement Organizations"): We would note that the characterization of the OPO certification period is not entirely accurate. The Balanced Budget Act of 1997 (BBA) amended Section 1138(b)(1)(A)(ii) of the Social Security Act to permit the Secretary of HHS to expand the certification period of OPO from two years to four if the Secretary determines appropriate for an organization on the basis of its past practices." See Section 4642 of the BBA (Pub.L. 105-33, Sec. 4642). We would recommend revising this paragraph to reflect the statutory change.

Appendix, Page 27, note 4, and Page 28, note 9: Per 42 C.F.R. 486.310(b). OPOs must meet at least 75% of the national mean on four (not three) of the five performance standards. This note should be revised to reflect this.

At the bottom of Page 17, the report mentions the Consortia leads and indicates they are responsible for training State surveyors. It fails to mention that in this context States survey only hospitals; HCFA regional office staff conducts OPO surveys.

Many of the OPOs use the services of Statline as an intermediary in obtaining information about pending deaths in hospitals. OPOs and hospitals should be encouraged to collaborate their efforts through Statline.

APPENDIX B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Health Resources and
Services Administration
Rockville MD 20857

TO: Inspector General, OS

FROM: Deputy Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report "Medicare Conditions of Participation for Organ Donation: An Early Assessment of the Donation Rule" OEI-01-99-00020

Attached in accordance with your May 26 request are HRSA's comments to the subject draft report.

Staff questions may be referred to Jeanellen Kallevang at (301) 443-5181.

Thomas G. Morford

Attachment

APPENDIX B

Health Resources and Services Administration (HRSA) Comments on the Office of the Inspector General (OIG) Draft Report "Medicare Conditions of Participation for Organ Donation: An Early Assessment of the Donation Rule" OEI-01-99-00020

GENERAL COMMENTS

Thank you for the opportunity to review and comment on the subject draft report. The Health Resources Services Administration's (HRSA's) overall impression of the report is very positive. However, we would like to offer a few thoughts about the report.

- The report refers to difficulties in the relationship between some organ procurement organizations (OPOs) and hospitals. Since this document will likely be read by procurement and hospital professionals, it might be helpful to share effective, collaborative practices by featuring some specific examples in the final report.

- Page 18 mentions the 40 percent donation increase in eastern Pennslyvania subsequent to enactment of PA Act 102. No similar donation increases were experienced after the Medicare Hospital Conditions of Participation (CoP) went into effect. What explanation, if any, can the OIG offer regarding this disparity? Are there unique circumstances in eastern Pennsylvania to account for this? Was there a specific methodology or philosophy on the part of the OPO during PA Act 102's implementation that resulted in significant success?

- HRSA recommends that the OIG recommend that HCFA require hospitals to submit data to HCFA on referrals and organ recovery.

- The report recommends that HRSA: 1) require that OPOs, as members of the Organ Procurement and Transplantation Network, submit hospital specific data on referrals (of potential organ donors) and on organ recovery (we concur, especially considering the above suggestion that hospitals be required to submit data to HCFA which would make it available to OPOs); 2) in its funding initiatives, support demonstration projects on training and using designated requestors (we concur); and

- 3) develop an award that recognizes hospitals that demonstrate exemplary performance in donation. HRSA concurs with each of these recommendations (we concur). Relative to the first recommendation, we suggest the report include language clarifying how OPOs would be able to collect this data, especially if there were not full cooperation from the hospitals.

APPENDIX B

AOPO
Association of
Organ Procurement
Organizations

July 14, 2000

June Gibbs Brown
Inspector General
Department of Health and Human Services
Washington DC 20201

Dear Ms. Brown:

Thank you for providing the Association of Organ Procurement Organizations (AOPO) an opportunity to review and comment on your draft inspection report providing an early assessment of hospitals' and organ procurement organizations' (OPOs) responses to the Medicare hospital conditions of participation (COP) for organ donation. The Association has consistently been a strong supporter of these regulations and welcomes this opportunity to comment on the subject report.

General Comments

1. An underlying presumption of the Report is that organ donation will substantially and immediately increase nationally if there is significantly increased or complete hospital compliance with the COP on routine referral. Although AOPO believes that the COP is a necessary condition for raising the levels of organ donation and recovery, considerations relevant to public and health professional attitudes, as well as causes and rates of death, need to be included in any general assessment of current and future trends regarding organ donation. This recognition needs to be made explicitly in the Report, particularly to avoid perpetuating an unrealistic expectation that 100 percent compliance with COP is a necessary **and** sufficient condition for remedying the ongoing shortage in organs available for transplantation.

2. AOPO commends the Report in its call for joint ownership and accountability between the OPO and the hospital. The Association has been on the record with DHHS on earlier occasions calling for such shared accountability. Significantly, however, the Report falls short of extending this concept to organ donation and conversion generally. Although we recognize that the Report's focus is on the COP, recognition should be given in the Report and to DHHS of the importance in applying performance measures regarding effectiveness in organ recovery to both hospitals and OPOs. Hospital accountability for referrals of deaths and imminent deaths alone does not address broader hospital ownership of ongoing

Share your life. Share your decision.®
One Cambridge Court • 8110 Gatehouse Road • Suite 101 West • Falls Church, VA 22042 • 703-573-AOPO • Fax 703-573-0578

efforts and attitudes for increasing organ donation and recovery (e.g. timely availability of hospital operating rooms for organ recovery.)

3. The Report cites the earlier empirical research used by DHHS to develop the COP and designated requestor requirement. That research included a finding that consent for organ donation is highest when one of the practices includes that "the request is made by the OPO coordinator and a member of the hospital staff together." Although the Report relies heavily on this research to develop its findings and recommendations, no reference is provided to important, recent empirical work on the matter of increasing consent, which has been sponsored by the Agency for Health Care Quality. As Siminoff, et. al., have found in their first study (HS 06579), the major limiting factor in the success of required request State laws (i.e. the forerunners to the Federal COP) to significantly increase the number of organs recovered was the families' frequent refusal to consent to donation. Their second study (HS 08209), completed in December, 1999, noted that the request for donation was most effective when the key requestor was an OPO coordinator. That study also identified other factors relevant for increasing the effectiveness of the consent approach (e.g. that the first person to discuss donation with the family was not a physician; that families were not told by a health care provider that they were required by law to request donation, etc.). These research findings, in our view, are sufficiently significant for the Office of Inspector General to review the ACHR-supported work and revisit its theses, findings, and recommendations in the Report before publishing it as a final document.

4. The Report's treatment of the role of physicians in the overall organ donation and recovery process is insufficiently developed. We would direct the staff's attention to the latest edition of AMA News (July 10-17), which carries an article addressing physician concerns regarding the COP. Noticeably absent from the Report, furthermore, are any recommendations to DHHS and national organizations for addressing this area, including attention to this matter in medical education curricula, collaborative initiatives with relevant physicians' groups (e.g. neurological surgeons and neurologists), etc.

5. The Report correctly notes that the OPO community has adopted a collegial model for its interactions with the hospital community. We believe that this approach, strengthened by the concept of joint accountability noted above, represents the most productive approach for increasing organ donation and recovery. To that end, should DHHS mandate the regular receipt from OPOs of hospital-specific compliance and associated data, we would submit that DHHS, not the OPO community, should have the responsibility for any public reporting of the information. Collaborative relationships, in our view, would be seriously undermined by any requirement for public reporting on the part of the OPO community.

6. The Report makes an incomplete and perhaps erroneous conclusion regarding the relatively few number of designated requestors trained by OPOs. There is some evidence to suggest that hospital staff may be taking advantage of designated requestors to exclude OPOs from the donation process. Not having designated requestors does not necessarily mean that collaboration doesn't exist. It may suggest in some instances, in contrast, that hospital staff (i.e. often physicians) is interested in maintaining control of the donation process.

7. Interestingly, while the OIG Report specifically focuses on organ versus tissue donation, it is an important oversight for the Report to ignore the workload impact occasioned for hospitals, OPOs, and tissue banks by referring "all deaths." Attention to this issue would strengthen the Report's assessment of the first year experience of the COP.

8. It is noteworthy that the OIG Report lends further weight to the conclusions of the Institute of Medicine, the Harvard School of Public Health, the General Accounting Office, and AOPO regarding the inadequacies of population-based performance measures and the value of conversion data.

Specific Comments

Page 2. The discussion of "OPO resistance" is incomplete and misleading. Experience indicates that, notwithstanding research findings regarding the professional role of OPOs, many hospitals want to train their staff so that they will not have to proceed collaboratively. While HCFA has encouraged a collaborative approach, the specific HCFA Q and A on their COP web site says explicitly that once trained by an OPO, the hospital staff can do the job by themselves. Furthermore, in addition to the research cited, there is also research to indicate the need to have fairly extensive training, do it often, and to spend sufficient time with the family. The experience among OPOs is that these outcomes will not likely happen if hospital staff is trained.

Page 2. The referenced HHS "projections" are not empirically based and represent more of a challenge than a realistic projection. As such, it is somewhat disingenuous to place blame on the COP for not achieving a stated numerical goal. The fuller discussion on pages 18-19 is actually more complete and thoughtful.

Page 10. Although the OIG study definition of organs includes "intestines," HCFA has specifically excluded intestines as a reportable organ because it is not mentioned in NOTA. The legislation, however, does permit the Secretary to designate new organs beyond those mentioned.

Page 13. As noted earlier, inclusion here of the earlier referenced Siminoff research provides a different context and conclusion for the IG findings. This merits attention

before the report is finalized. Further, if the designated requestor is the OPO, the OPO still looks to hospital staff to assist in the approach, hardly a matter of "resistance."

Page 14. The suggestion that "OPOs have a pragmatic reason for maintaining control," based on performance measures, misses the point. Unlike hospital staff, OPO professionals are experts in approaching donor families, as evidenced by empirical research supporting the more favorable outcomes achieved when their expertise is put to work. As to the "Implications" section, if OPOs refuse to train designated requestors, such a practice is inappropriate under the COP. Most hospitals, however, as experienced by OPOs, do not want the time investment needed to train an appropriate number of staff so that a designated requestor will be available at all times.

Page 20. OPOs were required to assist hospitals in implementing the COP but HCFA provided no financial resources and very limited guidance to OPOs on implementing the rule.

Page 21. The inclusion of "imminent death" as a data collection statistic requires careful definition, particularly since not all "imminent deaths" become "deaths."

Endnotes. Both notes #4 and #9 should be corrected to note that OPOs have to meet 4 of the 5 HCFA standards.

Thank you again for this opportunity to provide comments on the Report.

Sincerely yours,

Paul M Schwab

Paul M. Schwab
Executive Director

cc. Susan Gunderson, President, AOPO

AHA
Advancing Health in America

Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802

(202) 638-1100 Voice
www.aha.org

July 20, 2000

June Gibbs Brown
Inspector General
Department of Health and Human Services
330 Independence Avenue, S.W., Cohen Building 5246
Washington, DC 20201

Dear Ms. Brown:

The American Hospital Association (AHA), on behalf of its 5,000 member hospitals and health systems, is writing to express our comments on the draft report "Medicare Conditions of Participation for Organ Donation: An Early Assessment of the New Donation Rule." The AHA strongly supports the goal of increasing organ donations and appreciates the opportunity to provide comment on the Office of Evaluation and Inspections' draft report.

To put the draft report's findings and recommendations in context, the AHA feels that it is important to emphasize that enforcement of the organ donation rule has been in effect for less than one year. Further, as the regulations rely heavily on building new collaborative relationships with organ procurement organizations (OPOs), staff training and awareness, and infrastructure investment, we believe that it is perhaps too soon to realize the rule's anticipated gains. At the same time, the AHA recognizes that an early assessment can be a useful tool in identifying unanticipated consequences of a regulation or areas that may warrant further attention or research. In addition, while the donation rule is important, ***the AHA strongly believes that the full freight of increasing organ donation nationwide cannot and should not rest on a regulatory solution***. It will take the active involvement of many community sectors, including religious institutions, educational entities, and the media to spur national organ donation rates.

The AHA also wishes to underscore the importance of maintaining a collaborative relationship between hospitals and OPOs. In issuing its final donation rule, the Health Care Financing Administration clearly recognized the importance of fostering a collaborative and trusting relationship between hospitals and organ procurement organizations (OPOs). Similarly the draft report reiterates the importance of "a collaborative approach between OPO staff and hospital staff [to] yielding the highest consent rates."[1] Given this background, the AHA is concerned that several of the recommendations contained in the draft report run contrary to this important tenet and could seriously jeopardize the shared goal of increasing donation. With this context in mind, the following are AHA's specific comments on the draft report.

[1] HHS Office of the Inspector General Draft "Medicare Conditions of Participation for Organ Donation: An Early Assessment of the New Donation Rule," May 2000, p.2.

OIG Recommendation: HCFA should require OPOs to provide hospital-specific data on referrals and on organ recovery. The AHA finds it odd that this recommendation seemingly flows from a general finding that OPOs should be "more accountable" for implementation of the donation rule. Relaying hospital data to the Department to be used to assess *hospital compliance* with the rule does nothing to increase *OPO* accountability. If there are concerns with OPO performance, those issues should be dealt with directly. Similarly, we also point out that the report does not assess OPOs' infrastructure capacity (i.e., 24-hour staff, development of designated requestor training programs, investment in new telephone systems, and relationships with eye and tissue banks), which directly impacts hospitals' ability to implement the rule's new policies.

Turning to the specifics of the recommendation, the draft report suggests that referral and donation data should be utilized to assess hospital compliance with the donation rule. AHA is very concerned that this recommendation could effectively nullify the collaborative foundation of the hospital/OPO relationship. As stated in our comment letter to HCFA, death record review should only be done for two purposes: on a case-by-case basis when the OPO and hospital are determining whether a specific patient was a potential donor, and as part of an internal quality improvement process. This review and this resulting data should not be used for external compliance purposes and, consequently, should not be submitted to either HCFA or the Organ Procurement and Transplantation Network. Compliance monitoring activities are the responsibility of HCFA and the state surveyors with which it contracts. In fact, HCFA emphatically states, in a department-published "Question and Answer" document, that the results from an OPO's review of hospital death records ***will not*** be used by HCFA to monitor hospital compliance with the regulation. The AHA believes it is wholly inappropriate and potentially very damaging to the goal of increasing organ donation to insert this thinly veiled oversight function into the hospital and OPO relationship.

Moreover, the draft report points out that, while referrals to OPOs have seen a marked increase, actual donation remains relatively flat. The AHA believes that this early data indicates the importance of looking beyond referral rates and toward identifying additional factors that may or may not influence donation rates, such as incentives to work in partnership with OPOs and availability of designated requestor training.

OIG Recommendation: HCFA should require OPOs to make hospital-specific data on donation publicly available. The AHA is very concerned that this recommendation is not founded in any cited evidence, nor do the authors provide a compelling rationale for its inclusion. As the research clearly underscores, organ donation is a complex issue that relies on partnerships and communication between and among caregivers, donor families, clergy, and local communities. Posting hospital-specific data on donation rates oversimplifies the issue and raises potential ethical concerns. For example, might the public prefer to go to a hospital where organ donation is less frequent, i.e., where there are fewer deaths or "imminent deaths"? Should the federal government set *de facto* thresholds for organ donation by hospital? Additionally, it is unclear what meaning the public should or will assign to hospital specific referral and donation rates. Again, this recommendation smacks of further regulation without justification. While the AHA agrees with the stated aim that opportunities to foster public discussion and education

should be pursued, we firmly caution that efforts to increase organ donation should not rely on potentially perverse incentives that may distort sensitivity to this very personal decision.

OIG Recommendation: The Health Resources and Services Administration (HRSA), in its funding initiatives, should support demonstration projects on how to effectively train and make use of designated requestors. The AHA agrees with the recommendation that HRSA should consider innovative programs for training designated requestors as part of its grant making function. Increasing the pool of individuals available for, and skilled in, discussing organ donation and securing consent is an important baseline goal. To this end, the AHA believes that hospitals should be able to develop their own in-service training, provided it meets certain criteria. Hospitals should also have access to federal grant money to undertake training initiatives. Hospital-based training is particularly important in rural areas were an OPO may cover a broad geographic region.

In a similar vein, the AHA proposes that the agency consider establishing demonstration projects to further the research on successful models for securing organ donation consent and community based activities that encourage organ donation decision making in the population at large. These efforts would support AHA's belief that significant increases in organ donation will be achieved through efforts that focus less on regulation and more on education and public awareness. We would be happy to work with HRSA, the organ procurement organizations, and other interested groups to publicize best practices or model programs and develop materials to help OPOs and hospitals implement such practices. It is our understanding that the agency is working on a designated requestor training manual, which is sure to be a useful tool to expand the number of individuals skilled in discussing organ donation with families. We look forward to its publication.

AHA believes that it is critical to assess the effectiveness of regulations and commend you for taking on this task. We sincerely appreciate the opportunity to review and comment on this draft assessment of the organ donation rule and hope our comments are useful as HHS considers its responses to the proposed recommendations. Should you have any questions, please call me or Anne Berdahl at (202) 626-4628.

Sincerely,

Rick Pollack

Rick Pollack
Executive Vice President

APPENDIX C

Endnotes

1. HHS Fact Sheet, "National Organ and Tissue Donation Initiative," April 16, 1999. In 1998, organ donation increased 5.7 percent, the first substantial increase since 1995. Data on size of the waiting list are updated through August 6, 2000, using data from the United Network for Organ Sharing, at http://www.unos.org.

2. HHS Fact Sheet, "National Organ and Tissue Donation Initiative," April 16, 1999.

3. By May, 2000, this number had decreased to 59 OPOs, as service areas were merged. We conducted our survey at the end of 1999, and use 61 as the number of OPOs in this report.

4. To be recertified, OPOs must meet at least 75 percent of the national mean on four of the following five standards, measured per million population, in their service area:

- organ donors
- kidneys procured
- kidneys transplanted
- extra renal organ procured
- extra renal organs transplanted.

The Balanced Budget Act of 1997 authorizes the Secretary to expand the certification period for an OPO to four years if appropriate on the basis of its past practices (P.L. 105-63, Sec. 4642).

5. HCFA recognized that full implementation of this rule could take up to a year, although it expected hospitals to make progress toward implementation during the phase-in period.

6. 42 C.F.R., sec. 283.45 was added at 63 Fed. Reg. 33,875, June 22, 1998, effective August 21, 1998. The full regulation reads as follows:

> **§ 482.45 Conditions 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 the staff on issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while testing and placement of potential donated organs, tissues, and eyes take place.

7. William DeJong *et al.*, "Requesting Organ Donation: An Interview Study of Donor and Nondonor Families," *American Journal of Critical Care* 7 (January 1998) 1: 13-23; Michael J. Evanisko *et al.*, "Readiness of Critical Care Physicians and Nurses to Handle Requests for Organ Donation," *American Journal of Critical Care* 7 (January 1998) 1: 4-12; Patrick McNamara and Carol Beasley, "Determinants of Familial Consent to Organ Donation in the Hospital Setting," *Clinical Transplants 1997*, Cecka and Terasakai, Eds., (UCLA Tissue Typing Laboratory, 1998), 219-229.

8. Confidence intervals for all estimates appear in Appendix A.

9. To be recertified, OPOs must meet at least 75 percent of the national mean on four of the following five standards, measured per million population, in their service area:

OPO Performance Standards: Average per year for 1999 and 1998		
Measure	Mean*	Range*
Donors per million population	21.5	13.4 - 38.0
Kidneys procured per million	39.3	25.0 - 69.4
Kidneys transplanted per million	34.0	22.3 - 61.9
Extra renal organs procured per million	38.0	19.0 - 70.7
Extra renal organs transplanted per million	34.4	15.2 - 67.7

APPENDIX C

* The Puerto Rico OPO is included in the mean, but excluded from the range presented here

10. 42 C.F.R., sec. 482.45 (a) (3)

11. Office of Inspector General, *The External Review of Hospital Quality: A Call for Greater Accountability* (OEI-01-97-00050), July 1999, p. 16.

12. LifeGift, the Houston-based OPO, provides hospital by hospital performance data in its annual report.

13. The State surveyors survey only hospitals. The OPO surveys are conducted by HCFA regional office staff.

14. Hospitals that receive Joint Commission accreditation are deemed to meet the Medicare conditions of participation.

15. Office of Inspector General, *The External Review of Hospital Quality: The Role of Medicare Certification* (OEI-01-97-00052), July 1999, p. 10.

14. For Joint Commission standards that relate to patient care or outcomes of care, hospitals may receive a rating that ranges from 1 to 5, with 1 being "substantial compliance" and 5 "noncompliance." In assessing a provision such as a hospital's compliance with the donation rule, the worst score possible is a 2, which stands for "significant compliance."

17. Fed. Reg. 33,871 June 22, 1998.

18. The rule was effective August 21, 1998. The data reported here compare calendar years 1998 and 1999. These data are reported to HCFA for the OPO certification process.

19. In responses to our survey, OPOs indicated that the following States have laws that require hospital to notify their OPO of all deaths. We have not done an independent legal review to confirm these laws, or their specific provisions and limitations: Arizona, Delaware, Florida, Hawaii, Maryland, Michigan, Mississippi, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Tennessee, Texas, Virginia, Wisconsin.