CMS-3064-P-36 Organ Procurement Organization Conditions for Coverage

Submitter : Mr. Richard Luskin **Date & Time:** 06/06/2005

Organization : New England Organ Bank

Category : Organ Procurement Organization

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3064-P-36-Attach-1.PDF

Attachment 36

New England Organ Bank

June 6, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3064-P Medicare and Medicaid Programs; Conditions of Coverage For Organ Procurement Organizations

Dear Dr. McClellan,

It was my pleasure to meet with you and other CMS officials in April as part of the delegation from the Association of Organ Procurement Organizations (AOPO). We appreciated your time and your attention to the issues we raised. AOPO has submitted an extensive and detailed document commenting on the proposed regulations. I am in full support of the content of that document. Rather than repeat all those points in detail, I wish to comment here on just a few of the issues raised by the proposed regulations that are of the greatest concern to New England Organ Bank (NEOB).

As we discussed at our meeting, there are many positive aspects to the proposal. In particular we are pleased to see a movement away from using donors (and organs) per million population as the measure of OPO performance, as well as the inclusion of a framework for continuous quality improvement. Also, the recognition that successful organ donation requires a collaborative effort of both OPOs and hospitals is a welcome addition.

On the other hand, there are several aspects of the regulations that are concerning as they appear to be inconsistent with the wording of the Organ Procurement Organization Certification Act of 2000, PL 106-505 and/or the intent of Congress in adopting that statute, and may negatively impact organ donation.

First, the regulations propose a competitive methodology for use in the recertification and redesignation of OPOs. This seems to be a dated concept that actually has the potential to decrease donation, a direct contradiction of the regulations' stated intent. The

DHHS/HRSA sponsored Organ Donation Breakthrough Collaborative has demonstrated remarkable success over the past 20 months in increasing organ donation: 11% more nationally in 2004 vs. 2003. The increase is continuing in 2005. The Collaborative works because all OPOs share their knowledge and best practices under the Collaborative's motto of "All teach, all learn". This system of shared knowledge works. Yet the regulations propose to pit one OPO against one another every four years, even if the OPO is fully compliant with all required performance standards. This is counterproductive. Rather than focusing on eliminating OPOs, we believe it will be more effective to focus the regulations on enhancing the performance of all OPOs. We strongly urge you to change the final regulations to require recertification and redesignation of all OPOs that meet the OPO performance regulations, while providing incentives for all OPOs to engage in continuous quality improvement.

Second, the proposed regulations have responded to the requirement for a meaningful appeals process with a new, vaguely defined and untested appeals procedure. The AOPO commentary describes in great detail the legal and practical reasons why this proposal is unacceptable. We urge you to reconsider this proposed appeals process and adopt the recommendations of AOPO.

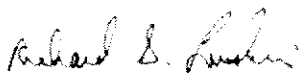
Third, the proposed regulations are silent on an effective date for implementation of the numeric performance regulations. As we are now in the 41st month of a 48 month review process, and there are significant unanswered questions concerning the definitions to be used in calculating OPO performance, we would strongly recommend that these performance standards be applied only prospectively. We would welcome the opportunity to work with CMS staff to reach an appropriate understanding of how performance will be measured, so that the process can begin in January 2006 for the next four-year cycle. For example, it is essential that the regulations recognize OPOs for their efforts to implement protocols for the recovery of organs from Donors after Cardiac Death (DCD). DCD is a major initiative of the DHHS Donation Collaborative and is growing rapidly. In 2004 DCD represented almost 5% of all US organ donors. For some OPOs like NEOB, DCD accounted for almost 20% of all donors recovered in 2004.

Fourth, we are concerned about the overly broad definition of "adverse event". As currently proposed it appears to include any organ not recovered from a consented donor. Obviously there are many reasons why a consented organ would not be recovered and almost all of them are clinical; i.e. the organ is medically unsuitable for transplant. We would assume it was not CMS' intent to include organs such as this and therefore would appreciate a clarification in the final rule.

Fifth, we were pleased to be recognized by name in the regulations' preamble as an OPO that had successfully revised its Board structure to deal with issues of conflict of interest. We are pleased with our Board membership and function and believe it effectively serves both the public and transplant community. Therefore we find it most ironic that the Board you praised would not be permitted under the proposed regulations. The proposal to require the creation of an advisory board and completely separate it from the governing board is neither practical nor effective. Moreover, your suggestion that it might be appropriate to have a single executive serve the functions of the governing board is in direct conflict with state laws concerning oversight of non-profit organizations. There must be a representative board responsive to the public that serves in a governing role for the OPO.

We appreciate the opportunity to comment on these proposed regulations. Please contact me if I may be of assistance in further refinement of the final regulations.

Sincerely,



Richard S. Luskin
Executive Director

CMS-3064-P-37 **Organ Procurement Organization Conditions for Coverage**

Submitter : **Mr. Joe Roth** **Date & Time:** **06/06/2005**

Organization : **AOPO**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-3064-P-37-Attach-1.DOC

AOPO
Association of
Organ Procurement
Organizations

Attachment #37
June 6, 2005

Mark B. McClellan, MD, PhD.
Administrator
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington DC 20201

Re: CMS-3064-P Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs) – Follow Up

Dear Dr. McClellan:

On June 1, we submitted our formal response from the Association of Organ Procurement Organizations (AOPO) to the proposed CMS rule (CMS-3064-P) regarding Medicare and Medicaid Programs: Conditions for Coverage for Organ Procurement Organizations (OPOs).

That AOPO communication, as part of our comments regarding proposed changes to ***§ 486.316 ("re-certification and competition processes)***, included national data on organ recoveries on a monthly basis through April 2005. We have just been informed today of the preliminary data for May 2005 and wanted to be sure that these data were submitted to CMS as part of the formal public comment period. Preliminary data indicate 669 deceased donors recovered in May 2005, compared to 607 the same month a year earlier and 544 in May 2003. The results continue to be record setting and continue to demonstrate the extraordinary effectiveness of the HHS Organ Breakthrough Collaborative in achieving new levels of deceased organ donor recovery in the US.

Thank you for this opportunity to provide follow up information. We are always available for any clarification you may need of the analysis and recommendations included in our overall response.

Sincerely,

Joseph Roth
President

Paul Schwab
Executive Director

CMS-3064-P-38 **Organ Procurement Organization Conditions for Coverage**

Submitter : **Mr. Thomas Beyersdorf** **Date & Time:** **06/06/2005**

Organization : **Gift of Life Michigan**

Category : **Organ Procurement Organization**

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-3064-P-38-Attach-1.PDF

Attachment 5

GIFT OF LIFE

MICHIGAN ORGAN & TISSUE DONATION PROGRAM

DONATE LIFE

A Donate Life Organization

June 6, 2005

CMS-3064-P
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear CMS Officials:

We are pleased to provide our response to the proposed CMS rule (CMS-3064-P) regarding Medicare and Medicaid Programs: Conditions for Coverage for Organ Procurement Organizations (OPO). Gift of Life Michigan is the designated OPO for the vast majority of the state of Michigan. These comments are arranged in sequence of paragraphs as they appear in the proposed regulations, not necessarily in order of importance.

1. **Appeals**

The Association of Organ Procurement Organizations (AOPO) has included remarks about this topic in their comments. We echo and support the AOPO position that Section 498 appeals procedures should be reincorporated into the regulations.

2. **Recertification and competition processes**

We believe that it is counter productive to allow for open competition of service areas of those OPOs which are found to be in compliance with performance measurements. This would cause substantial distraction by the management of every OPO trying to protect its own territory. It would actually be a disincentive towards sharing of any "best practices" among OPOs. The HRSA Breakthrough Collaborative on Organ Donation has shown that cooperation is an effective and successful means to improving organ donation rates. In fact, it has been the single most successful factor ever to have such an effect. Our own donation rate increased by more than 30% from 2003 to 2004, largely attributable to the effects of the HRSA Breakthrough Collaborative.

If no OPO applies for an open service area, we believe that such area should not be involuntary forced upon neighboring OPOs, either whole or in part. Rather, CMS should first allow for application by other OPOs of portions of the open area. Then, for any areas still open, CMS may wish to use such

opportunity to allow for the introduction of entirely new organizations to qualify as an OPO to service such area.

3. **Outcome measures**

We believe that whatever threshold levels are determined as inadequate performance, that they should also be statistically significant at $p<.01$. That is to say that if 75% of the mean of some parameter is selected as the outcome measure, that an OPO must achieve both less than 75% of that mean and the OPO's performance must be statistically significantly lower than others.

This same concept of statistical significance should also be applied to any other comparative performance measures used anywhere in the regulations, such as, having a conversion rate more than 15% higher than another OPO for competition purposes. Such a 15% differential should also be evaluated for statistical significance.

4. **Administration and governing body**

We believe that CMS should remove the restriction to overlapping membership on both the advisory board and the governing board. This proposed restriction would inhibit communications and coordination between the two groups, and would deny both groups access to appropriate qualified individuals to serve in such board capacities.

5. **Human resources**

We believe the proposed language in this section is overly prescriptive in defining job titles and duties, especially as it relates to a medical director. Within the medical community, the concept of an organizational medical director implies certain obligations, responsibilities, authority, and power. While it is appropriate that an OPO be required to have a structure and resources to accomplish all the functions normally assigned to a medical director, it is unnecessary and overly prescriptive to require that a single individual be accorded that title and accompanying power.

6. **Requesting consent**

The proposed regulations are again overly prescriptive and detailed as to the amount and types of information to be included in the consent process. We believe that whatever is required under state anatomical gift laws to constitute a donor document should suffice. For example, the proposed requirement to list all possible uses for donated organs or tissues could become extremely lengthy, time consuming to explain, and in some cases, simply too graphic to be appropriate for a conversation which is required elsewhere to be conducted in a compassionate, sensitive manner.

GIFT OF LIFE
MICHIGAN ORGAN & TISSUE DONATION PROGRAM

DONATE LIFE
A Donate Life Organization

Similarly a description of the screening and recovery processes, and information about all potential organizations which might recover, process, or distribute tissue could generate substantial amounts of paperwork, and simply be more distracting and confusing to the family rather than helpful or informative.

7. **Donor evaluation and management and organ placement and recovery**

We concur with the AOPO comment in this area about the use of the phrase, "best practices."

8. **Quality assessment and performance improvement**

We concur with the AOPO comments regarding adverse event reporting, and the potential problems inherent in protecting the confidentiality of such reports.

9. **Living donation**

While some OPOs may currently have a limited involvement with living donation activities, we believe it is premature at this time to include any references in the regulations to this area of activity.

Thank you again for the opportunity to comment.

Sincerely,

Thomas M. Beyersdorf

Thomas M. Beyersdorf
Executive Director

2203 Platt Road • Ann Arbor, MI 48104 • 800.482.4881 • fax 734.973.3133 • giftoflifemichigan.org

CMS-3064-P-39 **Organ Procurement Organization Conditions for Coverage**

Submitter : **Ms. Laura Blum** **Date & Time:** **06/06/2005**

Organization : **JCAHO**

Category : **Private Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3064-P-39-Attach-1.DOC

Joint Commission

Setting the Standard for Quality in Health Care

Attachment #39

June 6, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: Comments on the proposed rule "Medicare and Medicaid Programs; Conditions for Coverage for Coverage for Organ Procurement Organizations (OPOs)

File Code: CMS-3064-P

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) appreciates the opportunity to comment on the proposed rule that would set forth new conditions for coverage for organ procurement organizations (OPOs). Founded in 1951, the Joint Commission is the nation's oldest and largest standard-setting and accrediting body in health care. The Joint Commission evaluates and accredits more than 15,000 health care organizations in the United States, including the preponderance of our nation's hospitals. The Joint Commission is also active internationally and has provided consultation and accreditation services in over 60 countries.

The Joint Commission's Board of Commissioners has identified the challenge of increasing organ donation as one of its top public policy priorities. Our recommendations on this subject are discussed in the Joint Commission's comments on Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants" (CMS-3835-P).

It is evident that in the course of drafting the proposed rule, CMS staff had to address a myriad of complex issues associated with improving OPOs performance and increasing organ donation. Specifically, this letter addresses the definition of organ donation potential in §486.302, re-certification and competition in §486.316 and outcome measures in §486.318. If you have any question or require additional information regarding the comments provided below, please contact Trisha Kurtz, Director of Federal Relations at pkurtz@jcaho.org or Laura Blum, Associate Director, Federal Relations, at lblum@jcaho.org. Both Trisha and Laura can be reached by telephone at 202.783.6655.

Definitions (§486.302)

CMS proposes several amendments and additions to the definitions that are relevant to the OPOs. In particular, CMS proposes eliminating the term "potential donor" and replacing it with "organ donation potential". This proposed definition differs somewhat from that used currently in the OPTN reporting requirements for OPOs which could cause confusion and lead to mistakes and inaccuracies. In this vein, the Joint Commission recommends a uniform definition for "organ donor potential." Specifically, the Joint Commission encourages CMS to consider the Association of Organ Procurement Organization's proposed definition of "organ donor potential" which they submitted with their formal comments to CMS on June 1, 2005.

Re-certification and Competition (§486.316)

The opening of every service area at the end of every 4-year cycle is potentially divisive and conflicts with the successful work of the HRSA-sponsored, Organ Donation Breakthrough Collaborative. The rule proposes competitive framework options to introduce competition to service areas at the end of every 4-year certification cycle. The Joint Commission is concerned about a competition framework that would allow the takeover of a certified OPO's service area by another OPO even if the OPO is performing well. Lack of competition should be the reward for meeting a wide, full range of performance measures.

Outcome Measures (*§486.318)*

When drafting the new regulations, it is imperative that CMS identify and adopt a comprehensive set of performance measures to assess the OPO's performance. As mentioned in our comments on *§486.316,* the Joint Commission recommends that CMS consider a strategy that would reward OPOs that performed well on the measurement set.

CMS-3064-P-40 Organ Procurement Organization Conditions for Coverage

Submitter : Dr. Anil Kumar **Date & Time:** 06/06/2005

Organization : Hahnemann University Hospital

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3064-P-40-Attach-1.DOC

CMS-3064-P-40-Attach-2.PDF

Attachment #40

CMS-3064-P
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-3064-P

Dear CMS Officials:
I am pleased to provide the following comments regarding the proposed CMS rule (CMS-3064-P) regarding Medicare and Medicaid Programs: Conditions for Coverage for Organ Procurement Organizations (OPOs). As a **transplant surgeon,** and a member of the Gift of Life Donor Program Board of Directors, I applaud the efforts undertaken by CMS to promote organ donation and transplantation. Gift of Life Donor Program is the OPO serving the eastern half of Pennsylvania, southern New Jersey and the state of Delaware.

In addition to the comments submitted by Gift of Life Donor Program, I would like to focus on the following issues raised in the proposed CMS rule:

1. Administration and Governing Body (Proposed § 486.324)
The proposed rule mandates that an OPO have a separate and distinct governing body (an Administrative Board), as well as an advisory board (Advisory Board). The Advisory Board would be comprised of all persons mandated under the Public Health Services Act, such as members who represent hospital administrators, members of the public, surgeons from each transplant center, etc. **The proposed rule would prohibit any cross membership between an OPO's governing body and the required advisory board.** The stated objective of this very onerous administrative structure is to avoid conflict of interest, particularly with regard to an OPO's financial policies, including establishment of standard acquisition charges.

The proposed rule ignores the already existing state and federal laws which address conflicts of interest. Under existing state corporate laws, as well as common law, there are clear standards requiring board members to uphold their fiduciary responsibility to the organization whose board they are serving. Federal law governing tax- exempt organizations also imposes standards and safeguards, some of which have been recently highlighted in the expanded enforcement authority provided under the Intermediate Sanctions. There are already standards imposed that address and require organizations to mediate conflict of interest issues. Added to the existing laws, the corporate compliance programs recommended to organizations also impose standards to protect against conflicts of interest which might adversely impact fiduciary decision-making.

The Gift of Life Donor Program Board underwent a significant restructuring which became effective 1999. This restructuring was a result of a more than 2 year process undertaken to ensure that constituencies served by the organizational mission were included in the process and that board members represented these different constituencies. This includes transplant centers, donor hospitals, health professionals, donor family members, recipients, clergy and others. The composition of board membership is designed to protect against "insider" and "self" interests.

The enhanced and balanced board membership allows for a meaningful and thoughtful discussion of the issues that an OPO must face by those who are familiar with the issues. Prohibiting this type of dialogue may deprive an OPO of the very type of governing body direction

which it needs most. A conflict of interest may exist because someone in fact has an "interest" in the subject matter- those who have this interest are most frequently those who have the knowledge and desire to serve. There are effective mechanisms available to address conflicts of interest and at the same time allow for the very valuable insight and information needed in order to provide an OPO with the overview and guidance which are the functions of a board.

Additionally, mandating an organizational structure of multiple oversight bodies through a governing body and advisory boards may adversely impact the actual operation of the OPO. Multiple bodies may cause a delay in decision-making, may be burdensome in terms of identifying persons willing to serve in the board capacities, and integrating the decisions and recommendations of multiple groups. I also note that there are many other health and public service organizations which deal with critical public health issues which are permitted to provide governance under the guidance provided by state and federal laws applicable to non-profits and tax exempt organizations which mange conflict of interest issues successfully. OPOs are not unique in having the potential for conflicts of interest among their board members.

Therefore, I strongly urge CMS to modify the proposed regulations to allow OPOs to continue to have one "fiduciary" governing board which includes all of those constituent members cited in the PHS law, or alternatively to have one fiduciary governing Board with one or more advisory boards/bodies. I do recommend that in either case the transplant surgeon/transplant physician representation on the governing board be no more than 50% and there should be strong conflict of interest policies in place.

Additionally, I note that CMS is requesting input on the proposal that a single individual be designated to assume full legal authority and responsibility for the management (and by inference the governance) of an OPO instead of the Board of Directors. I strongly oppose this proposal in that it is inconsistent with state and federal standards regarding governance, as well as it is inappropriate to charge one individual with all of these functions without oversight. Certainly, OPOs should continue to have the ability to have a chief executive officer who is charged with day-to-day management of the organization but who remains subject to the Board's oversight. Ultimately, a governing body such as a board of directors should be responsible and have full legal authority and responsibility for the organization.

2. Proposed OPO Outcome Measures
"Outcome Measure (proposed § 486.318)"

The CMS proposed rule focuses exclusively on conversion rates as its outcome metric. I urge CMS to identify at least 2 distinct outcome measures, focusing on an overall conversion rate and organs transplanted per donor ratio.

While the proposed rule does include an overall conversion rate as a metric, with the number of donors as the numerator and the "potential donors" as the denominator, it is problematic as it is currently defined. First, as noted by AOPO in its comments, the actual definition of organ donor potential must be standardized. However, even if one definition of "organ donor potential" is adopted, if it is NOT applied uniformly, there will be significantly inter-OPO variability compromising the validity of the outcome measure.

The need for uniform application of the definition refers both to a uniform interpretation of the term "organ donor potential" (or the term "eligible deaths" as proposed by AOPO) as well as the need for uniform death record review practices.

I agree that death record reviews are an essential aspect of improving donation rates and Gift of Life has a well-documented death record review practice. In fact, Gift of Life published one of the first studies in the country regarding organ donor potential in Pennsylvania utilizing death record reviews. However, if an OPO does not regularly conduct death record reviews, or applies the definition of "organ donor potential" very restrictively during the review, then the denominator of

its conversion calculation is likely to be smaller, yielding an "enhanced" or improved conversion rate. Another OPO may have a very effective medical record review practice, which identifies patient deaths as "potential donors" where the medical record reveals support was removed from a patient it appeared would otherwise have progressed to brain death, but a referral was not made. That second OPO will consider the patient as a potential organ donor or an eligible donor, the denominator of its conversion calculation will be larger, potentially yielding a "reduced" conversion rate. If the overall objective of the proposed rule is to increase donation, which practice is likely to best support that objective? It would seem that the latter OPO's practices would provide enhanced opportunities for performance improvement, but its "Performance" indicator might well be weaker than the first OPO's. **Consequently, until a uniform death record review practice is instituted among OPOs (which I encourage), including "missed referrals" identified in death record reviews as a component of the denominator of the conversion rate is inequitable as applied to OPOs.**

In order to mediate some of the inter-OPO variability on the issue of "missed referrals" and death record reviews, I recommend that such information not be included in calculation of the conversion rate for purposes of comparing an OPO to the mean until a uniform death record review practice has been instituted across the country. I also recognize that the current OPTN data base (which does not take into account missed referrals) requires additional validation in order to accurately predict donor potential. I would encourage such validation of the information with the support of third parties such as the SRTR.

I also urge CMS to adopt an organs transplanted per donor ratio as a measure. This ratio should include a "case mix" aspect which addresses the variation in the expected number of organs that can be transplanted from a particular type of donor. The case mix should take into account not only subgoals for Standard Criteria Donors, Donation after Cardiac Death, Expanded Criteria Donors, but also donors that may be testing positive for infectious diseases and/or have other co-morbid factors.

3. Medical Director
"Human Resources (proposed § 486.326)" and "Donor Evaluation and Management, Organ Placement and Recovery (proposed § 486.344)"

The proposed rule's requirement that an OPO's medical director be responsible for ensuring, among other items, that every potential donor is thoroughly assessed for medical suitability for organ donation and clinically managed to optimize organ viability and function may have the effect of inappropriately interfering with an individual transplant surgeon's judgment and area of expertise. Within the standard of acceptable and common current medical practice, there is certainly a range of practices. Not every surgeon will view a potential donor similarly, that is why each surgeon has the ability under the current allocation system to accept or reject a particular organ for a particular patient. Mandating that a medical director make the suitability decision, including a decision to rule out, impedes the role of the attending surgeon/physician and potentially interferes with the surgeon's/attending physician's decision as to whether to accept a particular organ for transplant into a particular patient. Moreover, mandating that a medical director participate in every single case may also add time to the already time sensitive process. Ultimately, requiring a medical director to make every suitability decision may result in fewer patients transplanted, not more. The appropriate role for a medical director is to be available to provide consultation on donor evaluation and management as needed by the OPO staff on specific cases, not to evaluate every case. The role between the patient awaiting transplant and his or her treating physician/surgeon must be preserved and honored.

Thank you for your consideration,

CMS-3064-P-41 **Organ Procurement Organization Conditions for Coverage**

Submitter : **Mr. Timothy M. Goldfarb, CEO** **Date & Time:** **06/06/2005**

Organization : **Shands HealthCare**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

CMS-3064-P-42 **Organ Procurement Organization Conditions for Coverage**

Submitter : **Katrina Crist** **Date & Time:** **06/06/2005**

Organization : **American Society of Transplant Surgeons**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-3064-P-42-Attach-1.DOC

Attachment #42

Filed Electronically

June 6, 2005

Mark McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244-1850

Re: Conditions of Participation for Organ Procurement Organizations; CMS 3064-P

Dear Dr. McClellan:

The American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) are pleased to comment on the proposed conditions of participation for organ procurement organizations (OPOs) published in the February 4, 2005 Federal Register, as they relate to the impact on transplant centers.

ASTS is an organization comprised of almost 1000 transplant surgeons and physicians dedicated to excellence in transplantation surgery through education and research with respect in all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure.

AST is an organization of more then 2,200 transplant professionals dedicated to research, education, advocacy and patient care in transplantation, whose goal is to offer a forum for the exchange of knowledge, scientific information and expertise in the field of transplantation.

ASTS and AST fully support CMS' goals of emphasizing quality and continued quality improvement to ensure that OPOs use best practices. Our organizations have been involved in the Organ Donation Breakthrough Collaborative and we support the efforts of that initiative to improve OPO performance and increase organ donation. However, we are concerned that there is an inconsistency between the goals of the OPO regulation and the goals of the proposed transplant center regulation.

Performance Measures for OPOs (Sections 486.304, 486.316, 486.318)

The OPO performance measures would create an incentive for OPOs to procure as many organs as possible, including organs from extended criteria donors (ECDs) and donation after cardiac death (DCD) donors, without any specific attention to the transplantability of these organs, particularly extra-renal organs, and without an emphasis on graft and recipient outcomes. At the same time, the proposed transplant center regulations establish outcome standards based on one-year patient and graft survival rates. As explained more fully below, we are concerned that the goals of these two proposals are not entirely consistent and that the OPO outcome measures could serve to undermine the goal of the transplant center regulations to ensure good patient outcomes.

The proposed OPO performance measures would require OPOs to achieve at least 75 percent of the national mean in 4 of 5 performance categories, averaged over 4 calendar years. One of the most important changes in the OPO performance measures is the use of "organ donor potential" instead of population in the service area as the denominator in the performance percentage. The definition of "organ donor potential" is limited to donors age 70 or less who meet death by neurological criteria and who do not have standard clinical contraindications. This would exclude organs procured from DCD donors from the denominator as well as organs from certain extended criteria donors (ECDs); however such organs would count as organs procured and organs transplanted and thus would be included in the numerator of the performance percentage.

The five performance outcomes are (1) organ donors/organ donor potential; (2) kidneys procured /organ donor potential; (3) kidneys transplant/ organ donor potential; (4) extra-renal organs procured/organ donor potential; and (5) extra-renal organs transplanted/organ donor potential. However, in the current proposal, an OPO need only meet four of the five criteria to be in compliance.

We are concerned that the fact that OPOs need to meet only four out of five standards, combined with the fact that organs from older donors and DCD donors count in the numerator but not the denominator of the performance percentage creates an incentive for OPOs to increase procurement of organs from older donors as well as DCD donors. This would potentially result in two negative consequences. First, there would be an incentive for OPOs to identify DCD and certain ECD donors preferentially, since this would increase the numerator but not the denominator, hence increasing the organ donor to organ donor potential ratio (the first performance measure). Second, since we know that the average yield of transplanted organs is much lower for both DCD (2.04) and ECD donors than for standard donors (3.62), it would negatively affect the number of extra-renal organs transplanted. Finally, since the hazard ratio for delayed graft function in kidneys and graft survival for livers exceeds 1.7 and 1.85 respectively for organs from DCD donors which implies a statistically significant decrease in outcomes, both transplant recipients and transplant centers could potentially be penalized as a result of the proposed rule as written.

Thus, the proposed performance measures create an incentive for an OPO to focus efforts on ECD and DCD donors, thereby increasing the likelihood that it will meet OPO outcomes measures. However, the net result for transplant centers of such an approach would be the retrieval of a disproportionate number of DCD and ECD renal organs and virtually no non-renal organs suitable for transplantation, potentially resulting in a negative impact on graft and patient survivals for kidneys and no extra-renal organs to transplant.[1] We therefore urge CMS to consider

[1] The yield for DCD donors is 2.04 compared to 3.62 for non-DCD donors which suggests that kidneys are generally the only organs transplanted from DCD donors.

the impact the proposed OPO standards might have on transplant centers that are required to meet new CMS standards for patient and graft survival. If OPOs shift toward procuring more DCD organs relative to the number of non-DCD organs, survival rates will likely decrease.

Moreover, the OPO suffers no reimbursement consequences for procuring organs that are not accepted for transplantation. Under Medicare rules, the OPO must charge a transplant center its standard organ acquisition charge, which is calculated by averaging its total costs of procuring organs over the number of billable organs. See Provider Reimbursement Manual Part 1, §§2771; 2773. Thus, the costs of procuring organs that are not accepted for transplantation effectively increase the OPO's standard acquisition charge paid by transplant centers for organs which are accepted. As a result, OPOs are able to pass through their costs to transplant centers in the form of higher standard acquisition charges, with some of those costs being passed on to the Medicare program in the form of transplant center organ acquisition costs. Moreover, as CMS notes in the preamble to the regulation, if an OPO's costs of recovering organs exceeds payments received for organs, Medicare covers a large portion of the additional costs. 70 Fed. Reg. 6093 (February 4, 2005).

CMS states that it is seeking comments on whether OPOs should be required to meet all five, instead of only four of the performance measures. Such a requirement would be helpful in addressing the concern described above. If an OPO has to meet all five measures, it would have to ensure that at least some of the extra-renal organs it procures are acceptable for transplantation. Therefore, ASTS and AST support extending the performance measures to require compliance with all five criteria. At a minimum, we believe compliance with the fifth criteria related to number of extra-renal organs transplanted should be mandatory. [2]

Definition of Organ Donor Potential (Section 486.302)

CMS has also requested comment regarding the proposed definition of "organ donor potential" and whether DCD donors should be included in the denominator. We believe it is inappropriate to include DCD donors and donors over the age of 70 in the numerator but not the denominator of the performance measure percentage. We believe this creates in inappropriate incentive to procure organs from DCD donors or older donors at the possible expense of non-DCD or standard donors.

In this regard, we note that the statistics on the number of DCD donors cited by CMS in the proposed rule are from 2000 and 2001 when there were far fewer DCD donors than there are now. The number of DCD donors as well as older donors has risen dramatically since that time. For example, in the first 7 months of 2004 compared to the same period in 2003, there was a 10.5 percent increase in total donors, an 8.7 percent increase in organs recovered and a 6.8 percent

[2] In an effort to eliminate any potential ambiguity in our comments and to facilitate CMS's consideration of our recommendations, we have incorporated our suggested changes in proposed regulatory language, which is included at Attachment 1 to these comments. We offer this mark-up as an illustration of how our suggestions might be incorporated into the Proposed Rules, and hope that CMS finds it helpful. The sections of the comment letter that address each of the proposed changes are cross-referenced for ease of reference.

increase in organs transplanted. Forty-two percent of this increase is from DCD and ECD donors. The total number of DCD donors increased by 38.5%. [3]

At the same time, a DCD donor yields only 2.04 transplanted organs per donor compared to 3.62 for non-DCD donors. An OPO that aggressively pursues procurement of DCD donors would improve its conversion statistic, i.e. donors (numerator) versus potential donors (denominator) but at the risk of procuring fewer transplantable organs as well as increasing the risk of graft failure in those organs that are transplanted.

For that reason, we believe that organs from DCD donors should not be included in either the numerator or the denominator of the performance measure percentage. For the same reasons we recommend that organs from donors over the age of 70 also be excluded from both the numerator and denominator. We would also support separate tracking and reporting of organs from DCD donors and donors over 70 and a separate conversion statistic. This would yield useful data which could inform future policy making in this area.

If organs from DCD donors and donors over 70 are not excluded from the numerator, as recommended above, then we recommend that they be included in both the numerator and the denominator in order to avoid the possible adverse consequences described above.

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We appreciate the opportunity to comment on this proposed rule. Please contact the ASTS Executive Director, Katrina Crist, at 703-684-5990, if you have any questions about this letter.

Sincerely yours,

A. Benedict Cosimi

A. Benedict Cosimi, M.D.
President
American Society of Transplant Surgeons

Richard N. Fine, M.D.
President
American Society of Transplantation

Enclosure: Attachment 1

[3] Data presented at the National Consensus Conference on Donation after Cardiac Death, Philadelphia, April 7-8, 2005; White Paper pending.

ATTACHMENT 1

Sec. 486.302 Definitions.

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Donor means a deceased individual whose age is 70 or less and who meets death by neurological criteria, based on generally accepted practice parameters for determining brain death from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is recovered for the purpose of transplantation.

******

Organ means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine) procured from a donor, as defined in this section.

******

Organ donor potential means the number of patients whose age is 70 or less meeting death by neurological criteria, based on generally accepted practice parameters for determining brain death, who do not have any of the following clinical indications:

(1) Tuberculosis.
(2) Creutzfeldt-Jacob Disease or any other prion-induced disease.
(3) Viral septicemia.
(4) Rabies.
(5) Reactive hepatitis B surface antigen.
(6) Any retro virus infection.
(7) Active malignant neoplasms, except primary central nervous system tumors and basal and squamous cell carcinomas.
(8) Aplastic anemia.
(9) Agranulocytosis.
(10) Active viral and systemic fungal infections.
(11) Gangrene of bowel.
(12) Extreme prematurity.
(13) Positive serological or viral culture findings for HIV.
(14) Chagas disease.

Sec. 486.304 Requirements for designation.

(a) Designation is a condition for payment. Payment may be made under the Medicare and Medicaid programs for organ procurement costs attributable to payments made to an OPO by a hospital only if the OPO has been designated by the Secretary as an OPO.

(b) Requirements for designation. An OPO must do the following:

(1) Be certified as a qualified OPO by the Secretary under 42 U.S.C. 273(b) and Sec. 486.303.

(2) Enter into an agreement with CMS that meets the requirements set forth in paragraph (c) of this section.

(3) Document that it has a defined service area that meets the requirements of Sec. 486.306.

(c) Agreement with CMS. In order for the organ procurement costs attributable to the OPO to be reimbursed under Medicare and Medicaid, an OPO must enter into an agreement with CMS. The agreement is effective upon submission by the OPO and acceptance by CMS but may be canceled by either party. If an OPO is de-certified under Sec. 486.312, payment for organ procurement services attributable to that OPO will not be made for services furnished on or after the effective date of the de-certification. In the agreement, the OPO must agree to do the following:

(1) Maintain compliance with the requirements of titles XVIII and XIX of the Act, section 1138 of the Act, section 371(b) of the Public Health Service Act, and applicable regulations, including the conditions set forth in this subpart and the rules and requirements of the OPTN, as defined by Sec. 486.320, and to report promptly to the Secretary any failure to do so.

(2) Become a member of the OPTN.

(3) File a cost report in accordance with Sec. 413.24(f) of this chapter within 5 months after the end of each fiscal year.

(4) Permit CMS to designate an intermediary to determine the interim payment rate payable to transplant hospitals for services provided by the OPO and to make a determination of reasonable cost based on the cost report in the OPO files.

(5) Provide budget or cost projection information as may be required to establish an initial interim payment rate.

(6) Pay to CMS amounts that have been paid by CMS to transplant hospitals as Medicare payment for organ recovery fees that are determined to be in excess of the reasonable cost of the services provided by the OPO.

(7) Not charge an individual for items or services for which that individual is entitled to have payment made under the Medicare program.

(d) Application for designation. An OPO that has met all of the 5 outcome performance measures at or above the mean for the previous re-certification cycle may apply for designation for the service area of an OPO that did not meet the conditions for coverage for the previous re-certification cycle. An OPO that has met all of the 5 outcome performance measures at 100 percent of the mean may apply for designation whenever a service area becomes an open area if the OPO's conversion rate of potential donors to actual donors is at least 15 percentage points greater than the conversion rate of the OPO currently designated for the service area.

(e) Designation periods--

(1) General. An OPO is normally designated for 4 years. A designation period may be shorter, for example, an interim designation for the service area of an OPO that has terminated its agreement with CMS. A designation period may be longer, for example, a designation may be extended if additional time is needed to select a successor OPO to an OPO that has been de-certified.

(2) Re-designation. Re-certification and re-designation must occur not more frequently than every 4 years.

Sec. 486.316 Re-certification and competition processes.

CMS opens all OPO service areas for competition at the end of every re-certification cycle.

(a) OPO meets conditions for coverage. When an OPO meets the outcome measures in Sec. 486.318 and has been found to be in compliance with the process performance measures and other requirements in Sec. Sec. 486.320 through 486.348, CMS will open the OPO's service area for competition. An OPO may compete for the open area only if it met all 5 outcome measures at or above 100 percent of the mean for the preceding re-certification cycle and its conversion rate of potential donors to actual donors is at least 15 percentage points higher than the conversion rate of the OPO currently designated for the service area. The OPO must compete for the entire service area. The incumbent OPO may compete for its own service area.

(b) OPO does not meet conditions for coverage. If CMS notifies an OPO that it will be de-certified because its agreement will not be renewed or will be terminated by CMS, and the OPO does not appeal within the time frame specified in Sec. 486.314(a) or the OPO's de-certification is upheld on appeal, CMS will open the OPO's service area for competition from other OPOs. An OPO may compete for the open service area only if it met all 5 outcome measures at or above the mean for the preceding re-certification cycle. The OPO must compete for the entire area.

(c) Criteria for selection. CMS will designate an OPO for an open service area based on the competing OPOs' degree of success in meeting the process performance measures during the preceding re-certification cycle and the submission of an acceptable plan to increase organ donation in the open service area. An acceptable plan to increase organ donation, at a minimum--

(1) Is based on the competing OPO's experience and success in its own service area;

(2) Includes an analysis of existing barriers, both internal and external, to increasing organ donation in the open area; and

(3) Provides a detailed description of specific activities and interventions for increasing organ donation in the open service area.

(d) No OPO applies. If no OPO applies to compete for the open area, CMS may select a single OPO to take over the entire open area or may adjust the service area boundaries of two or more contiguous OPOs to incorporate the open area. CMS will make its decision based on the OPOs' success in meeting the process performance measures during the preceding re-certification cycle.

Sec. 486.318 Condition: Outcome measures.

(a) With the exception of OPOs operating exclusively in non-contiguous U.S. States, U.S. territories, U.S. possessions, or U.S. commonwealths, an OPO must achieve at least 75 percent of the national mean in the 5 following performance categories, averaged over the 4 calendar years before the year of re-certification:

(1) Donors, as a percentage of the potential donor denominator.

(2) Number of kidneys procured, as a percentage of the potential donor denominator.

(3) Number of kidneys transplanted, as a percentage of the potential donor denominator.

(4) Number of extra-renal organs procured, as a percentage of the potential donor denominator.

(5) Number of extra-renal organs transplanted, as a percentage of the potential donor denominator.

(b) An OPO operating exclusively in non-contiguous U.S. States,

U.S. territories, U.S. possessions, or U.S. commonwealths must meet the following outcome measures at 50 percent or more of the national mean, averaged over the 4 calendar years before the year of re-certification:

(1) Number of kidneys procured, as a percentage of the potential donor denominator.

(2) Number of kidneys transplanted, as a percentage of the potential donor denominator.

CMS-3064-P-43 **Organ Procurement Organization Conditions for Coverage**

Submitter : **Ms. Susan Stuart** **Date & Time:** **06/06/2005**

Organization : **Center for Organ Recovery & Education**

Category : **Organ Procurement Organization**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3064-P-43-Attach-1.PDF

Attachment 43

CORE
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ELECTRONIC SUBMISSION ONLY
(cms.hhs.gov/regulations/ecomments)

June 6, 2005

Ms. Marcia Newton
Center for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: Conditions for Coverage for OPOs
CMS-3064-P

Dear Ms. Newton:

The following comments are submitted by the Center for Organ Recovery and Education ("CORE"), whose headquarters are in Pittsburgh, Pennsylvania. CORE's designated service areas are the 31 counties in Western Pennsylvania, 45 counties in West Virginia, several waiver hospitals in non-designated West Virginia counties, and 2 counties in Southwestern New York.

These comments are in response to the February 4, 2005, Proposed Rules with respect to the new Conditions for Coverage for OPOs.

As a preface, we concur in the comments prepared by the Association of Organ Procurement Organizations ("AOPO"). We participated in preparation of their comments and support them in their entirety. Additionally, our law firm, Kirkpatrick & Lockhart Nicholson Graham LLP, assisted AOPO in the preparation of its comments and assisted us in the preparation of our comments. This will explain an overlap of some of the legal issues raised in our comments.

Section 304 – Requirements for Designation

1. CORE joins AOPO in objecting to the ability of a "better" performing OPO to acquire the service area of a second, certified OPO that meets the outcome and process performance requirements. The objection is two-fold:

   (a) For reasons mentioned in AOPO's comments (and with which we agree), the performance parameters are not sufficiently reliable enough to definitively establish that OPO "A" is in fact better than OPO "B" or that it will be more successful in "B's" service area.

   (b) The notion of open competition by otherwise compliant OPOs creates a specter of distrust and is inimical to the Collaborative initiative sponsored by HRSA. HHS is sending contradictory messages through two of its main agencies. On the one hand, HRSA is establishing initiatives and incentives to share data and encouraging OPOs to be Collaborative and to work with one another, while on the other hand CMS is simultaneously creating disincentives to work together and to share data. The end result is that since the Collaborative is voluntary and designation is necessary, OPOs will err on the side of designation and will not cooperate in the Collaborative with the same degree of enthusiasm and effort as they do now. Neither "super-performers" nor "moderate-performers" will have an incentive to share information with each other. Super-performers will want to retain their advantage; moderate-performers will have no incentive to share their successes with the super-performers least they create or sustain a class of possible predatory super-performers. As a result, the gap between the leaders and the rest of the field never closes, and the Collaborative collapses.

Section 308 – Designation of One OPO for Each Service Area

2. CORE agrees with AOPO that hospital waiver requests generated by corporate events (e.g., merger or acquisition of a hospital into another system) make sense. However, it is concerned that the waiver process not be used to dilute or undercut a service area allocation to a particular OPO. OPOs are all too familiar with territorial changes engineered for political reasons or occasioned by the

relocation of transplant surgeons who may have their own agendas rather than for legitimate substantive or performance-based reasons.

CORE recommends the insertion of language establishing a presumption against the creation of new waivers; this presumption can be overcome if the situation warrants, but the evidentiary burden should be high. The language in subsection (d) could be altered by adding a sentence that indicates that there is a presumption against granting waivers and that waivers will only be granted upon a showing of good cause. The standard should be adjusted to permit a waiver only if there is a *material* deficiency which is not likely to be cured other than by the granting of the waiver.

Section 310 – Changes in Ownership or Service Area

3. Subsection (a) provides for change in ownership; ownership is not ordinarily relevant in nonprofit corporations. Rather, control is the critical factor. If CMS desires to detect changes of ownership or control, it should add the word "control" and a definition of control to subsection (a). For instance, if an OPO is to become the subsidiary of a holding company that is simultaneously the parent of other OPOs, the legal mechanism is not achieved by transferring "ownership" of the OPO's assets to the parent; rather, it is achieved by the conveyance of reserved powers over the OPO to the parent. Without adding the term "control," the existing language would not address this situation.

   There is no indication of the timeframe within which CMS must make its decision to approve a change of ownership or control. We propose that the OPO must provide 15 or 30 days notice of the impending change to CMS and CMS must make its determination within 30 days of the receipt of the information requested by it. This would eliminate the uncertainty of a possible CMS challenge under paragraph (b) and would not hold up the consummation of a change of ownership or control transaction.

   The information that is required to be submitted under subsection (a)(2) should only be that information which is required for designation. The last sentence of (a)(2) should say: ". . .necessary for designation under *Section 486.303* and *Section 486.304*."

Section 312 – Decertification

4. The phrase "urgent need" in paragraph (b) needs a more detailed definition. The proposal only identifies the discovery of "unsound medical practices"; there is no sense of the severity of the unsound medical practices. The definition of "urgent need" should include something along the lines of an "imminent and incurable threat to public safety, to donors, or a material failure of governance, management, or recovery practices and procedures which imminently threaten public safety and which cannot be or which are not likely to be cured by or with the cooperation of the OPO."

5. CORE adopts and incorporates the comments of AOPO with regard to the decertification criteria in §312(b) and (c).

Section 314 – Appeals

6. Rather than repeat AOPO's comments in this response, please see AOPO's comments which we adopt and incorporate in their entirety.

Section 316 – Recertification and Competition Processes

7. Section (c) sets forth criteria for the selection of a successor OPO. These criteria are substantially less definitive than the existing regulations, which provide for six "tiebreakers." (Existing Section 486.316(a)).

   The replacement standard suggested in the proposed regulations is amorphous and affords complete discretion to the Agency. CMS's decision-point criteria are whether (i) there is a "degree of success" in meeting process performance cycles during a prior cycle, and (ii) the bidding OPO has submitted an "acceptable plan" for the service area. Although there are three sub-criteria that attempt to describe an acceptable plan, there is no measure set forth as to how those criteria are to be evaluated or weighed. In short, CMS has virtually no criteria to use other than its own subjective judgment. CORE believes that CMS should either reinstate the tie-breakers or develop new criteria that are quantifiable and externally measurable using SRTR data or other reported data.

8. CORE does not understand why an underperforming OPO which loses its designation to a "better" performing OPO status can access the hearing and appeals provisions of Section 314, while an OPO that meets all applicable designation criteria could lose its designation without a hearing. Although CMS may respond that the government is permitted to select contractors, this response overlooks the fact that the decertified OPO is losing an important property interest and that it presently has a hearing right under the existing regulations. Any OPO that loses its designation, whether due to allegations of underperformance or to a "super-performing" OPO, should have a hearing right. Our comments in this section will be moot if CMS accepts AOPO's and CORE's suggestion to eliminate open competition for the DSAs of adequately performing OPOs.

Section 318 – Outcome Measures

9. CORE agrees with the comments submitted by AOPO with respect to outcome measures. CORE is recognized as one of the more aggressive OPOs with respect to performing DCDs and ECDs. CORE's DSA has a predominantly older population (second only to St. Petersburg, Florida) and thus many of its donors are older. It takes more effort to develop protocols and perform recoveries from DCD and ECD donors. OPOs that undertake these additional efforts should realize the fruits of these efforts.

We agree that even if the national averages are not inclusive of DCDs and ECDs, those OPOs that do perform DCDs and ECDs should receive credit for investing the time and effort in doing so. This is a recognition of a basic tenet that those OPOs that work harder and try new and difficult procedures should receive the benefit of that effort in the calculation in their outcome standards.

Section 322 – Relationships with Hospitals

10. Section (c) should indicate that an OPO is only obliged to have an arrangement with a tissue bank if that tissue bank in turn has a direct relationship with the OPO. It is not enough to suggest that an OPO must have a relationship with a tissue bank simply because that tissue bank in turn has a contractual relationship with an OPO hospital. This is like saying that A and C must cooperate simply because A has a relationship with B and B has a relationship with C. A should

only have to interact with C if A and C agree to interact. The fact that they each interact with B should be irrelevant. CORE has a primary relationship with one tissue bank for its entire service area. (CORE also deals with several eye banks, but these are excluded for purposes of this discussion.) CORE has gone to great lengths to build and nurture this relationship so that it can effectively coordinate the activities of the tissue and organ recovery simultaneously. CORE shares its consent and medical and social history data with the tissue bank so that families are only approached once in the process. CORE has made substantial efforts to familiarize itself with the policies, practices, and down-stream tissue distribution practices of this tissue bank. CORE does not want to have to deal with another tissue bank if it cannot reach an understanding with respect to consents and the recovery logistics or is uncomfortable with the down-stream practices of a tissue bank. This calculus should not change simply because a hospital and tissue bank enter into their own contractual relationship.

Section 324 – Administration and Governing Body

11. Subsection (a)(2) expands the existing requirement of subsection 306(f)(1) with respect to tissue bank representatives. Existing regulations only require that there be an individual who represents tissue banks. This section tracks the PHS Act. This requirement technically could be fulfilled by a representative of any tissue bank, and not necessarily a tissue bank from the OPO service area. Congress only seemed to want the input of an individual with tissue banking expertise. The proposed regulation expands this requirement and seeks to require the appointment of an individual who represents "all tissue banks who have agreements with hospitals with which the OPO has an agreement."

This regulatory language exceeds the statute by adding two new requirements: (i) it now limits tissue bank candidates to tissue banks working in the OPO's service area; and (ii) it explicitly requires the tissue bank representative to "represent all tissue banks."

The former is problematic because it adds a locality requirement that does not appear in the statute. Instead of finding the best tissue bank board candidate, regardless of locality, the individual has to be from a tissue bank that is either a competitor or possibly a vendor.

The latter is problematic because, as a *representative*, the tissue bank designee now has a duty to the tissue bank constituency which could conflict with its state corporate law duty to the OPO board of directors.

For instance, in CORE's case, there is only one tissue bank working in its service area; CORE and this tissue bank have an exclusive working agreement. Thus, this tissue bank is not a competitor but is a major vendor. If another tissue bank were to enter the CORE service area, how could the present tissue bank fairly represent its own interests, the interests of its competitor, and CORE's interests? Additionally, CORE believes that it is inappropriate to have a major vendor on the board of directors as well. If an OPO wants to sever its vendor relationship, is it not problematic to sever this vendor relationship and still have that individual serving as a director? Should the OPO have to replace a director and invest in the education of a new director simply because of a failed vendor relationship?

Read together, these two sections appear to expand the statutory objective of securing the availability of tissue bank technical expertise to a market objective of assuring that the commercial issues of competitive or vendor tissue banks in the OPO's service are addressed by the OPO. CORE questions whether CMS should be concerned about tissue banks since they are not entities regulated by CMS. Moreover, the Preamble does not identify a significant historical problem that is to be rectified by this proposal. Instead, CORE suggests retaining the language in the present regulation. The only real concern of CMS should be whether OPOs are making good-faith efforts to cooperate with tissue banks.

12. Section (c) prevents individuals who serve on an advisory board from serving on the OPO's governing board or board of directors. The last sentence of (c) is not clear whether the prohibition against serving on "any other OPO board" means any other internal, advisory board or alternatively the board of a different OPO. If it is the former, it should read: "any other board (advisory or otherwise) of the OPO."

CORE does not understand why individuals who are serving on an advisory board (as suggested under paragraph (a)) cannot also serve on a fiduciary board. These individuals are permitted to serve as directors in the instance of a single governing board. How can there be a permissible membership (or overlap) in one situation but a prohibition against the overlap in the other?

CORE believes that the expertise of these individuals should be available to a governing or fiduciary board, and that this concept is consistent with the statute. CORE suggests that the overlap between advisory boards and the full boards should be such that the advisory board members do not compose more than a majority of the directors on the governing or fiduciary board if an OPO decides to have both a fiduciary board and an advisory board(s).

13. The Preamble requests comments on whether there should be representatives on the board from other constituencies, notably hospitals. CORE's sense of this is that there should not be any additional mandatory requirements. It is already very difficult for an OPO to create an effective board within the confines of the existing statutory requirements and the regulatory limitations on the roles of fiduciary versus advisory boards. OPOs are more likely to develop strong boards if they have the ability and freedom to select strong directors, regardless of whether these directors are from hospitals or the healthcare field. OPOs need the flexibility to reach out to the general public and find capable directors, whether from the clergy, the media, universities, or the general public. By comparison, there is no such requirement in the hospital conditions of participation, which is interesting and instructive given that hospitals are more diverse, multifaceted, and serve constituencies broader than OPOs.

14. CMS poses the question on page 6105 as to whether the "legal authority and responsibility for the management and provision of all OPO services [should] lie with an individual rather than a governing body." We are not clear whether this individual is intended to replace the governance function (e.g., replacing the governing body) or whether it is to provide management and executive services (e.g., a CEO). It appears to be aimed at the former. If this is the intent behind the suggestion, CORE would not support it. This structure would not satisfy state corporation laws, would not satisfy the requirements of a 501(c) tax exemption, would override the checks and balances of a multi-person board, and would be contrary to all existing principles of effective governance.

15. We suggest that paragraphs (a) and (e) should be reversed. The most important principle of §324 is in paragraph (e) which is why we believe it should be redesignated as (a).

16. CMS should consider adding language in (b) further describing the expectations and duties of "advisory board members." Paragraph (b) describes what specific subject matters the designated individuals may address, but it does not identify

the standard this group is to apply in fulfilling its designated tasks nor does it describe how the governing or fiduciary board is to consider or evaluate their contributions. Paragraph (c) adds a negative cast by describing what this group is prohibited from doing. The additional language in (b) should provide that the individuals described in paragraph (a) are expected to assist the governing body in fulfilling its fiduciary duties and its functions by contributing special expertise and perspective. These perspectives and viewpoints are to be considered by the board along with other inputs and factors as may be permissible under each state's nonprofit corporation law in the board's discharge of its fiduciary duties. In other words, the new language would make clear what the individuals in the statutory constituencies are expected to contribute, that their contributions are advisory, and they may be weighed, considered, or rejected by the full fiduciary board in the discharge of the fiduciary board's obligations.

17. CORE agrees with most of the sentiment expressed in the final paragraph of §324 of the Preamble on page 6105. CORE believes that an OPO should have the flexibility and freedom to "choose the most efficient and effective form of administration and governance to suit its own needs and to fulfill its mission of minimizing organ donation." For the reasons expressed above, however, CORE does not agree that all of the proposals in the proposed regulations actually provide an OPO with this degree of flexibility and freedom.

There is presently a great deal of self-focus and evaluation being undertaken by nonprofit and for-profit corporations to improve the governance function. Governance standards and benchmarks are likely to change as a result of this scrutiny and introspection. The regulations should be broad enough to absorb the changes and improvements in governance structure and practice that are likely to develop over the next few years. The Preamble of the final regulations, if not the regulations themselves, should incorporate the concept that each OPO should, within the confines of the regulations, be free to choose (and possibly to experiment with) efficient and effective forms of governance. The benefit of including this language would be to permit, if not foster, innovations in governance and management.

CORE supports the concept of an OPO studying and ultimately selecting the most effective form of governance and management. CORE recently undertook an extensive reorganization and reevaluation of its board. The board hired a nationally recognized governance consultant who worked extensively with legal

counsel to restructure the board and encourage the adoption of a series of "best practices." The result is a board that is structured to function like a public company, i.e., it sets strategic goals, imposes performance measures upon management, and is responsible for the overall direction, financial solvency, and quality performance of the organization. OPO's boards should be expected to meet the same performance standards that are expected of Fortune 500 companies and leading hospitals across the country. CMS should support this effort and should incorporate language in the regulations signaling to OPOs that this is an acceptable goal and outcome from CMS's prospective. To do this, we suggest incorporating the following language into the final regulations, possibly as a new paragraph (b) (assuming that (a) and (e) are switched):

> CMS encourages an OPO to study and choose the most efficient and effective form of administration and governance to suit its needs and to fulfill its mission of maximizing organ donation, provided that the structure is consistent with the statute and industry standards.

Section 326 – Human Resources

18. The new regulations require that the OPO provides sufficient coverage so that medical donors are evaluated from medical suitability in a timely manner. OPOs do not make "suitability determinations." Suitability is strictly the exclusive prerogative of the recipient's transplant surgeon. CORE, like many OPOs, has been dismissed from "bad organ" malpractice cases by being able to show that it does not make a judgment of suitability. Including language suggesting that OPOs should be making medical suitability determinations would impose a new area of liability exposure for OPOs under state tort law.

19. Likewise, the language in paragraph (b) suggests that a medical director is responsible for donor management and placement. CORE's medical director does not make decisions regarding donor management; these are the decisions of either the donor's family or the suggestions of the recipient's transplant surgeon. This language should be deleted for the same reason set forth above.

Section 342 – Requesting Consent

20. This section requires in paragraph (a)(8) that information be provided to a potential donor's family about the "procedure for filing a complaint." Information about claims or a complaint process is not a standard element of informed consent. This provision could actually undercut the success of the consent process. OPO coordinators work for hours to obtain a family's consent. This suggested language adds a suggestion that ultimately the recovery will be unsuccessful or that the family may be dissatisfied with the results of the process, which is counter to the efforts of the OPO coordinator to achieve the consent in the first place.

    It has been our experience that if family members are unhappy with the OPO, they have no difficulty knowing how or where to find the OPO. All they need to do is call and express their dissatisfaction and their complaints will be addressed. Adding this into the consent process is counterproductive and inconsistent with the established informed consent procedures and protocols. (It is not, for instance, a requirement in the hospital COPs.)

Section 348 – Quality Assessment and Performance Improvement ("QAPI")

21. CORE supports QAPI efforts.

22. The proposed regulations require two disclosures to CMS of the occurrence of an "adverse event" within 10 and 15 "business days" respectively of the adverse event. The first question is what constitutes a "business day" for an organization that functions 365/24/7? Secondly, while this information is likely protected under many if not most of the states' peer review statutes, it would not be protected from redisclosure by CMS. Consequently, a family member's designated representative can simply file an FOIA request and all the information must be disclosed. This undercuts the basis premise of peer review, i.e., that adverse events or practices can be examined and reviewed candidly without fear of retribution or discovery.

23. Additionally, CMS has not indicated how it will use this information internally. Will it use this to make redesignation decisions, will it allow other OPOs to subpoena this information in designation disputes, will it potentially sanction an OPO if it has "too many" reports?

24. We recommend that CMS refrain from implementing this system until such time as it can determine how it will store this information, what assurances and protections with respect to confidentiality that it can provide, and how it will use this information in the certification/designation process. CMS should explore other methods of gathering or reviewing this information (e.g., on-site inspections, etc.).

We compliment CMS in the preparation of an exhaustive and comprehensive set of proposed regulations. Our comments are offered in the spirit of improving the final outcome and addressing your concerns and ours, namely that the regulations afford the public a measure of confidence that OPOs are doing the best job possible.

Please call me directly if you have any questions or if I can provide any clarifications.

Sincerely,

Susan A. Stuart
President and CEO

CMS-3064-P-44 **Organ Procurement Organization Conditions for Coverage**

Submitter : **Mr. Timothy M. Goldfarb** **Date & Time:** **06/06/2005**

Organization : **Shands HealthCare**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment."

CMS-3064-P-44-Attach-1.DOC

Attachment #44
June 3, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

CMS-3064-P
"Re-certification and competition" §486.316

As CEO of Shands Healthcare, I am writing to comment on the Medicare and Medicaid programs; Conditions for Coverage for Organ Procurement Organizations (OPOs) proposed rule CMS-3064-P. The proposed rule, while providing some limitation on competition for service areas at the end of a re-certification cycle, nonetheless permits a level of competition that may severely undermine a Department of Health and Human Services (HHS) initiative known as the Organ Donation Breakthrough Collaborative. That initiative encourages collaboration among OPOs in order to increase the number of organs available to the almost 90,000 Americans awaiting organ transplants. Unless competition for a service area is limited to cases in which the incumbent OPO has been de-certified, competition for service areas will interfere with the collaborative efforts currently underway.

The Organ Donation Breakthrough Collaborative has engaged the OPO community and the nation's largest hospitals to increase the number of organs available for transplant. Shands is part of this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. The model facilitates the implementation of best practices for increasing the rates of organ donation through the sharing of data and information among participants.

While participating in the Collaborative, our hospital, Shands at the University of Florida, and our OPO, LifeQuest, have been able to achieve a 75% conversion rate at this hospital over a 12-month period. This success has earned us a Medal of Honor from HHS.

As an organization that has been involved with the important work of increasing the number of organs available for transplant, we strongly support further use of the collaborative model. Unless the competition-based model of the proposed rule is limited to service areas for which the designated OPO is de-certified, competition for service areas could stifle the sharing among OPOs of best practices that have been developed and fostered through the Organ Donation Breakthrough Collaborative.

Sincerely,

Timothy M. Goldfarb
Chief Executive Officer

CMS-3064-P-45 **Organ Procurement Organization Conditions for Coverage**

Submitter : **Ms. Martha Anderson** **Date & Time:** **06/06/2005**

Organization : **Musculoskeletal Transplant Foundation**

Category : **Organ Procurement Organization**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3064-P-45-Attach-1.DOC

Attachment 45

Musculoskeletal Transplant Foundation

125 May Street
Edison, NJ 08837
(732) 661-0202
www.mtf.org

June 6, 2005

CMS-3064-P
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-3064-P

Dear CMS Officials:

I am pleased to provide the following comments regarding the proposed CMS rule (CMS-3064-P) regarding Medicare and Medicaid Programs: Conditions for Coverage for Organ Procurement Organizations (OPOs). As a Tissue Bank Representative and a member of the Gift of Life Donor Program Board of Directors, I applaud the efforts undertaken by CMS to promote organ donation and transplantation. Gift of Life Donor Program is the OPO serving the eastern half of Pennsylvania, southern New Jersey and the state of Delaware.

In addition to the comments submitted by Gift of Life Donor Program, I would like to focus on the following issues raised in the proposed CMS rule:

1. Administration and Governing Body (Proposed § 486.324)
The proposed rule mandates that an OPO have a separate and distinct governing body (an Administrative Board), as well as an advisory board (Advisory Board). The Advisory Board would be comprised of all persons mandated under the Public Health Services Act, such as members who represent hospital administrators, members of the public, surgeons from each transplant center, etc. **The proposed rule would prohibit any cross membership between an OPO's governing body and the required advisory board.** The stated objective of this very onerous administrative structure is to avoid conflict of interest, particularly with regard to an OPO's financial policies, including establishment of standard acquisition charges.

The proposed rule ignores the already existing state and federal laws which address conflicts of interest. Under existing state corporate laws, as well as common law, there are clear standards requiring board members to uphold their fiduciary responsibility to the organization whose board they are serving. Federal law governing tax- exempt organizations also imposes standards and safeguards, some of which have been recently highlighted in the expanded enforcement authority provided under the Intermediate Sanctions. There are already standards imposed that address and require organizations to mediate conflict of interest issues. Added to the existing laws, the corporate compliance programs recommended to organizations also impose standards to protect against conflicts of interest which might adversely impact fiduciary decision-making.

The Gift of Life Donor Program Board underwent a significant restructuring which became effective 1999. This restructuring was a result of a more than 2 year process undertaken to ensure that constituencies served by the organizational mission were included in the process and that board members represented these different constituencies. This includes transplant centers, donor hospitals, health professionals, donor family members, recipients, clergy and others. The composition of board membership is designed to protect against "insider" and "self" interests.

The enhanced and balanced board membership allows for a meaningful and thoughtful discussion of the issues that an OPO must face by those who are familiar with the issues. Prohibiting this type of dialogue may deprive an OPO of the very type of governing body direction which it needs most. A conflict of interest may exist because someone in fact has an "interest" in the subject matter- those who have this interest are most frequently those who have the knowledge and desire to serve. There are effective mechanisms available to address conflicts of interest and at the same time allow for the very valuable insight and information needed in order to provide an OPO with the overview and guidance which are the functions of a board.

Additionally, mandating an organizational structure of multiple oversight bodies through a governing body and advisory boards may adversely impact the actual operation of the OPO. Multiple bodies may cause a delay in decision-making, may be burdensome in terms of identifying persons willing to serve in the board capacities, and integrating the decisions and recommendations of multiple groups. I also note that there are many other health and public service organizations which deal with critical public health issues which are permitted to provide governance under the guidance provided by state and federal laws applicable to non-profits and tax exempt organizations which manage conflict of interest issues successfully. OPOs are not unique in having the potential for conflicts of interest among their board members.

Therefore, I strongly urge CMS to modify the proposed regulations to allow OPOs to continue to have one "fiduciary" governing board which includes all of those constituent members cited in the PHS law, or alternatively to have one fiduciary governing Board with one or more advisory boards/bodies. I do recommend that in either case the transplant surgeon/transplant physician representation on the governing board be no more than 50% and there should be strong conflict of interest policies in place.

Additionally, I note that CMS is requesting input on the proposal that a single individual be designated to assume full legal authority and responsibility for the management (and by inference the governance) of an OPO instead of the Board of Directors. I strongly oppose this proposal in that it is inconsistent with state and federal standards regarding governance, as well as it is inappropriate to charge one individual with all of these functions without oversight. Certainly, OPOs should continue to have the ability to have a chief executive officer who is charged with day-to-day management of the organization but who remains subject to the Board's oversight. Ultimately, a governing body such as a board of directors should be responsible and have full legal authority and responsibility for the organization.

2. Proposed OPO Outcome Measures
"Outcome Measure (proposed § 486.318)"

The CMS proposed rule focuses exclusively on conversion rates as its outcome metric. I urge CMS to identify at least 2 distinct outcome measures, focusing on an overall conversion rate and organs transplanted per donor ratio.

While the proposed rule does include an overall conversion rate as a metric, with the number of donors as the numerator and the "potential donors" as the denominator, it is problematic as it is currently defined. First, as noted by AOPO in its comments, the actual definition of organ donor potential must be standardized. However, even if one definition of "organ

donor potential" is adopted, if it is NOT applied uniformly, there will be significantly inter-OPO variability compromising the validity of the outcome measure.

The need for uniform application of the definition refers both to a uniform interpretation of the term "organ donor potential" (or the term "eligible deaths" as proposed by AOPO) as well as the need for uniform death record review practices.

I agree that death record reviews are an essential aspect of improving donation rates and Gift of Life has a well-documented death record review practice. In fact, Gift of Life published one of the first studies in the country regarding organ donor potential in Pennsylvania utilizing death record reviews. However, if an OPO does not regularly conduct death record reviews, or applies the definition of "organ donor potential" very restrictively during the review, then the denominator of its conversion calculation is likely to be smaller, yielding an "enhanced" or improved conversion rate. Another OPO may have a very effective medical record review practice, which identifies patient deaths as "potential donors" where the medical record reveals support was removed from a patient it appeared would otherwise have progressed to brain death, but a referral was not made. That second OPO will consider the patient as a potential organ donor or an eligible donor, the denominator of its conversion calculation will be larger, potentially yielding a "reduced" conversion rate. If the overall objective of the proposed rule is to increase donation, which practice is likely to best support that objective? It would seem that the latter OPO's practices would provide enhanced opportunities for performance improvement, but its "Performance" indicator might well be weaker than the first OPO's. **Consequently, until a uniform death record review practice is instituted among OPOs (which I encourage), including "missed referrals" identified in death record reviews as a component of the denominator of the conversion rate, outcome measures will be inequitable as applied to OPOs.**

In order to mediate some of the inter-OPO variability on the issue of "missed referrals" and death record reviews, I recommend that such information not be included in calculation of the conversion rate for purposes of comparing an OPO to the mean until a uniform death record review practice has been instituted across the country. I also recognize that the current OPTN data base (which does not take into account missed referrals) requires additional validation in order to accurately predict donor potential. I would encourage such validation of the information with the support of third parties such as the SRTR.

I also urge CMS to adopt an organs transplanted per donor ratio as a measure. This ratio should include a "case mix" aspect which addresses the variation in the expected number of organs that can be transplanted from a particular type of donor. The case mix should take into account not only subgoals for Standard Criteria Donors, Donation after Cardiac Death, Expanded Criteria Donors, but also donors that may be testing positive for infectious diseases and/or have other co-morbid factors.

Thank you for your consideration,

Sincerely,

Martha Anderson

Martha Anderson
Executive Vice President, Donor Services

cc: Howard Nathan, President & CEO, Gift of Life Donor Program

CMS-3064-P-46 Organ Procurement Organization Conditions for Coverage

Submitter : Barry Cockrell **Date & Time:** 06/06/2005

Organization : On behalf of Mississippi Organ Recovery Agency

Category : Organ Procurement Organization

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3064-P-46-Attach-1.DOC

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June 10, 2005

Attachment #46
VIA ELECTRONIC SUBMISSION

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention/Reference: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: CMS Proposed Rules Establishing New Conditions for Coverage for Oran Procurement Organizations

Dear Sir or Madam:

On behalf of the Mississippi Organ Recovery Agency, Inc. ("MORA"), we are submitting the following written comments in connection with the above-referenced proposed rule. On February 4, 2005, the Center for Medicare and Medicaid Services ("CMS") published a proposed rule establishing new conditions for coverage for organ procurement organizations ("OPOs"), including multiple new outcome and process performance measures based on donor potential and other related factors in each service area of qualified OPOs. While MORA supports many of CMS's proposed changes, there are some areas that are particularly concerning to MORA and the OPO community as a whole. MORA fully endorses the Association of Organ Procurement Organization's ("AOPO") comments regarding the CMS proposed rule, and would like to emphasize certain areas that will have significant and potentially negative impact on MORA and Mississippi's residents.

A. Overview of the Rule.

The Organ Procurement Organization Certification Act of 2000 "OPOCA" directs the Secretary to establish regulations for OPOs that include four major requirements. These are to: (1) increase the re-certification cycle for OPOs from two to at least four years; (2) establish outcomes and process performance measures based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service are of qualified OPOs; (3) establish multiple outcome

measures; and (4) establish a process for OPOs to appeal a de-certification on substantive and procedural grounds.

OPOs are government contractors that play a crucial role in ensuring that scarce transplantable human organs are provided to seriously ill patients suffering from end-stage organ failure. OPO performance is one of the most critical elements of the organ transplantation system. To foster enhanced performance of OPOs, CMS has included in the proposed rule new regulations regarding both an appeals and competition process and multiple outcome and process performance measures.

Although CMS states that its overall goal is to improve the functioning of poorly performing OPOs rather than simply terminating them, both AOPO and MORA believe that the regulation's proposed competitive framework, its proposed continued use of a performance outcome measurement approach that automatically makes decertification of some OPOs a mathematical certainty regardless of performance, and the absence of any corrective action plans for improvement are not supportive of such a stated intent and actually call into question the potential for achieving the stated intent.

AOPO has stated the following as its key concerns with the proposed rule:

(1) the data presented on organ recoveries, in part used to justify certain aspects of the proposed rule, are dated and do not consider the significant national increase in organ recoveries and transplants since the second half of 2003;

(2) the term "best practices" should not be used, as it takes on different implications when stated as an organizational requirement in regulations;

(3) the appeals and competition processes advanced in the proposed rule would significantly increase the level of uncertainty identified by Congress as a major problem inherent with earlier CMS rules regarding OPO performance;

(4) the proposed outcome measures fall short of Congress's requirement to establish multiple outcome measures because each measure is highly correlated with the other. Further, the proposed outcome measures do not address other related factors in each service area; and

(5) many of the proposed regulations in the proposed rule are overly prescriptive, resulting in an overload of resources and requirements that run counter to evolving science and professional experience. It is suggested that OPOs should be required to have plans and policies in place to cover a variety of specified areas with CMS establishing surveys focusing on the review of and conformance of practice to policy.

B. Certification and Designation Requirements: MORA's Primary Concern.

MORA agrees with AOPO's key concerns, but in particular MORA is concerned with (1) CMS's proposed standards for OPO certification and (2) that under CMS's proposed standards for re-

certification, the threat of consolidation will adversely affect the recovery and transplantation of organs in Mississippi and potentially result in the closure of UMMC's transplant center.

Currently, one OPO is designated for each service area. Unless granted a waiver by CMS, hospitals are required to have an agreement only with the OPO designated to serve the area in which the hospital is located. To be the designated OPO, the OPO must first be certified. Until the OPOCA was enacted in 2000, OPOs were certified for a two-year period. This certification period has been increased to four years, which MORA supports. MORA is concerned with the proposed rule's re-certification and de-certification processes.

1. Proposed De-certification Standards.

In proposed section 486.312 (c), CMS proposes that the only decision point with respect to a decertification is whether the OPO meets the mathematical outcome tests or measures of section 318. Specifically, CMS will not voluntarily renew its agreement with an OPO if the OPO fails to meet the conditions for coverage under section 318 based on data from the most recent re-certification cycle or if the OPO's designation has been terminated. The outcome measures of section 318 do not incorporate the OPO's compliance with the process performance measures and other criteria described in sections 312 (b) and 320-346.

MORA agrees with AOPO that CMS review should incorporate these additional criteria, including becoming a member of the organ procurement and transplantation network, establishing relationships with hospitals, critical access hospitals and tissue banks, complying with certain conditions for administration, governing body, and human resources, data reporting, information management, donor evaluation and management, organ placement and recovery and organ preparation and transport. Such criteria should be included because decertification is a major action that should only be undertaken after a thorough review of all relevant criteria, and the relevant criteria must include more than mathematical outcome measures. Further, under the proposed rule, substantive due process would be denied because an automatic decertification denies the OPO the opportunity to provide any evidence of the important factors unique to the OPO's service area or how any of the process performance factors and "other requirements" apply.

MORA agrees with AOPO that section 312 (c) should be changed to require that: (1) the specified criteria for decertification incorporate the process performance criteria and "other related factors" so that it is not a self-activating, automatic decision, and that (2) the decision be made by the agency, that the OPO have input into the agency before the decision is made, and that the decision and reasons therefore be set forth in a written opinion.

2. Proposed Standards for Re-certification and the Threat of Consolidation.

MORA believes that CMS's proposed standards for re-certification results in a threat of consolidation that will adversely affect the recovery and transplantation of organs in Mississippi and

potentially result in the closure of UMMC's transplant center. Even for OPOs meeting both outcome and process measures, opening service areas in their entirety to competition at the end of every four-year certification cycle results in the threat of consolidation which only harms Mississippians. As a practical effect, recovered organs will be shipped out of Mississippi. MORA agrees with AOPA that this untested framework is a divisive approach conflicting with the successful work of the national Organ Donation Breakthrough Collaborative, and fails to see how this best effects Mississippi residents.

CMS supports its decision to change the re-certification requirements by citing Congress's statement that the OPO re-certification process has "created a level of uncertainty that is interfering with the effectiveness of organ procurement organizations in raising the level of donation." MORA, along with AOPO, strongly opposes any process that would allow an OPO to takeover another certified OPO.

CMS proposes two re-certification and competition options: (1) the "highly restricted competition process," and (2) the less restricted options. Under the less restrictive options, all service areas would be open for competition, but the criteria OPOs would be required to meet to compete for open areas would differ. MORA supports the highly restricted competition process, which would open competition only in service areas of OPOs not meeting the conditions for coverage (the outcome performance measures at 318 or the process performance measures and other requirements at 320-348). Any OPO meeting the conditions for coverage would be re-certified, re-designated for its services area, and its agreement with CMS would be renewed for another four years. This competition process would, as Congress requested, considerably reduce the uncertainty in the re-certification process.

Sincerely,

BAKER, DONELSON, BEARMAN,
CALDWELL & BERKOWITZ, PC

Original signed by Barry K. Cockrell

Barry K. Cockrell

BKC:jlm

CMS-3064-P-47 **Organ Procurement Organization Conditions for Coverage**

Submitter : Mr. Howard Nathan **Date & Time:** 06/06/2005

Organization : Gift of Life Donor Program

Category : Organ Procurement Organization

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.