

**Submitter :** Mr. Patrick Giordano  
**Organization :** Texas Organ Sharing Alliance  
**Category :** Organ Procurement Organization

**Date:** 05/25/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-3064-P-19-Attach-1.DOC

Attachment #19  
May 25, 2005

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

To Whom It May Concern:

The Texas Organ Sharing Alliance respectfully submits comments related to the proposed CMS regulations for organ procurement organizations (OPOs) published on February 4, 2005.

**486.316 Re-certification and Competition Processes:**

We believe that it is inappropriate to initiate takeover action by an OPO against another OPO which has met all of the standards, is not the subject of substantiated complaints by associated agencies, and has not acted inappropriately.

**486.324 Administration and Governing Body:**

It is recommended that cross representation between the advisory board and governing board be allowed. Transplant physicians and surgeons should be limited to less than 50% of the membership of the governing board.

**486.318 Outcome Measures:**

The proposed outcome measures are based upon referrals which are self reported by the OPOs. There is no provision for independent verification of this self-reported data. This is especially concerning since this self-reported data, under the proposed regulations, could be used to attempt a takeover of another OPO presumably meeting the standards.

In addition, the self-reported SRTR referral data only reflects referrals provided by the OPO from hospitals which the OPO has chosen to develop. Hospitals which were not developed or developed well would be expected to have lower referral activity. As a result, an effect of the suppression of these referrals would likely occur in hospitals which were under developed by the self-reporting OPO. The result would be a "false high" conversion rate which would at best, be misleading as to which OPOs are higher performers and at worst, be the basis of a takeover attempt of a well performing OPO which does a better job of developing its donor potential hospitals. The regulations regarding this issue are in need of revision. If there is no assurance that all of the potential referrals are included in the conversion rate, then the credibility of any performance indicators for OPOs would be potentially compromised.

This input is provided with the aim of developing effective regulations focused on determining verifiable performance within a framework of fairness for OPOs. In addition, it is our hope that the regulatory process supports, guides, and allows OPO to be strengthened as we continue to focus on increasing lifesaving organ donation for the patients we all serve.

If you have any questions or would like further clarification, please contact me at your convenience.

Yours truly,

Patrick J. Giordano, MHA, CHE  
Chief Executive

**Submitter :** Mr. Paul Schwab

**Date:** 06/01/2005

**Organization :** Association of Organ Procurement Organizations

**Category :** Health Care Provider/Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-3064-P-20-Attach-1.DOC



Attachment #20  
June 1, 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

Joseph S. Roth, New Jersey  
*President*

Thomas Beyersdorf, Michigan  
*President - Elect*

William H. Marks, M.D., PhD, Washington  
*Medical Advisor*

Daniel H. Hayes, MD, North Carolina  
*Medical Advisor - Elect*

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*Member - At - Large*

Richard S. Lusk, Massachusetts  
*Immediate Past-President*

Paul M. Schwab, Virginia  
*Executive Director*

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

Dear Dr. McClellan:

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 (OPOs). The Association of Organ Procurement Organizations (AOPO), represents all fifty-eight federally designated OPOs in the country. The comments presented here are the result of an extensive, participative process by our membership over a period of several months.

The proposed regulations have an important role in supporting our work to maximize organ donation and transplantation. They contain many positive aspects. Chief among them is the objective to help advance joint accountability for organ donation between OPOs and hospitals. This has been critical for increasing donation rates. However, while the regulations take appropriate approaches in some areas, there are other areas that create significant concern for the OPO community. Our response covers both of these matters.

The proposed rule incorporates many positive features that are supportive of organ donation, program accountability, and reduced uncertainty. These include but are not limited to such provisions as: (a) recognition of the importance of shifting OPO performance analysis from the historical donors per million measure to a metric which better reflects donation experiences; (b) acceptance of the concept that differences in performance should be significant to better reflect "true" differences; (c) incorporation of a new continuous quality improvement framework for organ procurement organizations; and (d) a call for comments regarding the advancement of joint accountability for organ donation between OPO and hospitals

At the same time, there are areas in the proposed rule where modification is warranted. These include but are not limited to the following major areas: (a) a decertification

AOPO Letter and Attachment to Dr. McClellan process and overall framework grounded

Re: CMS-3064-P

June 1, 2005

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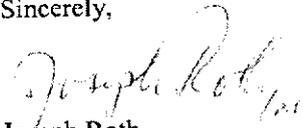
in collaboration rather than competition; (b) an enhanced framework for multiple outcome performance measures; (c) the adoption of an appeals process that provides greater certainty and fairness for all parties; and (d) the use of a broader but defined approach for process performance measures modeled after the approach advanced in the regulation for the quality assessment and performance improvement provisions.

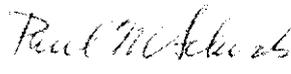
We were surprised the proposed new Conditions of Participation did not acknowledge the lateness of the CMS response to the Organ Procurement Organization Certification Act of 2000, P.L. 106-505, legislation that called for new standards to improve the certification process of OPOs. Nor did the proposed rule explicitly state how the agency intended to implement the rule since its publication fell within the 38<sup>th</sup> month of a forty-eight month performance cycle currently in force. We are appreciative and encouraged that recent informal communications by CMS officials have clarified the agency's intent to move ahead with prospective application of final regulation requirements. We provide these comments with these recent informal communications in mind and assume prospective application of the regulations as the Agency moves forward to finalize the rule.

The detailed AOPO response which follows covers many areas of the proposed rule, in addition to those mentioned above. Our objective throughout is to provide constructive views and recommendations. We share common goals with CMS regarding increasing organ donation and transplantation and assuring program accountability. We can accomplish these worthy goals together if we focus more on continuous quality improvement and less on distractions such as organizational consolidation.

Thank you again for this opportunity to comment. We are always available for any clarification you may need of the analysis and recommendations included in our response.

Sincerely,

  
Joseph Roth  
President

  
Paul Schwab  
Executive Director

Share your life. Share your decision.®

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**Association of Organ Procurement Organizations**  
**Detailed Response to Proposed CMS (HHS) Regulations**  
**Conditions of Coverage for Organ Procurement Organizations**  
**Reference: CMS-3064-P**  
**June 1, 2005**

The comments which follow on these and other aspects of the regulation are provided in order of the sections and related headings in the proposed rule.

**I. Background**

The Centers for Medicare and Medicaid Services (CMS) introduce the proposed rule by stating that, "Our proposals would fundamentally change the existing OPO regulations to emphasize quality and continuous quality improvement. The changes would ensure that each OPO utilizes best practices to improve its efficiency, effectiveness, and quality. While the requirements in the proposed rule apply to all OPOs, we have specifically targeted the requirements toward OPOs that may not understand the value of incorporating best practices into the structure of their organizations. Thus, our overall goal is to improve the functioning of poor performing OPOs, rather than simply to terminate them." The Association of Organ Procurement Organizations (AOPO) applauds CMS' intent to use the rule to improve the quality of OPOs. As our comments below explain, however, the rule's proposed competitive framework, its proposed continued use of a performance outcome measurement approach that automatically makes de-certification of some OPOs a mathematical certainty regardless of performance, and the absence of any corrective action plans for improvement are not supportive of CMS' stated intent and could actually undermine OPO performance.

We offer the following additional comments regarding the "Background" section:

1. The data presented on organ recoveries in the US, in part used to justify specific aspects of the regulations, are very dated, with no recognition provided of the extraordinary national increases recorded in organ recoveries and transplants since the second half of 2003.
2. We would submit that the term "best practices," while frequently used as a popular reference, takes on different implications when stated as an organizational requirement in regulations. Our views on this matter are elaborated upon in comments regarding §344 and §302.
3. As AOPO has conveyed informally, the appeals and competition processes advanced in the regulation, in our view, would significantly increase the level of uncertainty identified by Congress as a major problem inherent with earlier CMS rules regarding OPO performance. This point is elaborated upon in our comments regarding §314 and §316, respectively.

4. The proposed replacement of a population-based outcome measure with a measure that aims to be a reasonable surrogate for potential organ donors is a major improvement over earlier regulatory approaches. However, since the five proposed measures are highly correlated, we submit that the proposed requirements fall short of the Congressional requirement to “establish multiple outcome measures.” Similarly, although there is an emphasis on organ donor potential, the proposed outcome measures do not address “other related factors in each service area.” These points, and respective AOPO recommendations can be found in our comments regarding §318. Comments regarding CMS’s proposed definition regarding “organ donor potential” and AOPO recommendations are included in comments regarding §302 and §318.
  
5. AOPO recognizes the value of multiple process measures as part of the certification process and as stated by Congress. At the same time, we question the level of detail and prescriptiveness included in the proposals. First, evidence exists that variations in practice can result in intended outcomes. Second, the level of prescriptiveness has significant resource implications. Third, and most importantly, such detail can result in requirements that run counter to evolving science and professional experience. For example, some of the proposed requirements are already dated given developments in OPTN policies. OPTN site survey experiences, furthermore, have demonstrated that discrepancies between practice and policy occasionally reflect policies being dated with practices actually keeping up with scientific change. We believe that such an outcome is hampered by a regulatory approach over emphasizing prescriptive standards. As noted in our comments, we would recommend that CMS require OPOs to have plans and policies in place to cover a variety of specified areas and that CMS coordinator surveys focus on reviewing the conformity of practice to policy.

## II. Provisions of the Proposed Regulations

### Proposed General Requirements

#### “Basis and Scope (proposed §486.301)”:

AOPO concurs with the proposed requirements.

**“Definitions (proposed §486.302)”:**

While AOPO fully supports the inclusion of attention to adverse events, the definition of an “adverse event” needs clarification. As stated, for example, the definition would include circumstances where organs were not recovered from a consented potential donor. The use of the term “wrong organ,” furthermore, might simply include circumstances where an organ was medically unsuitable for an intended recipient. We do not believe that the intent behind requiring adverse event reporting extended to such situations. Additional comments regarding the matter of adverse event reporting can be found in AOPO’s comments below regarding § 486.348.

The term “donor” is in need of modification given the requirements of Public Law 108-362 covering pancreata recovered and used for islet cell research.

The term “designated requestor” would benefit by incorporating the HRSA Organ Breakthrough Collaborative experiences with “effective requestor” and “effective requesting process.” The earlier focus on “designated requestor” may be somewhat dated given evolving practices between OPOs and hospitals in approaching families.

The proposed definition for “organ donor potential” differs from the definition of eligible donor used in the OPTN system for OPO reporting. Since the rule indicates that CMS intends to use the OPTN-collected data for its proposed outcome measure, we assume that this discrepancy is a matter of either a dated reference or an oversight. Notwithstanding these comments, AOPO has concerns regarding the definition. These concerns and our proposed definition can be found in our comments below regarding proposed §486.318.

**Requirements for Certification and Designation**

**“Requirements for Certification (proposed §486.303)”:**

The proposed rule states that an OPO must “have received a grant under 42 U.S.C. 273 (a)” as a requirement for certification. AOPO assumes that this requirement is an error. In its present form, there is a conflict between (i) the Preamble (p. 6086, col. 3, para. 3) and 42 U.S.C.A. section 1320B-8(b)(1)(a)(i) on the one hand,<sup>1</sup> and (ii) proposed section 303(a), on the other. Section 1320B of the statute clearly provides that an OPO is qualified if it has received a grant or is otherwise certified by the Secretary. The Preamble correctly reflects the statutory requirement. Proposed subsection (a) seems to make it a mandatory requirement, whereas we would submit that it is an alternative requirement.

<sup>1</sup> §1320B-8(b)(1)(A)(i) states: “...is a qualified organ procurement organization...under section 371(a) of such Act, or (ii) has been certified...” (Emphasis added)

**“OPO service area size designation and documentation requirements (proposed §486.306)”:**

AOPO concurs with the proposed requirements. AOPO recommends that the 24-donor exception be retained only for Hawaii, a non-contiguous state with significant geographic challenges for organ placement outside Hawaii.

**“Designation of one OPO for each service area (proposed §486.308)”:**

AOPO does not object to the continuation of the hospital waiver option, however, we recommend that clarification be provided regarding appropriate purposes for waivers to avoid alternative attempts at “cherry picking” or opportunity to influence allocation patterns without consideration of patient access to organs.

AOPO recommends that new conditions for eligibility to seek a waiver be included, which incorporate key features of CMS’s interpretative guidance for hospital compliance with their Conditions of Participation (published in June, 2004). AOPO recommends, furthermore, that the CMS review process for granting a waiver incorporate additional important factors, such as key recommendations advanced by the Secretary’s Advisory Committee on Transplantation (ACOT) and the status of Joint Commission of Accreditation of Healthcare organizations (JCAHO) accreditation reviews.

To be consistent with CMS interpretative hospital COP guidelines effective June 1, 2004, AOPO recommends that the following additional conditions be met before a hospital would be eligible to seek a waiver under this provision:

1. The hospital must have written policies and procedures to address its organ procurement responsibilities, with each element identified in the CMS interpretative guidelines addressed by the written documents;
2. Verification that the hospital’s governing body has approved the hospital’s organ procurement policies;
3. Verification that the organ, tissue, and eye donation program is integrated into the hospital’s Quality Assurance and Performance Improvement (QAPI) program; and
4. The hospital must have in place policies to ensure that potential donors are identified and declared dead within an acceptable time frame by an appropriate practitioner.

AOPO recommends that CMS incorporate the following additional considerations in its review process to determine whether to grant a waiver:

1. The outcome of the most recent JCAHO review of the accreditation status of the applicant hospital, with specific attention given to organ donation-related

aspects of the accreditation process (Note: JCAHO's recently announced conversion rate requirement will be effective July 1, 2005);

2. For a hospital with more than 100 beds, whether the hospital has identified an advocate for organ and tissue donation from within the hospital's clinical staff (ACOT recommendation to modify CMS COP for hospitals);
3. Whether the hospital has "policies and procedures in place to manage and maximize organ recovery from donors without a heartbeat" (ACOT recommendation to modify CMS COP for hospitals); and
4. Whether the hospital has policies and procedures in place so that any failure to identify a potential organ donor and/or refer such a potential donor to the OPO in a timely fashion would be investigated and reviewed by the hospital in a manner similar to that for other major adverse healthcare events (consistent with ACOT recommendation). It is presumed that this additional consideration may not be relevant for any hospital that has been fully engaged in the Department of Health and Human Services (HHS) Organ Breakthrough Collaborative, given the collaborative work emphasized to address this essential area.
5. Whether the acquiring OPO is certified.

**"De-certification (proposed §486.312)":**

AOPO has two significant concerns with §312. First, the definition of "decertification" is not consistent with the underlying statute. Second, even if CMS believes the definition to be consistent with the statute, the grounds for decertification contained in §486.312 are not consistent with either the regulatory definition or the statute.

1. The definition of "decertification" is inconsistent with the authorizing legislation because it permits decertification without consideration of all the statutorily mandated criteria.

As CMS noted in the Preamble to the regulations, the Organ Procurement Organization Certification Act of 2000, (section 7 of Public L. 106-505A, codified at 42 U.S.C. §273(b) (1) (hereinafter "the 2000 amendments") required the Secretary to promulgate regulations that determine certification and recertification based upon, among other things:

- (a) "outcome and process performance measures that are based on empirical evidence... and other related factors in each service area;
- (b) multiple outcome measures, and..."

42 U.S.C. §273(b) (ii) (II) and (III).

The use of the word "and" throughout this section makes it clear in our view that Congress specifically intended that certification, recertification (and, by logical

extension, decertification) decisions be based on a multiplicity of factors, rather than any single factor considered in isolation. CMS recognized this in the Preamble when it stated:

“Congress noted that current OPO regulations do not permit consideration of outcome and performance measures that ‘would more accurately reflect the relative capability and performance of each organ procurement organization.’”

70 FR at 6088, col. 2.

The proposed definition of “certification” expressly refers to a determination by the Secretary that an OPO “meets the requirements at § 486.303 and is eligible for designation if it meets the additional requirements for designation.” In contrast, the proposed definition of “decertification”:

“means a CMS determination that an OPO no longer meets one or more conditions for coverage, including the outcome measures, the process performance measure and other requirements, or no longer meets the requirements for certification or designation. In addition, if an OPO’s agreement with the CMS is terminated or is not renewed, the OPO is de-certified.

It is unclear why this definition is not the mirror image of the definition of “certification.” The proposed regulation appears to authorize decertification if the OPO fails a single certification requirement or, alternatively, meets all the certification requirements, but fails to meet one of the separate designation requirements. To the extent the Conference Report accompanying the legislation is relevant, it confirms the plain reading of the statute, when it states that one of the weaknesses in the then existing certification process was:

“the exclusive reliance on population based measures of performance that do not account for the potential in the population for organ donations and do not permit consideration of other outcome and process standards that would more accurately reflect the relative capability and performance of each program procurement organization.”

Section 219(a) (4) (A); 114 Stat. 2763A-28, Public Law 106-554 (Appendix A).

The proposed definition, however, appears to authorize exactly that which Congress prohibited: a decertification decision based solely on one criterion.<sup>2</sup>

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<sup>2</sup> This definition may be inconsistent with the statute for an additional reason. Whereas certification is a determination by the Secretary, decertification is a determination by the CMS. The authorizing legislation clearly provides for review by the Secretary. 42 U.S.C. §273(b)(1)(D)(ii)(IV). In light of the proposal for appeals (discussed below) that only allow review by CMS with no further review by the Secretary, it would appear that this proposal constitutes an irrevocable delegation of authority that is inconsistent with the statute. Flav-O-Rich, Inc. v. National Labor Relations Board, 531 F.2d 358 (6th Cir. 1976). [It is a

► AOPO therefore recommends that the definition of decertification be changed to read as follows:

“means a CMS determination by the Secretary that an OPO no longer meets ~~one of the requirements for certification contained in § 486.303 more conditions for coverage, including the outcome measures, the process performance measure and other requirements, or no longer meets the requirements for certification or designation.~~ In addition, if an OPO’s agreement with the CMS is terminated or is not renewed, the OPO is decertified.

2. The grounds for implementing the decertification process as proposed in § 486.312(b) and (c) are not consistent with the statute or other sections of the proposed regulations.

The proposed regulation specifies three ways that decertification can occur:

- (a) decertification due to voluntary termination of agreement; §486.312(a).
- (b) decertification due to involuntary termination of agreement; §486.312(b);  
or
- (c) decertification due to non-renewal of agreement; §486.312(c);

Sections 312(b) and (c) describe the two circumstances under which an ‘involuntary’ decertification could occur: (i) either during the term of the agreement (§ 486.312(b)) or (ii) at the end of the agreement, if it is not to be renewed (§ 486.312(c)). Grounds for termination contained in these two sections are not consistent, and CMS provided no explanation for this disparity.

AOPO believes that such grounds should be consistent, or the administrative record should indicate the legal and policy reasons why they differ.

- 2.a. Section 486.312(b) includes improper grounds for decertification during the term of the agreement.

AOPO has three major concerns with proposed §486.312(b), relating to decertification during the term of the agreement. First, it permits decertification based upon considerations not authorized by the 2000 amendments. Second, it is inconsistent with the definition of “decertification” in the proposed regulations. Third, it is inconsistent with the conditions upon which certification is granted.

Specifically, this proposed regulation authorizes decertification if CMS finds that the OPO:

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fundamental rule of administrative law that “[t]he one who decides [a case] must hear [it].” United States v. Morgan, 298 U.S. 468, 481, 56 S.Ct. 906, 80 L.Ed.2d 1288 (1936)].

- "...no longer meets the requirements for certification..." or
  - "...no longer meets the requirements for ... designation..."
- or
- "...is not in substantial compliance with any other applicable Federal regulation..." or
  - "... is not in substantial compliance with provisions of titles XI, XVIII, or XIX of the Act..." or
  - "...CMS may terminate ...in cases of urgent medical need..."

Section 486.312(b) [emphasis added].

First, this provision is inconsistent with the 2000 amendments. The legislation makes it clear that compliance with outcome and performance process measures, and multiple outcome measures, is specifically identified as the collective bases for certification decisions. 42 U.S.C. §273(b)(1)(D)(ii)(II), (III). By specifically requiring consideration of these outcome and performance process measures in the certification and recertification process, it necessarily follows that Congress could not have been authorizing the CMS to exclude some of these statutory factors in its decertification decision-making process. (*Jewish Hosp. v. Secretary of Health & Human Servs.*, 19 F.3d 270 (6th Cir. 1994)); *Doucette v. Ives*, 947 F.2d 21 (1st Cir. 1991). But proposed §486.312(b) appears to do just that: it authorizes CMS to decertify based on failure to meet designation standards or "other applicable federal regulations," (e.g., these could be Department of Labor or Department of Revenue regulations, each with its own remedies) or the provisions of titles XI, XVIII or XIX (again, presumably with their own remedies), regardless of compliance with certification conditions.

Second, there is an inconsistency between §302 and 312(b). Section 312(b) authorizes decertification for failure to be in substantial compliance with "any other applicable federal regulation." But the §302 definition of "decertification" does not mention failure to comply with "other applicable federal regulations" as part of its meaning.

Third, this proposal is inconsistent with the definition of "certification" proposed in the regulation, and the terms governing "certification." "Certification" is defined as "meeting the requirements of proposed §486.303." See proposed §486.302. No apparent reason exists for permitting decertification" on grounds different than the definition of "certification." Moreover, CMS has not proposed that there be compliance with "other applicable federal regulations" as a condition of certification. At most, under the proposed regulation, certification requires compliance with "other requirements" for conditions of coverage. See proposed §486.303(h). This creates an anomalous situation in which CMS could certify an OPO even if that OPO was not meeting "any other applicable federal regulation" and then decertify the same OPO even without any change in condition or conduct by the OPO. The same is true with respect to the provision authorizing decertification for failure to comply with provisions of titles XI, XVIII, or XIX. Those requirements are not present as certification conditions, yet appear to be an independent and sufficient basis for decertification. APOPO is unaware of any basis in the record that would support this apparent inconsistency.

► APOPO therefore recommends that §486.312(b) be changed to read:

(b) Decertification due to involuntary termination of agreement. CMS The Secretary may terminate an agreement with an OPO if CMS finds that the OPO no longer meets the requirements for ~~designation or certification in section 486.318~~ ~~the conditions for coverage in this subpart or is not in substantial compliance with any other applicable Federal regulations or provisions of titles XI, XVIII, or XIX of the Act.~~ CMS may also terminate an agreement immediately in cases of urgent need, such as the discovery of unsound medical practices. CMS will decertify the OPO as of the effective date of the involuntary termination.

- 2.b. Section 486.312(c) includes improper grounds for decertification when that process takes place at the end of the agreement term (non-renewal).

CMS proposes only one criterion that would trigger decertification by means of involuntary non-renewal at the end of the agreement term: whether the OPO meets the outcome measures of § 486.318. Thus the entire process becomes self-executing. This proposal has three defects. First, it is inconsistent with the underlying statute. Second, it is inconsistent with the substantive grounds for decertification set forth in subsection 486.312(b). Third, it is inconsistent with the definition of “decertification.”

This proposal is inconsistent with the 2000 amendments. As explained above, the authorizing legislation makes it clear that compliance with outcome and performance process measures, and multiple outcome measures, is specifically identified as the collective bases for certification decisions. 42 U.S.C. §273(b)(1)(D)(ii)(II), (III). APOPO believes that by enacting the 2000 amendments Congress intended CMS to simultaneously consider all three categories and to recognize that a failure to achieve a numerical target in one category could be offset either by the “related factors in each service area” or the OPO’s own performance characteristics (e.g., the “process performance measures”). The 2000 amendments were enacted after the Arkansas Regional Organ Recovery Agency, Inc. v. Shalala, 104 F. Supp. 2<sup>nd</sup> 1084 (E.D. Ark. 2000). This case held that a decertification based on strict adherence to a single numerical target without “examination of specific and pertinent factors would not be an accurate measure of efficiency” and was “arbitrary, capricious, and an abuse of discretion” (at 1090). Less than 5 months later, Congress enacted the 2000 PHS amendments mandating that all three performance characteristics be incorporated into the certification process. The Conference Report shows that this was not a coincidence, and that automatically triggering decertification based solely on one criterion, and especially the outcome measures criterion, is exactly what Congress did not what to happen:

“[the] exclusive reliance on population based measures of performance that do not account for the potential in the population for organ donations and do not permit consideration of other outcome and process

standards that would more accurately reflect the relative capability and performance of each program procurement organization.” [Emphasis added.] Section 219(a)(4)(A); 114 Stat. 2763A-28, Public Law 106-554 (Appendix A).

By specifically requiring consideration of all outcome and performance process measures and other factors in the certification and recertification process, it necessarily follows that Congress could not have been authorizing the CMS to accomplish decertification by excluding consideration of some of these factors. Jewish Hosp. v. Secretary of Health & Human Servs., 19 F.3d 270 (6th Cir. 1994); Doucette v. Ives, 947 F.2d 21 (1st Cir. 1991).

CMS has suggested that as the agreement nears its termination, there is not enough time to consider all these factors, complete the decertification process, and permit some sort of appeal rights, but still introduce competition so that the decertified OPO can be replaced without creating a “gap” in coverage for the geographic area. Thus the Preamble to the proposed regulations notes: “The existing time frame generally did not permit a decision to be made on an appeal prior to a successor OPO taking over the service area when the de-certified OPO’s agreement with us expired on August 1.” 70 FR at 6092 col. 2.

In response, decertification is a terminal action that should only be undertaken after a thorough review of all relevant criteria, and the relevant criteria need to include more than simply arithmetic outcome measures. Congress specifically directed the agency to provide OPOs with the right to appeal decertification decisions based on all these factors. 42 U.S.C. §273(b)(1)(D)(ii)(IV). The legislative history specifically underscores Congress’ concern that no one single factor be the sole or exclusive criterion considered. In our assessment, nothing authorizes the CMS to simply eliminate consideration of statutorily mandated grounds for decertification when it intends to decertify an OPO at the end of an agreement term, while retaining those grounds if the decertification occurs during the agreement term.

Second, this proposal is inconsistent with § 486.312(b). Although subsection (b) has other defects, at least it recognizes the existence of other criteria for certification, including process performance measures (§§ 320-346). There is no explanation in the record addressing why decertification at the end of the contract period may be accomplished by consideration of only outcome measures, but decertification during the term of the agreement could be based on other factors. This makes it easier to be decertified than recertified.

Third, section 486.312(c) is inconsistent with the §302 definition of “decertification.” The decertification definition, although defective for reasons explained above, at least recognizes the process performance criteria and “other requirements.” These “other requirements” are the other regulatory performance process measures.<sup>3</sup> It is inconsistent

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<sup>3</sup> As noted above, by using the disjunctive “or,” decertification is defined in a manner that is inconsistent with the statute, which repeatedly uses “and.”

to define “decertification” using one set of criteria, but permit decertification without regard to those criteria.

In sum, we believe there is no legally permissible reason to distinguish the grounds for involuntary decertification based on when decertification takes place (i.e., whether the effective date of decertification is on the date of non-renewal, or on some earlier date). The 2000 amendments expressly preclude limiting grounds for termination to one criterion alone. Administrative concern over the timing of any appeal of a notice of decertification and the need to avoid a ‘gap’ in coverage for the area can be, and should be addressed in the appeal process, as discussed below, not by eliminating statutorily required considerations.

- ▶ **AOPO therefore recommends that subsection 486.312(c) be deleted.**

**Appeals (proposed §486.314):**

AOPO recommends that a corrective action plan should be identified as one of three alternate outcomes of the appeals process, that is, (1) decertification, (2) restoration of status subject to successfully achieving a corrective action plan, or (3) restoration of status without the need for a corrective action plan. The remainder of the comments which follow address the rule’s proposed new appeals process.

There are a number of very serious concerns with this proposal which entirely eliminates the current clear and understandable appeals process and replaces it with an unspecified commitment to due process. These include:

- (1) The proposal to replace Part 498 hearings with an unspecified process is inconsistent with the authorizing legislation which requires a process comparable to what the Secretary created in Part 498.
- (2) The proposed appeals process is inequitable and inadequate, and provides less, rather than more clarity.
- (3) The appeals process being proposed is constitutionally defective.

AOPO has attached to these comments a specific proposal for addressing these concerns. (See Attachment A.)

1. *The proposal to replace Part 498 hearings with an unspecified process is inconsistent with the authorizing legislation which requires a process comparable to what the Secretary created in Part 498.*

As explained below, since March 1, 1988, the Secretary has consistently provided OPOs with the appeal rights outlined in 42 CFR §498. 53 FR 6526. The authorizing legislation and the regulations implementing this legislation have consistently provided that appeal rights at least as protective as those provided for in § 498 must be afforded to OPOs facing decertification. We believe that is more than just a discretionary process that CMS

can remove; rather, we believe it is what the law requires, as the statutes that created this program illustrate.

Prior to the enactment of legislation that resulted in the current program for OPOs, the organ procurement activity covered by Medicare was limited to kidneys and procurement services were provided as part of and through End State Renal Disease Programs ("ESRD"). Title XVIII, although not addressing OPOs, did address the rights afforded entities seeking payment for kidney procurement benefits provided under ESRD, including kidney procurement. 42 U.S.C. §1395rr (previously 42 U.S.C. §1881). The statute provided, among other things:

(3) A facility dissatisfied with a determination by the Secretary under paragraph (1) shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 405 (b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405 (g) of this title.

42 U.S.C. §1395rr(g)(3).

Consistent with this requirement, on July 12, 1987, the Secretary promulgated regulations, making it clear that Part 498 was designed to give affected facilities a hearing to the extent provided in sections 205(b) and 205(g) of the Act, respectively. 52 FR 22444 (Medicare Program; Appeals Procedures for Determinations That Affect Participation in Medicare) codified at 42 C.F.R. §498.2 (specifying coverage for ESRD entities).

Meanwhile, the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99-509), which included section 1138 of the Social Security Act established conditions of coverage for the approval of organ procurement organizations for participation in the Medicare and Medicaid programs. The statute contained did not specifically address appeal rights of OPOs. It did provide, however, that:

The Secretary shall designate and maintain an identifiable administrative unit in the Public Health Service to—

(1) administer this part and coordinate with the organ procurement activities under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.]

42 U.S.C. §274c.

On July 31, 1987, the Secretary of HHS approved the issuance of proposed regulations implementing §1138 to provide for participation by OPOs in Medicare and Medicaid. 52 FR 28666. The Secretary noted at the time:

Our current regulations discuss OPOs primarily in the context of the Medicare ESRD program. That is, their focus has been on kidney

procurement. Current §413.178 discusses reimbursement of costs to independent OPOs. These rules would not change except for technical conforming changes...

\* \* \*

We would add an OPO's appeal rights to 42 CFR §498, to assure that a decision not to designate an OPO, to suspend or cease payment (i.e., determine that the OPO does not meet the conditions for coverage), or to terminate the agreement with Secretary is subject to administrative review.

The final regulations that implemented this proposal were described as follows:

If the OPO did not come into compliance, we planned to proceed to terminate the agreement to reimburse costs of organs procured from the OPO under Medicare and Medicaid and the agreement that the OPO is the designated one for its service area. We proposed to provide the right to appeal a proposed suspension of payment or termination of agreement. This appeal right was to be the same as that granted to other providers and suppliers and is found in §§498.3 and 498.5 (see 52 FR 22444).

53 FR at 6533 col. 3 (March 1, 1988) [emphasis added].

Thus, even before the 2000 amendments, the statutory and regulatory language demonstrates that for purposes of appeals, OPOs were embedded in the ESRD rubric and were entitled to the same or equivalent process that ESRD's have under 42 U.S.C. § 1395rr. In other words, the Secretary's inclusion of OPOs in the Part 498 hearing procedures is based on statutory obligations and is not discretionary. As such, we would submit that it is incumbent on the CMS to provide either the Part 498 hearing or a process that is equivalent to the process described in Part 498.

The 2000 amendments underscore this obligation by including new language specifically addressing the rights of appeal for OPOs, and requiring the right to appeal a "substantive and procedural grounds." 42 U.S.C. § 273(b)(1)(3)(D)(ii)(IV). The Conference Report requires an "equitable" proceeding, which, until now has been the Part 498 process. Yet the proposed regulation appears to respond to this statutory mandate for an equitable and comprehensive appeal process by completely eliminating the Part 498 process. It eliminates the procedure under which a party can currently obtain reconsideration even before pursuing a formal appeal. It eliminates any description of how appeals will be pursued, and how a party could be assured of its rights to obtain all information relevant to the determination at issue. It eliminates any mention of subpoena powers and process that assure a party of access to pertinent information. It eliminates any requirement for an independent adjudicator. And it eliminates almost all the time frames during which certain actions could or must be taken.

The proposal replaces the carefully constructed and time tested Part 498 process with a hearing officer whose powers and duties are nowhere defined.<sup>4</sup> The proposal requires that the notice state “the reason” for the decertification, but it does not require that any evidence used to support the notice be provided to the OPO. It imposes on the OPO the obligation to file a response to a notice of decertification within 30 days of receipt, regardless whether the substance of a notice involves 1 or 10 grounds for the notice. It also requires the OPO to identify, develop and submit any evidence opposed to decertification within that same 30 day period, but imposes no similar obligation on CMS.

The elimination of Part 498 is also inconsistent with the MMA. This law requires that “suppliers” be afforded a hearing identical or comparable to what the Secretary provides under Part 498. As explained below, OPOs are entitled to a complete administrative hearing process because they are suppliers. AOPO recognizes that an administrative agency is entitled to establish definitions and that in this case, there maybe more than one forum or venue that can provide an adequate administrative hearing. But here there is an underlying statutory definition which speaks directly to the matter.

Section 936 of the MMA specifically provides for an ALJ hearing using the same procedures set forth in 42 USCA § 405(b). In order to qualify for § 936, an OPO must be a “supplier”. Section 901 of the MMA defines “supplier” as ...“a facility, or other entity (other than a provider of services) that furnishes items or services under this subchapter”. CMS in its Preamble concludes that this definition does not include OPOs, even though, as noted above, CMS had determined that for the last 17 years, an OPO was a supplier.<sup>5</sup>

The MMA definition is an expansive definition, meant to capture as many types of entities or persons as possible. The definition basically provides that anyone or any entity that provides services pursuant to or under the Medicare program and that is paid under the program is a supplier (as long as it is not a provider). This definition contemplates different types of suppliers. With a program as broad and comprehensive as Medicare, not all suppliers (just like not all providers) look alike or have identical definitional characteristics. There are many examples in the Medicare program where

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<sup>4</sup> After numerous inquiries and research, AOPO has learned that there are no mandatory and enforceable regulations or even written policies of any sort that reflect their general rules of procedure or how a hearing would proceed. The Preamble (pg. 6092), but not the regulation generally describes some aspects of what this hearing might be like, but that description is not binding. This is not to suggest in any way that the integrity or competence of a hearing officer should be questions. Our concerns are focused only on the institutional protections that exist, not the performance of particular individuals.

<sup>5</sup> Even if the statute did not mandate Part 498 hearings, the CMS must provide a reasoned analysis for its apparently change in its longstanding interpretation of “supplier.” *Rust v. Sullivan*, 500 U.S. 173 (1991); *San Luis Obispo Mothers for Peace v. United States NRC*, 789 F.2d 26, 50, n.6 (D.C. Cir. 1986). The CMS has also taken the position that the appeal process for OPOs should be extensive and exhaustive in order to (a) give the agency the chance to use its expertise; and (b) to avoid burdening the courts. See Defendants’ Response to Motion for a Preliminary Injunction and Temporary Restraining Order and Motion to Dismiss filed in *Arkansas Regional Organ Recovery Agency, Inc. v Shalala*, 104 F. Supp.2d 1084 (W. Div. E.D. Ark. 2000), at 9. Again, if CMS believes that this is no longer the case, it should explain why in our view.

certain types of program participants have overlapping characteristics of providers or suppliers, yet are treated as one or the other for payment or certification purposes.

**Comment (h1):**  
Ed, do we have examples of this?

OPOs provide direct services to the program (consent from families where appropriate, organ recovery, suitability testing). They are parties to a specific program agreement, follow specific regulations, file cost reports, host survey and certification teams, and generally have a far greater connection to the program than does a neighborhood pharmacy. More importantly, if a pharmacy loses its designation status, it can still remain in business. By law, an OPO cannot. If it loses its designation, it is put out of business.<sup>6</sup> We do not believe there is any statutory support to demonstrate that Congress meant for an OPO to have fewer or different rights than it gave to other types of suppliers with less of a connection to the program.

CMS's discussion in the Preamble attempts to distinguish OPOs from "typical" suppliers because an OPO does not bill the patient directly and does not receive payment directly from Medicare in the first instance.<sup>7</sup> It is not, in the words of the Preamble, a "typical" supplier. If it is not a "typical" supplier, it apparently cannot, according to the Preamble, be a supplier. But the MMA does not distinguish between "typical" and "atypical" suppliers. It includes any type of "other entity" that provides services. The only exclusion is if the "context" (which has to mean statutory context) "otherwise requires." There is no other statutory context which "otherwise requires." The Preamble is silent on this point. The MMA does not "otherwise require" that an OPO sacrifice its supplier designation in the interests of a quicker hearing; there is no legislative history or suggestion that Congress intended or desired this result.

It is unlikely that Congress intended both to grant OPOs an express right to appeal decertifications on procedural and substantive grounds in an equitable and support CMS's narrow interpretation of the expansive term "supplier" to cut off the existing proves. When Congress amended the PHS in 2000, OPOs had been suppliers for 13 years. At least three Civil Remedies Division cases had specifically recognized the supplier status of OPOs and two district court decisions had not set aside that status. Congress clearly was aware of the Secretary's conclusion that OPOs were suppliers and clearly relied on that designation when it enacted the 2000 amendments. There is no evidence that Congress, in passing the MMA, meant to undo the administrative hearing rights that it relied upon OPOs having when it enacted the 2000 amendments.

The reason for this change appears to be unrelated to statutory definitions that can be read to require (or even support) a change in supplier status. Instead, this change would seem to be motivated CMS's attempt to shorten the administrative hearing process: "This alternative appeals process is necessary because there is a limited time period from the

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<sup>6</sup> As noted in our discussion of constitutional concerns below, serious due process issues arise when an entity with a demonstrably greater property interest has far fewer administrative appeal rights than one with a lesser interest.

<sup>7</sup> OPOs do annually reconciliation with the program and may receive payments directly from the program.

date that the outcome performance data are available to the date when the OPO contract cycle ends. ...Therefore,... OPO appeals must be expedited and completed....” 70 FR at 6093 col. 2. As AOPO understands it, ALJs were so burdened by other processes, that OPO hearings often were delayed. To accomplish this, CMS had to disqualify OPOs from Part 498, which meant that it had to remove from OPOs their “supplier” designation.

In summary, Congress required that the OPO program be administered and coordinated with other organ procurement activities. 42 U.S.C. § 1395rr, which addresses such organ procurement activities clearly affords review under section 405(b). The Secretary has implemented section 405(b) in the Part 498 procedures. In the 2000 amendments Congress specifically required an equitable hearing in which OPOs could be assured of their rights to appeal on all procedural and substantive grounds. Eliminating access to the Part 498 procedures, eliminating any opportunity for reconsideration prior to the hearing, eliminating any appeal beyond the hearing officer, and eliminating any written procedures that explain how this appeal process will work is inconsistent with the governing law, and inconsistent with the Secretary’s long held view of its requirements, and we believe should be addressed.

AOPO does not oppose modifications to an administrative hearing process as long as: (1) the replacement process provides the same caliber of hearing process and protections and (2) permits sufficient time for a complete and meaningful hearing. AOPO does not believe that CMS’s suggested replacement process, as publicly disclosed at this point, meets these two criteria. As written, AOPO believes the modifications contradict the statute and are inconsistent with the sense of Congress, which clearly relied on the Secretary’s prior designation of OPOs as suppliers entitled to a Part 498 hearing. Our comments below will suggest ways that AOPO believes can effectively address the issues identified.

► **AOPO recommends that the Part 498 appeal process be retained with some changes to expedite appeals. This proposal satisfies the twin objectives of avoiding an unnecessarily prolonged administrative process and still preserve the important protections in existing Part 498. (See Attachment A).**

2. *Even if the 2000 amendments could be read to permit elimination of the protections afforded by Part 498, the proposed process is inequitable and inadequate.*

The Preamble justifies replacing the existing Part 498 process with the abbreviated and unspecified ‘hearing officer’ process on two grounds. First it says that a shorter process is necessary because “Although the OPO was given the right to appeal under Part 498, it was not possible to complete the appeals process prior to expiration of our agreement with the OPO on August 1.” 70 FR at 6092 col. 2. Second, the Preamble suggests that OPOs are neither suppliers nor providers, and therefore including them in those categories for purposes of Part 498 hearings is not required by law. This second ground is addressed above. AOPO is pleased that CMS recognizes the need to preserve the OPO’s business unless and until a final decertification decision is made, and the need to

assure that the area served is not left without an OPO to cover it. AOPO respectfully submits that there are means of addressing these concerns and remain consistent with statutory obligations. But there are numerous reasons in our view why the process proposed to replace the Part 498 process is inappropriate, inequitable, and will not address the asserted need to make sure that the appeal is completed before decertification takes effect.

First, there is no basis in the record upon which it can be concluded that the current process is problematic. The Preamble explains that the Part 498 process has proven inadequate because the appeals could not be completed before the OPO contract terminated, thus creating a situation in which competition by other OPOs would begin before the final decision on decertification is complete. 70 FR at 6092, col. 1. That is unfair to an OPO which is entitled to preserve its business unless and until a final unreviewable decertification decision is made. But CMS does not indicate how many decertification appeals it has been a party to and how long it has been since CMS actually had to conduct a decertification appeal. Nor does the record contain a single example of a case in which the administrative process could not be completed in time<sup>8</sup>. In short, there is no correlation between any actual deficiency identified by CMS and its purported cure. It is incumbent on the agency to provide record support for its regulatory proposal, and to provide that support in the record so that the public has the opportunity to comment. Portland Cement Ass'n v. Ruckelshaus, 486 F.2d 375 (D.C. Cir. 1973).

AOPO understands that the Part 498 process can be time consuming, apparently because of the substantial ALJ work load. It is also clear from the Preamble that historically there was a second complicating process at work, namely the two year certification cycle. It was possible for a certification appeal to consume a substantial portion or all of the period following a decertification notice, creating confusion which carried over into the following certification period and which delayed the process of designating a replacement (p. 6092, Preamble). This confusion was exacerbated, in turn, by the continuing uncertainty over the applicability of the CMS recertification cycle, which ultimately was resolved through Congress remedied this deficiency by expanding the recertification cycle to 4 years. It would be incorrect, therefore, to conclude that the purported delays or other shortcomings of the appeals process is attributable solely, or even in major part, to Part 498.

Second, according to the Preamble, the timing of decertification is only an issue if occurs at the end of the Agreement term. We do not believe there is any basis in the record concluding that a decertification proceeding begun during the term of the Agreement, and

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<sup>8</sup> There are only three reported Civil Remedies Division Appeals from 1994 through the issuance of the proposed regulations in 2005. Only one appeal involved a loss of certification; the other two involved disputes between OPOs for contested areas. There was one reported case where an OPO obtained an injunction against termination pending its challenge to regulations. Arkansas Regional Organ Recovery Agency, Inc. v. Shalala, 104 F. Supp.2d 1084 (W. Div. E.D. Ark. 2000). In this case the challenge was to the validity of the regulations, not to the application of those regulations to the facts. Nothing in the instant proposal would address this issue, since hearing officers lack the authority in any event to declare the regulations invalid.

intended to be effective prior to the end of the term, suffers from the same timing issues. Consequently there does not appear to be any reason at all for eliminating the §498 process for involuntary decertifications taking place during the term of the agreement. Third, the proposal places the entire burden of meeting a shortened appeal time on the OPO. As noted above, AOPO is not aware that appeals have been delayed by OPOs nor is there anything in the record to support such a conclusion. Moreover, it is the AOPO's understanding that the delays which may have occurred in the few hearings that have been conducted were primarily the result of workload issues that overburdened administrative law judges have as a result of other programs. Assuming this is true (and there is nothing in the record to address it) it is not an adequate basis for removing appellate rights of OPOs.

Fourth, shortening the appeal period in our view will not solve the problem described in the proposal (that the Agreement will end before the decertification review process is complete.) While the proposal requires an appeal to be filed within a specified time frame, and requires that the hearing officer set a hearing quickly, there is nothing that guarantees that a hearing will actually be held within that time period. As we understand it, hearing officers do grant continuances. Unlike the Part 498 hearing procedures, which at least require 'good cause' for such delays, there are no clear or written standards governing hearing officers.

Moreover, current law provides OPOs with a right of judicial review once the administrative process is concluded. At a minimum that review is available under 28 U.S.C. §1331. Even assuming that the current proposal is adopted, a decertification decision is still subject to judicial review. Thus, it is unlikely that a final unappealable decertification decision will be made before the Agreement terminates in any event.

Fifth, the problem as described in the Preamble is not that the process takes too long. Rather, the problem is that the process may not end before the agreement expires. The proposal addresses this by shortening the appellate process on the back end, thus putting the entire burden on the OPO. To address this, CMS could start the decertification analysis sooner than the ending date of the re-certification cycle currently set as December 31. For instance, the notice of impending decertification could be sent to the OPO immediately after the end of the 42<sup>nd</sup> month (e.g., June 30, 2009, assuming a 4 year certification period running from 01/01/2006 to 12/31/2009), with an effective date of July 31<sup>st</sup> of the following year (as is in the proposed rule). The certification data still would be based on the prior 48 months of data, applying whatever metric to this data that CMS has finally determined is the best measure of an OPO's performance (AOPO hopes that it CMS adopts the metrics suggested in this response). This would add an extra six months to accommodate the administrative hearing process, the time frame coincidentally that the Office of Hearings estimates would be consumed by an appeal if the OPO appeals track the experience of the Medicaid State Plan appeals.

Under this alternative, CMS is still using 48 months of data. The statute does not mandate that the data derive from the identical 48 month period as the agreement cycle. In fact, as presently structured, CMS is already using data from a certification cycle that

ends 7 months before the agreement ends (December 31 vs. the following July 31). Increasing this period by six months is far preferable to a truncated appeals process. An OPO could advance the argument that the data could be weighed disproportionately towards an earlier period and does not reflect current, more positive trends. This would be corrected if CMS adopts our two earlier proposals, namely allowing the program officials to consider (i) process performance and other related factors and (ii) current reconsideration data.

Alternatively, CMS should provide some type of pre-termination notice. The proposed rule only requires CMS to provide a reason why its agreement is not being renewed. Given that the rule presently envisions only a mathematical test, it does not require CMS to provide any type of advance notice of the imminent non-renewal, nor does it provide any opportunity for the OPO to provide any information to CMS in advance of the non-renewal notice. It is conceivable that a non-renewal could be avoided (and the cost and inconvenience to both parties of an appeal there from) if CMS provided some type of preliminary or provisional notice of an imminent or likely non-renewal and permitted the OPO the opportunity to provide additional, responsive material prior to a non-renewal/termination design. Our proposal in Attachment A addresses these concerns.

Sixth, the unknown nature of the proposed procedure, and lack of any written regulations governing it cannot cure the "uncertainty" that the Preamble claims currently exists. CMS has proposed to use a CMS hearing officer from its Office of Hearings. At the moment it is impossible to examine the proposed procedures because they have not been reduced to writing and are not available electronically (e.g., a website). Likewise, the proposed regulation is silent on any of the important technical procedural or substantive hearing processes. Consequently, OPOs have no information regarding how a hearing is to be conducted. We understand that CMS intends to publish, at a later date, more details on the actual CMS Hearing Officer process. This does not provide the public with the opportunity to meaningfully comment on the current proposal to eliminate Part 498 hearings.

Although AOPO may have the ability to comment when the CMS hearing officer procedures are published, AOPO cannot know at this time whether, when or what format these procedures will be published.<sup>9</sup> Accordingly, AOPO must express its concerns now to the dilution of a known regulatory appeal process and its replacement by an unpublished and unknown (at least to OPOs) hearing process. If one of the purposes of this proposal is to provide greater certainty to OPOs, eliminating a known and certain process with an unwritten and unknown one does not achieve that goal. Consequently, AOPO does not regard the substitution of Part 498 with the CMS hearing officer as an improvement, in large part because of the inability to inspect and compare this process to the Part 498 hearing process and because of the uncertainty on a number of major procedural provisions (discussed below).

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<sup>9</sup> AOPO does not know whether these procedures will be published in the form of a manual or as a regulation. If the former process is used, then CMS has no obligation to provide any opportunity to comment and no obligation to consider those comments.

Seventh, the proposal does not afford any right to reconsideration by CMS, which does exist under Part 498. An important check and balance of the CMS review process is the requirement for reconsideration set forth in §498.22 -- §498.25. In two of the three reported ALJ decisions involving OPOs, the ALJ determined that HCFA (now CMS) did not properly follow these reconsideration provisions; each of these cases was remanded to HCFA with instructions to conduct an appropriate reconsideration of its initial determination. One important consequence of the elimination of the Part 498 is that the reconsideration provisions are also eliminated, thereby voiding an important procedural safeguard.<sup>10</sup> Reconsideration benefits both CMS and OPOs. Reconsideration permits the agency to consider new information or to re-examine previously submitted information in a new light. It is an excellent chance to correct the record and avoid mistakes. Any reconsideration process should permit the OPO to submit information up through the date of reconsideration. If this additional information is determinative, it could prevent the disruption and uncertainty of a decertification and recertification of a new OPO.

Eighth, there is no enforceable means for OPO to be assured it gets all relevant information necessary to make its appeal meaningful. One key element of an administrative hearing that is data dependent, is the ability to discover documents used by program officials and to depose program officials prior to a hearing. The ability of an ALJ to compel discovery of departmental documents and/or personnel is a key and undisputed power that ALJs possess. It is our understanding that there are no written legally enforceable mechanisms available to the hearing officer. Again, if the Part 498 procedures are used as the template for the CMS hearing officer hearings, this problem should be alleviated.

Ninth, the final rule should explicitly provide that the CMS agreement and payment for services continue during an appeal (termination or non-renewal). Under the proposed regulations, the possibility exists that an OPO may not be paid during the pendency of an appeal. Because (i) there are no time limits provided for the length of time that a CMS hearing officer may take to decide an appeal and/or (ii) the entire notification process might "slip" or run behind schedule,<sup>11</sup> there is a very real probability that a final decision from the CMS hearing officer could be rendered after July 31st (see, §314(c)). If the CMS schedule is adhered to, July 31st would be the last day that a not-to-be-renewed agreement would be in effect. The proposed rules indicate that an OPO will not be paid unless it is designated and has an agreement in effect (§304(a) and §312(e)). It appears

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<sup>10</sup> In the Arkansas Organ Recovery case (*supra.*), the Department argued that exhaustion of administrative remedies, which includes reconsideration, is an important and necessary process. Please refer to Defendants' Response to Motion for a Preliminary Injunction and Temporary Restraining Order and Motion to Dismiss filed in *Arkansas Regional Organ Recovery Agency, Inc. v Shalala*, 104 F. Supp.2d 1084 (W. Div. E.D. Ark. 2000), at 9.

<sup>11</sup> CMS must provide 90 days notice of its decision not to renew; because a CMS-OPO agreement expires July 31<sup>st</sup>, this would mean that it must notify and OPO by May 1<sup>st</sup>. However, CMS only has from the prior December 31<sup>st</sup> for the OPTN and the SRTR to compile, calculate, and compare OPO data. CMS admits this could take two months (e.g. January and February). This leaves only March and April for CMS to make a non-renewal decision. Given the amount of data to be compared, the newness of this process, and considering other governmental exigencies, it is likely that this schedule will slip. Preamble, page 6095.

that CMS has the discretion to extend the agreement, particularly if it relates to a decision to designate a successor (§304(e)(1) and §314(e)), but this extension is discretionary (not mandatory) and is only for 60 days. AOPO recommends that there be express language that unconditionally protects the incumbent OPO's payment stream if it has appealed and is awaiting a decision from the CMS hearing officer after July 31st.

The proposed regulations are also uncertain with regard to payment during an appeal for an involuntary termination (as compared to a non-renewal). In an involuntary termination, the CMS-OPO agreement can be terminated immediately. Apparently, the filing of an appeal does not "stay" or permit the continued payment of the OPO during the appeal. Section 314(b) indicates that if the OPO wins on appeal, CMS will not decertify the OPO "at that time" (emphasis added). Does "at that time" mean the time the hearing officer's decision is announced or is it retroactive to the date CMS imposed the involuntary termination? This point is unclear. If there is no retroactive payment, no OPO can afford to take the practical risk of continuing to operate during an appeal process (particularly since the rules do not impose any time frame for decision making by the CMS hearing officer). This effectively eviscerates any appeal right. If an appeal right is to be meaningful, the OPO must continue to be paid during the pendency of any appeal.

Tenth, we recommend that the final rule should provide that if the hearing officer reverses the decision to decertify, CMS's original decertification notice be "expunged" and not be a factor with respect to CMS's subsequent decision regarding competition for the service area.

In summary, OPO believes that the use of the CMS hearing officer may be feasible, but we suggest that the final regulations require the CMS hearing officer to adopt the Part 498 procedures for OPO decertification appeals. We understand that CMS's major concern with Part 498 is the designation of a Departmental ALJ, which creates time constraints because of the ALJ work load. The perceived advantage of the CMS hearing officer is that the CMS Office of Hearings work load is lighter, which permits the hearing to occur sooner. Use of the procedural mechanics of a Part 498 hearing is not likely to consume anymore time, regardless of whether the procedures are used in a Part 498 hearing or a CMS hearing officer hearing. If the time consumed by using the Part 498 procedures is neutral, there is no disadvantage to CMS to follow the Part 498 procedures. In effect, it is the same hearing process known to Congress in 2000, albeit applied in a different venue. Additionally, the Part 498 process could be revised to include general time frames for key events. An OPO decertification appeal is not dissimilar from a Medicaid State Plan appeal, which consumes roughly six months, including discovery, inevitable extensions, and briefing. It would not be complicated or arduous to review the existing state plan appeals and graft reasonable time frames into the Part 498 rules.

AOPO believes its proposal, contained in Attachment A, addresses these concerns.

### 3. *The proposed process is constitutionally defective.*

The proposed appeal process raises two constitutional concerns both grounded in the due process protections of the Fifth Amendment to the United States Constitution. The first

is a concern over whether the proposed process is constitutionally adequate. The second focuses on whether there the process adequately protects against unconstitutional commingling of prosecutorial and adjudicatory functions.

More precisely, our prior decisions indicate that identification of the specific dictates of due process generally requires consideration of three distinct factors: First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

Matthews v. Eldridge, 424 U.S. 319, 334-5 (1976). As explained above, the decertification process is not just a dispute over individual payments. Decertification will necessarily destroy an OPO's business. Few property interests under any HHS-administered programs reach this level of significance, and those that do (such as ESRD programs) have Part 498 protections.

By terminating the agreement on July 31, and only allowing a discretionary extension, the proposal fails to adequately protect an OPO's constitutionally protected property interest. Arkansas Regional Organ Recovery Agency, Inc. v Shalala, *supra*, demonstrates the judicial recognition of the significance of the OPO property interest at issue in an involuntary termination proceeding. The CMS recognizes this by offering a 60 day discretionary extension of any Agreement if the administrative review is not complete. But this does not address the due process deprivation that will result if involuntary termination is put in effect but that is reversed on appeal. It would be reasonable for the agency to construe its authority to extend a contract beyond the 60 days provided for in the current proposal at § 486.314(e) and to include the time period necessary to complete judicial review. There are numerous avenues available to the agency to expedite that process. <sup>12</sup>

The risk of erroneous deprivation is significant. As noted above, in the few decertification efforts attempted, most have been in error and those were under the more comprehensive Part 498 process.

Finally, it is also not at all clear that the government's burden and expense would be any less than that which exists using the Part 498 process. Given the recognition in the Regulatory Flexibility Act analysis, that only a few OPOs will ever face decertification, the burden on the CMS is minimal under either procedure.

Second, the proposed process is likely to cause an unconstitutional commingling of prosecutorial and adjudication functions. Under § 486.312(c), the CMS may issue a

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<sup>12</sup> While it is certainly the case that an OPO can seek interim judicial relief from the impacts of a decertification decision, it would appear to be an inefficient use of judicial resources to require that this be litigated.

notice based solely on failure to meet the outcome measures set forth in proposed § 486.318. However, the preamble to the proposed regulations permit the CMS hearing officer to consider additional evidence not considered by the primary CMS decision maker<sup>13</sup>, including substantive and procedural evidence. It describes at length the additional evidence that a CMS hearing officer can consider that was not considered by the program officials. 70 FR 6092. This includes, but is not limited to, process performance criteria, other requirements including demographic data, special consent issues, public education efforts, and so on. In effect, the CMS hearing officer is considering this information, on behalf of the agency, for first time. The CMS hearing officer is not reviewing the agency's initial determination, he/she is making it.

There are no written rules or procedures that govern the conduct of the hearing officer who will adjudicate a decertification proceeding. AOPO has been advised that the hearing officer reports to the CMS Administrator, which also handles the CMS program function. While we are told that the hearing officer is 'separated from' and 'independent of' the CMS program function,<sup>14</sup> there is no regulation, policy or other written document that obligates the hearing officer to maintain this independence.

Both of the foregoing concerns raise questions regarding whether the use of hearing officers with unwritten rules and practices, and who report to the CMS Administrator, constitutes unconstitutional commingling of prosecutorial and adjudicative functions. See In re Murchinson, 349 U.S. 133, 136 (1955); Brown v. U.S., 377 F. Supp. 530, 539 (N.D. Tex 1998); Hoberman v. Lack Houser Hospital, 377 F. Supp. 1178, 1186 (M.D. Pa. 1994).

**"Re-certification and competition processes (proposed §486.316)":**

Even for OPOs meeting outcome and process measures, the rule proposes competitive framework options to open service areas in their entirety to competition at the end of every 4-year certification cycle. For the reasons elaborated upon below, AOPO strongly opposes any competition framework that would allow the takeover of a certified OPO's service area by another OPO. As such, AOPO agrees with the option included in the proposed rule, identified as the "highly restricted competition process," with competition only occurring among OPOs in cases where an incumbent OPO has been de-certified.

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<sup>13</sup> On the other hand, if a Hearing Officer is obligated to follow the regulations, he or she could be precluded from even considering process performance or other related factors in a decertification proceeding based on subsection §314(c) [end of term non renewal], since it is expressly limited to outcome measures. An administrative hearing officer is obligated to follow the existing regulations. It is possible that a hearing officer could be persuaded that the language in §314, which permits an appeal on procedural or substantive grounds, only applies to those procedural and substantive issues relating specifically to the outcome measures, and would not include mitigating evidence of process performance or other related factors.

<sup>14</sup> As noted earlier, we have no concerns with the integrity or competence of any hearing officer, and our comments are not meant to suggest otherwise. Our focus is on the institutional and enforceable protections that need to be in place.

The opening of every service area at the end of every 4-year cycle is an untested framework and potentially divisive approach that conflicts with the successful work of the national Organ Donation Breakthrough Collaborative. The OPO community joined then-HHS Secretary Tommy Thompson in signing a "Contract for Results" and entering a compact with the nation's largest hospitals and the government to achieve unprecedented donation results through active pursuit of a collaborative model. All 58 federally designated OPOs have either fielded teams in the Collaborative or assigned responsibility to designated improvement leaders for spreading the initiative's successes. In fact, the association has already made bold commitments to institutionalize the success of the Collaborative, which have been provided to the Department.

HHS has demonstrated and publicized the effectiveness and success of its investment in the collaborative model approach of the Collaborative. Extraordinary results in organ procurement and transplantation across the nation have been achieved over the past 20 months. We believe that the Collaborative model has already evidenced its promise in achieving the national targets for the organ transplantation system as advanced in the federal Performance Assessment Rating Tool Performance Measurements and Goals. The accomplishments of the Collaborative are worth highlighting:

- OPTN/UNOS data show that donation rates nationwide in 2004 increased 10.8 percent over 2003, with rates at hospitals participating in the Collaborative increasing by 16 percent and by 9 percent in nonparticipating hospitals (and records continue to be registered in 2005 with an additional 9 percent increase through the first four months).
- The number of deceased donors recovered each month since October 2003 has achieved a level higher than recorded in the same month a year earlier (and this pace has continued for 20 months in a row as of the end of April 2005), while the number of deceased donors recovered per day achieved 22 in April 2005 compared to 16 in 2002;
- The number of standard criterion donors recovered, after a decade of little change, has averaged more than 500 per month in 2005 in contrast to more than 400 a month at the outset of the Collaborative;
- The overall number of transplants in the US increased by 1,500 in 2004, owing in large part to the application of the collaborative model;
- One of the most important high-leverage changes in the Collaborative has been a focus on donation after cardiac death (DCD) programs. The number of donation service areas with first-time DCDs recovered this past year increased, with each participating OPO and hospital acknowledging the role of the collaborative model in achieving that outcome;

- In the Collaborative's first phase, 95 hospitals and 45 OPOs with the highest number of eligible donors in the country replicated "what worked" in high-performing OPO/hospital systems. The Breakthrough Collaborative began its second phase in September 2004, and the additional 131 hospitals and 50 OPOs now participating are using the lessons learned from the first phase and working to increase "conversion rates" in their program. Overall, all organ procurement organizations have been participants in the collaborative, either having one or more teams (54) or being an improvement leader (4).
- Overall, as highlighted in the First Annual Organ Donation National Learning Congress, the distribution of conversion rates among the 366 largest hospitals in the nation (i.e. having 8 or more eligible deaths per annum) evidenced a significant shift towards higher conversion rates.

A major development of the Collaborative related to lives saved has been the increase in the rate of timely notifications by hospitals to OPOs. Empirical information exists to substantiate the association of the family consent process with consent regarding the donation decision. According to the work of Laura Siminoff, PhD, regarding the effect of early referral on consent rates, for example, there was little difference in consent rates between requesting at the time the family was told of a patient's death or requesting after the family was told of the patient's death. Statistically significant differences in consent rates (yes versus no) were shown, however, when donation was requested either before the family was told the patient was dead (63 percent of the study population said yes to the request) or while brain death tests were being conducted (65.4% percent of the study population said yes to the request).<sup>15</sup>

More recently, Dr. Siminoff provided equally important empirical results in 2003. The data are part of a current study funded by the Health Resources and Services Administration and have not been published yet.<sup>16</sup> For the hospitals included in the study population at the time, 63.6% of referrals to the OPO were timely. As reviewed by the OPO in the study population, approximately 184 donors were lost due to late referrals. These data reflect a study population and time period prior to the Organ Breakthrough Collaborative. They are submitted as empirical estimates of lives saved owing to increases in timely notification resulting from the Collaborative model.

Empirical information also exists to substantiate the relationship of process timing and the viability of organs for transplant. Specifically, delayed referral notification can adversely affect organ functional reserve in the donor which, in turn, can negatively impact organ utilization and transplant outcomes. Improperly administered hospital-OPO

<sup>15</sup> Siminoff LA, Gordon N, Hewlett J, Arnold RM. "Factors Influencing Families' Consent for Donation of Solid Organs for Transplantation," *Journal of American Medical Association*, 286(1): 71-77,2001.

<sup>16</sup> Siminoff LA. "Family Consent: Developing a Model Intervention to Increase Consent to Organ Donation." (Plenary Speaker) Presented at UNOS Research to Practice: A National Consensus Conference, Orlando, Florida; April 2003. Referenced here with permission of author.

clinical trigger notifications can delay required potential organ donor clinical interventions that are shown to improve the odds of successful transplant outcomes. It is well established that the requirement for increased blood pressure support, elevated serum sodium, and prolonged admission to a critical care unit increase the odds ratio for transplant graft failure.<sup>17</sup> There is also an unmeasured impact on organ recovery rates, from the aforementioned preventable clinical conditions, that cause previously suitable organs to not be recovered and transplanted due to lack of timely notification.

Much of the Collaborative's success is attributable to how it has facilitated the sharing of data and information regarding what works. Its measurement strategy, pursued individually and collectively by participating teams, focuses on outcome measures (i.e. conversion rates, medical examiner denials, and referral rates,) and process measures (i.e. timely notification and appropriate request). This new way of doing business so to speak, shared jointly between OPOs and hospitals, has many notable accomplishments to date, including real time physician, hospital administration, and family support in hospitals; death record reviews on demand; new access for OPOs to hospitals, including opportunities for office space and physical presence not available earlier; multi-area collaborative approaches; first time breakthroughs in donation after cardiac death recoveries; more directed interactions with medical examiners and coroners; greater involvement of critical care medical personnel in donor management following brain death declaration; incorporation of organ donation quantitative goals and responsibilities in hospital operating plans and corporate compliance policies; an increased emphasis on pediatric recovery; and the identification and practice of clinical champions for organ donation in hospital settings.

This new model of collaboration has been cited by the healthcare quality improvement community for its effectiveness, standing in sharp contrast to a proposed competitive model without evidence of its potential for similar outcomes. In February 2005, the prestigious Institute for Healthcare Improvement (IHI) called attention to the collaborative model successes in its newsletter article entitled "Finding the Right Opportunities in the Right Places: A New Model for Organ Donation." As noted in the article, "using methodology proven to help improve care in a wide range of areas, the Organ Donation Collaborative has begun to promote positive change in an area of health care that has often been viewed as a medical, legal, ethical, and emotional minefield."

In its March 24 newsletter issue, the IHI presented an article entitled "Spreading the Gift of Life: Organ Donation Breakthrough Collaborative." As stated in the article: "Scientists and providers focused on this problem have identified significant untapped resources that could vastly reduce the waiting list and save thousands of lives a year. The work is the product of a national initiative called the Organ Donation Breakthrough Collaborative,

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<sup>17</sup> (a) Briceno, J, et al. "Influence of Marginal Donors on Liver Preservation Injury," *Transplantation* 2002, Aug 27; 74(4):522-6. (b) Tisone, G, et. al. "Marginal Donors in Liver Transplantation," *Transplant Proc.* 2004, Apr; 36(3):525-6. (c) Rocha MD, et al. "Can the Use of Marginal Liver Donors Change Recipient Survival Rate?," *Transplant Proc.* 2004 May; 36(4):914-5. (d) Totsuka, E, et. al. "Analysis of Clinical Variables of Donors and Recipients with Respect to Short-term Graft Outcome in Human Liver Transplantation." *Transplant Proc.* 2004, Oct; 36(8): 2215-8.

launched in 2003 by the Secretary of Health and Human Services (HHS), Tommy G. Thompson, and based on IHI's Breakthrough Series change methodology. In the Collaborative, teams of physicians, nurses, hospital executives, and leaders from key organizations with a role in organ donation and transplantation have been aggressively and successfully challenging the status quo. The group has demonstrated that, if all parties involved follow proven best practices, the supply of healthy organs available to patients in need would increase dramatically. In fact, by doing things more effectively and following uniform standards, 50 percent more patients could receive the gift of life."

Recognition of the value of the Collaborative model has in fact extended throughout the healthcare industry. The Leadership Coordinating Council (LCC) of the Collaborative includes many major national healthcare organizations, including those that have not traditionally been heavily engaged in addressing quantified national goals in donation (e.g. JCAHO, Association of Critical Care Nurses, Neurocritical Care Society, etc.) The Council has members that have assisted work at the local level to make increased donor recoveries a reality (e.g. working with State Hospital Associations, medical examiners and coroners, etc.). The LCC, furthermore, with the active support of the American College of Healthcare Executives, has played a major role in engaging CEOs and the leadership of the nation's largest hospitals in support of increasing organ donation and saving lives. This unique body, given its membership cutting across the healthcare field, is committed to action and has already made significant policy and collaborative inroads to date (e.g. joint communications regarding conversion rates to hospitals; posting of data on national web sites regarding medical examiner and coroner denials; collaborative training of accreditation surveyors; participation at national meeting of other organizations; etc.).<sup>18</sup> HHS has indicated its commitment, furthermore, to continue support of this Council this coming year. A number of participants in the Collaborative are pursuing the potential for establishing similar LCCs at State levels. The Collaborative and its successes were additionally featured in the January-February 2005 edition of UNOS's Update, in its article entitled "Seeing New Growth: The HHS' Breakthrough Collaborative is resulting in increases in donation."

The value of the Collaborative and the need to support this collaborative model has been recognized by Congress too. The House Appropriations Committee, as part of House Report 108-636 accompanying the FY 2005 appropriations bill for DHHS, noted the following: "The Committee is encouraged by the initial success of the organ donation collaborative project. This project is focused on the nation's largest hospitals and has adopted the goal of assisting these hospitals achieve organ donation rates of 75% or higher, which will result in at least 6,000 additional organs available for transplantation."

Significantly, HHS itself has expounded on the successes of the past 18 months and the effectiveness of the collaborative model. The following press release was issued by HHS on March 29, 2005, days before the first deadline for public comment on the regulation expired:

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<sup>18</sup> Labb D. "Increasing Organ Donation and Procurement: The Hospital Leader's Role," *Healthcare Executive*, May/June 2005: pp. 25-30.

*"Headline: NEW HIGH SET FOR ORGAN TRANSPLANTS  
Nearly 27,000 individuals received transplants last year*

*HHS Secretary Mike Leavitt announced today that 26,984 Americans received an organ transplant last year, setting a new national record. The increase in organ donations come in the wake of concentrated efforts led by HHS to boost consent rates for organ donation, which began in 2001. (underlining added)*

*"I am heartened that the promise of organ donation continues to save more and more lives every year," Secretary Leavitt said. "For each life saved, hope, for others in need, grows; we must continue to grow and share that hope across the nation."*

*Deceased donors can give multiple organs that will improve or save the lives of several people. In 2004, there were more than 20,000 transplant operations utilizing organs from more than 7,000 deceased donors, an increase of close to 11 percent over the 2003 total. That increase was the largest in the last 10 years and the second highest annual increase since national records began to be collected in 1987. (underlining added) Organ transplants from deceased donors rose by 1,368 (18,650 to 20,018) from 2003 to 2004, a 7.3 percent increase.....*

*Tommy G. Thompson, within his first 100 days as HHS Secretary, announced his commitment to develop a new national effort to encourage organ donation. That commitment, also known as the Gift of Life Donation Initiative, led to 2004's record transplant totals through which the number of transplant candidates who died waiting for an organ fell below 6,000 for the first time in six years.*

*In 2003, HHS's Health Resources and Services Administration (HRSA) launched the "Organ Donation Breakthrough Collaborative," to bring together donation professionals and hospital leaders to identify and share best practices to maximize donation rates from potential organ donors who die in their facilities. While donation from deceased donors rose both in hospitals participating in the collaborative and in those not taking part, the increase was higher for those in the collaborative (16 percent compared to 2003) than for non-participating hospitals (9.4 percent).* (underlining added)

The Collaborative Co-Chairs and Faculty emphasized the new national sense of teamwork and collaboration as part of the May 18-19, 2005 First Annual Organ Donation National Learning Congress. Particular attention was directed to the impact of timely notification, effective requesting, and unparalleled hospital-OPO relationships across the country. Significantly, the Collaborative approach was characterized as the "implementation of a competitive spirit grounded in teamwork, recognition, and results."

In brief, these are the results at risk by pursuing the proposed competitive framework outlined in the regulation. The proposed competitive framework is antithetical to the findings of Congress that the prior process was disruptive and that regulatory reform needed to be undertaken. Under the proposed framework, the taking away of an incumbent OPO's service area is quite independent of the OPO's success in meeting the stated performance standards. As a result, it provides substantial incentives for an OPO to divert attention away from its core mission of increasing organ donation and recovery towards defending against the potential loss of its service area. Of perhaps even greater concern, the proposed framework would encourage OPOs to devote scarce resources towards taking over other areas rather than improving performance in their own areas. Indeed, the proposed framework degrades the point of having performance measures and only serves to foster a "predatory culture" of pre-Collaborative years.

Finally, it would seriously undermine the prospects for sustaining the recent donation outcomes attributable to the Collaborative, principally by promoting a return to proprietary information and limited data transfers between OPOs rather than advancing the sharing of "best practices" and change strategies (a point of particular relevance for adjacent OPOs).<sup>19</sup> The untested approach would place the stability of OPO-hospital relationships into jeopardy as well.<sup>20</sup> The regulation clearly understates the enormous, real cost in lives lost by pursuing an alternative competitive framework premised solely on theoretical benefits to patients on the waiting list.

With regard to competition when an OPO does not meet conditions for coverage, AOPO agrees with CMS that an incumbent de-certified OPO should not be permitted to compete for its service area and agrees with CMS' recommendations regarding competition only for an entire service area. AOPO also agrees that the criteria OPOs must meet to compete for an open area should recognize higher performance. With regard to the latter, AOPO has provided recommendations for defining a high performing OPO.

AOPO recommends that no OPO competition decision should be implemented until both the incumbent de-certified OPO and the competing OPO(s) are able to reasonably and independently verify the outcome measures reported which were the basis for the de-certification and competition decision for both the incumbent OPO as well as for the competing OPO. This analytic audit should include, but not be limited to, death record

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<sup>19</sup> Successful new OPO-OPO relationships, including teamwork involving adjacent OPOs, were highlighted at the May 2005 National Learning Congress. A case in point was the presentation of new joint initiatives conducted by the Washington Regional Transplant Consortium and the Transplant Resource Center of Maryland.

<sup>20</sup> Of note is the fact that "building and maintaining strong relationships" was also cited at the National Learning Congress (by Cliff Goodman, Lewin and Associates) as one of the seven principles gleaned from case studies developed to provide the empirical framework for the new National Organ Transplantation Collaborative. This focus on relationships was also cited by Dr. Anthony D'Alessandro, Co-Chair of the National Organ Transplantation Collaborative, as one of the five change strategies for the initiative.

reviews and analysis of data which would be associated with hospital donor potential in each service area, and other empirically obtained information.

AOPO recommends that a 180 day transition period be used to design the audit process, including data and documents that OPOs would be required to maintain for audits. (Please see our comments addressing §486.318 for more specifics about the proposed 180 day transition period). AOPO recommends, furthermore, that an onsite audit be conducted by an independent entity.

If no OPO applies for an open service area, AOPO recommends that such an area should not be involuntarily forced upon another OPO, either whole or in part. As such, AOPO recommends that CMS should first allow other OPOs to apply for portions of the open area. For any areas still open, CMS may wish to use such an opportunity to permit the introduction of entirely new organizations to qualify as OPOs to service such areas.

Should no OPO apply for de-certified territory under any circumstances and should CMS assign the territory(ies) to one or more OPOs, AOPO recommends that the receiving OPO(s) should be subject to recertification performance criteria only for their historical service area for the ensuing performance cycle.

This section also references outcome performance measures applicable to different competition approaches. Our comments regarding the proposed outcome measures, including means for distinguishing respective performance levels, can be found in our comments below regarding §486.318.

AOPO notes that the proposed competitive framework advanced by CMS contains, in addition to the shortcomings described above, many procedural deficiencies in the competitive process whereby CMS selects one OPO over another for a contested area.<sup>21</sup>

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<sup>21</sup> Although the comments which follow could be included in the comments regarding §486.314, AOPO believes that a certified OPO that has lost its certification because of a take-over by a higher performing OPO should be entitled to a hearing. It is particularly noteworthy in the rule that a low performing OPO which is decertified by CMS is entitled to a hearing, but a certified OPO which is decertified because of a successful territorial challenge by a "better" performing OPO is not. This observation and comment does not obviate AOPO's objection to the regulation's provision allowing competition for a certified OPO's territory; AOPO still objects to open competition. If CMS accepts AOPO's comments and eliminates open competition, the need for a hearing is eliminated and this specific comment is moot. If CMS does not accept AOPO's comment, however, then it should reinstitute the right to a hearing that it deleted.

1. In a situation where an incumbent OPO is certified (i.e., it meets all of the outcome and performance measures, §316(a)) but is challenged by a “better performing OPO”, and the incumbent loses, there is no procedure, hearing, or venue for the incumbent OPO to challenge CMS’ decision. In effect, a completely compliant OPO can lose its certification and designation without any due process appeal. However, by contrast, a poor performing OPO can challenge its decertification and receive a hearing before a CMS hearing officer.<sup>22</sup>
2. The proposed regulations do not set forth quantitative criteria for CMS’s selection of one OPO over another. This is a substantive due process failure. The two criteria considered by CMS (i.e., (i) the performance of the applying OPO in its own service area and (ii) an “acceptable” plan to recover organs in the contested area) are devoid of any specific, meaningful comparisons. CMS has full discretion to define and apply these criteria. In comparison, the existing regulations set forth six specific, measurable tie-breaker criteria (§316).

The proposed rule essentially would (i) eliminate any tangible criteria to compare competing OPOs, (ii) grant CMS officials unlimited discretion to apply the three very vague comparative and minimal standards of §316(c)(1)-(3), and (iii) eliminate any administrative review of this decision.

Reinstatement of the “tie-breaker” decision criteria into proposed §316(c) would be an improvement. There should be some concrete, measurable means to measure the success of the bidding OPO. These measures should be applied to the plan for and likely success in the disputed area (and not simply a re-hash of the bidding OPO’s statistics in its present area.)

3. Even if any of the competing OPOs could appeal a CMS decision for a contested area, with respect to the criteria set forth in proposed §316(c), there is no indication of how much weight is to be put on each of these criteria. For example, if applicant A has better performance data in its own area, but applicant B has a better plan for the contested area, which factor is to be given more weight?

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<sup>22</sup> Although the OPO’s agreement is being terminated (or not renewed) because the challenging OPO has “won”, the proposed regulations do not provide for an appeal unless the incumbent OPO is being involuntarily terminated or not renewed beforehand. Each of these events requires a finding of non-compliance, §312(b) and §312(c). In this instance, there is no non-compliance by the incumbent, only “better” compliance by the challenger, thus no §314 hearing.

4. The proposed regulations do not provide for an appeal by any of the unsuccessful prospective bidders for the open area (i.e., the incumbent or the challenger). The existing regulations permit an unsuccessful bidder to appeal using the procedures set forth in §498. (§316(b)).
5. In addition to the absence of a hearing, there does not appear to be an opportunity for an OPO to inspect or challenge the assertions made by a competing OPO in its application (e.g. through some type of review and rebuttal procedure). This shortcoming removes an important safeguard and requires CMS to make decisions based merely on the assertions of an applicant.

AOPO suggests that the regulations should be changed to permit §498 appeals between or among potential bidders for an open area (including incumbents). Additionally, we would recommend that CMS insert objective outcome criteria in place of the less quantifiable performance criteria when comparing OPO applicants. In that regard, we recommend that CMS indicate in advance the degree of weight that it intends to place on each decision factor that it uses. Finally, as part of an appeal to a contested area (if there is one), the submissions of each applicant should be available to other applicants and each applicant should have the ability to contest or rebut the assertions made by the other contestants.

### **Proposed OPO Outcome Measures**

#### ***“Outcome Measures” (proposed §486.318) :***

AOPO is pleased to see the emphasis in the rule on organ donor potential. It is a welcome change to the earlier population-based metrics advanced as OPO performance standards, and represents an important component for outcome measurement. This is an area where CMS, HRSA, UNOS, the SRTR, and AOPO have worked over the years to improve the analytics. We believe, however, that some important enhancements should be made to the proposed outcome performance framework.<sup>23</sup> Our comments below are provided as constructive suggestions for improving the measurement approach and we believe are in full accord with legislative intent and specific statutory language. The recommendations, furthermore, largely make use of data processes in place and therefore do not impose significant additional regulatory costs for implementation.<sup>24</sup>

<sup>23</sup> An excellent and timely reference regarding the current status of the development of outcome measures can be found in: Ojo, Akinlolu, Pietroski, R. O'Connor, K. McGowan, J. Dickinson, D. "Quantifying organ donation rates by donation service area." *American Journal of Transplantation* 2005; 5 (Part 2):958-966.

<sup>24</sup> As the analytics evolve, we would also reference important recommendations advanced by the Joint Commission on Accreditation of Healthcare organizations in its June 2004 publication "Health Care at the Crossroads." Of note are the following two action recommendations: (a) "develop and implement new requirements for the periodic assessment and improvement of organ donation conversion rates" (with accountability accorded to CMS and JCAHO) and (b) "develop standardized consensus measures respecting organ donation performance" (with accountability accorded to the Agency for Healthcare Quality, JCAHO, CMS, and the National Quality Forum).

The Preamble of the proposed rule contains an extended discussion regarding the outcome measures and their analytic development. In our review of this discussion, we found a number of misunderstandings and misstatements regarding AOPO. Our response to this section of the rule addresses these inaccuracies in order to provide CMS with formal clarification of the AOPO position on outcome measures, particularly with respect to some of the statements and references cited by CMS in the beginning parts of this section.

A Current Outcome Performance Standards. Although this section uses the term “current,” the outcome performance standards described have not been actually used in a certification process by CMS since 2000.

B Evaluation of Alternative Methods for Determining Organ Donor Potential

Regression Models for Estimating Donor Potential While there is value in reviewing methodological developments and background, the analysis presented in the proposed rule is somewhat incomplete and dated. For example, the General Accounting Office report cited was followed by many analytic developments which also called attention to the shortcomings of outcome measures in use by CMS (then HCFA) at the time. These included, for example, the work published by Ojo in the February 27, 1999 issue of *Transplantation* (“A Practical Approach to Evaluate the Potential Donor Pool and Trends in Cadaveric Kidney Donation”), the paper published by the Lewin Group on March 18, 1998 for the HHS Office of the Assistant Secretary for Planning and Evaluation (“Increasing Organ Donation and Transplantation: The Challenge of Evaluation”), and the Institute of Medicine report, entitled “Organ Procurement and Transplantation,” published in 1999.

We believe that the extended discussion in the proposed rule of the “Harvard and Partnership for Organ Donation model” and “AOPO model” does not accurately reflect AOPO’s past or present views. AOPO has never proposed that either regression model be used for certification purposes, a point clarified by CMS in the following section of the rule. The primary purpose of the association’s work was to develop an empirical estimate of organ donor potential in the United States. The results of the research effort were published in the August, 2003 issue of the *New England Journal of Medicine*, and have been widely referenced as an authoritative empirical source.

AOPO Recommendations. It is important to note that the recommendations advanced by AOPO to CMS and referenced in the rule were done so two months after passage of Public Law 106-505, in January 2001, with a view at the time that *transitional* recommendations would be helpful to CMS in complying with the legislative requirements in a timely manner. In the fall of that year, HHS began requiring that OPOs submit data on eligible donors to the OPTN. The regulations themselves were published four years following the informal sessions with CMS initiated by AOPO in early 2001.

## C Outcome measures

Problems with Two-Tier Assessment. As noted above, the AOPO recommendations advanced to CMS were identified as transitional and were offered prior to a decision by HHS to require OPO submission of eligible donor data to the OPTN. The rule's discussion regarding the difficulties in obtaining "a national conversion rate," moreover, does not acknowledge the HHS-supported publication by the Scientific Register of Transplant Recipients (SRTR) of donation rates by donation service area and the US, which was initiated in January 2004. For the period July 1, 2003 to June 30, 2004, for example, the SRTR web site (<http://www.ustransplant.org>) indicates a "crude donation rate (organs per 100 eligible deaths)" for the United States of 50.9 percent.

OPTN Data as Alternative Data Source This section of the rule acknowledges the practice of OPO reporting of data to the OPTN initiated September 2001. AOPO participated with the Health Resources and Services Administration (HRSA) and its OPTN contractor UNOS to implement the new requirements. The participation of the association focused primarily on definitions recommended for the new data submission requirements.

In the summer of 2001, AOPO proposed to HRSA that the data submission be pilot tested, to examine possible inter-OPO differences in reporting due to different standards of practice notwithstanding the use of a uniform definition. Although steps were undertaken by the SRTR at HRSA's direction to assess the completeness of data submitted by individual OPOs, no testing was undertaken to assess inter-OPO variations. A subsequent analysis done by AOPO, distributed to CMS and HRSA, as well as to the SRTR and UNOS, included a case study approach which revealed variability in reporting of "eligible deaths" across OPOs. To our knowledge, an independent analysis of this variation has not been conducted, although SRTR's use of "notifiable deaths" has been a statistical effort to account for such variations. In April 2005, AOPO recommended to HRSA that training be conducted through the OPTN framework regarding submission of data by OPOs to the OPTN.

AOPO agrees that "eligible deaths" is substantially more predictive of actual donors. With regard to the matter of "data completeness," however, we believe that a more complete and balanced discussion of the OPTN data would recognize the matter of inter-observer variability in reporting and the fact that an independent analysis of such variability has not been conducted.

### Standardized Definition of Organ Donor Potential.

As noted earlier in comments regarding §486.302, the CMS proposed definition of "organ donation potential" differs somewhat from that used currently in the OPTN reporting requirements for OPOs. These differing reporting measures cause confusion

in the field and lead to mistakes and inaccuracies. AOPO recommends that there be one uniform definition for "organ donor potential."

AOPO has undertaken an analytic review of this matter and has shared its preliminary views with CMS and HRSA earlier in 2004. AOPO intends to finalize its analysis and proposed definition for "organ donation potential" by the end of June 2005. Further refinement of the definition, based on input from AOPO and subsequent review by the OPTN and others, would be recommended for inclusion in the upcoming performance cycle if at all possible and for subsequent performance cycles. Enclosed in Attachment B is our definition proposal as of this writing. We intend to review this definition at our June annual meeting and will forward a follow up communication should there be any modifications.

OPTN Data The statistical methodology used by the SRTR "to validate the data OPOs report to the OPTN" may not fully substitute for an independent assessment of inter-OPO variability in reporting. The proposed requirement for OPOs to publish hospital-specific organ donation data annually is unnecessary in view of the publication of such data by the SRTR, the regular reports provided to hospital chief executives by JCAHO and UNOS, and the JCAHO announced inclusion of conversion rates as part of the hospital accreditation process. This point is included in our subsequent comment regarding §486.328.

Death Record Reviews as Alternative Data Source Although AOPO does not recommend basing OPO outcome measures on the number of potential donors as determined by death record reviews, it also questions reliance by OPOs on death record reviews as a check on the validity of OPTN data submissions across service areas. As noted above, OPO correction of its own submission is important for maintaining the accuracy of intra-OPO reporting but is quite independent of any assessment of inter-OPO variations in reporting.

AOPO supports the CMS proposal to require death record reviews as a component of every OPO's QAPI program. We recommend that CMS specify that an OPO be required "to conduct death record reviews in every Medicare or Medicaid participating hospital with which it has an agreement if the hospital has 150 or more acute care beds, *with an ICU and ventilator*, or if it has a level I or level II trauma center." (italicized words added by AOPO). AOPO further recommends that the HHS technical assistance program regarding QAPI include appropriate training and guidance for conduct of standardized death record reviews.

#### Outcome Performance Standards and Thresholds

The proposed CMS rule, which focuses exclusively on conversion rates as its outcome metric, is consistent with the HHS Secretarial donation rate initiative for the nation's largest hospitals, and discards the earlier donors per million approach. As noted earlier, this change in approach is an important and welcome improvement in the performance measurement framework.

We understand from informal statements made by CMS officials that the numerator in the conversion rate measure includes all donors (e.g. donation after cardiac death donors or DCDs, donors greater than 70 years old), while the denominator, which focuses on brain dead organ potential 70 years and younger, is more restrictive. However, the actual wording in the regulation regarding the numerator is somewhat unclear.

Despite the improvements made, we would submit that the multiple measures advanced in the proposed rule are highly correlated with themselves and essentially represent one outcome measure (i.e. overall conversion rate), place disproportionate attention to the role of self reported data, and, unlike the transplant center conditions of participation regulations published on February 4, do not incorporate SRTR-related metrics and related statistical methodology.

AOPO recommends that two outcome measures be used for assessing OPO performance: overall conversion rate and organs transplanted per donor ratio.

*Overall Conversion Rate:* Our analysis indicates that if an OPO does not meet the threshold for the overall conversion rate (i.e. the first measure), it is highly unlikely that the OPO will be able to meet the threshold on the four remaining measures. In fact, the correlation between kidneys recovered per eligible death, kidneys transplanted per eligible death, extra-renal organs recovered per eligible death, and extra-renal organs transplanted per eligible death with organ donors per eligible death is very high and ranges from .81 to .97. Given the high inter-correlation between the five proposed conversion ratios, little additional information regarding performance is provided by the inclusion of the proposed four organ-related conversion ratios. Consequently, we recommend that one single conversion rate measure be adopted rather than the five conversion rates advanced by CMS.

AOPO agrees that any conversion rate outcome measure should include incentives for proactive attention to organ recovery. The incorporation of DCDs and older donors in the numerator alone, however, places a disproportionate weight on these areas in any performance comparison for certification purposes and may inadvertently mask opportunities for improvement in recovery of standard criteria donors. Inclusion of these donors as part of the national conversion rate benchmark (which is used as the benchmark for outcome comparisons among OPOs), furthermore, is problematic in the absence of estimates of donor potential for these groups. The AOPO recommendation, consequently, excludes these donors from the national rate but includes them in the numerator and denominator of an individual OPO for incentive and comparison purposes as adjustments to individual OPO conversion rates.

The conversion rate metric, in addition, should also incorporate statistically-derived expected conversion rates as part of its comparison. (This is in reference to

the analytic contributions of the SRTR to assessing conversion rates and is discussed below in the section on “transition period and final outcome measures.”)

*Organs Transplanted per Donor Ratio:* The adoption of a “yield”<sup>25</sup> measure as the second metric more fully meets the legislative expectation of multiple measures, is consistent with the recently launched HHS Organ Transplantation Initiative, provides incentives for greater recovery and transplant of extra-renal as well as renal organs, and allows for incorporation of legislative expectations regarding pancreas recovery for islet cell transplantation and research.

AOPO recommends that the measure be similar to that used by HHS in its initiative, that is, organs transplanted per donor (except that a case-mix expected rate be used for comparison purposes, as described later in this section). With a single conversion rate as an outcome measure rather than five conversion rates, the organs transplanted per donor ratio is a more suitable opportunity for incorporation of the legislatively-mandated islet cell transplantation and research incentive measure. Unlike the four organ-related conversion rates proposed in the rule, furthermore, the unit of analysis in the AOPO proposal is the donor rather than a self-reported eligible donor population. A more complete quantitative approach to acknowledging both number and quality is advanced (i.e. the number of medically suitable individuals “converted” to donors and the quality of those donors as measured by the number of organs transplanted) with a “yield” measure as well.

As part of the Organ Transplantation Initiative, HHS has identified sub goals for (a) Standard Criteria Donors (SCDs), (b) DCDs, and (c) Expanded Criteria Donors (ECDs). AOPO recommends that a case-mix expected rate be incorporated to account for important variations reflecting types of donors, as well as the age and race of donors.<sup>26</sup> The use of such an approach for outcome performance purposes provides a sounder analytic basis than using unadjusted measures to make inter-OPO assessments. Adjusting OPO-specific yield measures for pancreas outcomes, rather than incorporating adjustments to the national mean, furthermore, allows for more appropriate weighting of such outcomes in OPO comparisons given variations in pancreas recovery across the nation.

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<sup>25</sup> Although the term “yield” has been used in publications, AOPO believes that organs transplanted per donor or organs transplanted per donor ratio would be a preferable term in keeping with sensitivities raised regarding terminology by donor families and recipients. As such, the use of the term “yield” is limited in this response. Not unrelated, it is worth noting that the published tables by the SRTR reference “donation” rates rather than “conversion” rates. We use the terms conversion and donation rate interchangeably in this response.

<sup>26</sup> To our knowledge, SRTR has yet to develop a statistical approach to this area other than to use eligible donors as the unit of analysis rather than a donor. This may be an area for future research and application which may affect future iterations of outcome measures used for performance assessment.

AOPO recommends, therefore, that an OPO's organs transplanted per donor rate (adjusted for pancreata recovered for islet cell transplant or islet cell research) be compared against the OPO's case mix expected organs transplanted per donor rate. The pancreas adjustment would provide appropriate incentives since each recovered pancreas used in islet cell transplantation or placed for research would be added to the total organs transplanted numerator for individual OPOs and the number of organ donors with only the pancreas recovered for islet cell transplant or research would be added to the denominator of the measure. This treatment is consistent with the Pancreatic Islet Cell Act of 2004 in that it would permit pancreases used for islet cell transplantation and research to be counted towards an individual OPO's performance. The OPO's case mix expected measure for comparison purposes would incorporate the variations in organs transplanted per donor noted above regarding type of donor and age and race of donors. We believe that such a measure would adjust for important differences in recovery that affect the OPO's overall average and allow for appropriate incentives to OPOs to recover organs from all donors without worrying about the negative impact on their organs transplanted per donor measure. An illustration of the application of these proposed outcome measures can be found in Attachment C.

In view of their special circumstances, AOPO recommends that the thresholds for Puerto Rico and Hawaii be 50 percent, instead of 75 percent, of the national mean for both conversion and organs transplanted per donor. Additionally, AOPO recommends that the organs transplanted per donor measure for Puerto Rico and Hawaii be based only on kidneys recovered per donor and that a national mean be calculated for kidneys recovered per donor solely for the purpose of determining if Puerto Rico and Hawaii exceed 50 percent of the national mean on this measure. In sum, AOPO recommends that these be the only outcome performance measures and thresholds used by CMS for assessment of performance for these two service areas.

The proposed CMS rule is silent on the matter of retroactive versus prospective application of performance outcome measures. Based on public pronouncements by CMS officials during the comment period for the rule and informal responses given to AOPO upon request, AOPO understands that CMS intends to apply final outcome performance measures only for OPO performance cycles beginning after the effective date of the final rule. As such, our response assumes that proposed performance measures will only be used prospectively to assess OPO performance, i.e. for periods commencing upon the later of January 1, 2006 (assuming that the final version is promulgated prior no later than July 1, 2005) or the actual implementation date (assuming a period of 180 days following the promulgation of the final regulation).

The rule advances a continuation of the "75 percent of the mean" threshold as the marker for adequate OPO performance. The rule also proposes that the relationship of an OPO's performance relative to the mean, as well as a 15 point conversion rate spread, should be used to measure significant performance differences between OPOs. The rule does not

discuss the potential application of SRTR-based metrics in its proposed outcome measures.

In recent years, HHS has supported innovative analytic work conducted by the SRTR to improve donation rate measurement. The SRTR has made significant strides in the development of a statistical method for identifying a comparison metric to evaluate donation performance levels across OPOs. These SRTR rates are already in use within the hospital industry.<sup>27</sup> The outcome metrics in the proposed rule, nonetheless, appear to have been crafted well before the development of the SRTR's recent OPO-specific performance algorithm and the subsequent adoption of those metrics by hospitals and OPOs.

The inclusion of the SRTR statistically derived measures in the overall donation rate would provide an opportunity for assessing OPO performance, both in comparison to other OPOs and in comparison to an OPO's statistically expected conversion rate. In particular, their addition to the outcome metrics would provide an independent statistical assessment of how OPOs perform relative to their own service area capabilities, such as the presence or absence of large hospitals, trauma centers, etc. The inclusion of the SRTR methodology, moreover, would provide an approach grounded in science similar to the SRTR work featured prominently in the proposed transplant center regulations while adding to the return on investment of HHS's ongoing support in this area. We also believe that the incorporation of the SRTR analysis and measures would address the earlier-noted shortcoming of a performance measure framework built on the arithmetic certainty that some organizations would automatically fall below a threshold every cycle, regardless of their individual performance.

AOPO recommends that CMS add the SRTR statistical methodology and overall donation (conversion) rates to the proposed outcome measures framework. Some refinements to the measures, however, are necessary in order to address the following issues:

- 1 the SRTR has acknowledged its need to review patient-specific data for refining the methodology, with an 11 OPO pilot project targeted to investigate these data beginning in mid-2005 (presenting a later opportunity for case-mix adjusted conversion rates);
- 2 the SRTR analysis has yet to incorporate DCDs and ECDs into its methodology;

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<sup>27</sup> On February 7, 2005, Friedrich Port, MD, President of the University Renal Research and Education Association (URREA) wrote to all hospital administrators in the US bringing to their attention the public availability of measures of donation rates by hospital on the SRTR web site. On March 3, JCAHO formally communicated this development to hospital executives. The matter of "hospital donor procurement data available at SRTR," furthermore, was subsequently featured by JCAHO in its April 2005 issuance of JCAHOnline.

3 the statistical analysis has yet to be reviewed for an entire four year period since the data collection was only initiated by the OPTN in the fall of 2001;

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4 an opportunity has yet to be undertaken to address the effect of statistical bias introduced by the use of dated International Classification of Disease codes on the organ-specific donation rates first published by the SRTR in January 2005; and

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5 despite OPO-specific reviews of data by the SRTR, there has yet to be an independent validation of inter-OPO reporting of data. (AOPO has conducted such an analysis but understands the need for "independent" review.)

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With additional refinement and validation, the SRTR-based measures could be ready for use by CMS within 180 days after the effective date of the regulation (again, assuming that this would be no earlier than January 1, 2006). Thus, AOPO further recommends that an intensive refinement and validation process be conducted by the SRTR and completed in time for the SRTR-based metrics to be incorporated into the outcome measures within 180 days after the effective date of the final regulations. As part of the analytic effort, AOPO would additionally suggest that an independent validation of self-reported data be undertaken as well as an examination of the impact of an outcomes approach heavily reliant on referral data.

For outcome measures for use with the period starting 180 days after the effective date of the final regulation, AOPO recommends that the threshold for inadequate performance of an OPO be:

- not achieving 75% of the overall conversion rate, and
- having a SRTR-based donation rate for at least 3 years of the four year cycle statistically lower than expected<sup>28</sup>, and
- not achieving 75% of a case-mix expected organs per donors transplanted measure<sup>29</sup>

If an OPO meets or exceeds 75% of either or both the conversion and organs transplanted per donor ratio measures, but had a SRTR-based donation rate statistically lower than expected for at least 3 years of the four year cycle, AOPO recommends that the OPO would not be subject to de-certification but would be placed on an improvement plan by CMS.

<sup>28</sup> As noted earlier, individual OPO conversion rates would be adjusted by inclusion of DCDs and older donors in both the numerator and denominator of OPO-specific rates.

<sup>29</sup> As noted earlier, individual OPO yield measures would be adjusted by inclusion of recovered pancreas used in islet cell transplantation or placed for research in both the numerator and denominator of OPO-specific measures.

AOPO recommends that, for purposes of competition when an OPO does not meet conditions for coverage and service area territory becomes available for competition, the threshold for high performance by a challenging OPO to compete would be it achieving 110% of the mean for the overall conversion rate or having a SRTR-based donation rate for at least 3 years of the four year cycle statistically higher than expected.

As noted above, Attachment C provides a specific illustration of the application of the AOPO-proposed outcome performance measures advanced in these comments.

### **Transition Period and Recertification of OPOs – NEW**

The timing of these proposed regulations (given the passage of the legislation in 2000) creates the need for an interim course of action. This is particularly the case since, as noted earlier, AOPO assumes that proposed performance measures will only be used by CMS to assess OPO performance in future performance cycles.<sup>30</sup>

It is important that CMS have the ability to monitor and intervene during this four year period. CMS should be able to intervene in any of several circumstances: (1) a calamitous failure of the OPO, its governance, or management; (2) an exceptionally poor performance in a CMS survey, and/or (3) poor performance (e.g. via outcome and process performance measures) at the end of the second year of the four year designation cycle.

AOPO recommends that, at the end of the second year of the four year cycle following the effective date of the final regulation, CMS would apply the three aforementioned proposed final outcome measures to all certified OPOs. If an OPO failed any one of these three outcome measures<sup>31</sup>, it could be placed on “conditional certification” (the equivalent of probation). Conditional certification would permit CMS to institute a series of remedial measures designed to improve that OPO’s performance during the last two years of the four year cycle (i.e. an “Improvement Plan”<sup>32</sup>). These measures need to be

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<sup>30</sup> The assumption of CMS implementing OPO outcome and process performance measures only prospectively is based on informal remarks provided by senior CMS officials during the public comment period, including statements made by CMS officials at a national audio-conference call held on March 10. The regulation itself, however, is silent on this matter. Should CMS reject informal statements of its officials and the assumption made by AOPO in this response, and plan to undertake some form of rulemaking applying outcome or process performance measures on a retroactive basis, the Association requests an opportunity for this matter to be the subject of public review and comment prior to any finalization of the regulation.

<sup>31</sup> In the instance of the SRTR-derived conversion rate measure, under performance would mean having a conversion rate statistically lower than expected for each of the first two years of the overall performance cycle.

<sup>32</sup> The proposed AOPO response distinguishes between a corrective action plan (i.e. a plan developed by CMS in circumstances when an OPO is subject to decertification) and an improvement plan (i.e. a plan developed by CMS at the mid point of the four year performance cycle when CMS determines that improvement is needed).

developed but could include mandatory consultation from outside experts/consultants, increased reporting requirements, a corrective action plan, etc. At the end of the four year cycle, OPOs under “conditional certification” would be assessed as all other OPOs regarding performance measures.

### **OPO Process Performance Measures**

The regulations propose process performance measures in numerous areas. The rule’s proposed new Quality Assessment and Performance Improvement (QAPI) requirements represent a particularly important and welcome addition to the regulatory framework. Of particular note is the direction taken in the QAPI provisions of emphasizing direction and content, yet maintaining program flexibility in implementation with oversight by CMS. In our view, the balance advanced by the QAPI requirements provides a model regulatory framework that should be applied to other process performance measures noted in this rule. In many instances the requirements are too rigid and needlessly prescriptive, such as in the areas of staffing, donor management, and designated requestors. More significantly, they represent an approach that is problematic with an evolving field which already has a regulatory framework to accommodate change over time.

Organ donation and recovery, as with organ transplantation, is a field where science and technology evolve. For example:

- The proposed ABO blood typing provisions in the rule are dated and have been modified by the national policy process in place by the HHS-supported OPTN structure;
- Similarly, the rule’s focus on “designated requestors” has changed in recent years in the Organ Breakthrough Collaborative to an emphasis on effective requestors and an effective requesting process;
- The Collaborative, furthermore, has demonstrated equally outstanding outcomes achieved by OPOs having multiple staffing arrangements and approaches;<sup>33</sup> and
- Recent developments in infectious disease and new knowledge in donor management have occasioned more of a team approach to medical involvement, where the skills and perspectives of infectious disease and critical care specialties complement the involvement of transplant surgeons and physicians.

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<sup>33</sup> The recently concluded First Annual Organ Donation National Learning Congress, furthermore, provided particular attention to the matter of OPO Redesign, and sought input for a special session on this matter which will occur later this summer. The focus of the Redesign discussions at the Congress addressed such matters as number of staff, type of staff, work organization, culture, methods and systems, and financial models, with a clear emphasis on opportunities for sharing “best practices” rather than directing attention to standardized, prescriptive human resource requirements.

In sum, the evolving science of organ procurement and transplantation, along with continuing changes in standards of practice, demands that OPOs modify their processes and practices in accordance with the newest information and guidance made available. Furthermore, each OPO has its own unique resources and confronts a unique set of challenges. As a result, different operational practices will be effective for different OPOs. A specific approach for satisfying a process measure may not be the best approach for every OPO.

AOPO recommends that the approach of accountability and flexibility advanced by the proposed QAPI requirements be substituted for the rule's proposed approach of establishing detailed, overly prescriptive requirements. This could be accomplished by CMS giving general guidance to OPOs and requiring that certain policies be in place but not prescribing specific activities to undertake.

The following comments address specific sections of the process outcome portion of the rule.

**"Participation in Organ Procurement and Transplantation Network (proposed §486.320)":**

It is our understanding that the words "participate in the OPTN" need to be added to the second line of the proposed §486.320 to be consistent with 42 U.S.C § 273(b)(3)(H), so that the sentence would read: "After being designated, an OPO must become a member, participate in and abide by the rules and requirements of the OPTN."

**"Relationships with Hospitals, Critical Care Access Hospitals, and Tissue Banks (proposed §486.322)":**

AOPO clearly supports OPOs having written agreements with hospitals, as well as inclusion of the terms "timely referral" and "imminent death" as defined by the client hospital's Policy for Organ and Tissue Donation. In view of the HHS Organ Breakthrough Collaborative initiatives, however, AOPO would suggest that consideration be given to use of the term "clinical triggers" for "imminent death," as suggested by many hospital staff across the country.

OPOs currently are required to have working relationships with at least 75 percent of the Medicare and Medicaid participating hospitals in their service areas that have operating rooms and equipment and personnel for organ recovery. There is no reason to change this requirement from 75 percent to 95 percent, as CMS is proposing. At the same time, however, we would recommend that written agreements be required with all hospitals having 150 or more acute care beds with an ICU and ventilator or hospitals having a level I or level II trauma center.

AOPO requests that written clarification from CMS be provided in the final rule regarding the information OPOs would need to provide in the case of a hospital failing to

sign an agreement in order to demonstrate that the OPO had attempted to have a hospital enter into an agreement.

With regard to OPO relationships with tissue banks, we believe that an OPO's principal obligation is to cooperate in making arrangements so that referrals from a shared hospital are routed in a timely fashion to the hospital's tissue bank of choice. AOPO supports cooperative arrangements with tissue banks and appreciates the inclusion of language in the proposed regulations stating that agreements are not required in instances in which a tissue bank is unwilling to have an arrangement with an OPO.

Nevertheless, we are concerned about one requirement in this area of the proposed regulations. Section (c) requires that an OPO must have an "arrangement to cooperate" with tissue banks engaged in agreements with those hospitals with which the OPO has agreements. The only premise offered by CMS for this required relationship is that both the OPO and the tissue bank each have independent relationships with a hospital. In our view, this premise would be equivalent to a proposition saying that organization A and organization C must develop a commercial relationship simply because A has a relationship with organization B and C has a relationship with organization B, even though organizations A and C have no relationship and may have deliberately avoided creating one. AOPO opposes this requirement since it needlessly forces OPOs to have commercial relationships with entities not regulated by CMS. In fact, while paragraph (c)(2) permits a tissue bank to reject an arrangement with an OPO, it gives no such option to an OPO desiring to reject an arrangement with a tissue bank.

AOPO believes that CMS should not require a CMS-regulated entity to have a relationship with an entity not regulated by CMS, particularly when the entity regulated by the agency has good faith reasons for not doing so. AOPO's members have advised the association that there are legitimate reasons why an OPO may deliberately avoid (and in some situations, already has avoided) a business relationship with a tissue bank(s). These reasons include substantial discomfort with or outright aversion to recovery practices (e.g., consent procedures and donor eligibility criteria), processing procedures, and downstream commercial practices (e.g. how and where the processed tissue is sold). Consequently, as they are now written, the proposed regulations may have the unintended consequence of protecting a tissue bank's commercial opportunities at the expense of ensuring good tissue practices and patient well being.

AOPO does not deny the fact that, as a gatekeeper, an OPO has access to families and donors. That relationship, however, should not require the imposition of a relationship with every tissue bank working in an area. If an OPO and a tissue bank can reach agreement on the key points of a relationship (e.g., consent procedures, notification of potential donors, recovery practices, relationship with families and providers) and the OPO is professionally comfortable with the overall business practices and ethics of the tissue bank, then the three requirements mentioned in paragraph (c) are appropriate items for discussion between the tissue bank and the OPO. This assumes, of course, that these three requirements are not mandatory, and that the OPO and the tissue bank can agree to the degree of cooperation between themselves on each of these items "as

appropriate".

Conversely, if an OPO and a tissue bank do not have a relationship, and the OPO in good faith determines that it does not want to have a relationship (or visa versa), then the only requirement that should be imposed upon the OPO is that it must pass along notice of a potential donor to the tissue bank, and only in the event the OPO is not to be involved in the recovery of an organ. The public is not harmed if the OPO does not use this particular tissue bank because it will be making referrals to a different tissue bank, which means that the tissue will be recovered in any event.

**"Administration and Governing Body (proposed §486.324):"**

AOPO is appreciative of CMS's attention to this area in the proposed rule, particularly regarding the recognition of potential conflict of interest issues. AOPO supports the incorporation of consistency between PHS Act requirements and the rule.

There are several potential downsides, however, inherent in the approach that CMS has taken with the proposed rule that will offset any advantages gained by placing all PHS board positions on a non-governing advisory board. These include:

- As mentioned in the preamble, several OPOs (e.g. New England Organ Bank and Donor Alliance) have only one board, which contains PHS positions, and they have successfully dealt with the conflict of interest position. The proposed rule would force several OPOs to revert to multiple boards unnecessarily.
- Advisory boards can be disengaged and ineffectual. The OPO needs constructive input from the PHS type positions.
- Recruiting effective and interested board members for positions on the advisory board will be much more difficult if no governing authority is attached to the positions.

CMS cites conflicts of interest problems between OPOs and their transplant hospital representatives as justification for prohibiting cross membership. We believe, however, that these potential conflicts can be managed through enhanced conflict of interest requirements. Prohibiting cross representation between advisory and governing boards would not ensure the elimination of conflicts of interest. For example, under the proposed provision, there is no limitation on transplant center representation on governing boards so governing boards could theoretically be entirely composed of transplant center representatives.

Another troubling issue is that advisory boards under the proposed regulations would have reduced influence, which we believe would likely result in disengagement and apathy. OPOs need meaningful input and participation from these members.

AOPO believes that an OPO should continue to be permitted to have one 'fiduciary' governing Board and/or one fiduciary governing Board with one or more advisory boards/bodies. Cross representation between the advisory Board and governing board

should be allowed. Therefore, AOPO recommends that CMS allow OPOs to choose to have one board with cross representation between the advisory board and the governing board or separate advisory and governing boards. In either case, transplant center representation on the governing board should be limited to less than 50 percent and there should be a strong conflict of interest policy in place. Such a limitation on transplant center representation, in conjunction with enhanced conflict of interest provisions, would allow for adequate protection from conflicts and simultaneously maintain the necessary consultation and input from the members represented on the advisory board. OPO governing bodies require this broad based engagement and continuity to provide effective leadership.

AOPO supports the proposition that OPOs consider representation from other stakeholders, but we do not believe that such representation should be required on the advisory board. To maximize effectiveness, OPOs must have the discretion to add stakeholders to the advisory boards consistent with the needs and priorities of the specific OPO. Constituents such as research facilities, donor family members, transplant recipients, coroners or medical examiners, social workers, and chaplains can all add valuable input for an OPO and bring considerable influence; OPOs must have the flexibility to bring those resources to bear as needed in each community.

CMS is seeking comment on the proposal that a single individual be designated to assume full legal authority and responsibility for the management (and presumably the governance) of an OPO instead of a Board of Directors. AOPO believes that the suggestion "that legal authority and responsibility for management and provision of all OPO services should lie with an individual rather than a governing body" is inconsistent with the requirements of every states' nonprofit corporation law, IRS rules for 501c (3) organizations, and the direction of Sarbanes-Oxley. This proposal should not be adopted in the final rule. Endowing a single individual with all legal authority and responsibility for an OPO would have the effect of eviscerating the valuable "checks and balances" provided by a Board of Directors. The OPO most likely would lose its tax exempt status as well.

AOPO opposes any requirement to have one tissue bank on the Advisory Board as the representative of all tissue bank(s) within the donation service area. This would create a severe conflict of interest situation when one tissue bank representative is expected to represent the best interests of competing tissue banks. More to the point, however, is the fact that the individual would be appointed to the board as a *representative* of an outside entity rather than as a fiduciary of the OPO. This individual would, by the very nature of the appointment, appear to have primary responsibilities back to the tissue bank. If the OPO is offering competitive tissue recovery or banking services, it is inappropriate to put a competitor on its board. If the OPO is not offering such services, then it is likely using a tissue bank or processor as a vendor. In our view, it would be just as inappropriate to place a major vendor on the board because the conflict would be too pervasive. Additionally, vendor relationships can change quickly, which could leave an ex-vendor on the board as a director.

Given the above comments, we would propose the following wording for the final rule regarding the administration and governing body provisions:

“(a) An OPO must have at least one board that serves as a governing body with full legal authority and responsibility for the management of and provision of all OPO services and must develop and oversee implementation of policies and procedures considered necessary for the effective administration of the OPO, including fiscal operation, the OPO’s quality assessment and performance improvement (QAPI) program, and services furnished under contract or arrangement, including agreements for these services. The governing body must appoint an individual to be responsible for the day-to-day operation of the OPO.

(b) An OPO must meet the requirements stipulated in Section 371 (b) (1) (G) of the PHS Act (42 U.S.C. 273 (b) (1) (G) and must have a board of directors or an advisory board that is composed of:

- Members who represent hospital administrators, intensive care or emergency room personnel, tissue banks, and voluntary health associations in its service area;
- Members who represent the public residing in such area;
- A physician with knowledge, experience, or skill in the field of histocompatibility;
- A physician with knowledge or skill in the field of neurology; and
- A surgeon from each transplant center in the OPO’s service area with which the OPO has arrangements to coordinate its activities.

(c) An OPO may choose to meet the stipulations in paragraph (a) and (b) by having one board which has the governing authority and which also has the representatives listed in paragraph (b) or it may choose to have an advisory board separate from the governing board with the positions listed in (b). If an OPO chooses the former option, the individuals listed in (b) may serve as directors or as non-director committee members, but in either event, it must have clear and strict policies and procedures for identifying and addressing conflicts of interest.

(d) Whether an OPO elects to have a single integrated governing board (e.g. one single governing board with the individuals enumerated in (b) above integrated thereon), or a separate governing board with one or more advisory boards, the governing board (with the assistance of individuals identified in (b)) is ultimately responsible for considering and adopting policies related to:

- (1) Procurement of organs.
- (2) Effective agreements to identify potential organ donors with a substantial majority of hospitals in its service area that have facilities for organ donation.
- (3) Systematic efforts, including professional education, to acquire all useable organs from potential donors.

- (4) Arrangements for the acquisition and preservation of donated organs and provision of quality standards for the acquisition of organs that are consistent with the standards adopted by the OPTN, including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome.
- (5) Appropriate tissue typing of organs
- (6) A system for allocation of organs among transplant patients that is consistent with the rules and requirements of the OPTN, as defined in 486.320 of this part.
- (7) Transportation of organs to transplant hospitals.
- (8) Coordination of activities with transplant hospitals in the OPO's service area.
- (9) Participation in the OPTN
- (10) Arrangements to cooperate with tissue banks for the retrieval, processing preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissue are obtained from potential donors if the OPO has a tissue recovery operation.
- (11) Annual evaluation of the effectiveness of the OPO in acquiring organs.
- (12) Assistance to hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

(e) An OPO with a separate advisory board as described in paragraph (c) of this section has no authority over any other activity of the OPO and may not serve as the OPO's governing body or board of directors. The separate advisory board will function in accordance with paragraph (d) of this section.

(f) An OPO with one governing board which includes the PHS Act positions listed in (b) of this section must have by-laws and/or policies addressing conflicts of interest of and among governing and/or advisory board members. This policy must include conflict of interest disclosure statements and shall be consistent with both state corporate law and Internal Revenue Service (IRS) requirements and practices.

(g) The OPO must have bylaws for each of its board(s) that address potential conflicts of interest, length of terms, and criteria for selecting and removing members."

**"Human Resources (proposed §486.326):"**

AOPO believes that highlighting a number of process areas in the rule as a whole will enhance OPO performance. We are concerned, however, about the cost implications and highly prescriptive nature of the proposed human resource standards. As discussed later in our comments, the regulatory impact calculations in the rule regarding the implementation of the human resources requirements are very much underestimated in

our view. Moreover, the detailed requirements specified by CMS do not allow OPOs much flexibility to put in place the staffing arrangements best suiting their needs.

Therefore, in lieu of detailed, prescriptive human resource requirements, AOPO recommends that CMS incorporate in the process measurements a requirement that each OPO have a human resources plan and policy in place and that practices be expected to conform to policy. The plan and policy should address such areas as staff adequacy, education and training, supervision, and performance assessment. Our recommendation for a less prescriptive human resources approach is bolstered by the recent HHS Organ Breakthrough Collaborative experience, which has demonstrated the accomplishment of successful outcomes with a variety of staffing configurations. Indeed, the Collaborative's "change package," which identifies high, leverage actions for increasing organ donation, explicitly underscores the point that alternative approaches can yield similar positive outcomes. The Collaborative has demonstrated, furthermore, that OPOs and hospitals should have the latitude for determining and monitoring the effectiveness of alternative, joint approaches as they move to optimize the consent rate in their donation service area. In sum, we recommend that respective regulatory provisions provide OPOs the latitude to work within their areas to determine and implement models that work best in that area.

CMS states in the proposed rule that it is important for CMS not to cross the line of telling OPOs their specific staffing levels. However, there are numerous areas in the rule that make reference to specific staffing levels, including the comment of "looking closely at hospital development staffing because effective hospital development creates a culture that supports and promotes donation..." Also, the rule addresses areas such as family support and consent, quality assurance, and information systems, all of which presumably would require the addition of personnel. Furthermore, the rule states that each OPO must create a staffing plan that optimizes staffing. Towards this end, the rule asks for comments on developing markers to assess adequate staffing levels. It seems that the intent of this request is to provide CMS OPO Coordinators with the means to evaluate whether OPOs have sufficient staffing levels and to make evaluations about the OPO staffing levels. This appears contrary to the aforementioned statement by CMS that CMS should not cross the line in telling OPOs what their staffing should be. Rather than be overly prescriptive, we would propose that adequacy of staffing levels be an element of any human resources plan which would provide ample review opportunities by CMS coordinators.

With regard to the rule's proposals regarding medical directors, AOPO recommends that OPO Medical Director(s) be physicians with expertise and practice in the specialty of organ donor intensive care medical management and/or the specialty of organ transplantation. The Medical Director(s) should provide medical consultation on the practice of donor evaluation and management as needed by OPO procurement staff on specific cases. The OPO Medical Director(s) should also guide the development of donor management policies. Organ offers and placement should be made by OPO staff in accordance with UNOS allocation policies. The determination of donor suitability should remain the decision of the transplant surgeon and/or physician responsible for listed patients.

The proposed rule adds a new requirement for OPOs regarding the qualifications of their recovery personnel. AOPO supports a requirement that OPOs, working with transplant programs within their service area, should have a process to ensure and document that their own surgical recovery teams have appropriate credentials (e.g. submission of medical education and licensure for physicians). AOPO recommends that surgical recovery teams currently provided recovery privileges by one OPO would be reciprocally granted recovery privileges by all other OPOs. All OPOs should be required to have in place a method for verifying physician privileging for other OPOs on a 24-hour basis. We would note in this regard that "Surgical Recovery Team" is not restricted to physicians.

AOPO also recommends that the verification of training and privileging of recovering physicians and other practitioners utilized by the OPO on an infrequent basis and outside the designated service area become a standard within the Hospital Conditions of Participation.

**"Reporting Data (proposed §486.328)":**

We believe the practice of the SRTR in publishing hospital-specific organ donation rates satisfies the proposed requirement for OPOs to publish these data "at least annually to the public." Consistent with the intent of the HHS Office of the Inspector General recommendations, the data have been published publicly since January 2003, and are updated on <http://www.ustransplant.org> at six-month intervals.

The proposed requirements regarding "individually-identifiable" data open up future opportunity for routine ability to calculate case-mix adjusted conversion rates for donation service areas. At the same time, however, clarification would be helpful in precisely identifying which data need to be "individually-identifiable," as this requirement without qualification would likely require significant change in the current data collection processes and could significantly add to response burden across organ procurement organizations.

"Hospital Accountability" AOPO applauds the steps taken to advance the concept and practice of shared accountability for organ donation, both by CMS, in its updated interpretative guidelines for the Hospital Conditions of Participation (COP) published in June 2004, and by JCAHO, in its recently announced conversion rate provision effective in its accreditation process July 2005. We have recommended specific suggestions to JCAHO for further revisions of their elements of performance addressing but not limited to the following areas:

1. hospital agreements with OPOs that would establish terms of mutual cooperation to achieve organ and tissue donation;
2. hospital timely notification elements which would be in accord with clinical triggers jointly developed with hospital medical staff and the designated OPO;

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3. hospital procedures, developed in collaboration with the designated OPO, to make certain that written documentation as to the outcome of medically suitable potential organ, tissue, or eye donors is maintained by the hospital's designated requestor; and
4. establishment of a donation policy, based on a mutually agreed organ potential by the designated OPO and hospital and medical staff, which addresses opportunities, if any, for asystolic recovery.

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AOPO recommends that CMS seek public comment regarding the following proposed additional requirements to the CMS Conditions of Participation for Hospitals, which AOPO believes would supplement existing donation-supportive initiatives and policies being pursued by CMS, HRSA, the American Hospital Association (AHA), and JCAHO: that hospitals have a mechanism in place to ensure that OPOs have access to key physicians and other healthcare professionals for organ donation; and that hospitals have provisions for neurologists or other qualified medical professionals to adopt brain death declaration criteria consistent with State law.

The Secretary's Advisory Committee on Transplantation (ACOT) recommended the following measures be added to the Medicare Hospital Conditions of Participation (CoP):

1. "Hospitals shall notify organ procurement organizations prior to the withdrawal of life support to a patient, so as to determine that patient's potential for organ donation. If it is determined that the patient is a potential donor, the OPO shall reimburse the hospital for appropriate costs related to maintaining that patient as a potential donor."

AOPO strongly supports this recommendation as an important incentive to hospitals and OPOs alike and joins ACOT in recommending its implementation by CMS.

2. "...that in order to ensure best practices at hospitals and organ procurement organizations, the following measure should be added to the Hospital COP: Each hospital with more than 100 beds should identify an advocate for organ and tissue donation from within the hospital clinical staff."

AOPO takes note of the fact that this practice has increased as a consequence of the HHS Organ Breakthrough Collaborative and related initiatives. Although AOPO does not object to the inclusion of such a condition of participation, we believe that the spirit and practice of this ACOT recommendation will be increasingly met through application of the revised JCAHO accreditation standards for organ donation and the continued work of the Collaborative.

3. "Each hospital should establish, in conjunction with its OPO, policies and procedures to manage and maximize organ retrieval from donors without a heartbeat."

Although we do not object to the inclusion of such a condition of participation, AOPO submits that the spirit and practice of this recommendation will be

increasingly met through application of the revised JCAHO accreditation standards for organ donation and the continued work of the Collaborative.

**“Requesting Consent (proposed §486.342)”:**

At the time of its HHS publication, AOPO strongly supported the recommendations set forth in the 2001 Office of the Inspector General Report on “Informed Consent in Tissue Donation,” which included the “Model Elements of Informed Consent for Organ and Tissue Donation” developed jointly by the American Association of Tissue Banks, AOPO, and the Eye Bank Association of America, as well as the recommendations of the National Donor Family Council Executive Committee. Although the rule’s recommendations expand beyond the model elements, AOPO does not object to the new requirements in the rule and would note that the proposals generally conform to current practice in the industry.

We are unclear, however, about the meaning and intent behind subparagraph (a)(8) (“information about the procedure to file a complaint”). To our knowledge, the doctrine of informed consent has never included a procedural component for filing a complaint. Moreover, AOPO is not certain to what the complaint would be related. Experience has shown that, without fail, if a party is unhappy with the manner of recovery or some other related event, the party has never had a difficulty with locating or approaching an OPO. The consent process is a very sensitive moment, often arrived at following hours of intervention and time spent with a family. In our view, introducing an unnecessary element, particularly one that suggests subsequent failure, unhappiness, or change of mind, will likely undercut the consent success rate that OPOs are struggling so hard to improve.

AOPO recommends that, apart from passing referrals to tissue banks having contractual arrangements with hospitals, OPOs should only be required to obtain consent or be involved in obtaining socio-medical histories for those tissue banks with which the OPOs have a formal working relationship. (Please see earlier comments regarding tissue relationships in §322.)

**“Donor Evaluation and Management, Organ Placement and Recovery (proposed §486.344)”:**

AOPO assumes here, and elsewhere, that the CMS proposed requirements are neither intended to conflict with OPTN requirements nor intended to cover circumstances that might be logistically impossible for an OPO to meet given OPTN requirements. With regard to potential conflicts between proposed CMS requirements and OPTN policies, consequently, we defer to HRSA and its OPTN contractor to identify such discrepancies (e.g. calling attention to OPTN definitions in 42CFR121.2 and other appropriate CFR sections) to the extent that they are not otherwise identified and commented on by AOPO in its response to the proposed rule.

The rule proposes under donor protocol management that the medical director is responsible for ensuring that donor evaluation and management protocols are implemented correctly and appropriately to ensure that every potential donor is thoroughly assessed for medical suitability for organ donation and clinically managed to optimize organ viability and function. We have already provided some comments regarding the role of the medical director with respect to §486.326 and request that the agency refer back to these comments in addition to considering the ones we have articulated below.

In some instances, a medical director who is a transplant surgeon may have limited experience in ruling in/out organs other than those he/she specializes in. This could lead inadvertently to the medical director prematurely ruling out a case before all options have been exhausted. Leaving the rule-in/out decision to one single entity, consequently, may do a disservice to the goal of maximizing organ utilization, a point highlighted in Organ Breakthrough Collaborative reviews. In addition, the OPO medical director may not always be the best physician to assist with donor management challenges faced in the field. In a number of circumstances, experience has demonstrated that critical care intensivist physicians have been in a better position to look objectively at the donor picture and provide management expertise.

According to the proposed rule, furthermore, the OPO must implement a system that ensures the medical director or other qualified physician is available to assist in the medical management of a donor when the surgeon on call is unavailable. We would refer back to our comments above. At the very least, a higher level of clinical expertise should be available to coordinators in the field. We believe how this happens should be left to the individual OPO. For instance, some OPOs have highly trained clinical experts who function in the role of donor management consultants on a case-by-case basis within their OPOs and have very high organs per donor yields. Other OPOs may consult with the intensivist groups at individual hospitals on a case-by-case basis to receive input on management and also have high organs per donor yields.

Under the proposed requirements for donor evaluation, we would suggest that “pertaining to death and/or declaration of death” be substituted for “pertaining to organ donation.” Furthermore, with regard to the provision noting that the OPO must “determine whether there are conditions that may contraindicate donation,” in our view, this requirement is overly broad and too generally stated. For example, it is unclear if it refers to the overall quality of the donor or to organ-specific decisions.

With respect to the requirement for OPOs to “obtain the donor’s vital signs and perform all pertinent tests,” we suggest requiring that those activities be performed according to current OPTN standards.

The proposed rule specifies that prior to recovery of an organ for transplantation, the OPO must have documentation from the OPTN showing, at a minimum, the intended recipient’s position on the waiting list in relation to other suitable candidates and the

recipient's OPTN identification number and blood type. This requirement is impossible to apply to kidney recoveries in light of current OPTN/UNOS practices. Because the OPTN/UNOS Organ Center places kidneys for payback to an OPO's service area, the recipient is not known at the time of recovery. In these situations, the recipient is often not known until the organ arrives at the receiving OPO and a negative crossmatch list is generated after trays are crossmatched against the donor blood/nodes. It is the responsibility of the receiving OPO, not the recovering OPO, to verify allocation from the UNOS matching process. The effect of these OPTN/UNOS practices is that the recovering OPO does not know the identity of the recipient prior to the kidney recovery and so does not have the ability to obtain the OPTN documentation required by the proposed rule.

The proposed regulation in this instance also limits placement that occurs post-crossclamp. For instance, pancreas and kidney calls may not be complete as the procurement procedure starts because of variables out of the control of OPOs, such as donor families wanting the procurement surgery to occur in a certain time frame. By mandating that the OPO have documentation showing the intended recipient pre-procurement, the rule may be a disincentive for OPOs to continue to place certain organs after the procurement starts.

To maintain consistent language and align practices between the OPOs, OPTN and transplant center policies for ABO blood type verification, AOPO recommends that the following sentence in the proposed rule be deleted: "The protocol for organ placement must include procedures to ensure that the blood type of the donor is compared with the blood type of the intended recipient by two OPO staff." Instead, AOPO recommends that the following sentences be added: "The OPO shall have two separate determinations of the donor's ABO type prior to incision for ensuring the accuracy of the donor's ABO during the OPTN match run. Each OPO shall establish and implement a procedure for proving on-line verification by another OPO staff person other than the one initially entering the donor's ABO into the OPTN donor's registration. The protocol for organ placement must ensure that all donor versus transplant candidate blood type verification will be completed through the OPTN match run."

AOPO also would call attention to Subparagraph (d)(2) which would require OPOs to incorporate "best practices" into protocols for donor evaluation, donor management, organ recovery, and organ placement. The use and interpretation of "best practices" in this context is problematic. There is no general consensus on "best practices" for donor evaluation and management or organ recovery and placement. In using the term "best practices," CMS would be mandating extremely unclear standards subject to varied interpretation. We are deeply concerned that some would interpret "best practices" to mean that an OPO should be held to standards far in excess of typical standards, and, if the OPO failed to meet them, would respond by initiating criminal and/or civil suits.

AOPO recommends either placing quotation marks around the phrase "best practices" or adding a definition to §302 that indicates the term reflects qualitative goals and is not an actual legal standard. Alternatively, AOPO recommends re-wording subparagraph (d)(2)

to delete both the term “best practices” and the suggestion that an OPO is required to adopt best practices and instead substitute the phrase “analyzing and consider adopting practices that have proven to be effective and feasible so as to maximize organ donation”. This would be consistent with §344 which uses the phrase “meet current standards of practice”.

**“Organ Preparation and Transport (proposed §486.346)”:**

The data referenced in the regulation as “recently documented” are somewhat dated as the OPTN/UNOS Board of Directors has approved policy changes that now prohibit reuse of organ shipment boxes. The OPTN, furthermore, has already implemented requirements the same as those proposed by CMS.

As proposed, the rule notes that two OPO staff members must verify that the documentation that accompanies an organ to a transplant center is correct. Some OPOs, however, may have only one staff member present in the operating room when the organs are packaged. We recommend changing the regulatory language of §486.346(b) to: “Two individuals, one of whom must be an OPO employee, must verify that the documentation that accompanies an organ to a transplant center is correct.”

As proposed in the rule, the protocol must include procedures to check the accuracy and integrity of labels, packaging, and contents prior to transport, including verification by two OPO staff members that information listed on the labels is correct. We are concerned about language suggesting that the OPO would be held responsible for ensuring that an organ would not compromise the health of a recipient. It is a transplant center’s decision as to whether the quality of an organ compromises the health of a recipient, not the OPO’s. The OPO’s responsibility is to ensure that organs are properly packaged and labeled. Even then, however, the handling and shipping of an organ is not necessarily under the control of the OPO at all points. We therefore recommend a modification in the language similar to the one recommended above for the verification of documentation. More specifically, we recommend that the regulatory language of §486.346(c) be changed to the following: “The protocol must include procedures to check the accuracy and integrity of labels, packaging, and contents prior to transport, including verification by two individuals, one of whom must be an OPO employee, that information listed on the labels is correct.”

**“Quality Assessment and Performance Improvement (proposed §486.348)”:**

AOPO agrees that it is critical for every OPO to have a comprehensive Quality Assessment and Performance Improvement (QAPI) program, and strongly endorses the proposal to have “a requirement for every OPO to develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate all donation services, including services provided under contract or arrangement.” This is consistent with the recommendation AOPO made to CMS in 2001 regarding the conditions of participation as well as with the work of the association’s Quality Council.

AOPO agrees that “the OPO’s QAPI program must include the use of objective measures to evaluate and demonstrate improved performance with regard to OPO activities,” and concurs with the proposed CMS approach to “not intend to stipulate specific activities an OPO must include in its QAPI program.” AOPO also strongly supports the proposal that a QAPI program must include objective measures to evaluate and demonstrate improved performance with regard to activities such as: hospital development; designated requestor training; donor management; timeliness of on-site response to hospital referral; consent practices; organ recovery and placement; and organ packaging and transport.” We believe that these measures are critical in allowing every OPO to track and improve its performance, and take actions to ensure that these improvements are sustained.

AOPO supports the CMS proposal that OPOs conduct hospital death record reviews as a crucial component in every OPO QAPI program. We agree with and support the notion that death record reviews provide critical information such as the timeliness of hospital referrals of potential donors, the timeliness of the OPO’s response, and the performance of the OPO’s hospitals in the donation process, which are extremely important in increasing organ donation rates. We also agree with CMS’ recognition that the information OPOs gain from conducting periodic death record reviews can be used to identify and correct systemic problems that interfere with organ donation, such as when missed opportunities for donation are identified.

We recommend that CMS slightly modify the criteria defining the hospitals for which death record reviews must be conducted. We urge CMS to specify that an OPO be required “to conduct death record reviews in every Medicare or Medicaid participating hospital with which it has an agreement if the hospital has 150 or more *acute care* beds, *an ICU and ventilator*, or if it has a level I or level II trauma center.” (*Note: italicized words recommended by AOPO*). AOPO further recommends that the HHS technical assistance program regarding QAPI implementation include appropriate training and guidance for the conduct of standardized death record reviews.

The proposed rule states: “Once the final rule is published, the CMS OPO Coordinators will provide guidance to OPOs so that they thoroughly understand how to implement the QAPI requirements in the regulation.” The proposed rule also makes reference to the availability of CMS Coordinators and HRSA’s Division of Transplantation as a resource to assist OPOs in implementing QAPI. AOPO strongly recommends that HHS, through its Division of Transplantation, adopt a model technical assistance program akin to the program managed by HRSA’s Office of Rural Health Policy to assist the nation’s rural health clinics in meeting the CMS QAPI requirements for those programs. This could take the form of continued institutional support for a strengthened and broadened Knowledge Management System as part of the Organ Breakthrough Collaborative, and would be fully consistent with the rule’s Preamble stating that “our proposals would fundamentally change the existing OPO regulations to emphasize quality and continuous quality improvement.”

As part of the QAPI process, CMS proposes that “an OPO would be required to investigate adverse events and complete a thorough analysis.” While AOPO supports the

process of analyzing adverse events, it has major concerns relating to the mechanical issues of the reporting, e.g. how will CMS protect this information, who else can access it, and what will CMS do with this information? AOPO's biggest concern is that CMS will not be able to hold this information in a confidential manner and will be obligated to disclose it pursuant to a FOIA request. In brief, information which is protected via state peer review statutes would lose this protection on the federal level, undermining one of the most important features of effective peer review.

We note in passing the provision in the CMS proposed transplant center regulations requiring that transplant centers "establish and implement a written policy to address adverse events that occur during any phase of the organ transplant process." That regulation does not recommend detailed elements of a reporting system.

As indicated earlier, AOPO's membership is most receptive to performing adverse event inquiries and analysis. In fact, it welcomes the attention to this matter (many of AOPO's members presently perform "sentinel events" protocols). In view of the concerns noted above, however, AOPO recommends that commencement of the real-time reporting phase be withdrawn and deferred until CMS is able to answer certain specific questions (presented below) and/or consider other reporting requirements.

1. The regulation requires reporting within 10 and 15 "business days". What is a "business day" for an organization operating 365 days a year, 7 days a week, and 24 hours a day? Would 15 and 30 calendar days be a better measure?
2. Shouldn't there be more time between the initial report and the second report? The rules only allow 5 days. If the purpose of the process is to be thorough and complete, sufficient time should be afforded to thoroughly analyze the event, attempt to design procedures to prevent re-occurrence (particularly if it is a systemic event), and write the report for CMS. Timeliness is the critical element of the first report, but thoroughness is the critical component of the second.
3. What assurance can CMS provide that the information submitted to it will be vigorously protected from re-release, that it will be designated as exempt from FOIA, and not otherwise available to third parties (e.g. potential malpractice plaintiffs)?
4. What will CMS do with this information? Can CMS use this information years later in certification or designation decisions?
5. Does CMS intend to publish or otherwise share (on a blind basis) the information (again, on a generic basis) with other OPOs so that they can avoid similar situations or process breakdowns?

### **Requests for Comments on Related Issues**

#### **"OPO Role in Living Donation":**

The association recognizes the importance of living donation. At the same time, however, AOPO agrees with CMS that the primary mission of OPOs is to increase the number of

deceased donors. Consequently, AOPO does not support living donation being part of OPO performance evaluation.

There exists a wide range of living related donation/transplantation being performed in transplant centers across the United States. The level of activity in transplant centers varies from very active to no living related donation and transplantation activity. Without activity and support from local OPO transplant center(s), living donation activity by an OPO will be extremely limited.

The association would like to take this opportunity to note the following:

1. AOPO supports programs modeled after two pilot programs currently operating in the New England Organ Bank and the Washington Regional Transplant Center. There is strong evidence that OPOs should work closely with their affiliated transplant program(s) to develop living donation options to facilitate more transplants.
2. AOPO supports OPOs developing the living related paired exchange (LRPE) program, where kidneys are shared between two sets of individuals. This would occur when the living donors cannot donate to their recipients, but the donor in each set is compatible with the recipient in the other set. A paired exchange would be facilitated to allow for two transplants. This program would be expanded from the current local allocation to regional and national sharing to allow more options for living donation, with the OPOs acting as the common link between transplant centers similar to how OPOs act in the current kidney payback system.
3. AOPO supports OPOs developing the living donor/list exchange (LDLE) program to facilitate more transplants. OPOs would coordinate this exchange with their local transplant programs when a living donor is identified but is not compatible with his/her recipient and LRPE is not an option. The living donor would donate a kidney that would be allocated in a manner keeping with the allocation policy for current deceased donated kidneys. The intended local recipient would then receive the next compatible kidney available from the OPO's deceased donor, thereby facilitating two transplants.

**"Public Education":**

Requirements for public education are absent from the proposed rule based on a stated perception by CMS that there is a lack of consensus by the OPO community on the effectiveness of public education activities in reducing barriers to donation. The commentary in the regulation also states that "some researchers, however, believe that available funding should go to basic research, professional education, and hospital development rather than public education."

AOPO recommends that OPOs be required to provide programming to address identified areas of need, be that in hospitals or the broader community, with review and process improvement integrated into the OPO's QAPI program.

The vast majority of OPOs find that public education is essential to reducing barriers to organ donation and have active public education programs that share the donation process and the benefits of organ donation. The goal of these programs is to ensure that families in crisis have already talked about donation as research has shown that they are more likely to make informed and affirmative decisions to donate. OPOs have three areas of public focus: first and short-term is work with families in a hospital at a time of crisis; second and mid-term is hospital services to improve referral, family support, and donor management; and third, and long-term, is public education. Work with families will help to save lives today. Work with hospitals will save lives over the next weeks and months. Work with the public will save lives over the coming months and years. Those in states with registries also find that focused public education has resulted in increased donor registrants.

### **III. Collection of Information Requirements:**

As with its assessment of the overall regulatory impact (please see following section), CMS in our view has similarly underestimated the collection of information burden associated with its proposed rules.

For example, regarding its proposals for administration and governing body requirements, CMS indicates that "it is usual and customary business practice to have such bylaws, policies, and procedures; therefore, there would be no additional burden." Redoing bylaws is not a ministerial act; on the contrary, it is more like an engineering project. Recasting a board generally involves the formation of a board committee, executive talent to staff that committee, lawyers or consultants to help redesign the board and write the bylaws, and eventually a full discussion by the board, often in the form of a board retreat. If the board is recast, it involves a major overhaul, because it affects all the "moving parts" of a board, e.g. terms of directors, the assignment of directors to classes, committee assignments, staggering of terms, etc. In brief, the additional burdens occasioned by this one set of requirements alone is significant. In the instance of just one OPO's experience this past year, the board changes took nine months and, start to finish, over \$50,000 of consultant and lawyer time.

### **V. Regulatory Impact:**

Based on input obtained from key financial personnel at a number of OPOs, AOPO believes that the \$2.5 million impact of the proposed rule, as estimated by CMS, is grossly understated. The estimate of economic impact on OPOs to meet these proposed requirements is closer to three times that amount—a total of \$7.5 million. This is based on the following information (more significant items included):

- **CMS Estimate: \$25,600 to develop bylaws for OPO boards - Realistic Cost: \$155,000**  
 Based on an APO survey of 2003 wages, OPO Directors show an average salary of \$150,000. If we adjust 2003 wages to 2005 rates it would equate to an average salary of \$159,000 or \$76 per hour. Inclusion of fringe benefits and supplemental pay would increase this amount to an estimate of \$115 an hour. The regulations indicate an estimate of 8 hours to perform development of each set of bylaws. A more realistic estimate would be around 15 hours; 4 hours for writing, 2 hours for review with lawyers, 7 hours for 2 committee reviews and one board meeting review, and 2 hours for oversight of meeting material preparation. Legal review of at least \$250 per hour should be included plus time for an administrative assistant (\$22 an hour including fringes for 2 hours) to prepare meeting materials, copy, mailing, etc. In addition, postage and paper for the distribution should be added of approximately \$150. To develop 64 sets of bylaws, a total cost of \$155,000 is more realistic. This is 6 times the estimated CMS cost.
- **CMS Estimate: \$375,000 annually for medical director salaries – Realistic Cost: \$1,350,000**  
 Notwithstanding the APO comments regarding the role of the medical director, the proposed CMS regulations note that the medical director is, ‘...involved in the day-to-day operations of the OPO because he or she would be responsible for implementation of protocols for donor evaluations and management and organ placement and recovery, as well as assisting in the management of donor cases if the surgeon on call were unavailable.’ The CMS estimated medical director wage was low based on several OPOs that have full-time medical directors currently. The average seems to be more in the \$175,000 range. When fringe benefits and supplemental pay and other increased office related expenses are added, the cost could well exceed \$300,000 annually. Based on CMS assumptions that 6 OPOs would need to hire a part-time or full-time medical director, we believe that the cost would be closer to \$1,350,000. This is based on 3 OPOs having to make a full-time hire and 3 OPOs having to make a part-time hire.
- **CMS Estimate: \$540,000 annually for additional staff to meet human resources needs - Realistic Cost: \$950,000**  
 The average base rate in 2003 for a procurement coordinator was \$57,300 according to an industry standard. Adjusted for inflation this would be \$60,800 in 2005. Benefits, not included in initial financial predictions, would bring this figure up to \$77,300. Based on CMS assumptions, 12 additional staff would cost close to \$950,000.
- **CMS Estimate: \$75,000 initial cost for staff training - Realistic Cost: \$300,000**  
 The regulation uses the assumption that OPOs will chose to use in-depth modular training, but does not focus on who will develop the modular training, or, if already developed, at what cost the module will be available for. Even if, as CMS comments, ‘good staff training need not be expensive’, the likelihood exists that

all staff in every OPO would need additional training in order to meet the requirements of the proposed rule. If all 58 OPOs were to be additionally trained at a cost of approximately \$5,000, the total cost would be \$290,000.

- **CMS Estimate: \$18,880 to develop hospital agreements - Realistic Cost: \$1,600,000**

CMS has routinely throughout these proposed regulations understated the amount that a lawyer would charge for professional services. This includes services to develop hospital agreements. Per one OPO's calculations, their legal representation is over \$250 per hour. At 8 hours of hospital agreement development time, this would come to \$2,000 or a total of \$116,000 for 58 OPOs to develop a standard hospital agreement for 100 hospitals. However, CMS acknowledges that based on past experience between 50 and 67 percent of the hospitals in a OPOs service area would sign the standard agreement with no changes. If that is the case, then between 33 and 50 percent of hospitals would not sign the standard agreement and would instead insist on changes to the contract. Assuming that it would take approximately 2 hours of legal time to customize 50 hospital agreements at \$250 per hour, this would add an additional \$25,000 per OPO or a total cost of \$1,475,000. This portion of the development of hospital agreements was not included in the original financial estimates but has been included here.

- **CMS Estimate: \$750,000 annually for QAPI staff - Realistic Cost: \$1,080,000**

OPOs without a current Quality Program are faced with more than just the annual wage cost of running a QAPI program. Consideration for recruitment, hiring, training, salary, benefits, office space and equipment, etc. have not been accounted for in the CMS proposed financial impact. In addition, the amount of additional staff may be underestimated by CMS in that a quality program may need to be multiple employees to meet all of the rules there, including a manager or director of quality systems, a data specialist, a medical record person, and a QI team leader. One OPO had a quality control manager in the past which alone was \$80,000 annually for wages and benefits. CMS did not factor in office space needed for the individual(s), training, or supplies. If we use CMS' assumption that 9 OPOs would need to add a full FTE, the annual cost would be closer to \$80,000 annually than the \$50,000 the agency proposes. For the 12 OPOs that would need an additional half of a full-time equivalent, we believe this to be closer to \$30,000 per year. As such, the total costs for QAPI would be closer to \$1,100,000 (9 OPOs adding one full-time at \$80,000 and 12 OPOs adding additional half staff at \$30,000). This number does not include recruitment, training, office space or equipment.

- **CMS Estimate: \$270,000 to perform death record reviews - Realistic Cost: \$600,000**

If we use the salary for a procurement coordinator (RN) as based on the 2003 AOPPO survey and adjust for inflation to 2005 (\$37.15 including benefits as established under bullet point 3) and add a half time employee of this caliber at

the 12 OPOs, the costs would total \$463,632. Adding on additional travel expenses and office expenses could easily increase this amount to \$600,000.

- **CMS Estimate: \$344,400 to develop protocols with transplant centers - Realistic Cost: \$900,000**

The impact to OPOs will be more wide reaching than the CMS estimate of the OPO medical director's 10 hours of developing a protocol with a transplant center. There is no allocation in the CMS assumption for any other review services. For example, one OPO would involve not only the medical director but also the Vice President of Administration and legal counsel and then use personnel to roll out the protocol at each transplant center. If we assume that the medical director will take approximately 10 hours for development of a protocol (\$120 per hour for 10 hours), that the protocol will be reviewed by legal counsel for approximately 1 hour (\$250 per hour for 1 hour), and that it will take approximately 3 hours to roll out the program by hospital development (\$30 per hour for 3 hours), then the cost for one protocol would equal \$1,540. If each OPO developed 14 protocols this would come to \$21,560. For 41 OPOs, this development would cost \$883,960.

## Appendix A

### AOPO Recommendations for Modified Appeals Procedure (486.314)

In light of the statutory and constitutional obligation to provide OPOs with an adequate notice and opportunity for a hearing prior to de-certification, we recommend continuing to use the Part 498 regulations as a basic framework. Special rules that have unique applicability to OPOs, and that address the timing concerns raised by CMS, could be included. This is already done for other entities in section 42 C.F.R. §498.29(a)(3) [special rules]. Those special rules could be included in a revised 486.314. The revisions would reflect the following principles:

- There should be an opportunity to seek reconsideration by CMS after the notice is given, but before a hearing is actually convened
- Strict and specific time frames for all steps should be included, and be binding on both CMS and the OPO; any request for an extension should require that the party seeking the extension meet a high burden before it is granted
- There should be an obligation imposed on CMS to make sure that any notice of de-certification is accompanied by an explanation of all reasons upon which the notice is based, and includes all documents and facts upon which CMS relied to reach that conclusion, and all persons involved in making the determination;
- The notice of termination should be issued no later than 10 days after CMS has made its internal determination, and no later than 180 days before the agreement ends;

The specific text and changes we propose are as follows:

Add a new line to 42 C.F.R. §498.20(c)(4) that would read as follows:

“Part 486 Subpart G -- for Organ Procurement Organizations when a notice of decertification is issued.”

Proposed section 486.314 should be revised as follows:

-In the introductory paragraph, the last phrase, “substantive or procedural” should be changed to “substantive and procedural.”

(a) Appeal Process. An OPO may appeal a notice of involuntary de-certification by following the procedures set forth in Part 498 as modified by this section.

(b) Appeal procedures with respect to Subpart B of Part 498.

(1) The Notice of De-certification issued under section 42 C.F.R. §386.312(b) shall be considered an initial determination for purposes of 42. C.F.R. §498.20.

(2) The Notice of De-certification shall be served on the OPO by overnight mail, and shall contain all reasons, bases and shall include all evidence which it is based. Failure to include all reasons, bases and evidence in the notice shall toll the time period for seeking reconsideration or other appeal.

(3) The OPO shall have ten (15) calendar days from receipt of the Notice of De-certification to seek reconsideration from the issuing CMS officer. One ten (10) calendar day extension to file the request for reconsideration may be granted if the OPO can demonstrate substantially good cause for such extension. The failure of the OPO to include all reasons for seeking reconsideration shall not preclude it from raising otherwise omitted reasons in a subsequent appeal.

(c) Subpart C of Part 498 (Reopening of Initial or Reconsidered Determination) shall not apply or be available to OPOs.

(d) Appeal procedures with respect to Subpart D of Part 498 (hearings)

(1) Manner and timing of request. (modifying §498.40(a))

(a) OPOs shall be entitled to a hearing with a hearing officer within the Office of Hearings and Appeals. For purposes of this process, all references in Part 498 to "administrative law judges" shall apply to hearing officers.

(b) The request for a hearing must be filed within 20 business days.

(2) Extension of time for filing a request for hearing. (modifying §498.40(c))

(a) An extension of time may be requested for a period of not to exceed 20 business days for good cause shown.

(b) No extension of time for filing a request for hearing exceeding twenty (20) days shall be granted unless the OPO can demonstrate compelling reasons for such an extension. The failure of the CMS to provide all the reasons, bases and evidence upon which the de-certification is based shall be presumed to be compelling reasons.

(3) For purposes of appeals of Notices of De-certification the term "Administrative Law Judge" or "ALJ" shall mean a hearing officer within the Office of Hearings and Appeals.

(4) Notice of Prehearing Conference (modifying §498.48)

(a) The hearing officer shall set a hearing conference for a date and time within two weeks of receipt of the request for hearing. Such notice shall include a date for hearing that shall be initially scheduled no later than 30 days after the date of the prehearing conference.

(5) Conduct of Prehearing Conference (modifying §498.49)

(a) At least five calendar days prior to the prehearing conference the parties shall exchange a list of witnesses, list of evidence, and list of any documents or other discovery that they seek from the other parties or third parties. This may be amended at the prehearing conference.

(b) At the prehearing conference the parties shall advise the hearing officer and each other as to those matters listed in §498.49 (c).

(c) the parties shall agree, or the hearing officer shall set, dates for production of any discovery from each other including depositions.

(d) No evidence, witnesses or other facts may be presented at trial that is not fully discussed at the prehearing conference.

(e) The hearing officer shall issue an order reflecting the results of the prehearing conference no later than seven (7) calendar days following completion of the conference. The parties shall have (3) business days to serve written objections to the Order. The hearing officer shall settle the order within (3) business days of receipt of objections.

(6) Time and Place of Hearing (modifying §498.52)

(a) The hearing officer shall the hearing no more than thirty (3) days after the prehearing conference unless the OPO the party has a compelling reason to set it at a later time.

(7) Hearing on new issues (modifying §498.56)

(a) In the event new issues or facts arise following the issuance of the Notice of De-certification, the parties may agree to stay the hearing and remand the matter back to the CMS hearing officer for further consideration, or have such matters heard by the hearing officer.

(8) Hearing Officer's decision (modifying§ 498. 68)

(a) The hearing officer shall render a decision on the Notice of de-certification within seven (7) business days of the hearing.

(e) Appeal procedures with respect to Subparts E and F of Part 498

(1) The provisions of Subpart E do not apply. The hearing officer is the designee of the Secretary for purposes of this section. The final decision of the hearing officer shall be considered final agency action. There is no right to appeal to the Appeals Council

(2) The provisions of Subpart F do not apply.

(f) Additional general provisions governing appeals of Notices of de-certification

(1) All reconsiderations and appeals under this subsection shall be conducted in an expeditious manner as possible.

(2) Effect of hearing procedure on agreement term.

(a) Any extension of time granted as a result of a joint request by the parties, the conduct or request of the CMS, or as an accommodation to the hearing officer shall result in an automatic extension of the term of the agreement for an equal duration of time.

(b) Except as provided for in subsection (a) above, [currently proposed (e).

(g) [currently proposed (b)

(h) [currently proposed (c)

**Attachment B**  
Comparison of Definitions of Eligible Death for Organ Donation

| OPTN   | CMS Proposed  | AOPO Proposed   |
|--|---|---|
| Tuberculosis<br>Human Immunodeficiency Virus Infection with Specified Conditions<br>Positive Serological or Viral Culture Findings for HIV | Tuberculosis<br><br>Positive serological or viral cultural findings for HIV<br>Creutzfeldt-Jacob Disease <i>or any prion-induced disease</i><br><i>Viral septicemia</i><br>Rabies<br>Reactive Hepatitis B Surface Antigen<br>Any Retrovirus infection | Tuberculosis<br><br>HIV infection by serologic or molecular detection<br><br>Creutzfeldt-Jacob Disease<br><br>Rabies<br><br>Reactive Hepatitis B Surface Antigen<br>All retrovirus infections including HTLV I/II<br><br>Current malignant neoplasms except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease |
| Creutzfeldt-Jacob Disease<br>Herpetic Septicemia<br>Rabies<br>Reactive Hepatitis B Surface Antigen<br>Any Retrovirus infection             | Active Malignant Neoplasms, except Primary CNS tumors and skin cancers  | Previous malignant neoplasms with current evident metastatic disease  |
| Hodgkin's Disease, Multiple Myeloma, Leukemia<br>Miscellaneous Carcinomas<br>Aplastic Anemia<br>Agranulocytosis                            | * NONE OF THREE MENTIONED<br>* NOT MENTIONED<br>Aplastic Anemia<br>Agranulocytosis<br>* Active viral and systemic fungal infections<br>(incorporated into above exclusion)  | A history of melanoma<br>Hematologic malignancies: Leukemias, Hodgkin's Disease, Lymphoma, Multiple Myeloma<br><br>Aplastic Anemia<br>Agranulocytosis<br>Fungal, Parasitic, or Viral Encephalitis or Meningitis   |
| Fungal and Viral Meningitis  |   |   |
| Viral Encephalitis   |   |   |
| Gangrene of Bowel  | Gangrene of Bowel   | Gangrenous bowel or perforated bowel with intra-abdominal sepsis  |
| Extreme Immaturity   | Extreme prematurity<br>* <i>Chagas' Disease</i>   | Extreme Immaturity (<500 grams or gestational age <32 weeks)<br>Chagas' Disease<br>Viremia: Herpes, Acute Epstein barr Virus (mononucleosis)<br>West Nile Virus infection   |

SARS

Active infection with *Trypanosoma cruzi*,  
*Leishmania*, *Strongyloides*

Active infection with *Cryptococcus*

Multi-system organ failure without sepsis  
defined as 3 or more systems in simultaneous  
failure for a period of 24 hours or more without  
response to treatment or resuscitation

Multi-system organ failure due to overwhelming  
sepsis defined as 3 or more systems in  
simultaneous failure for a period of 24 hours or  
more

Untreated bacterial or fungal sepsis  
(candidemia)

## Attachment C

### Illustration of Applying AOPO Proposed Outcome Measures

- Assume: National four-year conversion rate of 60 percent  
75% would be 45 percent  
National four-year organ transplanted per donor ratio of 3.6<sup>34</sup>
- OPO A: Unadjusted 4-year conversion rate: 42 percent  
Adjusted 4-year conversion rate: 44 percent<sup>35</sup>
- Organs transplanted per donor ratio (OTPD): 2.6<sup>36</sup>  
Case-mix adjusted expected organs transplanted per donor: 3.5<sup>37</sup>  
Ratio of OTPD to Case-mix expected organs transplanted  
per donor: 71 percent
- SRTR overall donation rate (hospital characteristics, notification rate) statistically lower than expected for three of the 4-years in the performance cycle<sup>38</sup>

In the above illustration, OPO A would be subject to decertification with the outcome performance measures proposed by AOPO.

- Its adjusted 4-year conversion rate (44 percent) was below 75 percent of the national four-year conversion rate (45 percent);
- Its ratio of organs transplanted per donor (2.6) compared to its case-mix expected organs per donor (3.5) was 71 percent (i.e. below 75 percent); and
- Its SRTR overall donation rate (hospital characteristics, notification rate) was statistically lower than expected for three of the 4-years in the performance cycle.

---

<sup>34</sup> National mean does not include the number of pancreata recovered for islet cell transplant or islet cell research.

<sup>35</sup> The number of DCD donors and donors over 70 years of age have been added to both the numerator and denominator, thereby increasing this OPO's conversion rate from 42 percent to 44 percent.

<sup>36</sup> Individual OPO organs transplanted per donor ratios include pancreata recovered for islet cell transplant or islet cell research. The number of pancreata recovered for islet cell transplantation and those placed for islet cell research have been added to both the numerator and denominator of the ratio, thereby increasing the OTPD from 2.4 to 2.6.

<sup>37</sup> The Case mix adjustment is based on individual OPO's mix of donors by donor age, type of donor (SCD,DCD,ECD) and donor race. The case mix adjusted organs transplanted per donor ratio does not include the number of pancreata recovered for islet cell transplant or islet cell research.

<sup>38</sup> This rate is published in Table 3 of the OPO Reports on SRTR's web site at <http://www.ustransplant.org>

If OPO A had either an adjusted 4-year conversion rate at or above 75 percent of the national mean or a ratio of organs transplanted per donor compared to its case-mix expected organs transplanted per donor at or above 75 percent, **but** still had a SRTR overall donation rate (hospital characteristics, notification rate) statistically lower than expected for three of the 4 years in the performance cycle, OPO A would not be subject to decertification but would be placed on an improvement plan by CMS.

To be considered a “high performing OPO,” under the AOPO proposed measures (for purposes of vying for a decertified territory or as proposed for the hospital waiver program), OPO A would have to have an adjusted 4-year conversion rate of at least 66% (i.e. 110 percent of the mean) or would have to have a SRTR overall donation rate (hospital characteristics, notification rate) statistically higher than expected for three of the 4 years in the performance cycle.

**Submitter :**

**Date: 06/02/2005**

**Organization :** ASHI

**Category :** Other Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-3064-P-21-Attach-1.DOC



**Attachment #21**

**Date: June 2, 2005**

**Organization: The American Society for Histocompatibility and Immunogenetics**

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

The American Society for Histocompatibility and Immunogenetics (ASHI) is pleased to have this opportunity to provide comments on the proposed rule on conditions for coverage for organ procurement organizations. We support regulation that encourages collaboration among OPOs in increasing the supply of organs for transplantation.

There are two areas that directly impact Tissue Typing Laboratories. The first is a change in regulation that would provide additional checkpoints to identify the ABO group of any organ for transplantation.

**§486.344(c) 4)** Document the donor's record with all test results, including blood type, before organ recovery.

**§486.344(d) 1)** The protocol for organ placement must include procedures to ensure that the blood type of the donor is compared with the blood type of the intended recipient by two OPO staff members before organ recovery

**§486.344(d) 2) d)** Documentation of recipient information. Prior to recovery of an organ for transplantation, the OPO must have written documentation from the OPTN showing, at a minimum, the intended recipient's position on the waiting list in relation to other suitable candidates and the recipient's OPTN identification number and blood type.

These changes in protocol are applicable to recovery of thoracic organs where identification of the intended recipient of the organs is complete prior to organ recovery. However, that is not the case for liver, pancreas and kidneys. Instituting this change would add hours to the donor workup, result in delays in recovery increasing the cost of donor management, and jeopardize the availability of organs from less stable donors.

We are also concerned about the lack of a requirement for OPOs to provide adequate samples for Tissue Typing and package them appropriately with organs for transplant. Language currently in OPTN/UNOS Policy 5.0 should be adopted and added to section **§486.346 b)**.

Thank you for the opportunity to submit these comments and for your consideration of our views.

**Submitter :** Dr. Robert Madden  
**Organization :** Western New England Renal & Transplant Associates  
**Category :** Physician

**Date:** 06/02/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

Re: CMS-3064-P

?Recertification and competition? ?486.316

I am a Transplant surgeon performing kidney transplants in Western Massachusetts, and I am writing to comment on the Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs) proposed rule CMS-3064-P.

As you know, we (large donor hospitals and their OPOs) are engaged in an attempt to increase the number of organs available for transplantation through the Organ Donation Breakthrough Collaborative. My transplant center, Baystate Medical Center, is part of this initiative. The Collaborative hopes to increase the rates of organ donation by using a best practices approach that is shared jointly with the OPOs and the large hospitals that account for most of organ donation.

So far, the Collaborative has achieved impressive results. Our hospital is in the process of implementing the Collaborative's model, but I have already seen the results from other large hospitals in our OPO, and they are impressive. The number of deceased organ donors increased significantly.

Concerning "Recertification and Competition", CMS is proposing a competitive model in which OPOs would be competing with each other to win the contract to serve their geographic areas. Obviously, a competitive model would essentially eliminate the sharing of best practices between OPOs and would reverse the increase in organ donation that has been gained through the Collaborative.

Therefore, as a transplant surgeon who has seen patients die from a lack of organs, I cannot support the competitive model that CMS has proposed.

Sincerely,

Robert L. Madden, MD  
Western New England Renal & Transplant Associates, Inc.  
Baystate Medical Center  
Springfield, MA  
robert.madden@bhs.org

**Submitter :** Mr. Brian Hutchison  
**Organization :** Regeneration Technologies, Inc.  
**Category :** Health Care Industry

**Date:** 06/03/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-3064-P-23-Attach-1.DOC



1102, Avenue of the  
Americas, Suite 2000  
Albany, NY 12242-2000  
USA  
Tel: 518-438-4444  
Fax: 518-438-4444  
www.regeneration.com

Attachment #23

June 3, 2005

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

RE: Open Comment for Proposed Rule 42 CFR Part 486

Dear Sir or Madame:

Please accept this letter as a comment to be considered in response to the proposed rule 42 CFR Part 486 by SMS regarding conditions of coverage for organ procurement organizations.

#### Discussion

**Regarding section 486.322(e) (2) (page 6134, col. 2), "An OPO is not required to have an arrangement with a tissue bank that is unwilling to have an arrangement with the OPO."**

We seek clarification on this point. Regulations must be set that would verify that unreasonable obstacles were not created by the OPO to create an unwillingness to have an arrangement with the OPO in an effort to keep certain tissue banks out of the hospital.

According to the current Conditions of Participation, any hospital may choose which tissue bank(s) they have agreements with. If all referrals must go through the designated OPO, any tissue bank with an agreement in a hospital should not be hindered from receiving referrals through the designated OPO.

Possible solution: Strengthen verbiage that the OPO must make every reasonable effort to have an arrangement with all tissue banks that serve their hospitals.

**Regarding section 486.342 (5) (page 6136, col. 1), "Information (such as for profit or non profit status) about organizations that will recover, process, and distribute the tissue."**

We object to the language of non profit and for profit tax designation used as a description for types of organizations involved, as the language is misleading and is not an appropriate differentiator for choosing a recovery organization or processor.

Points to consider:

- The public in general does not understand the differences and similarities between for profit and non profit organizations.
- When families choose to have non profit agencies deal with their loved one's tissue, they are of the mindset that no excess revenues or profits are being made by these companies. This is not true.
  - Even 501(c)3 companies must make profit—revenues over expenses—to invest in their organizations or they won't stay in business.
  - In 2003, Musculoskeletal Transplant Foundation (MTF), a 501(c)(3) non profit company, reported revenues of \$228 million, while Regeneration Technologies, a publicly held for profit company, reported revenues of \$75.5 million. Excess revenues, or profit, from both companies were used the same way — to reinvest in their own organizations.
- For-profit tissue preparation companies bring valuable science and innovation to the industry, resulting in greater benefit to donor families and recipients.
- A for-profit company is an equally caring and responsible steward of the gift as a non-profit company.
- Asking families to choose the path of their loved ones' tissue unnecessarily bogs down the consent process and is unfair to burden families with at the time of consent.
- According the Conditions of Participation, hospitals have the authority to work with the tissue banks they choose.
  - Giving power to choose where the tissue goes to the families diminishes the power of the hospital to work with the recovery agency or agencies they know to be competent.
  - When signing agreements with tissue banks, the hospitals educate themselves about each bank and sign agreements with banks that will serve their families, service the hospital staffs and be a responsible steward of the gift of donation. These are much more effective measures of any tissue bank than a tax status.
  - In order to truly have informed consent while still giving families the choice of for profit vs. non profit tissue banks, each family would have to go through a mass education about the options available to them in their community before making their choice during the consent process.
  - Families trust their lives to the professionals at the hospital. The hospital professionals should maintain the power to choose what organizations should be responsible for recovery in their hospitals.
- All tissue banks in the United States have strategic alliances between both for profit and non profit organizations. There is no tissue bank that can truthfully assure a family that the entire donation process can be done strictly non profit. To accept a donation from a family who does not wish to have their loved ones' tissue touched by a for-profit entity is misleading at best. (See Attachment A)
  - The referral and consent part of the process – the first part of the process where families would indicate their desire to only use non profit organizations – can often be completed by a for profit company.

- Almost all non profit organizations do not have the resources to invest in the research and development necessary to make tissue implants safer and to create new implants that will maximize each gift of donation.
- With the onset of CFR Part 1271, non profit tissue banks are relying on for profit tissue banks to assist them in becoming compliant with these new, stricter regulations that increase safety for recipients. Without the investment of the for profit agencies, the safety of tissue implants for patients be at risk.

### **Informed Consent**

We believe that the families of donors should be fully informed about the practices and operation of organizations, both for-profit and not-for-profit, that receive, process and distribute tissue. RTI Donor Services' consent process and consent form comply with standards established by the Department of Health and Human Services and the American Association of Tissue Banks.

- The consent form has been in use since April 2001.
- The informed consent process informs families about—
  - \* potential tissue uses including cosmetic and reconstructive surgeries;
  - \* potential international use;
  - \* RTI Donor Services' affiliation with both for-profit and non-profit partners.
- At any time during the process, a family may limit any portion of the consent, or decide not to donate at all.
- It is rare that RTI Donor Services families put limits on tissue use.
- Most families simply want to help others and ensure their loved ones' wishes are met.

### **Federal Supremacy**

We are supportive of a Federal Supremacy clause. If CMS changes the language for the proposed rule we believe the agencies ruling would have authority to override any state, local or private law or rule that is in conflict with this rule. We support this measure for the following reason:

- The conditions of participation has "occupied the field" of organ and tissue donation and has set a precedent.
- The industry is full of intrastate traffic that is visible in the referral, recovery, testing, processing and distribution of tissues for transplant.
- The federal interest is at stake. We do not want to create an environment that will hinder and frustrate the federal goals of increasing the donation and safety of Organ and Tissue transplants. Such an environment shall occur if each state is allowed to insert the language of non- profit and for - profit tax designation. As

mentioned before, the language is misleading and is not an appropriate differentiator for choosing a recovery organization or processor.

### **Summary**

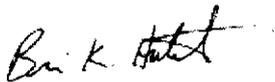
Regeneration Technologies, Inc., a for-profit company within the tissue banking industry, fully supports informed consent for donor families. Families are an essential component in giving the gift of life and we believe they deserve to be fully informed of the process and given the opportunity to carry out their loved one's wishes to the best of their ability.

Misleading language and verbiage that can distort the true image of our industry would only cause further disappointment and frustration for all involved in the process. We propose the following language be used in place of 42 CFR Part 486, Section 486.342, item #5:

“Consenting individuals must be informed that tissue will be collected, processed, stored and distributed in an efficient manner, following strict ethical guidelines, that minimizes costs and maximizes the benefit to patients and society, and that this will require the involvement of multiple organizations.”

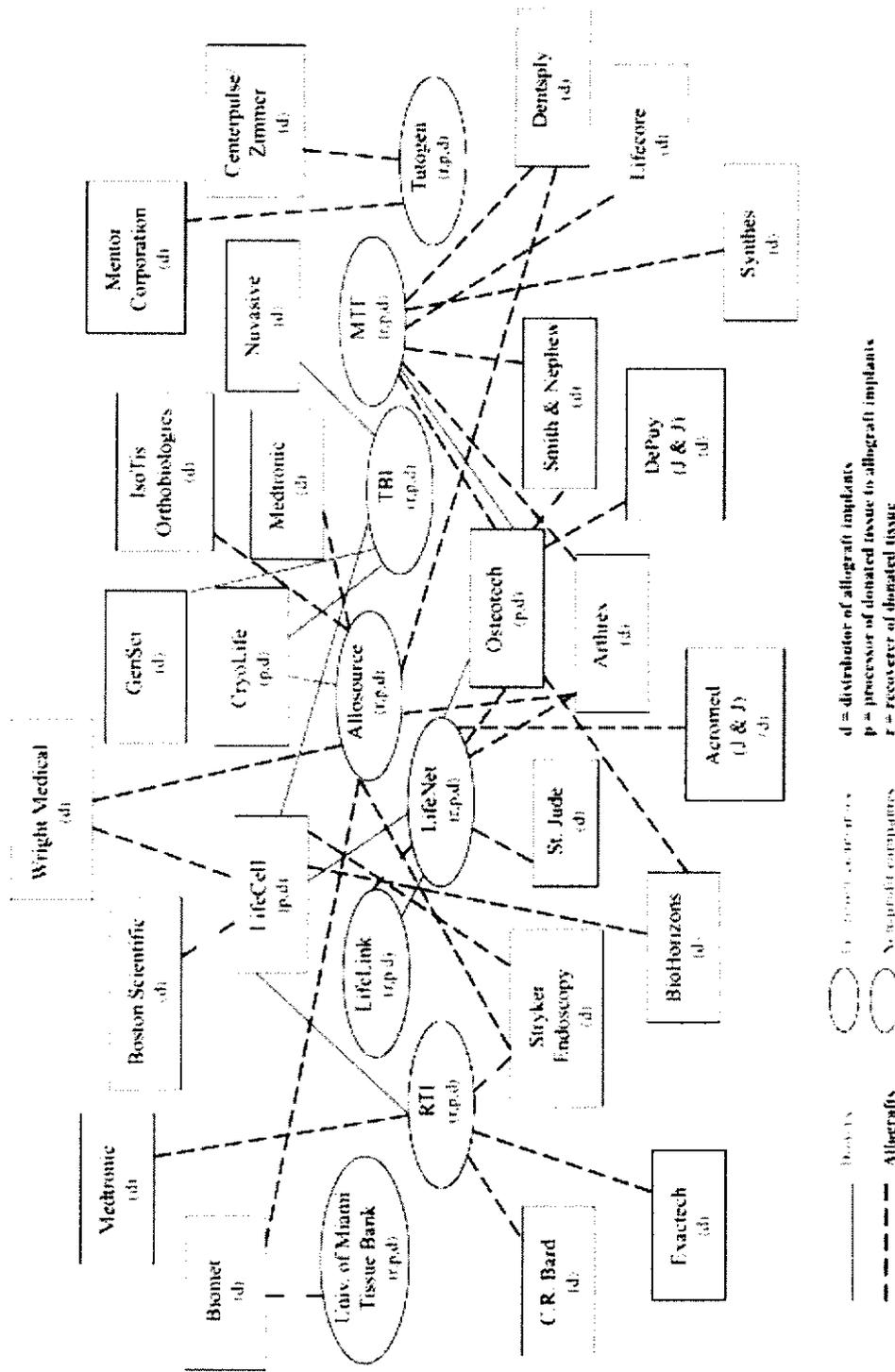
In addition, we would support CMS and their authority to apply the proposed rule, with suggested changes, on a federal level.

Thank you,



Brian K. Hutchison  
Chairman, President and Chief Executive Officer

# INDUSTRY RELATIONSHIPS



Corporate Communications (06.03.95)

**Submitter :** Dr. Marwan Abouljoud  
**Organization :** Henry Ford Hospital  
**Category :** Physician

**Date:** 06/03/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-3064-P-24-Attach-1.DOC



MICHIGAN ORGAN & TISSUE DONATION PROGRAM



A Donate Life Organization

Attachment 24

June 10, 2005

Centers for Medicare and Medicaid  
Department of Health and Human Services  
Attention CMS-3064-P  
Washington DC 20201

### **In support of Public Education for Organ Donation**

As chair of the External Relations Committee at Gift of Life Michigan, I am writing to encourage inclusion of public education in the CMS regulations for organ procurement organizations. Requirements for public education are absent from the proposed rule, and the effectiveness of public education is questioned in the report.

In Michigan, we have seen the positive effects of public education and its direct influence on our donor families. In a recent survey conducted of our donor families, 35% indicated that they initiated the discussion regarding organ donation and 26% initiated discussion with hospital staff regarding tissue donation. Almost 60% of the donor families who consented to organ donation had a family discussion prior to facing the decision in the hospital. Public education plays a key role in preparing families to consent to organ donation.

Organ Procurement Organizations need to be challenged to produce public education programs that produce quantifiable results. It is my concern that the lack of CMS regulations will hinder or completely discontinue public education efforts at a time that we need to concertedly join to raise the static national donation rate. It is imprudent to ignore the importance of long-term education of the public.

I would strongly ask you to include public education in the CMS regulations and reinforce to the organ procurement community the need to produce programs and initiatives which will directly affect the donation rate in our nation now and in the future.

Marwan S. Abouljoud, MD, FACS  
Chair, External Relations Committee, Gift of Life Michigan  
Director, Transplant Institute, Henry Ford Hospital

2203 Platt Road • Ann Arbor, MI 48104 • 800.482.4881 • fax 734.973.3133 • [giftoflifemichigan.org](http://giftoflifemichigan.org)

**G I V E S O O T H E R S C A N L I V E**

**Submitter :** Mr. Steven G. Anderson

**Date:** 06/03/2005

**Organization :** CryoLife, Inc.

**Category :** Device Industry

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-3064-P-25-Attach-1.DOC

**Comments of CryoLife, Inc. on  
Proposed Conditions for Coverage for Organ Procurement Organizations  
Condition: Requesting Consent (section 486.342)  
CMS-3064-P**

CryoLife, Inc. is pleased to submit these comments on the proposed conditions for coverage for organ procurement organizations (“OPOs”), 42 CFR Part 486. CryoLife, founded in 1984 and headquartered in Kennesaw, Georgia, is an innovator and leader in processing, preserving, and distributing living human tissues for use in reconstructive cardiac and vascular surgeries. As explained below, CryoLife will be significantly affected by the proposed condition for coverage for OPOs regarding “Requesting Consent”; CryoLife’s comments focus on this proposed condition.

**Comment – “Requesting Consent”  
Section 486.342**

The proposed Rule would establish new conditions of coverage for OPOs, including establishing minimum requirements for information that OPOs must provide to the individuals making the donation decision. The specific text on which we wish to comment is subsection 5 of this condition:

“The OPO would have to provide to the individual(s) making the donation decision, at a minimum, the following: . . . Information (such as profit or non-profit status) about organizations that will recover, process, and distribute tissue,” (emphasis added). CryoLife supports CMS’s decision to impose regulatory safeguards to ensure informed consent; however, as explained below, merely stating whether organizations that will recover, process, and distribute tissue are tax-exempt does not provide the individuals giving the consent for donation with information that is relevant and meaningful to the donation decision. As a result, the proposed language is misleading and inappropriate in this context.

Accordingly, CryoLife respectfully requests that CMS **strike the parenthetical reference to the tax filing status of organizations that will recover, process, and distribute tissue.**

In the alternative, if CMS feels that it needs to retain a parenthetical of some sort in the subsection, we recommend that CMS **replace the current language with the following: “An explanation that multiple organizations (non-profit and/or for-profit) may be involved in facilitating the gift(s).”** This reference would still further CMS’s goal of providing individuals with relevant information during the informed consent process but would more accurately reflect the information that such individuals have expressed as pertinent to their decisionmaking. The language we recommend comes directly from the Additional Elements of Informed Consent of the Model Elements of Informed Consent for Organ and Tissue Donation issued by the American

Association of Tissue Banks, the Association of Organ Procurement Organizations, and the Eye Bank Association of America.

If, however, CMS insists on retaining the language in the proposed Rule, CryoLife respectfully requests that CMS **clarify that, in the parenthetical, the phrase “such as” means “for example” rather than “including”**. This clarification would simply reflect the plain meaning of the phrase “such as”. As defined in the Merriam-Webster dictionary, “such as” means “of the same class, type, or sort.” To avoid confusion as to what the Rule requires, CMS should clarify that the reference in subsection 5 provides an illustration of the type of information that OPOs may choose to include on their informed consent forms, based on OPOs’ extensive experience with individuals making donation decisions, rather than mandating what OPOs must incorporate on the issue.

The basis for these recommendations is that: (1) merely providing the tax filing status of organizations that will recover, process, and distribute tissue is misleading and does not provide the type of meaningful information that individuals seek in order to provide informed consent to a donation; (2) requiring disclosure of tax-exempt status would be confusing and meaningless because the vast majority of tissue and organ transplants involve both non-profit and for-profit organizations; (3) current guidelines and industry standards reflect the supplemental nature of tax-exempt status information in making an informed donation decision; and (4) the proposed language does not meet the statutory standard for the conditions for coverage. Each of these grounds is discussed in more detail below, as is our recommendation that CMS invoke Federal supremacy to avoid a piecemeal approach across the country with respect to mandatory disclosure of tax-exempt status.

- 1. Merely providing the tax filing status of organizations that will recover, process, and distribute tissue is misleading and does not provide the type of meaningful information that individuals seek in order to provide informed consent to a donation.*

CryoLife agrees with CMS regarding the importance of obtaining informed consent in the donation process. CryoLife also agrees with CMS’s proposal to require that all requests by OPOs for tissue and organ donations include a properly executed informed consent process. CryoLife respectfully disagrees, however, with CMS’s suggestion, implied by requiring OPOs to provide information “such as” the tax-exempt status of organizations that will recover, process, and distribute tissue, that the mere tax filing status of such organizations is relevant to the informed consent process.

In fact, CryoLife believes that the proposed language in subsection 5 of section 486.342 of the proposed Rule is misleading because it reinforces misconceptions about the difference between non-profit and for-profit organizations and raises donor families’ expectations of the tissue transplantation system to an unrealistic level, precluding a true informed consent. These misconceptions are seen in the results of a national survey commissioned by Osteotech, Inc.<sup>1</sup> to better understand the factors that individuals consider most significant in making decisions

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<sup>1</sup> Osteotech processes human bone and connective tissue for transplantation and develops, manufactures, and markets biologic, biomaterial, and device systems for musculoskeletal surgery.

concerning organ donation.<sup>2</sup> The survey revealed a number of significant findings, including the following:

- When given the option of choosing to donate their organs or tissues to a “non-profit” or a “for-profit”, 80% of Americans selected “non-profits”; just 3% selected “for-profits”.
- Yet a wide majority (56%) of Americans who initially said that they would donate their organs/tissues to a “non-profit” over a “for-profit” also said that they would rather base their donation decision on which organization “uses the best technology and creates the most scientific breakthroughs” and not on whether or not an organization is “non-profit” or “for-profit”.
- Furthermore, 49% of Americans who initially favor donating to a “non-profit” over a “for-profit” say they would change their mind if they knew that “executives of the non-profit organization earned six-figure salaries and financial bonuses,” while another 18% are not sure how it would affect their decision. Just 33% say they would stay with the non-profit.

The survey also revealed that the general public is not well-informed about the significance of the distinction between “for-profit” and “non-profit” organizations in the context of tissue transplantation. Donors improperly assume that for-profit companies generate more revenues (63% thought “for-profits” generate more revenue while just 15% thought “non-profits” generated more revenues). In reality, a non-profit like The Musculoskeletal Transplant Foundation (MTF), the nation’s largest tissue bank, generated significant revenues – \$228 million – in 2003, which we believe may be more than any for-profit tissue bank. In fact, MTF issued a press release announcing that it was included in the 2003 Deloitte Technology Fast 50, a ranking of the fastest growing technology companies in New Jersey based on average percentage revenue growth over five years (1998 through 2002). Clearly, the idea among Americans that for-profits generate more revenue than non-profits is inconsistent with reality and further demonstrates the disconnect between donor beliefs and how the industry actually functions. In reality, the terms “for-profit” and “non-profit” simply refer to a tax status. “Non-profit” companies can and do make a profit. For-profit and non-profit companies are held to the same ethical standards. For-profit and non-profit companies charge similar fees for tissue.

The findings in the OIG Report are consistent with the survey findings that donors’ concerns about certain financial aspects of organizations involved in the donation process largely relate to both non-profit and for-profit organizations. The OIG Report states: “Large scale financial operations may overshadow the underlying altruistic nature of tissue donation,” OIG Report, p. ii. CryoLife acknowledges the OIG’s finding that, “[t]hese tensions have particular relevance to the operation of for-profit firms in what is, at least nominally, an altruistic enterprise based on donation” but believes it is significant that another major point the OIG raises relates to the level of salaries and costs incurred by both non-profit and for-profit firms. OIG Report, pp. 4-5. As the OIG concluded: “The importance of concerns about commercialization for informed consent relates to whether families may wish to know about commercial relationships that exist

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<sup>2</sup> Osteotech’s comments to the proposed Rule provide a more extensive discussion of the results of this survey.

between the agency to which it makes an altruistic donation, and an entity – *be it non-profit or for-profit* – that realizes revenue from the gift.” OIG Report, p. 5 (emphasis added).

In sum, if the language in the proposed Rule is adopted as drafted, many consenting individuals likely will choose to restrict the use of their loved ones’ tissue by for-profit companies, based on the belief that non-profit companies, by not generating surplus revenues designated as “profit”, are somehow more deserving of the gift of donation or that executives of non-profit organizations do not earn high salaries and financial bonuses. Restricting the amount of tissue sent to for-profit companies will needlessly deprive patients of the benefit of complex processing technologies that add clinical value to those tissues but that are predominantly dependent upon the services or technology of for-profit companies. This result would be the exact opposite of what donors and their families say they intend. Nor would such a system address the public’s concerns about financial incentives and company revenues in the tissue donation system, since these concerns apply to both non-profit and for-profit organizations. Accordingly, merely distinguishing between non-profit and for-profit organizations, as the proposed Rule does, is misleading and irrelevant. Therefore, CMS should remove the parenthetical from subsection 5 of section 486.342 of the proposed Rule.

2. *Requiring disclosure of tax-exempt status would be confusing and meaningless because the vast majority of tissue and organ transplants involve both non-profit and for-profit organizations.*

The proposed language of subsection 5 also fails to acknowledge the interrelationship between for-profit and non-profit organizations within the tissue banking system. No completely non-profit system exists that is capable of meeting the demands and needs of patients requiring musculoskeletal (MS) tissue transplants. The current tissue banking system is inherently a combination of the two. The following are a few examples from the tissue banking community of how non-profit and for-profit organizations interrelate to honor the wishes of donors and donor families and provide for the needs of patients who receive tissue.

- Non-profit OPOs and tissue recovery organizations recover tissue from donors, frequently in hospital operating rooms. Some of these hospitals are for-profit. Generally, the tissue recovery organization pays the donor hospital a fee for use of the hospital’s facilities.
- Out of necessity, non-profit recovery organizations utilize for-profit carriers to transport organs, tissue, and specimens for testing from the recovery site to the tissue bank that will prepare the tissue for transplant or directly to the hospital performing the transplant.
- Both non-profit and for-profit tissue banks use for-profit laboratories for testing donor specimens to ensure the safety of the tissue for transplantation.
- Perfusion, preservation solutions, and supplies utilized in the transport and preservation of organs and tissues are provided by for-profit companies.

- Tissue, particularly musculoskeletal tissue, must be altered from its original form in order to be beneficial to the patients who receive it. A tremendous, and very costly, amount of technology must be applied to the preparation of tissue for transplant in order to ensure that safe and effective allografts are available for the vast numbers of patients who require them. Non-profit tissue banks often rely on the technological capabilities developed by for-profit companies in order to enhance or improve the services they provide. For example, many non-profit tissue banks use technology or specialized processing that was developed by for-profit companies or forward tissue directly to for-profit tissue banks for that processing.
- Similarly, both non-profit and for-profit tissue banks may rely on the services of for-profit orthopaedic marketing and distributor organizations to offset the costs of employing their own marketing and distributor organizations, to offset the costs of employing their own marketing staff to educate surgeons on the use of allograft tissue, and to distribute tissue to hospitals nationwide.

As these examples illustrate, the role of for-profit organizations impacts every phase of the tissue donation process. As such, almost any tissue or organ donation will involve both non-profit and for-profit organizations, rendering the parenthetical language in proposed subsection 5 confusing and irrelevant. Therefore, CMS should remove the parenthetical from the Rule.

*3. Current guidelines and industry standards reflect the supplemental nature of tax-exempt status information in making an informed donation decision.*

The informed consent guidelines of leading industry groups reflect the supplemental nature of tax-exempt status information in making an informed donation decision. These guidelines focus instead on information such as an explanation of the recovery process and how the donation may be used as being of primary relevance to informed decisionmaking.

For example, the National Kidney Foundation's National Donor Family Council's Informed Consent Policy for Tissue Donation does not include for-profit versus non-profit language. Also, the Model Elements of Informed Consent for Organ and Tissue Donation issued by the American Association of Tissue Banks, the Association of Organ Procurement Organizations, and the Eye Bank Association of America address tax-exempt status under "Additional Elements of Informed Consent" rather than under minimum requirements in the "Basic Elements of Informed Consent". The Model Elements reference tax-exempt status in the Additional Element of: "An explanation that multiple organizations (non-profit and/or for-profit) may be involved in facilitating the gift(s)." OPOs currently operate within these existing guidelines and industry standards.

*4. The proposed language does not meet the statutory standard for the conditions for coverage.*

In the preamble to the proposed Rule, CMS explains that the Organ Procurement Organization Certification Act of 2000 and section 219 of the Consolidated Appropriations Act of 2001 require the Agency to propose "process performance measures that are based on empirical evidence obtained through reasonable efforts of organ donor potential and other related

factors in each service area of qualified organ procurement organizations.” CryoLife submits that the proposed requirement to include information such as the non-profit or for-profit status of organizations involved in the donation process does not meet this standard. As noted above, the leading guidelines on which information OPOs should provide to obtain informed consent either do not include any reference to tax-exempt status or simply state that both non-profit and for-profit organizations may be involved in facilitating the donation.

The proposed Rule also departs from Congress’ intent in enacting the Organ Procurement Organization Certification Act of 2000, in which Congress noted that the current process for certifying and recertifying OPOs had “created a level of uncertainty that is interfering with the effectiveness of organ procurement organizations in raising the level of organ donation.” Section 701, Pub. Law 106-505 (Nov. 13, 2000). For the reasons discussed above, the parenthetical in subsection 5 of section 486.342 of the proposed Rule does not further the goal of raising the level of organ donation, and may in fact hinder it. A regulation may not “conflict with the policy judgments that undergird the statutory scheme.” *Health Ins. Ass’n Of America v. Shalala*, 23 F.3d 412, 416 (D.C. Cir. 1994) (HCFA regulation went beyond the Agency’s statutory authority and therefore was invalid). Accordingly, CryoLife respectfully requests that CMS strike the proposed parenthetical language from subsection 5 of the proposed Rule or revise it, as proposed by CryoLife, to reflect these industry standards.

5. *CMS should invoke Federal supremacy to avoid a piecemeal approach to the treatment of for-profits and non-profits.*

Many organs and tissues offered for donation originate in states other than where the final recipient lives or where the hospital performing the final transplant procedure is located. If a state, locality, or organization is allowed to enact legislation or promulgate rules that contain language further restricting which type of organization (non-profit or for-profit) can receive organs or tissue, it could further complicate an already heavily regulated industry and add more hurdles to the overall goal of increasing organ and tissue donations nationwide.

Given this state of affairs, CryoLife believes that CMS should clarify that the new Rule overrides any state, local, or private law or rule that may be stricter or in conflict with the CMS Rule and its policy objectives as it relates to the required disclosure of the non-profit or for-profit status of organizations involved in the donation process. This proposal is justified by two primary rationales.

*First*, since CMS issued the proposed Rule in response to Congressional directives to address the organ procurement process, it follows that the broad authority given to Congress under the U.S. Constitution in relation to interstate commerce (the Commerce Clause, Article I, Section 8, Clause 3, provides that Congress has the power to “regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes”) means, by inference, that CMS’s final Rule applies to the interstate transport, use, processing, and marketing of organs and tissue (and to any funds being used on Indian reservations or in hospitals receiving funds for health care services to Indians, Alaska Natives, and Native Hawaiians) and merits Federal supremacy.

*Second*, since the Rule is intended to deal with procedures that are ultimately reimbursed using Federal funds (i.e., Medicare and Medicaid funds), the Federal government is entitled and

has a duty to ensure that no state, locality, or organization works to undermine the Federal goals of (i) increasing organ and tissue donation, (ii) reducing disincentives to or confusion that may accompany organ and tissue donation, and (iii) ensuring that hospitals, doctors, OPOs, and other organizations involved in the organ and tissue donation process operate under a uniform set of rules. To allow states, localities, or organizations to further complicate the organ and tissue procurement, processing, marketing, and transportation process with their own statutes, rules, or regulations would likely lead to more confusion, forum-shopping to circumvent the rules, and ultimately the potential for less, not more, organ and tissue donation.

For these reasons, we propose that CMS include the following language in the Final Rule:

“Because the Agency is responding to Congressional directives to address the organ and tissue procurement process, and because much of the organ and tissue donation process occurs across State lines, including the identification, procurement, processing, transportation, and marketing of organs and tissue, it is assumed that Congress used by inference its power under the Commerce Clause of the U.S. Constitution (Article I, Section 3, Clause 8) to address these interstate issues. In addition, because Federal funds are being used to reimburse hospitals or physicians for the organs and tissues used for Medicare and Medicaid beneficiaries, it is within our purview to insist on a uniform Federal application of the rules contained herein. Therefore, the following language will be added to the final Rule:

*“No state, locality, or organization that receives Federal Medicare or Medicaid funds or that acquires, transports, or offers organs or tissue for use in a state other than where the organ or tissue originated may, through legislation or rule, adopt language adding additional consent or informational requirements to the rules contained herein that: (1) distinguish between “for-profit” and “non-profit” organizations involved in the identification, location, collection, processing, marketing, and transportation of organs or tissue; (2) that, in the Agency’s opinion, are likely to result in confusion on the part of donors or their representatives; or (3) that, in the Agency’s opinion, are likely to reduce the overall amount of organs and tissue being donated on a national basis. Any entity that proposes to enact such a statute or regulation must submit the proposed language to CMS for examination and approval consistent with Federal statutes and this Rule, or the spirit or intent of this Rule, before any such language may become effective.”*

## **Conclusion**

Thank you for the opportunity to submit these comments. For the reasons discussed above, CryoLife respectfully requests that CMS strike from subsection 5 of section 486.342 the parenthetical reference to the tax filing status of organizations that will recover, process, and distribute tissue. In the alternative, if CMS feels that it needs to retain a parenthetical of some sort in the subsection, we recommend that CMS replace the current language with the following: “An explanation that multiple organizations (non-profit and/or for-profit) may be involved in facilitating the gift(s).” If CMS insists on retaining the language in the proposed Rule, CryoLife requests that CMS clarify that, in the parenthetical, the phrase “such as” means “for example” rather than “including”.

**Submitter :** Mr. Steven G. Anderson

**Date:** 06/03/2005

**Organization :** CryoLife, Inc.

**Category :** Device Industry

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-3064-P-26-Attach-1.PDF

Attachment 26



Biotechnologies for Medicine<sup>SM</sup>

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

Re:

**Comments of CryoLife, Inc. on  
Proposed Conditions for Coverage for Organ Procurement Organizations  
Condition: Requesting Consent (section 486.342)  
CMS-3064-P**

Gentlemen:

CryoLife, Inc. is pleased to submit these comments on the proposed conditions for coverage for organ procurement organizations (“OPOs”), 42 CFR Part 486. CryoLife, founded in 1984 and headquartered in Kennesaw, Georgia, is an innovator and leader in processing, preserving, and distributing living human tissues for use in reconstructive cardiac and vascular surgeries. As explained below, CryoLife will be significantly affected by the proposed condition for coverage for OPOs regarding “Requesting Consent”; CryoLife’s comments focus on this proposed condition.

**Comment – “Requesting Consent”  
Section 486.342**

The proposed Rule would establish new conditions of coverage for OPOs, including establishing minimum requirements for information that OPOs must provide to the individuals making the donation decision. The specific text on which we wish to comment is subsection 5 of this condition:

“The OPO would have to provide to the individual(s) making the donation decision, at a minimum, the following: . . . Information (such as profit or non-profit status) about organizations that will recover, process, and distribute tissue.” (emphasis added). CryoLife supports CMS’s decision to impose regulatory safeguards to ensure informed consent; however, as explained below, merely stating whether organizations that will recover, process, and distribute tissue are tax-exempt does not provide the individuals giving the consent for donation with information that is relevant and meaningful to the donation decision. As a result, the proposed language is misleading and inappropriate in this context.

Accordingly, CryoLife respectfully requests that CMS **strike the parenthetical reference to the tax filing status of organizations that will recover, process, and distribute tissue.**

In the alternative, if CMS feels that it needs to retain a parenthetical of some sort in the subsection, we recommend that CMS **replace the current language with the following: “An explanation that multiple organizations (non-profit and/or for-profit) may be involved in facilitating the gift(s).”** This reference would still further CMS’s goal of providing individuals with relevant information during the informed consent process but would more accurately reflect the information that such individuals have expressed as pertinent to their decisionmaking. The language we recommend comes directly from the Additional Elements of Informed Consent of the Model Elements of Informed Consent for Organ and Tissue Donation issued by the American Association of Tissue Banks, the Association of Organ Procurement Organizations, and the Eye Bank Association of America.

If, however, CMS insists on retaining the language in the proposed Rule, CryoLife respectfully requests that CMS **clarify that, in the parenthetical, the phrase “such as” means “for example” rather than “including”.** This clarification would simply reflect the plain meaning of the phrase “such as”. As defined in the Merriam-Webster dictionary, “such as” means “of the same class, type, or sort.” To avoid confusion as to what the Rule requires, CMS should clarify that the reference in subsection 5 provides an illustration of the type of information that OPOs may choose to include on their informed consent forms, based on OPOs’ extensive experience with individuals making donation decisions, rather than mandating what OPOs must incorporate on the issue.

The basis for these recommendations is that: (1) merely providing the tax filing status of organizations that will recover, process, and distribute tissue is misleading and does not provide the type of meaningful information that individuals seek in order to provide informed consent to a donation; (2) requiring disclosure of tax-exempt status would be confusing and meaningless because the vast majority of tissue and organ transplants involve both non-profit and for-profit organizations; (3) current guidelines and industry standards reflect the supplemental nature of tax-exempt status information in making an informed donation decision; and (4) the proposed language does not meet the statutory standard for the conditions for coverage. Each of these grounds is discussed in more detail below, as is our recommendation that CMS invoke Federal supremacy to avoid a piecemeal approach across the country with respect to mandatory disclosure of tax-exempt status.

- 1. Merely providing the tax filing status of organizations that will recover, process, and distribute tissue is misleading and does not provide the type of meaningful information that individuals seek in order to provide informed consent to a donation.*

CryoLife agrees with CMS regarding the importance of obtaining informed consent in the donation process. CryoLife also agrees with CMS’s proposal to require that all requests by OPOs for tissue and organ donations include a properly executed informed consent process. CryoLife respectfully disagrees, however, with CMS’s suggestion, implied by requiring OPOs to provide information “such as” the tax-exempt status of organizations that will recover, process, and

distribute tissue, that the mere tax filing status of such organizations is relevant to the informed consent process.

In fact, CryoLife believes that the proposed language in subsection 5 of section 486.342 of the proposed Rule is misleading because it reinforces misconceptions about the difference between non-profit and for-profit organizations and raises donor families' expectations of the tissue transplantation system to an unrealistic level, precluding a true informed consent. These misconceptions are seen in the results of a national survey commissioned by Osteotech, Inc.<sup>1</sup> to better understand the factors that individuals consider most significant in making decisions concerning organ donation.<sup>2</sup> The survey revealed a number of significant findings, including the following:

- When given the option of choosing to donate their organs or tissues to a "non-profit" or a "for-profit", 80% of Americans selected "non-profits"; just 3% selected "for-profits".
- Yet a wide majority (56%) of Americans who initially said that they would donate their organs/tissues to a "non-profit" over a "for-profit" also said that they would rather base their donation decision on which organization "uses the best technology and creates the most scientific breakthroughs" and not on whether or not an organization is "non-profit" or "for-profit".
- Furthermore, 49% of Americans who initially favor donating to a "non-profit" over a "for-profit" say they would change their mind if they knew that "executives of the non-profit organization earned six-figure salaries and financial bonuses," while another 18% are not sure how it would affect their decision. Just 33% say they would stay with the non-profit.

The survey also revealed that the general public is not well-informed about the significance of the distinction between "for-profit" and "non-profit" organizations in the context of tissue transplantation. Donors improperly assume that for-profit companies generate more revenues (63% thought "for-profits" generate more revenue while just 15% thought "non-profits" generated more revenues). In reality, a non-profit like The Musculoskeletal Transplant Foundation (MTF), the nation's largest tissue bank, generated significant revenues – \$228 million – in 2003, which we believe may be more than any for-profit tissue bank. In fact, MTF issued a press release announcing that it was included in the 2003 Deloitte Technology Fast 50, a ranking of the fastest growing technology companies in New Jersey based on average percentage revenue growth over five years (1998 through 2002). Clearly, the idea among Americans that for-profits generate more revenue than non-profits is inconsistent with reality and further demonstrates the disconnect between donor beliefs and how the industry actually functions. In reality, the terms "for-profit" and "non-profit" simply refer to a tax status. "Non-profit" companies can and do make a profit. For-profit and non-profit companies are held to the same ethical standards. For-profit and non-profit companies charge similar fees for tissue.

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<sup>1</sup> Osteotech processes human bone and connective tissue for transplantation and develops, manufactures, and markets biologic, biomaterial, and device systems for musculoskeletal surgery.

<sup>2</sup> Osteotech's comments to the proposed Rule provide a more extensive discussion of the results of this survey.

The findings in the OIG Report are consistent with the survey findings that donors' concerns about certain financial aspects of organizations involved in the donation process largely relate to both non-profit and for-profit organizations. The OIG Report states: "Large scale financial operations may overshadow the underlying altruistic nature of tissue donation," OIG Report, p. ii. CryoLife acknowledges the OIG's finding that, "[t]hese tensions have particular relevance to the operation of for-profit firms in what is, at least nominally, an altruistic enterprise based on donation" but believes it is significant that another major point the OIG raises relates to the level of salaries and costs incurred by both non-profit and for-profit firms. OIG Report, pp. 4-5. As the OIG concluded: "The importance of concerns about commercialization for informed consent relates to whether families may wish to know about commercial relationships that exist between the agency to which it makes an altruistic donation, and an entity – *be it non-profit or for-profit* – that realizes revenue from the gift." OIG Report, p. 5 (emphasis added).

In sum, if the language in the proposed Rule is adopted as drafted, many consenting individuals likely will choose to restrict the use of their loved ones' tissue by for-profit companies, based on the belief that non-profit companies, by not generating surplus revenues designated as "profit", are somehow more deserving of the gift of donation or that executives of non-profit organizations do not earn high salaries and financial bonuses. Restricting the amount of tissue sent to for-profit companies will needlessly deprive patients of the benefit of complex processing technologies that add clinical value to those tissues but that are predominantly dependent upon the services or technology of for-profit companies. This result would be the exact opposite of what donors and their families say they intend. Nor would such a system address the public's concerns about financial incentives and company revenues in the tissue donation system, since these concerns apply to both non-profit and for-profit organizations. Accordingly, merely distinguishing between non-profit and for-profit organizations, as the proposed Rule does, is misleading and irrelevant. Therefore, CMS should remove the parenthetical from subsection 5 of section 486.342 of the proposed Rule.

2. *Requiring disclosure of tax-exempt status would be confusing and meaningless because the vast majority of tissue and organ transplants involve both non-profit and for-profit organizations.*

The proposed language of subsection 5 also fails to acknowledge the interrelationship between for-profit and non-profit organizations within the tissue banking system. No completely non-profit system exists that is capable of meeting the demands and needs of patients requiring musculoskeletal (MS) tissue transplants. The current tissue banking system is inherently a combination of the two. The following are a few examples from the tissue banking community of how non-profit and for-profit organizations interrelate to honor the wishes of donors and donor families and provide for the needs of patients who receive tissue.

- Non-profit OPOs and tissue recovery organizations recover tissue from donors, frequently in hospital operating rooms. Some of these hospitals are for-profit. Generally, the tissue recovery organization pays the donor hospital a fee for use of the hospital's facilities.

- Out of necessity, non-profit recovery organizations utilize for-profit carriers to transport organs, tissue, and specimens for testing from the recovery site to the tissue bank that will prepare the tissue for transplant or directly to the hospital performing the transplant.
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- Perfusion, preservation solutions, and supplies utilized in the transport and preservation of organs and tissues are provided by for-profit companies.
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- Similarly, both non-profit and for-profit tissue banks may rely on the services of for-profit orthopaedic marketing and distributor organizations to offset the costs of employing their own marketing and distributor organizations, to offset the costs of employing their own marketing staff to educate surgeons on the use of allograft tissue, and to distribute tissue to hospitals nationwide.

As these examples illustrate, the role of for-profit organizations impacts every phase of the tissue donation process. As such, almost any tissue or organ donation will involve both non-profit and for-profit organizations, rendering the parenthetical language in proposed subsection 5 confusing and irrelevant. Therefore, CMS should remove the parenthetical from the Rule.

*3. Current guidelines and industry standards reflect the supplemental nature of tax-exempt status information in making an informed donation decision.*

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Additional Element of: "An explanation that multiple organizations (non-profit and/or for-profit) may be involved in facilitating the gift(s)." OPOs currently operate within these existing guidelines and industry standards.

4. *The proposed language does not meet the statutory standard for the conditions for coverage.*

In the preamble to the proposed Rule, CMS explains that the Organ Procurement Organization Certification Act of 2000 and section 219 of the Consolidated Appropriations Act of 2001 require the Agency to propose "process performance measures that are based on empirical evidence obtained through reasonable efforts of organ donor potential and other related factors in each service area of qualified organ procurement organizations." CryoLife submits that the proposed requirement to include information such as the non-profit or for-profit status of organizations involved in the donation process does not meet this standard. As noted above, the leading guidelines on which information OPOs should provide to obtain informed consent either do not include any reference to tax-exempt status or simply state that both non-profit and for-profit organizations may be involved in facilitating the donation.

The proposed Rule also departs from Congress' intent in enacting the Organ Procurement Organization Certification Act of 2000, in which Congress noted that the current process for certifying and recertifying OPOs had "created a level of uncertainty that is interfering with the effectiveness of organ procurement organizations in raising the level of organ donation." Section 701, Pub. Law 106-505 (Nov. 13, 2000). For the reasons discussed above, the parenthetical in subsection 5 of section 486.342 of the proposed Rule does not further the goal of raising the level of organ donation, and may in fact hinder it. A regulation may not "conflict with the policy judgments that undergird the statutory scheme." *Health Ins. Ass'n Of America v. Shalala*, 23 F.3d 412, 416 (D.C. Cir. 1994) (HCFA regulation went beyond the Agency's statutory authority and therefore was invalid). Accordingly, CryoLife respectfully requests that CMS strike the proposed parenthetical language from subsection 5 of the proposed Rule or revise it, as proposed by CryoLife, to reflect these industry standards.

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Many organs and tissues offered for donation originate in states other than where the final recipient lives or where the hospital performing the final transplant procedure is located. If a state, locality, or organization is allowed to enact legislation or promulgate rules that contain language further restricting which type of organization (non-profit or for-profit) can receive organs or tissue, it could further complicate an already heavily regulated industry and add more hurdles to the overall goal of increasing organ and tissue donations nationwide.

Given this state of affairs, CryoLife believes that CMS should clarify that the new Rule overrides any state, local, or private law or rule that may be stricter or in conflict with the CMS Rule and its policy objectives as it relates to the required disclosure of the non-profit or for-profit status of organizations involved in the donation process. This proposal is justified by two primary rationales.

*First*, since CMS issued the proposed Rule in response to Congressional directives to address the organ procurement process, it follows that the broad authority given to Congress under the U.S. Constitution in relation to interstate commerce (the Commerce Clause, Article I, Section 8, Clause 3, provides that Congress has the power to “regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes”) means, by inference, that CMS’s final Rule applies to the interstate transport, use, processing, and marketing of organs and tissue (and to any funds being used on Indian reservations or in hospitals receiving funds for health care services to Indians, Alaska Natives, and Native Hawaiians) and merits Federal supremacy.

*Second*, since the Rule is intended to deal with procedures that are ultimately reimbursed using Federal funds (i.e., Medicare and Medicaid funds), the Federal government is entitled and has a duty to ensure that no state, locality, or organization works to undermine the Federal goals of (i) increasing organ and tissue donation, (ii) reducing disincentives to or confusion that may accompany organ and tissue donation, and (iii) ensuring that hospitals, doctors, OPOs, and other organizations involved in the organ and tissue donation process operate under a uniform set of rules. To allow states, localities, or organizations to further complicate the organ and tissue procurement, processing, marketing, and transportation process with their own statutes, rules, or regulations would likely lead to more confusion, forum-shopping to circumvent the rules, and ultimately the potential for less, not more, organ and tissue donation.

For these reasons, we propose that CMS include the following language in the Final Rule:

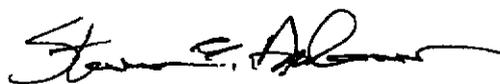
“Because the Agency is responding to Congressional directives to address the organ and tissue procurement process, and because much of the organ and tissue donation process occurs across State lines, including the identification, procurement, processing, transportation, and marketing of organs and tissue, it is assumed that Congress used by inference its power under the Commerce Clause of the U.S. Constitution (Article I, Section 3, Clause 8) to address these interstate issues. In addition, because Federal funds are being used to reimburse hospitals or physicians for the organs and tissues used for Medicare and Medicaid beneficiaries, it is within our purview to insist on a uniform Federal application of the rules contained herein. Therefore, the following language will be added to the final Rule:

*“No state, locality, or organization that receives Federal Medicare or Medicaid funds or that acquires, transports, or offers organs or tissue for use in a state other than where the organ or tissue originated may, through legislation or rule, adopt language adding additional consent or informational requirements to the rules contained herein that: (1) distinguish between “for-profit” and “non-profit” organizations involved in the identification, location, collection, processing, marketing, and transportation of organs or tissue; (2) that, in the Agency’s opinion, are likely to result in confusion on the part of donors or their representatives; or (3) that, in the Agency’s opinion, are likely to reduce the overall amount of organs and tissue being donated on a national basis. Any entity that proposes to enact such a statute or regulation must submit the proposed language to CMS for examination and approval consistent with Federal statutes and this Rule, or the spirit or intent of this Rule, before any such language may become effective.”*

## Conclusion

Thank you for the opportunity to submit these comments. For the reasons discussed above, CryoLife respectfully requests that CMS strike from subsection 5 of section 486.342 the parenthetical reference to the tax filing status of organizations that will recover, process, and distribute tissue. In the alternative, if CMS feels that it needs to retain a parenthetical of some sort in the subsection, we recommend that CMS replace the current language with the following: "An explanation that multiple organizations (non-profit and/or for-profit) may be involved in facilitating the gift(s)." If CMS insists on retaining the language in the proposed Rule, CryoLife requests that CMS clarify that, in the parenthetical, the phrase "such as" means "for example" rather than "including".

Very truly yours,



Steven G. Anderson  
President and CEO

Submitter :

Date: 06/03/2005

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-3064-P-27-Attach-1.PDF

June 3, 2005

Centers for Medicare & Medicaid Services (CMS)  
Department of Health and Human Services  
Attention: CMS-3064-P, PO Box 8013  
Baltimore, MD 21244-8013

We have the following comments regarding proposed Organ Procurement Organization (OPO) conditions of participation (CMS Docket ID: CMS-3064-P - Organ Procurement Organization Conditions for Coverage):

The proposed OPO regulations use unadjusted donation rates as one of the major criteria for evaluating OPO performance. We note that donation rates depend strongly on the choice of denominator. Eligible deaths, as proposed, are a very appropriate denominator to donation rates. Population counts, used previously, are far from optimal. The SRTR is investigating other even more useful denominators, based on expected number of donors given characteristics of the eligible deaths (rather than on the simple count of eligible deaths). Such models would offer CMS a more reliable measure of OPO performance.

Sincerely,

Friedrich K. Port, MD, MS  
President, University Renal Research and Education Association (URREA)

Robert M. Merion, MD  
Professor of Surgery, The University of Michigan Medical School

Robert A. Wolfe, PhD  
Professor, Department of Biostatistics, School of Public Health, The University of Michigan

**Submitter :** Mr. Doug Weeks  
**Organization :** Baptist Health Medical Center  
**Category :** Hospital

**Date:** 06/03/2005

**Issue Areas/Comments**

GENERAL

GENERAL

See attachment

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**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.

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Submitter : Mr. Joseph M. Gorrell

Date: 06/03/2005

Organization : New Jersey Organ and Tissue Sharing Network

Category : Organ Procurement Organization

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3064-P-29-Attach-1.DOC

# NJ Sharing

saving lives through  
organ and tissue donation

Attachment #29

June 3, 2005

## VIA ELECTRONIC DELIVERY

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-3064P-Proposed Rule, Conditions for Coverage of OPOs  
**Comment of the New Jersey Organ and Tissue Sharing Network, Inc.**

Dear CMS Officials:

Kindly accept this response to the proposed CMS rule (CMS-3064-P) regarding Medicare and Medicaid Programs: Conditions for Coverage for Organ Procurement Organizations (OPOs). The New Jersey Organ and Tissue Sharing Network (henceforth, the "Sharing Network") serves a population of over six and one-half million people in New Jersey. The President and Chief Executive Officer of the Sharing Network, Joseph Roth, also serves as the current President of the Association of Organ Procurement Organizations, ("AOPO") and thus has participated extensively in the process of preparing AOPO's response to these regulations. It should also be noted that Mr. Roth, as a former head of AOPO's Legislative Committee, participated in the process which brought about the OPO Recertification Act of 2000. Thus, The Sharing Network's response reflects the individual experience of this OPO, and will expand in some areas upon the comment submitted by AOPO.

We appreciate and support the joint goal of CMS and the OPO community, to save lives through maximized organ donation and transplantation. Further, we agree with AOPO that while the regulations take appropriate approaches in some areas, there are other areas that create significant concern for the OPO community. The Sharing Network's response focuses on several of the areas with which we have the most experience, both as a "sadder but wiser OPO," under the former rules for decertification and intra-OPO

*New Jersey Organ and Tissue Sharing Network, Inc.*

*841 Mountain Avenue • Springfield, NJ 07081*

*973-379-4535 • [www.sharenj.org](http://www.sharenj.org)*

*Fax (general): 973-379-5113 • Fax (clinical): 973-379-4311 • Fax (laboratory): 973-379-3719*

*Page 1 of 8*



A Donate Life Organization

competition, and as an OPO that has adopted successful strategies for maximizing organ donation, the success of which could be negatively impacted by the regulations proposed.

**I. Re-certification and Competition (proposed §486.316):**

**The Sharing Network joins with AOPO in strongly opposing competition for the service areas of OPOS which meet the conditions for coverage, as described in proposed §486.316(a).**

In 1996, the Delaware Valley Transplant Program (now Gift of Life Donor Program) petitioned to take over the Sharing Network pursuant to the competitive process described in the interim final regulation of September 1994. The resulting disruption to the Sharing Network, the morale of its staff and organ donation in the service area was immense. The costs in defending against this takeover were also enormous, as resources which might have been put towards continuing performance improvement measures, sharing of best practices and information, and public education were instead devoted to legal wrangling, and silence regarding successful approaches and projects for increasing donation, for fear that the “other” organization might co-opt the success.

Perhaps most damaging were the long term repercussions to the relationship between the Sharing Network and the Gift of Life Donor Program. These two programs, while serving the same state, and pursuing the same goal, were forced by an artificially competitive process to work against each other, when they should have been joining forces to serve the common good, as they do now. Several months, congressional communiqués, State Assembly resolutions and agency meetings after the original petition, the Sharing Network was allowed by HCFA to continue its primary job, serving the donation and transplantation community in its service area. The competitive process did not yield a single donor, or a single saved life. Further, as Congress has noted, the re-certification process “created a level of uncertainty that is interfering with the effectiveness of organ procurement organizations.”<sup>1</sup>

It is against the backdrop of this destructive experience that we oppose §486.316(a) of the proposed final rule, in which even those OPOs which meet stringent outcome and process measures will be subject to the same cut-throat competitive framework at the end of every 4-year certification cycle. This mandatory competition process imposes no costs on the aggressor OPO, and forces the incumbent to wage a defensive campaign just to exist.

This artificial structure is unique in the health care world, and probably in any service industry. It stands in stark opposition to the lessons learned in the Organ Donation Breakthrough Collaborative, in which the Sharing Network now works together with former competitor Gift of Life to identify successful strategies, with no “trade secrets” or “defense plans” getting in the way of communication. The positive results of this new paradigm have been thoroughly described in the AOPO response; suffice to say that Gift

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<sup>1</sup> Legislative findings, §219 Consolidated Appropriations Act, 2001

of Life and the Sharing Network have now formed an alliance with the New Jersey State Hospital Association in a Joint Organ Donation Taskforce. This would not have been possible in 1996, when the Hospital Association chose to take the Sharing Network's side in the battle of the OPOs.

The Agency has noted its intention to minimize "uncertainty" by imposing a swifter process, fewer disruptions to the service area, and a requirement that the competing OPO must be able to improve donation in the service area. Yet even "expeditious process" cannot mitigate the severity of the punishment, which is the equivalent of the death penalty. Preparing the case to either attack or defend is destabilizing in itself, as it diverts resources from the core mission. Thus, the only way to address the uncertainty is not to impose a competitive process upon fully certified, incumbent OPOs.

Respectfully, it is our opinion that it is the competitive process itself which results in "uncertainty," and in our experience, chaos, when it is applied to well-performing OPOs. Thus, due to painful and long-reaching organizational experience, the Sharing Network heartily concurs in the comments of AOPO on this section.

## **II. Administration and Governing Body (§486.324)**

The Sharing Network agrees with CMS that the issues of board composition and authority are important, especially with regard to the conflict of interest issues that seem inherent in both the structure described under the PHS Act and that currently described in the OPO regulations. As a non-profit 501 (c) (3) organization, incorporated in the State of New Jersey, we are also mindful of the structural requirements of state law. We support the language proposed by AOPO, which allows OPOs to continue to meet their required board composition in either an advisory board, or a governing board of directors, with the caveat that the conflict of interest issues must be dealt with in a straight-forward and consistent fashion.

In the Background Discussion to §486.324, CMS notes that there is a cross-referencing problem with the original PHS Act, and suggests an interpretation of the Act that allows it to function under what CMS perceives to be its intent. We believe that a similar interpretation needs to be applied to that section of the PHS Act which seems to state that the "compliant board," that is, that board which has the statutorily-required membership, should have "no other authority over any other activity of the OPO." This apparent requirement would be clear, if it were not for the fact that the same Act allows the compliant board to serve either as a Board of Directors, or as an Advisory Board. Under the non-profit corporation laws of most states, and indeed under the Model Non-Profit Corporation Act, a Board of Directors (or Trustees) must exercise the management of the Corporation. In a very real and binding sense, a non-profit can only act through its board of directors. And, as we know, OPOs are required by the same PHS Act to be non-profit 501 (c)(3) corporations. Thus, the only internally consistent interpretation of this section of the PHS Act is that Congress intended to require that those board members with

conflicting interests address those conflicts in such a way as to minimize their final authority over certain operational and fiscal activities of the OPO. This result can be obtained by means of regulatory requirements for conflict of interest disclosure and policies. Such disclosures and policies are not new to the non-profit world, and indeed have been used to prevent conflicts and self-inurement issues for non-profits for many years.

It must also be noted that not every member of the "compliant" board list is likely to have a conflict on every issue. Thus, while a transplant surgeon may have some conflict in voting on specific budgetary and SAC issues, a neurosurgeon or tissue bank representative may not. Hence, it is very possible to have a statutorily "compliant" board of directors, capable of functioning both on donation policy issues and other areas of OPO operation.

The Sharing Network, like many other OPOs, has over the last two years reassessed its board composition and structure. What we have found is that the number of available, knowledgeable, and committed board members, both in the mandated categories, and the general community are few. Such board members are an extremely valuable, and their single most scarce resource is time. We also found that the structure of an operational board, with a "compliant" advisory board, did not work, due to difficulties in recruitment, retention and attendance on the advisory board. We believe that this difficulty is reflected around the nation, and is due to the lack of real authority perceived to be inherent in the "advisory board member" role. Moreover, we found that while transplant physicians had many agenda items to discuss amongst themselves, the other "compliant" board members could not contribute to the physician discussion, and had concerns and expertise which were more pertinent to management and operational issues. Thus, the Sharing Network developed a Board of Directors, with a Transplant Advisory Board. The Board of Directors has the "compliant" members, who disclose their conflicts annually and as they arise, and the Advisory Board is now a vibrant, well-attended clinical policy-making entity.

Another benefit to this structure, which we believe is fully compliant with both the existing regulations, and the PHS Act as we interpret it, is that the Board of Directors has all the right people on it, working together. Not only do we have those members whom the Congress, acting in 1984, believed to be crucial to an effective donation process, but we also have room for members from minority communities, experts in media, marketing, and law, government, fiscal accountability, donor families and recipients. These members have as much of a contribution to make as those members originally envisioned by Congress.

We are concerned that a strict interpretation of the PHS Act will require many OPOs to create new, unwieldy and unnecessary boards, devoid of the commitment that any non-profit requires. For this reason, we support the proposed language submitted by AOPO.

### **III. Requesting Consent (proposed §486.342):**

Tellingly, there have been very few legal cases involving flaws in the informed consent process when conducted by OPOs, and in the courts that have considered evidence on consent conducted by OPOs have overwhelmingly found that consent was adequate and that operations were conducted in good faith. While information described in subparagraphs (a)(1) through (a)(8) may be important to many individuals, there are many individuals who need to hear information that is more specifically tailored to them and their stated needs. The consent of these people is as valid as that of those who have more need for detail, and we should be mindful that our desire to be informative does not trample on the sensitivities of willing donors.

The Sharing Network agrees with CMS that demonstrating discretion and sensitivity with respect to the circumstances, views and beliefs of potential donor families during the consent process is not only the minimum ethical and legal standard for requestors, but also the most effective means of increasing donation, now and in the future. We also believe that the prescriptive nature of §486.342, which lays out a laundry list of items of information which must be provided, whether the donating individual wishes or needs to hear them or not, is at odds with the statutory requirement of sensitivity to individual families. Increasingly, the donation community has heard feedback from donor families that the consent process itself can be abusive, due not only to its timing, but also due to its often formulaic and overly-detailed provision of information.

Nowhere else in relevant federal law and regulation is informed consent or adequate disclosure prescribed in such detail. In fact, the doctrine of informed consent with regard to medical decision making, and adequate disclosure in the realm of charitable gifting is a matter of state law and interpretation. In the unique forum of gifting organs, the actual gift is made pursuant to the Uniform Anatomical Gift Act ("UAGA") of the individual state, which governs how and by whom the gift can be made. The goal of this state law is to assure that the gift was truly voluntary and intentional, and will therefore stand up to legal challenge and ethical scrutiny. Good faith compliance with the UAGA also assures statutory immunity. It is not clear how new federal mandates impacting on the subject area of the UAGA might effect this essential good faith immunity, but it could have the impact of raising the bar of what constitutes "good faith" by requiring recitations of verbiage, where common sense and sensitivity ruled before.

In its legal usage, the term "informed consent" describes a patient's decision to consent to a procedure in light of adequate knowledge of the risk, benefit and alternatives available in a treatment setting. As we know, there is no medical risk or benefit involved in the recovery of organs or tissue from a deceased donor. Thus, in the strictest sense, the term is misapplied to the donation process. A more appropriate standard would be the standard we apply to charitable donation, i.e., adequate disclosure of who will benefit from this gift, and how will it be used. Because the proposed regulation uses the term "informed consent" we will utilize the term in this response, while defining the concept

to mean that enough information has been conveyed to the donor family to enable them to gift their loved one's body, free of invalid expectations or incorrect assumptions.

What does a donor family need to know in order to make this decision? CMS considered many important sources for the answer to this question, including the Donor Family Council of the National Kidney Foundation, the American Association of Tissue Banks, and AOPO. Yet, in the field, the most important source for the answer is the individual consenting party himself, engaged in the consent dialogue.

Consent is not a two-step transaction, where the requestor relays information, and the other party consents or denies consent. Effective consent is actually a conversation, in which issues about the decedent's personal beliefs, family and religious values, burial plans, altruism and donation myths may be discussed. If a donor asks a question, that question is legally and ethically relevant to the adequacy of consent and adequate disclosure. In short, if a consenting party wants information, he needs that information in order to lawfully consent. Thus, if a potential donor asks if he will be paid for the donation, or if the tissue can be sold at a profit, and is told an inaccurate or incomplete answer, consent may not have been lawfully obtained. If however a donating party fails to ask where the recovery will take place, and is not told that it will take place in an operating room, consent would be considered by most to still have been lawfully obtained, as it is based on adequate knowledge. Under the proposed regulation, it is possible that failure to convey "a description of the screening and recovery process" might invalidate a life-saving gift.

Of equal importance to what a donor must know is what a donor does not want to hear. For example, a donor family member may state, "Please, take everything, and use it however you wish. We're going to have his body cremated." §486.342(a)(1) of the proposed regulation could be read to require that the OPO still list the approximately twenty organs and tissues that may be recovered. Moreover, this list would have to be read (in the case of telephone consent) or initialed on a consent form, even if the consenting party specifically objected to hearing it. Further, the requesting party would have to describe the effect of donation on appearance and burial arrangements, even if the donor was to be cremated. This requirement, applied to the not uncommon hypothetical circumstance described above, would result in the height of insensitivity to a grieving family.

Similarly, under proposed §486.342(a)(2) the requestor would have to list "all possible uses," which could be interpreted to mean that rather than simply obtaining consent for transplantation, research, therapy and education, as is permitted now by the UAGA, some more specific description is required. The regulation is unclear as to how specific and exhaustive this listing must be. Does the requestor need to detail the research projects currently underway, or the many surgical procedures which utilize tissue?

The information required to be communicated in subparagraph (a)(3) would also be problematic if made mandatory. Subparagraph (a)(3) states that the individual must be informed of the right to limit or restrict the use of donated organs or tissues. This wording is ambiguous and difficult to apply. What are the parameters of this right? Clearly, in our system, an individual has the right not to donate at all. Similarly the UAGA gives the individual the right to choose whether to donate for transplant, research, therapy or education. This right is expressed in positive terms, i.e. as the right to give for certain purposes, rather than negative, i.e., the right to restrict or limit. The information requirements of the federal regulation should mirror the framework of the UAGA in this regard, and express the right to donate for specified purposes, as opposed to the right to restrict donation.

Most OPOs who work with for-profit processors or distributors of tissue inform donors of that fact at the time of consent, and this gives donors the option of not consenting if that issue troubles them, or, in some states, choosing a nonprofit option. The wording of subparagraph (a) (5) should be clarified to allow general statements about the types of organizations who recover, process, and distribute tissue, rather than the vague "information about" the organizations. The current language could mean that an OPO provide pamphlets on each of the four or more organizations which may be involved in recovering, processing and distributing the tissue from a single transplant donor. Given that different organizations are involved with different OPOs and hospitals, such specificity is impossible to achieve, and of no imaginable use to a donating individual.

Similarly, knowing to whom one may make a complaint, as specified in subparagraph (a) (8) seems to be an unusual and uncalled for addition to the consent process. All OPO consent forms identify the name of the organization, and most OPOs provide some form of continuing relationship with donor families. Absent further direction on some other agency prepared to take complaints on OPO consent-related issues, there would seem to be little purpose to requiring more language on the consent form for this purpose.

To summarize our concerns about the entire section on consent, the prescriptive nature of the requirements poses the risk of insensitivity to donor families, and needless legal uncertainty and risk. The effective and legally adequate consent process is one of the most studied areas of OPO operations, and one in which staff receive the most training. Due perhaps to the circumstances in which a request for organ and tissue donation is made, during a time of shock and tragedy, some potential donors actively resist hearing some information, and may ask the requestor to simply allow them to sign. Under the law of most states, this circumstance is considered a defense to malpractice claims based on a lack of informed consent. With mandatory elements of informed consent in place, this defense may become unavailable, leaving requestors in the uncomfortable position of forcing a speech on willing donors, and in effect, practicing a defensive approach for consent. By mandating specific elements which must be communicated, the donor family will be deprived of the ability to say "I have enough information, I consent," and OPO requestors will be forced to say "not yet, I have another ten items I must go through."

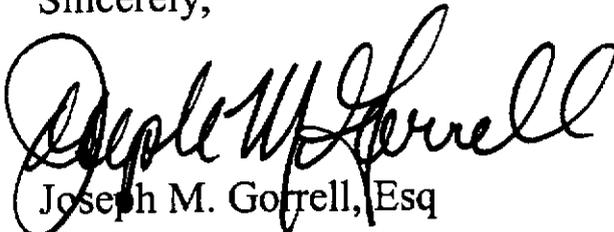
Respectfully, we believe that these concerns can be addressed by the following change in the language of §486.342(a):

“...The OPO must provide adequate information to the individual(s) responsible for making the donation, which may include at a minimum, the following if appropriate and if sensitive to the individual(s) circumstances, views, and beliefs...”

With the exception of AOPO's comment on §486.342, the Sharing Network joins in the detailed AOPO response, submitted under separate cover, in addition to the response outlined above.

Thank you again for this opportunity to comment. We hope to participate in further constructive dialogue with you, both before and after the finalization of the regulations.

Sincerely,

A handwritten signature in black ink, appearing to read "Joseph M. Gorrell". The signature is fluid and cursive, with a large initial "J" and "G".

Joseph M. Gorrell, Esq  
Chair

New Jersey Organ and Tissue Sharing Network, Inc.

Joseph M. Gorrell, Esq  
Chair  
New Jersey Organ and Tissue Sharing Network, Inc.

Date: 06/03/2005

Submitter : Mr. Michael Seely  
Organization : Pacific NW Transplant Bank  
Category : Organ Procurement Organization  
Issue Areas/Comments

GENERAL

GENERAL

See attachment

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**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.

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**Submitter :** Mr. Michael Seely  
**Organization :** Pacific NW Transplant Bank  
**Category :** Organ Procurement Organization

**Date:** 06/03/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attached.

CMS-3064-P-31-Attach-1.DOC



**PACIFIC NORTHWEST  
TRANSPLANT BANK**  
2611 S.W. THIRD, SUITE 320  
PORTLAND, OR 97201-4952

OFFICE: (503) 494-5560  
24-HOUR: (503) 344-8616  
FAX: (503) 494-4725

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

Attachment #31  
June 3, 2005

Electronically to <http://www.cms.hhs.gov/regulations/ecomments>

RE: CMS-3064-P  
"Recertification and Competition" (486.316)  
"Outcome Measures" (486.318)

To the Centers for Medicare & Medicaid Services:

I am writing behalf of the Pacific Northwest Transplant Bank (PNTB) to comment regarding the CMS proposed rule (CMS-3064-P), specifically the provisions concerning competition and outcome measures. PNTB is the designated organ procurement organization serving the state of Oregon, southwest Washington and western Idaho.

The proposed rule sets out a competitive framework that will prove detrimental to the recent successes of the Secretary's Breakthrough Collaborative Initiative and greatly dampen the willingness of OPOs to share and engage in best practices. PNTB suggests that CMS restrict regulatory reliance on competitive processes for OPOs solely to those service areas covered by OPOs that do not meet the CMS conditions for participation. The current proposal that would allow open competition at the end of every four-year certification cycle despite an incumbent OPO having met all standards of performance for recertification will distract and undermine organ recovery efforts and dissuade the spirit of collaboration.

Concerning "Outcome Measures" (486.318), PNTB commends CMS for replacing the former population-based model with outcome related performance measures. However, we are in full agreement and support of the Association of Organ Procurement Organization's (AOPO) position put forth to the Administrator and CMS officials in the current comment period. AOPO has constructively made suggestions that can improve the measurement approach and ultimately allow the rules to be in clearer concordance with legislative intent and specific statutory language.

Thank you for this opportunity to comment.

Sincerely,

A handwritten signature in black ink, appearing to read 'MS Seely', is written over a horizontal line.

Michael S. Seely, MS, CPTC  
Executive Director

**Submitter :** Mr. Eugene Osborne  
**Organization :** CA Transplant Donor Network  
**Category :** Organ Procurement Organization

**Date:** 06/03/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-3064-P-32-Attach-1.PDF

CMS-3064-P-32-Attach-2.DOC

Transplant Network

June 2, 2005



COLLABORATIVE LIFE

888.570.9400

MAIN OFFICE

MODESTO OFFICE

FRESNO OFFICE

PARTICIPATING TRANSPLANT CENTERS

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:

California Transplant Donor Network (CTDN) is providing our response to the proposed CMS rule (CMS-3064-P) regarding Medicare and Medicaid Programs: Conditions for Coverage for Organ Procurement Organizations (OPOs). The proposed regulations have an important role in supporting our mission to improve and save lives through organ and tissue donation. We will utilize the system recommended in the proposed regulation and address our comments by order of each section.

**“Re-certification and competition processes (proposed §486.316)”:**

CTDN strongly opposes any competition framework that would allow the takeover of a certified OPO’s service area by another OPO, but agrees with the option included in the proposed rule, identified as the “highly restricted competition process,” with competition only occurring among OPOs in cases where an incumbent OPO has been de-certified. With regard to competition when an OPO does not meet conditions for coverage, CTDN is aligned with o f t h e m a j o r i t y o f t h e O P O s w h o a g r e e w i t h C M S t h a t a n incumbent de-certified OPO should not be permitted to compete for its service area and also agrees with CMS’ recommendations regarding competition only for an entire service area (thus avoiding “cherry-picking”). Likewise CTDN also agrees that the criteria OPOs must meet to compete for an open area should recognize higher performance, not a minimum standard.

Most recently, significant performance improvements in organ procurement across the nation have been achieved over the past two years as a result of the Collaborative model. OPTN/UNOS data show that donation rates nationwide in 2004 increased 10.8 percent over 2003, with rates at hospitals participating in the Collaborative increasing by 16 percent and by 9 percent in nonparticipating hospitals (and records continue to be registered in 2005

with an additional 9 percent increase through the first four months). The proposed opening of every service area at the end of every 4-year cycle is an untested framework and potentially divisive approach that conflicts with the successful work of the national Organ Donation Breakthrough Collaborative.

Within our industry, all 58 federally designated OPOs have either fielded teams in the Collaborative or assigned responsibility to designated improvement leaders for spreading the initiative's successes. Two weeks ago, CTDN fielded a significant group of attendees to the Collaborative sponsored First Annual Organ Donation National Learning Congress in Pittsburgh. Particular attention was directed to the impact of timely notification, effective requesting, and unparalleled hospital-OPO relationships across the country. Significantly, the Collaborative approach was characterized as the "implementation of a competitive spirit grounded in teamwork, recognition, and results."

In brief, these are the results at risk by pursuing the proposed competitive framework outlined in the regulation. We believe the proposed framework would encourage OPOs to devote scarce resources towards taking over other areas rather than improving performance in their own areas and degrade the point of having performance measures, resulting in fostering a potentially "predatory culture".

**"Outcome Measures" (proposed §486.318):**

CTDN is encouraged to see the emphasis in the rule on organ donor potential. It is a welcome change to the earlier population-based metrics advanced as OPO performance standards, and represents an important component for outcome measurement. Beginning in September of 2001, HHS began requiring that OPOs submit data on eligible donors to the OPTN. CTDN agrees that "eligible deaths" is substantially more predictive of actual donors. Regarding §486.302, the CMS proposed definition of "organ donation potential" differs somewhat from that used currently in the OPTN reporting requirements for OPOs. These differing reporting measures cause confusion and lead to mistakes and inaccuracies. At the industry level, AOPO has undertaken an analytic review of this matter and shared its preliminary views with CMS and HRSA earlier in 2004. We are aware that AOPO intends to finalize its analysis and proposed definition for "organ donation potential" by the end of June 2005. CTDN supports that there be one uniform definition for "organ donor potential."

**OPTN Data**

CTDN supports the CMS proposal to require death record reviews as a component of every OPO's QAPI program. We recommend that CMS specify that an OPO be required "to conduct death record reviews in every

Medicare or Medicaid participating hospital with which it has an agreement if the hospital has 150 or more acute care beds, *with an ICU and ventilator*, or if it has a level I or level II trauma center.” (italicized words recommended by CTDN). CTDN further supports that the HHS technical assistance program regarding QAPI include appropriate training and guidance for conduct of standardized death record reviews.

### Outcome Performance Standards and Thresholds

The proposed CMS rule, which focuses exclusively on conversion rates as its outcome metric, is consistent with the HHS Secretarial donation rate initiative for the nation’s largest hospitals, and discards the earlier donors per million approach. Despite the improvements made, CTDN would submit that the multiple measures advanced in the proposed rule are highly correlated with themselves and essentially represent one outcome measure (i.e. overall conversion rate), placing disproportionate attention to the role of self reported data.

CTDN supports and recommends that two outcome measures be used for assessing OPO performance: overall conversion rate and organs transplanted per donor ratio.

*Overall Conversion Rate:* Our industry analysis, conducted by AOPO, indicates that if an OPO does not meet the threshold for the overall conversion rate (i.e. the first measure), it is highly unlikely that the OPO will be able to meet more than two of the remaining four measures. In fact, the correlation among the four measures ranges from .81 to .97, which is statistically significant. Given the high inter-correlation between the five proposed conversion ratios, little additional information regarding performance is provided by the inclusion of the proposed four organ-related conversion ratios. Consequently, we recommend that one single conversion rate measure be adopted rather than the five conversion rates advanced by CMS.

The incorporation of DCDs and older donors in the numerator alone, however, places a disproportionate weight on these areas in any performance comparison for certification purposes and may inadvertently mask opportunities for improvement in recovery of standard criteria donors. Inclusion of these donors as part of the national conversion rate benchmark (which is used as the benchmark for outcome comparisons among OPOs), furthermore, is problematic in the absence of estimates of donor potential for these groups. CTDN supports any recommendation, consequently, that excludes these donors from the national rate but includes them in the numerator and denominator of an individual OPO for incentive and comparison purposes as adjustments to individual OPO conversion rates.

*Organs Transplanted per Donor Ratio:* The adoption of a “yield” measure as the second metric consistent with the recently launched HHS Organ Transplantation Initiative, providing incentives for greater recovery and transplant of extra-renal as well as renal organs, and allowing for incorporation of legislative expectations regarding pancreas recovery for islet cell transplantation and research.

CTDN recommends that the measure be similar to that used by HHS in its initiative, that is, organs transplanted per donor. A more complete quantitative approach to acknowledging both number and quality is advanced (i.e. the number of medically suitable individuals “converted” to donors and the quality of those donors as measured by the number of organs transplanted) with a “yield” measure as well. As part of the Organ Transplantation Initiative, HHS has identified sub goals for (a) Standard Criteria Donors (SCDs), (b) DCDs, and (c) Expanded Criteria Donors (ECDs). CTDN agrees with these sub goals and forwards them as recommendations to the yield measure; and, therefore that an OPO’s organs transplanted per donor rate (adjusted for pancreata recovered for islet cell transplant or islet cell research) be compared against the OPO’s case mix expected organs transplanted per donor rate.

As such, our recommendation would include that proposed performance measures will only be used prospectively to assess OPO performance, i.e. for periods commencing upon the later of January 1, 2006 (assuming that the final version is promulgated prior no later than July 1, 2005) or the actual implementation date (assuming a period of 180 days following the promulgation of the final regulation).

Consistent with the Pancreatic Islet Cell Act of 2004, the pancreas adjustment should provide appropriate incentives since each recovered pancreas used in islet cell transplantation or placed for research would be added to the total organs transplanted numerator for individual OPOs and the number of organ donors with only the pancreas recovered for islet cell transplant or research would be added to the denominator of the measure. This treatment is in that it would permit pancreases used for islet cell transplantation and research to be counted towards an individual OPO’s performance.

The rule advances a continuation of the “75 percent of the mean” threshold as the marker for adequate OPO performance. The rule also proposes that the relationship of an OPO’s performance relative to the mean, as well as a 15 point conversion rate spread, should be used to measure significant performance differences between OPOs.

In recent years, HHS has supported innovative analytic work conducted by the SRTR to improve donation rate measurement. The SRTR has made significant strides in the development of a statistical method for identifying

a comparison metric to evaluate donation performance levels across OPOs. These SRTR rates are already in use within the hospital industry.<sup>1</sup> However, the rule does not discuss the potential application of SRTR-based metrics in its proposed outcome measures. The outcome metrics in the proposed rule appear to have been crafted well before the development of the SRTR's recent OPO-specific performance algorithm and the subsequent adoption of those metrics by hospitals and OPOs. The inclusion of the SRTR statistically derived measures in the overall donation rate would provide an opportunity for assessing OPO performance, both in comparison to other OPOs and in comparison to an OPO's statistically expected conversion rate.

### **OPO Process Performance Measures**

CTDN applauds the rule's proposed new Quality Assessment and Performance Improvement (QAPI) requirements as a welcome addition to the regulatory framework. Of particular note is the direction taken in the QAPI provisions of emphasizing direction and content, yet maintaining program flexibility in implementation with oversight by CMS. We believe the balance proposed by the QAPI requirements provides a model regulatory framework that should be applied to other process performance measures noted in this rule.

Organ donation and recovery, as with organ transplantation, is a field where science and technology evolve. For example:

- The proposed ABO blood typing provisions in the rule are dated and have been modified by the national policy process in place by the HHS-supported OPTN structure;
- Similarly, the rule's focus on "designated requestors" has changed in recent years in the Organ Breakthrough Collaborative to an emphasis on effective requestors and an effective requesting process;
- The Collaborative, furthermore, has demonstrated equally outstanding outcomes achieved by OPOs having multiple staffing arrangements and approaches;<sup>2</sup> and
- Recent developments in infectious disease and new knowledge in donor management have occasioned more of a team approach to medical involvement, where the skills and perspectives of infectious disease and

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<sup>1</sup> On February 7, 2005, Friedrich Port, MD, President of the University Renal Research and education Association (URREA) wrote to all hospital administrators in the US bringing to their attention the public availability of measures of donation rates by hospital on the SRTR web site. On March 3, JCAHO formally communicated this development to hospital executives. The matter of "hospital donor procurement data available at SRTR," furthermore, was subsequently featured by JCAHO in its April 2005 issuance of JCAHOnline.

<sup>2</sup> Our OPO attended the recently concluded First Annual Organ Donation National Learning Congress, which provided particular attention to the matter of OPO Redesign, and sought input for a special session on this matter which will occur later this summer of 2005. The focus of the Redesign discussions at the Congress addressed such matters as number of staff, type of staff, work organization, culture, methods and systems, and financial models, with a clear emphasis on opportunities for sharing "best practices" rather than directing attention to standardized, prescriptive human resource requirements.

critical care specialties complement the involvement of transplant surgeons and physicians.

In sum, the evolving science of organ procurement and transplantation, along with continuing changes in standards of practice, demands that OPOs modify their processes and practices in accordance with the newest information and guidance made available. Furthermore, each OPO has its own unique resources and confronts a unique set of challenges. As a result, different operational practices will be effective for different OPOs. A specific approach for satisfying a process measure may not be the best approach for every OPO.

**“Relationships with Hospitals, Critical Care Access Hospitals, and Tissue Banks (proposed §486.322)”:**

CTDN supports and practices having written agreements with hospitals, as well as inclusion of the terms “timely referral” and “imminent death” as defined by the client hospital’s Policy for Organ and Tissue Donation. In view of the HHS Organ Breakthrough Collaborative initiatives, however, CTDN supports that consideration be given to use of the term “clinical triggers” for “imminent death,” as suggested by many hospital staff across the country.

OPOs currently are required to have working relationships with at least 75 percent of the Medicare and Medicaid participating hospitals in their service areas that have operating rooms and equipment and personnel for organ recovery. There is no reason to change this requirement from 75 percent to 95 percent, as CMS is proposing. At the same time, however, we would recommend that written agreements be required with all hospitals having 150 or more acute care beds with an ICU and ventilator or hospitals having a level I or level II trauma center.

CTDN supports cooperative arrangements with tissue banks and appreciates the inclusion of language in the proposed regulations stating that agreements are not required in instances in which a tissue bank is unwilling to have an arrangement with an OPO.

Nevertheless, CTDN is concerned about one requirement in this area of the proposed regulations. Section (c) requires that an OPO must have an “arrangement to cooperate” with tissue banks engaged in agreements with those hospitals with which the OPO has agreements. CTDN supports the stance that CMS should not require a CMS-regulated entity to have a relationship with an entity not regulated by CMS, particularly when the entity regulated by the agency has direct evidence or good faith reasons for not doing so. In fact, while paragraph (c) (2) permits a tissue bank to reject an arrangement with an OPO, it gives no such option to an OPO desiring to reject an arrangement with a tissue bank. Consequently, as they are now

written, the proposed regulations may have the unintended consequence of potentially protecting a tissue bank's commercial opportunities at the expense of ensuring good tissue practices and patient well being.

**“Administration and Governing Body (proposed §486.324 ):”**

CMS's attention to this area in the proposed rule, particularly regarding the recognition of potential conflict of interest issues, has CTDN's support regarding the incorporation of consistency between PHS Act requirements and the rule.

There are several potential downsides, however, inherent in the approach that CMS has taken with the proposed rule that will offset any advantages gained by placing all PHS board positions on a non-governing advisory board. These include:

- OPOs having only one board (including CTDN), which contains PHS positions, have successfully dealt with the conflict of interest issues. The proposed rule would force several OPOs to revert to multiple boards unnecessarily.
- Advisory boards can be disengaged and ineffectual. The OPO needs constructive input from the PHS type positions.
- Recruiting effective and interested board members for positions on the advisory board will be much more difficult if no governing authority is attached to the positions.

CMS cites conflicts of interest problems between OPOs and their transplant hospital representatives as justification for prohibiting cross membership. We believe, however, that these potential conflicts can be managed through enhanced conflict of interest requirements. Prohibiting cross representation between advisory and governing boards would not ensure the elimination of conflicts of interest. For example, under the proposed provision, there is no limitation on transplant center representation on governing boards so governing boards could theoretically be entirely composed of transplant center representatives.

Another troubling issue is that advisory boards under the proposed regulations would have reduced influence, which we believe would likely result in disengagement and apathy. OPOs need meaningful input and participation from these members.

CTDN supports the position that an OPO should continue to be permitted to have one 'fiduciary' governing Board and/or one fiduciary governing Board with one or more advisory boards/bodies. Cross representation between the advisory Board and governing board should be allowed. Therefore, CTDN supports a recommendation that CMS allow OPOs to choose to have one board with cross representation between the advisory board and the

governing board or separate advisory and governing boards. In either case, transplant center representation on the governing board should be limited to less than 50 percent and there should be a strong conflict of interest policy in place.

CTDN opposes any requirement to have one tissue bank on the Advisory Board as the representative of all tissue bank(s) within the donation service area. If the OPO is offering competitive tissue recovery or banking services, it is inappropriate to put a competitor on its board. If the OPO is not offering such services, then it is likely using a tissue bank or processor as a vendor. In our view, it would be just as inappropriate to place a major vendor on the board because the conflict would be too pervasive. Additionally, vendor relationships can change quickly, which could leave an ex-vendor on the board as a director.

Given the above comments, we would support a proposal containing the following wording for the final rule regarding the administration and governing body provisions:

“(a) An OPO must have at least one board that serves as a governing body with full legal authority and responsibility for the management of and provision of all OPO services and must develop and oversee implementation of policies and procedures considered necessary for the effective administration of the OPO, including fiscal operation, the OPO’s quality assessment and performance improvement (QAPI) program, and services furnished under contract or arrangement, including agreements for these services. The governing body must appoint an individual to be responsible for the day-to-day operation of the OPO.

(b) An OPO must meet the requirements stipulated in Section 371 (b) (1) (G) of the PHS Act (42 U.S.C. 273 (b) (1) (G)).

(c) An OPO may choose to meet the stipulations in paragraph (a) and (b) by having one board which has the governing authority and which also has the representatives listed in paragraph (b) or it may choose to have an advisory board separate from the governing board with the positions listed in (b). If an OPO chooses the former option, the individuals listed in (b) may serve as directors or as non-director committee members, but in either event, it must have clear and strict policies and procedures for identifying and addressing conflicts of interest.

(d) Whether an OPO elects to have a single integrated governing board (e.g. one single governing board with the individuals enumerated in (b) above integrated thereon), or a separate governing board with one or more advisory boards, the governing board (with the assistance of individuals identified in (b)) is ultimately responsible for considering and adopting policies related to:

- (1) Procurement of organs.
- (2) Effective agreements to identify potential organ donors with a substantial majority of hospitals in its service area that have facilities for organ donation.
- (3) Systematic efforts, including professional education, to acquire all useable organs from potential donors.
- (4) Arrangements for the acquisition and preservation of donated organs and provision of quality standards for the acquisition of organs that are consistent with the standards adopted by the OPTN, including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome.
- (5) Appropriate tissue typing of organs
- (6) A system for allocation of organs among transplant patients that is consistent with the rules and requirements of the OPTN, as defined in 486.320 of this part.
- (7) Transportation of organs to transplant hospitals.
- (8) Coordination of activities with transplant hospitals in the OPO's service area.
- (9) Participation in the OPTN
- (10) Arrangements to cooperate with tissue banks for the retrieval, processing preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissue are obtained from potential donors if the OPO has a tissue recovery operation.
- (11) Annual evaluation of the effectiveness of the OPO in acquiring organs.
- (12) Assistance to hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

(e) An OPO with a separate advisory board as described in paragraph (c) of this section has no authority over any other activity of the OPO and may not serve as the OPO's governing body or board of directors. The separate advisory board will function in accordance with paragraph (d) of this section.

(f) An OPO with one governing board which includes the PHS Act positions listed in (b) of this section must have by-laws and/or policies addressing conflicts of interest of and among governing and/or advisory board members. This policy must include conflict of interest disclosure statements and shall be consistent with both state corporate law and Internal Revenue Service (IRS) requirements and practices.

(g) The OPO must have bylaws for each of its board(s) that address potential conflicts of interest, length of terms, and criteria for selecting and removing members."

**"Human Resources (proposed §486.326):"**

CTDN is concerned about the cost implications and highly prescriptive nature of the proposed human resource standards. The detailed requirements

specified by CMS are too prescriptive to allow for staffing arrangements best suiting their needs.

CTDN supports recommends that CMS incorporate in the process measurements a requirement that each OPO have a human resources plan and policy in place and that practices be expected to conform to policy. The plan and policy should address such areas as staff adequacy, education and training, supervision, and performance assessment.

With regard to the rule's proposals regarding medical directors, CTDN recommends that OPO Medical Director(s) be physicians with expertise and practice in the specialty of organ donor intensive care medical management and/or the specialty of organ transplantation. The Medical Director(s) should provide medical consultation on the practice of donor evaluation and management as needed by OPO procurement staff on specific cases. The OPO Medical Director(s) should also guide the development of donor management policies. Organ offers and placement should be made by OPO staff in accordance with UNOS allocation policies. The determination of donor suitability should remain the decision of the transplant surgeon and/or physician responsible for listed patients.

The proposed rule adds a new requirement for OPOs regarding the qualifications of their recovery personnel.

CTDN supports the recommendation that OPOs, working with transplant programs within their service area, should have a process to ensure and document that their own surgical recovery teams have appropriate qualifications (e.g. submission of medical education and licensure for physicians). CTDN recommends that surgical recovery teams currently provided recovery privileges by one OPO would be reciprocally granted recovery privileges by all other OPOs; and in this regard, "surgical recovery team" is not restricted to physicians.

Respectfully Submitted,

Eugene W.  
Osborne

Digitally signed by Eugene W. Osborne  
DN: CN = Eugene W. Osborne, C = US, O  
= CA Transplant Donor Network, OU =  
Acting CEO  
Date: 2005.06.03 15:52:14 -0700

Eugene Osborne  
Acting Chief Executive Officer  
California Transplant Donor Network

**CMS-3064-P-33      Organ Procurement Organization Conditions for Coverage**

**Submitter :** Dr. Michael Moritz

**Date & Time:** 06/06/2005

**Organization :** Gift of Life Donor Program

**Category :** Organ Procurement Organization

**Issue Areas/Comments**

**GENERAL**

GENERAL

see attachment

CMS-3064-P-33-Attach-1.DOC

Attachment #33

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 member of the Gift of Life Donor Program Board of Directors and a transplant surgeon at Hahnemann University Hospital, Philadelphia PA, 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 that address and require organizations to mediate conflict of interest issues. Added to the existing laws, corporate compliance programs recommended to non-profit organizations also impose standards to protect against conflicts of interest which might adversely impact fiduciary decision-making.

In 1999, the Gift of Life Donor Program restructured its Board of Directors. This was the result of a multi-year process undertaken to expand the Board beyond transplant surgeons and centers, and ensure that all constituencies served by the organization were represented on the Board, akin to the Board of the OPTN (presently UNOS). The Board now has representation that includes transplant centers, donor hospitals, non-transplant health professionals, donor family members, recipients, clergy, minorities, and others. The composition of the board is designed to protect against "insider" and "self" interests.

This broad and balanced board membership allows for a meaningful and thoughtful discussion of the issues that an OPO faces by those who are familiar with the issues. Prohibiting this type of dialogue by segregating advisory and administrative functions 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. Decision-making will be delayed by the awkwardness of communications between the two bodies. Identifying persons willing to serve in the separate board capacities may be difficult, especially in smaller OPOs. Also, there are many other health and public service organizations dealing with critical public health issues which are permitted to provide governance under a single administrative Board with the guidance provided by state and federal laws applicable to non-profits and tax exempt organizations and successfully manage conflict of interest issues. Potential conflicts of interest among board members are typical of non-profit organizations, not only OPOs, and the proposed governance rules are self-defeating in terms of creating effective, efficient, productive OPOs.

**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 should be limited to 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 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 Board 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 exclude a potential donor, impedes the role of the transplant surgeon/physician and interferes with the transplant surgeon's/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, as only that individual can judge his/her patient's needs.

Thank you for your consideration,

Michael J. Moritz, MD  
Member of the Board, Gift of Life Donor Program  
Chief, Abdominal Transplantation, Hahnemann University Hospital  
Professor of Surgery, Drexel University College of Medicine

**CMS-3064-P-34      Organ Procurement Organization Conditions for Coverage****Submitter :** Ms. Danielle Cornell**Date & Time:** 06/06/2005**Organization :** LifeQuest Organ Recovery Services**Category :** Organ Procurement Organization**Issue Areas/Comments****Issue**

Re-certification and competition

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 Executive Director of LifeQuest, a hospital-based Organ Procurement Organization, 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 may severely undermine a critical 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. LifeQuest is part of this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. The model aims at implementing best practices for increasing the rates of organ donation through the sharing of data and information.

The Organ Donation Breakthrough Collaborative has achieved extraordinary results in the past 12-18 months. Nationally, the number of deceased organ donors has increased by nearly 11%. In fact, this collaborative model has been widely studied and cited by the greater healthcare quality improvement community for its effectiveness.

Under the proposed rule every OPO would be competing every four years to continue to serve its area whether or not the incumbent OPO has been de-certified. This competition-based model could disrupt the sharing among OPOs of best practices that have been developed and fostered through the Organ Donation Breakthrough Collaborative.

As LifeQuest has worked together with our participating hospitals over the past year and a half we have seen some phenomenal things. Four of our

hospitals have achieved the 75% conversion rate stretch goal that former HHS Secretary Tommy Thompson set two years ago. All four hospitals were proud to send their CEOs on May 19 to receive the HHS Medal of Honor for achieving such a high donation rate during a 12-month period.

This success, which has saved lives, has been due to the hard work of hospitals and OPOs together as a team. It can also be attributed to the exceptional sharing of information across OPOs and hospitals to understand what is working to increase conversion rates in different parts of the country. Sharing best practices is the hallmark of this program.

LifeQuest has worked diligently with the local hospitals to build relationships and bridge the gaps that existed in the past.

The Collaborative Team has used strategies and change concepts to create opportunities in the donation process:

1. Developed clinical trigger criteria ? making referrals more timely and consistent
2. Increased timely death record reviews so that missed opportunities could be addressed
3. Identified high level hospital ?champions? to make organ donation a priority for our hospital

As an OPO 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,

Danielle Cornell

**CMS-3064-P-35      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

## 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.

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  
Executive Director