

CMS-3064-P-48 Organ Procurement Organization Conditions for Coverage

Submitter : Dr. Jim Boyer

Date & Time: 06/06/2005

Organization : American Liver Foundation

Category : Organ Procurement Organization

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3064-P-48-Attach-1.DOC

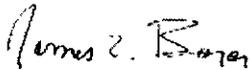
procurement from referral, to conversion of consent, to donor evaluation, donor management, organ recovery (of each organ type transplanted), organ placement, preservation, and organ function at transplant should have a Quality Improvement program accompanying it and each of the tasks should be weighted to the end result of a functioning transplant.

OPO Role in Living Donation

Unless they are in the top 1/3 of performing OPOs in the US they should not be required to play a role in living donation at the present time. Adding a responsibility for living donation could dilute the OPO's attention to increasing deceased donation and divert resources that should more appropriately be directed to increasing deceased donation. Living donation should be arranged between transplant centers and potential donors, with the assistance of living donor advocate(s) or a living donor advocate team.

On behalf of the members of the American Liver Foundation, I wish to thank CMS for its efforts to increase the supply of organs available for transplantation and for the opportunity to respond to the Proposed Rules for Conditions of Coverage for Organ Procurement Organizations.

Sincerely,



James L. Boyer
Chairman of the Board

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CMS-3064-P-49 Organ Procurement Organization Conditions for Coverage

Submitter : Ms. Martha Anderson

Date & Time: 06/06/2005

Organization : Musculoskeletal Transplant Foundation

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3064-P-49-Attach-1.DOC

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June 6, 2005

Attachment #49
CMS-3064-P
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

Dear CMS Officials:

We are pleased to provide our response to the proposed CMS rule (CMS-3064-P) regarding Medicare and Medicaid Programs: Conditions for Coverage for Organ Procurement Organizations (OPOs). The Musculoskeletal Transplant Foundation (MTF) is the largest full service tissue bank in the United States and thus works closely with its many recovery partners, including 35 OPOs. These proposed changes by CMS would have a direct impact on tissue donation in this country. We believe our comments relate well to our industry and the OPO area as well.

Re-Certification and competition process (proposed 486.303, 486.312, 486.316)

The current recertification process has continued to allow OPOs performing at historically low levels to continue to operate. In many areas this has led to increased waiting times for local transplant recipients. We believe that the proposal to allow unrestricted competition for all service areas every four years will result in the diversion of OPO attention and resources away from their primary mission of organ recovery to one of protecting and defending their service area as the recertification date comes closer. OPOs have had several recertification cycles with little increase in donation rates. Only through programs such as the Collaborative on Organ Donation have we seen increases in donation rates. Anything that causes a departure from that successful program should be reconsidered.

We support the Association of Organ Procurement Organization's (AOPO) comments regarding the Transition Period and Recertification of OPOs.

Non-Profit Organization

June 6, 2005

Not all OPOs meeting the performance standards should be allowed to compete for open service areas. There are OPOs which are just themselves starting to see increases in their local donation rates after many years of stagnancy. Some of these OPOs are in service areas that contain large organ transplant programs in need of increased renal and extra renal organs. Increasing the OPO service area may be driven by the local transplant center needs and not in the best interest of the OPO. These OPOs should be required to continue to concentrate on their own local efforts and not be distracted trying to increase the size of their service area.

CMS must be mindful many OPOs have expanded their services to include tissue and in some cases eye recovery. These services have become vital to the health care of the local populations that they serve. An OPO that becomes decertified could have a ripple effect on the tissue and eye recovery efforts impacting thousands of patients a year. OPOs that do not provide tissue services would still be impacted as all OPOs are required to receive all hospital death referrals and in many cases provide educational efforts as well as donor related activities such as medical social screening and evaluations for local tissue and eye banks.

Relationships with tissue banks (486.322)

MTF supports the efforts of CMS to foster continued cooperation between tissue banks and OPOs. We applaud CMS for continuing to expect cooperation and collaboration. We agree with AOPO's position that OPOs should have the ability to elect with which tissue banks or tissue processors they choose to affiliate, and that there are some instances in which an OPO may choose, for very good reasons, not to affiliate with a particular tissue bank. However, we do not agree that an OPO need not pass on a tissue referral to a hospital's designated tissue bank if the OPO is involved in the recovery of an organ. It is clearly the obligation of the OPO, as the "gatekeeper" of donor referrals, to maximize all opportunities for donation. It would helpful if CMS could also provide guidance to OPOs, tissue banks and hospitals in cases of Medical Examiner/Coroner cases – in many instances, an ME or Coroner may have an affiliation with a tissue bank and may refuse to honor a hospital's agreement with a different tissue bank (or the OPO) for tissue donation, choosing, rather to "assert jurisdiction" over the body and pass the referral to its affiliated tissue bank, one not chosen by the hospital to serve its patients and families.

Requesting Consent (proposed 486.342)

All organizations involved in the donation process want to see families provided with information on all suitable organs and tissues that can be recovered to help others. We do not object to the new requirements in the rule, as they generally conform to current practice in the industry.

Administration and governing body (proposed 486.324)

We question the need for any additional oversight within the OPO such as assuring the establishment of an Advisory Board. Most OPO boards have the authority being proposed by CMS. The addition of such an Advisory Board seems to be a duplication of

efforts with expenses that could be better spent on organ recovery activities. Conflicts of interest can be handled within the current board structure of OPOs without the need for a separate Administrative Board. MTF does support the CMS proposal for including donor families, transplant recipients, coroners and medical examiners as well as others representing the community on the Boards of all OPOs.

The requirement to have unaffiliated tissue banks on the OPO board needs more clarification. The definition of a tissue bank must be developed for the OPO industry. There are many types of tissue banks. Some recover donated tissues and send them to other companies for processing and distribution to hospitals. While others recover and do their own processing and distribution. Additionally, some processors are tissue specific. Two examples are LifeCell that processes donor skin tissue and CryoLife that processes and distributes heart valves. MTF provides musculoskeletal tissues, cardiovascular tissues as well as skin to hospitals and patients throughout the United States. OPOs may work with several specialty processors and CMS needs to more clearly define the type of tissue bank facility they are proposing to include within an OPO.

MTF does not support the proposal to allow non-affiliated tissue banks representation on OPO boards. Our definition in this case is a bank that provides all are part of the tissue recovery, processing or distribution services. The tissue industry is different than organ recovery in many ways. There is an inherent level of competitiveness when there are multiple organizations providing the same service. Allowing a non affiliated tissue bank to have direct access to information and in some cases financial information is an unfair business practice that would not be tolerated in any other organization or industry. We recognize there must be a certain level of cooperation between an OPO and an unaffiliated tissue bank. We believe this cooperation can be achieved through meetings and other means other than representation on the OPO Board. At the same time, few if any OPOs are granted a seat on an unaffiliated tissue bank board thus showing the unfairness of the proposal.

COMMENTS ON RELATED ISSUES

Reporting of data

The proposal to have hospital specific donation related information published yearly is one that is current practice for many OPOs. The usual vehicle has been to publish this information in newsletters showing specific donation rates by hospital and organ type as well as donors. While many hospitals have shown interest in seeing other hospital levels of participation, we have not seen any increase in donation activities because of them.

Compliance by hospitals to the CoP's should be part of the routine JCAHO and state regulatory body documentation requested during site visits. Hospitals have had opportunities to increase their level of participation through the Collaborative on Donation as well as through partnering efforts with OPOs. Hospital compliance needs to

June 6, 2005

be scrutinized and when deficient corrective actions should be required and monitored by credentialing and certification organizations. This would also allow these agencies to confirm OPO reported data through death record review summaries.

Regulatory Impact

The proposed rule establishes a broad variety of additional positions for OPO personnel including: Administrative Board, Full-time Medical Director, Procurement Coordinators, QAPI Staff and administrative responsibilities including the revision of by-laws, negotiation of additional hospital agreements and transplant center agreements and death record reviews. CMS' estimates of these costs appear to be grossly underestimated. If the Federal Government is willing to pay the full cost of these changes, without passing them onto OPOs (and ultimately patients who may not benefit from such changes), we would not be opposed. However, it is standard practice for an OPO to allocate a significant portion of all overhead onto their tissue recovery costs. Tissue banks and processors are expected to pay these rapidly increasing costs without receiving any attendant increase in tissue donation; indeed, many OPO's tissue donation activity has decreased in the past year, at a time when organ donation rates are rapidly increasing. Whether this decrease can be attributed to anything specific is unclear; however, it is evident that dramatically increased costs passed onto tissue donation have not been associated with an improvement in tissue recovery rates. We strongly urge CMS to re-evaluate and re-consider the impact of such requirements not only on organ procurement and transplant costs, but also on the costs of tissue procurement and transplant (which are not directly reimbursable to tissue banks).

MTF thanks CMS for the opportunity to reply to these proposed regulations.

Sincerely,



Martha Anderson
Executive Vice President, Donor Services

cc: Bruce Stroeve, President & CEO
Tom Byersdorf, Chairman, Donation Board of Trustees

CMS-3064-P-50 Organ Procurement Organization Conditions for Coverage

Submitter : Mr. Howard Nathan

Date & Time: 06/06/2005

Organization : Gift of Life Donor Program

Category : Organ Procurement Organization

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3064-P-50-Attach-1.DOC

Attachment #50
June 6, 2005

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

RE: CMS-3064-P

Dear CMS Officials:

These comments addressing the proposed CMS rule (CMS-3064-P) regarding Medicare and Medicaid Programs: Conditions for Coverage for Organ Procurement Organizations (OPOs) are submitted on behalf of Gift of Life Donor Program ("Gift of Life"), the federally designated non-profit organ procurement organization serving the Eastern half of Pennsylvania, southern New Jersey and the State of Delaware. Founded in 1974, Gift of Life is one of the oldest of the federally designated organ procurement organizations ("OPOs"), as well as one of the most active.

In calendar year 2004, and for the eighth consecutive year, Gift of Life coordinated more organ donations and transplants than any other OPO in the U.S. In 2004 alone, 1,131 people received transplants through gifts of life from 387 organ donors coordinated by Gift of Life (a 13% increase since 2003) as compared to 618 transplants just a decade ago, making Gift of Life the most active organ procurement organization in the United States. During the past decade, Gift of Life has seen an 86% increase in donations.

Gift of Life attributes its continued success to its organizational structure, its internal practices and procedures, its partnerships with health care professionals in its region, and its public education initiatives. Gift of Life has been a leader in the field, as well as a collaborating partner nationally and locally. Gift of Life staff are regular presenters at national forums on initiatives to increase donation and transplantation. Most recently, Gift of Life was selected as one of six sites for the upcoming Transplantation Collaborative which will focus on strategies to increase organ transplantation per donor.

Gift of Life, like the rest of the donation and transplantation community applauds the efforts by CMS to institute measures and performance standards that will increase donation. Gift of Life believes, based upon its own experience the past 30 years, as well as its most recent successes the past 10 years that changes in the conditions of participation for OPOs are important. Gift of Life is hopeful that the regulations, when finally adopted, will be in a form and of content that will have the same positive impact on donation that the changes in conditions of participation for hospitals did in 1998. Those regulations, which among other items incorporated "routine referral" of every hospital death to the servicing OPO, were based in large part on the OPO experience in Pennsylvania, including Gift of Life's experience.

Gift of Life notes that CMS has invited comments and feedback on the proposed regulations in a variety of forums. While Gift of Life participates in other organizations which may be

submitting comments, these comments are the only ones which are exclusively representative of Gift of Life. Gift of Life does refer throughout this document to the comments submitted by the Association of Organ Procurement Organizations ("AOPO") as the "AOPO Comments".

Finally, Gift of Life believes that in reviewing all of the public comments, CMS must be mindful that OPOs are not hospitals, nursing homes or other "traditional" licensed health care facilities. OPOs are "coordinators" of service that in many instances actually support the delivery of service in and by third party institutions. Therefore, many of the standards which prescribe behavior/staffing levels and exclusive responsibility which may be well suited for health care facilities may not have the same application in the OPO setting. Likewise, while hospitals and nursing homes deal with urgent care situations, they do not operate under the same exigent circumstances as OPOs. OPOs must of course be accountable for their actions, but at the same time OPOs must have flexibility in how they operate. The proper balance must be struck. As noted below in certain instances, as well as noted in the AOPO comments, Gift of Life believes the proposed rule is too prescriptive and if adopted as proposed may adversely impact advancement in donation.

Our comments on the specific standards or areas for comment follow:

Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations

Definitions (proposed § 486.302)

Gift of Life supports the focused attention on Adverse Event but similar to AOPO believes the definition requires clarification. Moreover, Gift of Life notes that the concept of "not the same blood type" should be replaced with the phrase "incompatible blood type"; that the concept of "transmission of a disease" should refer to a disease that would be physically harmful to the recipient and wasn't anticipated at the time of donation. Gift of Life also questions the practicability of defining an "avoidable" loss of a donor.

Gift of Life supports the other AOPO Comments regarding the definitions.

Re-certification and De-certification

De-certification (proposed § 486.312)

Gift of Life supports the AOPO Comments regarding de-certification. Like AOPO, Gift of Life posits that the rule as proposed has due process limitations. Decertification is a major action having significant ramifications. Decertification as a process must be consistently implemented whether decertification is due to "non-renewal" or "involuntarily" action. The factors considered and standards applied should be consistent in both cases and should include the more comprehensive factors addressed in an involuntary decertification.

Of equal import is the effect of a decertification based upon non-renewal on the appeals process. An OPO should be able to provide information during such an appeal regarding

process performance measures and other requirements that may relate to its service area. Moreover a basic tenant of a review process is that the appeal is limited to the issues addressed in the underlying decision. This is not the case in the appeal process set forth in the proposed rule. Instead a CMS hearing officer can apparently consider information in addition to that relied upon by the initial decision-maker. This is de facto inequitable and is tainted as an improper commingling of executive and adjudicative functions. In what other arena does the "hearing officer" not only review an agency's initial decision but also "make" an independent decision based upon evidence being evaluated for the first time?

In order to insert due process and to promote optimal performance, Gift of Life supports the AOPO recommendations that

- 1) the de-certification criteria applied to non-renewals include the process performance and other criteria applicable to involuntary terminations and in fact be a "process" rather than self-executing;
- 2) all information be presented to a knowledgeable CMS program officer before the time of the initial decision rather than at a hearing officer level;
- 3) the CMS program officer make the initial de-certification/non renewal decision BUT only after the OPO has had the opportunity to provide input well in advance of the decision; and
- 4) any decision be in writing with a clear and detailed statement as to the reasons for the decision.

Appeals (proposed § 486.314)

As noted in the AOPO Comments, including the concept of a "corrective action plan" into the possible outcomes of the appeals process would provide flexibility into the process. In essence it provides CMS with an "intermediate sanction" to achieve its stated objectives of enhancing OPO performance. In other regulatory environments, federal agencies have opted to add a less extreme remedy than de-certification; consider the IRS intermediate sanctions providing the IRS with an intermediate remedy that is more consistent with achieving its goals than stripping an organization of its exempt status for every infraction where the "remedy" might be disproportionate to the area that needs redressing. The corrective action plan would allow for a focused and directed opportunity for remediation and if not successful, would result in de-certification.

The most problematic aspect of the appeals section of the proposed rule is the elimination of a true appeals process. Gift of Life agrees with AOPO that the elimination of the current § 498 appeals is improper. The § 498 appeals process is a well-defined process. The proposed rule provides no similar definition as to what real process would be available. Imagine, introducing a set of regulations that impose many new and onerous standards to an OPO but no real relief in the event that CMS determines an OPO is misinterpreting the standards or is non-compliant.

The legislative history does contemplate an appeals process that will be fair and equitable and decisions based upon substantive and procedural grounds. The proposed rule revisions don't

guarantee such relief. In fact, the proposed rule doesn't specify what the process will entail, the timing of the process, etc. The AOPO Comments articulate these concerns well.

Like AOPO, Gift of Life notes that OPOs are in fact "suppliers" of service under the Medicare Program and that as "suppliers" are to receive full due process rights. For CMS to impose significant new administrative and other standards because OPOs play such an important role in donation and transplantation but to then diminish their appeal rights because of their somehow "reduced" status is disingenuous. Gift of Life supports the reintroduction of the § 498 process, as well as the other AOPO specific recommendations to ensure the process is consistent with Congressional intent and the law.

Organ Procurement Organization Outcome Requirements Outcome Measure (proposed § 486.318)

The CMS proposed rule focuses exclusively on conversion rates as its outcome metric. Like AOPO, Gift of Life urges 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 in the AOPO 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 significant 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.

Gift of Life agrees 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 Gift of Life encourages), 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, Gift of Life recommends 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. Gift of Life also recognizes that the current OPTN database (which does not take into account missed referrals) requires additional validation in order to accurately predict donor potential. Gift of Life encourages such validation of the information with the support of third parties such as the SRTR. Validation of the SRTR data and the current limitations of such data are addressed in the AOPO Comments.

In order to fulfill the Congressional intent that there be multiple performance measures, Gift of Life, like AOPO urges CMS to adopt an organs transplanted per donor ratio as a measure. However, in order to establish valid measures, this ratio must 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 sub-goals for Standard Criteria Donors, Donation after Cardiac Death, Expanded Criteria Donors, but also donors that may have positive serological test results e.g. hepatitis B core Ab, HCV etc. or may otherwise be at risk for transmitting disease, e.g. prior history of cancer or a medical social history indicating high risk factors as per the CDC guidelines.** It has been Gift of Life's experience that a significant percentage of donors which might otherwise be characterized as “standard” have the above donor conditions which greatly diminishes the likelihood that more than 3 organs per donor would be transplanted. Unless these variations are taken into account through the establishment of sub-goals for these different groups, an OPO's performance cannot be evaluated for improvement or for comparison with other OPOs.

Gift of Life notes that there is no clear direction in the proposed rule regarding the planned implementation of any rules adopted in final. Gift of Life urges CMS to apply the rules prospectively once they have been finalized and there has been an ample opportunity to train staff on the rules, institute some of the standards being proposed for the first time and actually implement the final rules. To apply the final rule retrospectively would violate the OPOs' due process and would not foster the collaborative environment CMS is seeking to promote.

Organ Procurement Organization Process Performance Measures

Generally these measures highlight areas that OPOs should focus on, however the manner in which CMS is prescribing organizational activity is overly restrictive. OPOs must have the flexibility to respond to the most immediate changes in the medical community, some of which will be dictated by external organizations. While CMS is providing some flexibility in the area of Quality Assessment and Performance Improvement (QAPI), it does not take the same approach in the areas of staffing, donor management, and designated requestors. Particularly troubling is the proposed role of the medical director as discussed more fully below.

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

The proposed rule requires that an OPO must be a member of the OPTN and abide by the rules and requirements of the OPTN, as approved by the Secretary. Besides the proposed addition of the phrase "participate in the OPTN" as identified in the AOPO Comments, Gift of Life would request clarification on CMS' view of the interplay between state laws that are being developed impacting organ allocation, and the allocation standards of the OPTN. For example, it is Gift of Life's understanding that Illinois law has been revised to provide that organs donated from HIV infected persons may be used for transplant into HIV infected recipients. This would appear contrary to the current OPTN allocation standards. How will CMS interpret an OPO's compliance or non-compliance with state laws that are contrary to OPTN standards, some of which have never been approved by the Secretary?

Condition: Relationships with hospitals, critical access hospitals, and tissue banks (proposed § 486.322)

Gift of Life supports the AOPO Comments addressing the hospital relationships OPOs should be required to establish. Gift of Life emphasizes as well that OPOs should not be required to have an arrangement with every tissue bank. The fact is that hospitals are free to select the providers of service at that institution. It is the hospital that should be required to have an arrangement or agreement with providers of service at that hospital. There is no basis by which CMS should mandate that an OPO have an "arrangement to cooperate" with a non-CMS regulated body. An OPO may be under an obligation to refer a patient death to a tissue bank without being required to have a more fulsome "arrangement" that begins to sound like a contractual relationship.

This section of the proposed rule also mandates the offering of designated requestor training on at least an annual basis. This conflicts with the current hospital conditions of participation which mandates training only if a hospital requests it and also runs contrary to demonstrated best practices which partners the trained OPO representative with the hospital staff. OPOs should be required to provide training if it is requested. Note that the term "effective requestor" is utilized in current practice.

Condition: 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 on whose board they are serving. Federal law governing tax- exempt organizations also imposes standards and safeguards, some of which have been recently highlighted in the expanded enforcement authority provided under the Intermediate Sanctions. There are already standards imposed that address and require organizations to mediate conflict of interest issues. Added to the existing laws, the corporate compliance programs recommended to organizations also impose standards to protect against conflicts of interest which might adversely impact fiduciary decision-making.

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

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

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

Therefore, Gift of Life strongly urges 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. Gift of Life does recommend that in either case the transplant surgeon/transplant physician representation on the governing board be no more than 50% and there should be strong conflict of interest policies in place.

Additionally, Gift of Life notes 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. Gift of Life strongly opposes this proposal in that it is inconsistent with state and federal standards regarding governance, as well as it is inappropriate to charge one individual with all of these functions without oversight. Certainly, OPOs should continue to have the ability to have a chief executive officer who is charged with day-to-day management of the organization but who remains subject to the Board's oversight. Ultimately, a governing body such as a board of directors should be responsible and have full legal authority and responsibility for the organization.

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

Gift of Life supports the AOPO Comments with regard to the adverse impact associated with a movement toward regulating the actual numbers of staff and the assessment of staff "markers". This does not take into account that many OPOs adopt different staffing models that have proven successful.

Of particular concern is the proposed standard regarding a "medical director". The proposed rule's requirement that an OPO's medical director be responsible for ensuring, among other items, that every potential donor is thoroughly assessed for medical suitability for organ donation and clinically managed to optimize organ viability and function may have the effect of inappropriately interfering with an individual transplant surgeon's judgment and area of expertise. Within the standard of acceptable and common current medical practice, there is certainly a range of practices. Not every surgeon will view a potential donor similarly, that is why each surgeon has the ability under the current allocation system to accept or reject a particular organ for a particular patient. Mandating that a medical director make the suitability decision, including a decision to rule out, impedes the role of the attending surgeon/physician and potentially interferes with the surgeon's/attending physician's decision as to whether to accept a particular organ for transplant into a particular patient.

Moreover, mandating that a medical director participate in every single case may also add time to the already time sensitive process. Ultimately, requiring a medical director to make every suitability decision may result in fewer patients transplanted, not more. The appropriate role for a medical director is to be available to provide consultation on donor evaluation and management as needed by the OPO staff on specific cases, not to evaluate every case. The role between the patient awaiting transplant and his or her treating physician/surgeon must be preserved and honored.

Condition: Reporting of Data (proposed **§ 486.328**)

As noted above in connection with performance outcomes, Gift of Life believes that death record reviews are an essential element of identifying organ donor potential. However, until such time as a uniform death record review process has been implemented, Gift of Life urges that such data not be included in the potential donor denominator referenced in this section.

Condition: Requesting consent (proposed **§ 486.342**)

Gift of Life is a strong proponent of disclosure and provision of information to families. Consent to donation is an issue which has historically been within the province of state laws and the respective states' uniform anatomical gift acts. Given that such laws have been enacted by each and every state, it would appear that this section may be unnecessary. However, if CMS is to regulate the contents of consent, it should be noted that the phrase "all" possible uses for the donated organs or tissues may be unreasonable. It may be more appropriate to eliminate the word "all". Each OPO presumably provides information regarding the potential use of the gift, including research. Does every research project have to be disclosed? Does every type of therapeutic surgical procedure for which donated gifts can be used have to be disclosed to a family? This would seem overly burdensome and not what a "reasonable" person would wish to hear—the typical standard under state law.

Further, proactively describing the applicable process for "filing" a complaint would appear to be a departure from standard practice and presumes a problem with the donation. Certainly, the draft rule already mandates that contact information is to be provided so that if there are questions they can be addressed. This is appropriate. There is no reason to predispose a family to a problematic approach.

Condition: Donor evaluation and management, and organ placement and recovery (proposed **§ 486.344**)

As noted above, Gift of Life agrees with the AOPO comments that the proposed rule regarding the medical director does not reflect an approach that will maximize donation and transplantation. It would be improper to have one person be the arbitrator of what organs should or should not be transplanted- that is a medical decision within the discretion of an individual transplant surgeon and/or transplant physician. CMS is going too far in positioning the OPO as a medical decision maker when such decisions should be that of a recipient and his/her treating physician. The Medical Director should be a person under arrangement with an OPO (and need not be a full time employed position) that is available to oversee/participate in the development of policy and is available for case specific questions. If the medical director role would proceed as identified by CMS, it would be an anomaly. In no other aspect of the medical community does a person other than the TREATING physician have control over medical decisions affecting the patient.

Condition: Organ preparation and transport (proposed **§ 486.344**)

Gift of Life supports AOPO Comments on this section. Gift of Life notes with concern that CMS appears in this section, as well as throughout the proposed rule, to hold OPOs accountable for all aspects of the donation and transplantation process. The OPOs are unique from other Medicare participants in that they coordinate and facilitate much of the process, but ultimately the decision as to accept or reject any particular organ for transplant is the responsibility of the transplanting surgeon/transplanting physician after dialogue with his/her patient.

Condition: Quality assessment and performance improvements (QAPI) (proposed § 486.348)

Gift of Life echoes the comments of AOPO with regard to the need for uniform death record reviews. In order for those reviews to be comparative, there should be uniformity as to which hospitals undergo review as well as the frequency of the review and the definition of "eligible" or potential donor.

Gift of Life also believes that before a full adverse event reporting procedure can be implemented it is essential that the questions and concerns raised in the AOPO Comments be addressed.

Other items:

OPO Role in Living Donation- Gift of Life, as well as many of the other OPOs, are recognized within their respective communities as being the source of information on donation, whether it is deceased donation or living donation. Gift of Life receives numerous calls from persons with questions regarding living donation and its volunteer groups including a strong contingent of living donors and living recipients. While Gift of Life does not believe that living donation can be incorporated in a meaningful manner into the performance standards at this time, it does believe that CMS should encourage OPOs to serve in a coordinating role, particularly for unrelated living donors.

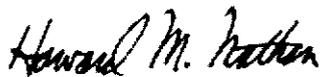
Public Education- Gift of Life has a community relations department that has 8 full time personnel supporting it in addition to hundreds of volunteers. The department supports more than 600 public education events each year, in addition to newsletters, advertising and other public awareness and outreach programs. Gift of Life firmly believes that public outreach is an essential component to predisposing the public to saying yes to donation. It is currently evaluating the most effective means for public education and methods for measuring effectiveness of programs. Its partnering initiatives include important partnerships with the Commonwealth of Pennsylvania (Departments of Health and Transportation), the State of New Jersey (Departments of Health and Social Services and Transportation) and the State of Delaware (Departments of Health and Social Services and Transportation). More than 4.3 million Pennsylvanians have said yes to donation on their drivers' license and more than 50% Delawareans have said yes to donation on their drivers license. Information is in the processing of being made available from New Jersey.

Regulatory Impact

CMS has severely underestimated its assessment of the collection of information requirements and the regulatory impact of the proposed rule. The proposed rule, if enacted in its current form, would significantly change the organizational structure and dynamic of Gift of Life. The changes would flow from a restructuring of its governance down to the establishment of new protocols and reporting requirements. While some changes from the proposed rule are likely to enhance donation practice overall, all of the changes come with a cost. The impact on an urban based OPO would be significantly more than the average cost identified by CMS and AOPO. It is possible that the cost to Gift of Life alone might exceed \$600,000 as a result of complying with the standards as proposed. This figure does not take

into account the likely increase associated with insurance coverage as a result of CMS' drive to place the medical decision of whether to transplant an organ with the OPO and not the transplant centers. Nor does the proposed rule recognize that there is an already existing and on-going polarization between the standards CMS and the National Collaborative would have OPOs adopt and the actual reimbursement that the fiscal intermediary will pay. In the proposed rule, each "kidney" recovered, whether recovered en bloc or not, would count for purposes of the conversion calculation. The National Collaborative promotes the recovery and transplantation of every organ, every time. There is no reconciliation that this is not the "approach" or "count" that is utilized by the intermediary when making reimbursement decisions. As CMS pushes OPOs to perform at higher levels, there must be an understanding that reimbursement must be made available to support these initiatives.

Sincerely,

A handwritten signature in black ink that reads "Howard M. Nathan". The signature is written in a cursive, slightly slanted style.

Howard M. Nathan
President & CEO

CMS-3064-P-51 Organ Procurement Organization Conditions for Coverage

Submitter : Ms. Robyn Kaufman-Miller

Date & Time: 06/06/2005

Organization : Finger Lakes Donor Recovery Network

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3064-P-51-Attach-1.WPD

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

CMS-3064-P-52 Organ Procurement Organization Conditions for Coverage

Submitter : Ms. Louise Jacobbi

Date & Time: 06/06/2005

Organization : Organ Recovery Systems, Inc

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3064-P-52-Attach-1.TXT

CMS-3064-P-52-Attach-2.TXT

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

CMS-3064-P-53 Organ Procurement Organization Conditions for Coverage

Submitter : Mr. David Kravitz

Date & Time: 06/07/2005

Organization : Organ Recovery Systems

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3064-P-53-Attach-1.TXT

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

CMS-3064-P-54 Organ Procurement Organization Conditions for Coverage

Submitter : Dr. Stuart Weinstein

Date & Time: 06/07/2005

Organization : American Academy of Orthopaedic Surgeons

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3064-P-54-Attach-1.DOC

| Attachment #54

June 3, 2005

Mark B. McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS – 3064 – P
PO Box 8015
Baltimore, MD 21244-8015

Re: **CMS – 3064 – P**

Dear Dr. McClellan:

The American Academy of Orthopaedic Surgeons (AAOS/Academy), representing over 19,000 Board certified orthopaedic surgeons, welcomes the opportunity to comment on the proposed rule *Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations*, as published in the Federal Register on February 4, 2005.

Orthopaedic surgeons are frequent users of musculoskeletal tissues and tissue products. Tissues are, of course, donated at the same time and through the same consent process as are organs. The Academy, our surgeons, and our patients are exceptionally grateful for the altruistic tissue donations made by so many each year. We support donation protocols for organ procurement organizations (OPOs) that are informed, responsive to donor and donor families' needs, and enhance donation rates in order to maintain the nation's supply of organs and tissues.

The Academy wishes to bring to the attention of the CMS an issue that may have an unintended effect on the donation of tissues for implantation. We are concerned that without delineating the differences between a "for-profit" and "non-profit" entity, the consent process may not be fully informed, and donation rates may subsequently be affected. The AAOS notes that within the context of organ and tissue procurement, the public may be unaware of the benefits provided by both for-profit and non-profit associated entities.

The AAOS would like to impress upon the CMS that significant contributions are made by both non-profits and for-profits in the tissue safety field. Altruistic missions and the delivery of quality products are facets of both for-profits and non-profits. Both types of organizations contribute to the scientific body of knowledge, advancing safe processing

techniques through research and development. Society as a whole benefits from these mutual efforts.

There has been much lay press coverage over the past years that has prominently featured the negative aspects of OPOs and tissue processors. We believe that acknowledging the contributions of both for-profit and non-profit associated entities will facilitate a truly informed consent process.

It would be detrimental to the entire tissue supply, and more importantly, to our patients' health, if the availability of tissue for orthopaedic patients became compromised as a result of a lack of information or misperception regarding a distinction between for-profit and non-profit associated entities.

We thank you for this opportunity to express our concern, and we look forward to working with you on future initiatives.

Sincerely,

A handwritten signature in cursive script that reads "Stuart Weinstein". The signature is written in black ink and is positioned above the typed name.

Stuart L. Weinstein, MD
President