

Submitter : Mrs. Cassandra Smith-Fields
Organization : Children's Memorial Hospital
Category : Hospital

Date: 03/10/2005

Issue Areas/Comments

GENERAL

GENERAL

One of the proposed recommendations for the administration and governing body of the advisory board of the OPO is to include a transplant surgeon from each transplant hospital. I would recommend that you have this language read "a transplant physician from each unique UNOS transplant center within the OPO". If you have it read hospital, a single center may contain a number of hospitals. That center could then send multiple representatives to the board. I think your intention here is to limit the representation. Also, why does this have to be the transplant surgeon? Sometimes the more thoughtful voice for policy and procedure within an organization could be the medicine partner in transplantation. By requiring the transplant physician you avoid eliminating potentially good input.

Submitter : Barbara Brandess
Organization : Barbara Brandess
Category : Individual

Date: 03/11/2005

Issue Areas/Comments

GENERAL

GENERAL

Please See Attachment

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

Submitter : Ms. Catherine DeLair
Organization : University of Wisconsin Hospitals and Clinics
Category : Hospital

Date: 04/05/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3064-P-3-Attach-1.DOC

Attachment #3

(One original and two copies)

Electronically we can submit at <http://www.cms.hhs.gov/regulations/ecomments>

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

**Official Copy submitted
to DHHS Website on
INSERT DATE**

Dear Secretary Leavitt,

The University of Wisconsin Hospitals and Clinics Authority Organ Procurement Organization (UWHCA OPO) is pleased to have the opportunity to comment on the Secretary's proposed modifications to the "Conditions for Coverage for Organ Procurement Organizations; Proposed Rule". UWHCA OPO is one of the few hospital-based Organ Procurement Organizations (OPO) in the country having the highest conversion rate in the nation in 2003. The UWHCA OPO was recognized as a best practice site by Health Resources Services Administration (HRSA). Further, UWHCA OPO has participated in the HRSA Breakthrough Collaborative on Organ Donation and appreciates DHHS's efforts to memorialize some of the evidence-based practices into the Conditions for Coverage for Organ Procurement Organizations. The UWHCA OPO respectfully submits the following comments on the proposed rule for your consideration.

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§486.316 Recertification and Competition Process

UWHCA OPO appreciates the Secretary's desire to rectify differences in OPO performance and create competitive pressure to achieve higher donation rates. However, UWHCA OPO does not agree with the proposed standard to open competition to any OPO that meets re-certifying criteria to all OPO services areas for the following reasons: donation rates will not necessarily increase because a higher performing OPO assumes a service area, open competition will eliminate the collaborative environment created by the Breakthrough Collaborative, and open competition will divert resources and attention from the core mission of OPOs.

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First, the open competition model is based upon a premise that does not consider regional variation in donation service area cultures. UWHCA OPO is known for having a model of partnering with donor hospitals that has been recognized as a best practice within the collaborative, and is unique in the country. Many other hospitals and OPO teams disagree that the UWCHA OPO model would work within the culture of their donation service area. Consequently, because an OPO performs well in their home donation service area, and perhaps

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better than an OPO serving in a different donation service area, it does not necessarily follow that the more successful OPO will be able to improve donation rates in a new service area with a different culture. Further, there is a risk in allowing OPOs to assume new service areas under this assumption because we have learned in the collaborative that relationships with donor hospitals are key to the successful functioning of OPOs. If an OPO assumes a new donation service area, begins new relationships with every donor hospital, and is implementing new ways of approaching organ donation, given the amount of change and lack of established relationship, it is more likely donation rates could decrease rather than increase.

Second, UWCHA OPO is concerned that the open competition proposal would stifle the recent increased collaborative nature between OPOs as a result of the HRSA Breakthrough Collaborative on Organ. This collaboration within the OPO community has resulted in increased donation rates nationally. Allowing open competition would stifle, if not eliminate, sharing of best practices and thus negate the progress achieved by the national collaborative on organ donation. Given the enormity of investment made by DHHS, OPOs and donor hospitals in the past two years to carry out the national collaborative on organ donation, open competition would diminish the value of the resources committed by eliminating the foundation of the collaborative, which is an environment that strives to increase donation rates of all OPOs through open sharing of best practices.

Third, UWCHA is concerned with the time and resources necessary to meet this standard. Open competition will shift the OPOs' resources from its core mission of organ recovery to obtaining additional sources of organs. As written, the proposal estimates that preparing for such a process would only require 16 hours of labor on the part of the OPO bidding for a new donation service area. Based on the preparation time required for re-certification in the current state, 16 hours is not an adequate estimate of labor hours. Open competition would involve data gathering about foreign donation service areas and the creation of a formal proposal for how the OPO would assume the service area and increase the success. This would likely take a minimum of 80 labor hours.

UWHC does not recommend that CMS adopt the limited competition model as suggested in the alternatives for the same concerns expressed above related to open competition. Instead, UWCHA OPO recommends that CMS adopt the alternative proposal that would allow for highly restricted competition. This option will reduce distraction from an OPO's core mission, will allow the OPO community to continue the collaborative culture that has evolved as a result of National Organ Donation Collaborative (which has proven to increase donation rates), and will minimize unnecessary resource utilization involved in the bidding for new areas. Additionally, we suggest that only OPOs with contiguous service areas be allowed to participate in the competition to reduce inefficiencies created by operating multiple service areas that are not geographically proximal. Permitting only contingent OPOs to compete for donation service areas would also increase the chance that competing OPOs would have greater knowledge of the donation service area, thus supporting smoother transitions and a greater likelihood of increasing the donation rate.

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§486.322 Condition: Relationships with Hospitals, Critical Access Hospitals and Tissue Banks

"Relationships with Tissue Banks"

UWHCA OPO understands that many OPOs also provide tissue services and agrees that informed consent regarding tissue donation is important to maintain a positive image of donation in the public domain. There are several OPOs including UWHCA OPO, that do not provide tissue services. However, such OPOs do work collaboratively with the tissue banks on combined organ and tissue donors. In those cases, when a donor family has specific questions about tissue donation, the tissue bank is contacted and works directly with the donor family. Since we are one of several OPOs that do not provide tissue services, UWHCA OPO does not support CMS's proposal to hold OPOs responsible for providing information to donor families about tissue donation or obtaining informed consent related to tissue donation.

UWHCA OPO believes that tissue banks should be held accountable for this process as an integral part of their business practice and service to donor families. If CMS is concerned about patients receiving appropriate informed consent because tissue banks are not currently regulated by CMS, then perhaps adding this requirement to the Conditions of Participation for Hospitals. By requiring hospitals to provide the information proposed, all tissue donors would receive this information. The current proposal would only address combined tissue and organ donors for OPOs without tissue banks, which represent a small fraction of the total tissue donors nationally.

However, UWHCA believes that OPOs should continue to work collaboratively with tissue banks in the informed consent process.

§486.326 Condition: Human Resources

Verification of Physician Credentials

UWHCA OPO agrees with the intention of the proposal to verify a physician's credentials to ensure that organs are not jeopardized in the recovery process. Additionally, UWHCA OPO is supportive of the requirement of OPOs to maintain credentialing records for surgeons who routinely perform recoveries in their service area. However, for visiting teams, the proposal states that the OPO would call the transplant hospital to verify credentials of the recovery surgeon. UWHCA has a practical concern about this requirement. Credentialing offices that usually provide this information do not operate 24 hours a day, seven days a week. As a result, the OPO would have to request verification from the surgeon directly, who may or may not have their credentials available at the time requested. UWHCA OPO requests clarification regarding its responsibilities in the recovery process if a surgeon's credentials cannot be verified at the time of organ recovery.

As an alternative, UWHCA OPO proposes that transplant centers be held responsible for verifying a physician's credentials prior to recovering organs as a "Conditions of Participation:

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Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants. Adding this requirement would hold transplant hospitals accountable for sending qualified staff. This alternative would appear to be the most practical way to ensure that qualified staff are sent to recover organs.

Duration of Orientation

As one of the Best Practice Sites identified by HRSA's Breakthrough Collaborative on Organ Donation, we agree that well trained dedicated staff is essential to achieving above average donation rates. While we agree that the rules should contain recommendations regarding the need to have an appropriate orientation for each staff member, UWHCA is opposed to requiring a specific number of cases or a specific duration within the final rule. Staff orientation should be a formalized program with specific learning objectives. Progress within orientation, however, is highly individualized and dependent upon the person being trained and the manager or supervisor providing the orientation. Also, providing such a specific number of cases or duration of orientation may motivate some OPOs to perform only at that level without consideration for how the individual may perform.

§486.328 Condition: Reporting of Data

The estimated impact of the data requirement is one (1) hour per week. While UWHCA supports the outcome measures required by the proposal, this estimate is not reflective of the burden of labor hours that will be required. UWHCA suggests that twenty (20) hours per week reflects a more accurate estimate of effort required to be in compliance with this Condition.

§486.330 Condition: Information Management

The proposal requires that the OPO not only retain donor records related to the organ donation, but also tissues and eyes recovered from the donor. As stated above, UWHCA is not a tissue or eye recovery agency, and as such, is opposed to being held responsible for maintaining records for such agencies.

§486.348 Condition: Quality Assessment and Performance Improvement (AQPI)

UWHCA agrees, in general with the requirements proposed under this section. However, UWHCA OPO disagrees that the preparation time required to create and send an adverse event report to CMS would require only thirty (30) minutes of labor time. As a hospital based OPO, UWHCA has had experience preparing adverse event reports for internal and external reporting. These adverse event reports typically a minimum of six to eight hours of staff time to prepare, exclusive of the time it takes to investigate the actual event. Such a report is typically prepared by a member of the quality team and then reviewed by the parties involved in the adverse event for accuracy and the leadership team of the OPO.

Request for Comments on Related Issues

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OPO's Role in Living Donation

UWHCA OPO is strongly opposed to OPOs becoming involved in living donation. Though UWHCA OPO is a hospital based OPO within a transplant hospital, the OPO's core mission is to increase deceased organ donation. Requiring or allowing OPOs to expand their operations to encompass elements of living donation only serves to distract the OPO from its core mission. Working with living donors and deceased donor families are two distinct and disparate processes. OPOs currently lack the skills and staffing to address the unique needs and processes related to living organ donation. Furthermore, allowing OPOs to become involved in living donation creates a duplication of expertise and resources within transplant overall, as these resources already exist within a hospital's transplant program. Finally, relationships between OPOs and transplant hospitals have become strained when OPOs have been involved in living donation because transplant centers perceive that OPOs are not devoting adequate attention to deceased organ donation rates.

Sincerely,

Donna Sollenberger
President and CEO
University of Wisconsin
Hospitals & Clinics Authority
608/263-8025

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The estimated impact of the data requirement is one hour per week. While UWHCA supports the outcome measures required by the proposal, this estimate is not reflective of the burden of labor hours that will be required. UWHCA suggests that ?? is a more realistic estimate of effort required to be in compliance with this Condition.*

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Donation has increased communication and collaboration among OPO's regarding best practices.

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Finally, the open competition model is based upon a premise that does not consider regional variation in donation service area cultures. UWHCA OPO is known for having a model of partnering with donor hospitals that has been recognized as a best practice within the collaborative, and is unique in the country. Many other hospitals and OPO teams disagree that the UWCHA OPO model would work within the culture of their donation service area. Consequently, because an OPO performs well in their home donation service area, and perhaps better than an OPO serving in a different donation service area, it does not necessarily follow that the more successful OPO will be able to improve donation rates in a new service area with a different culture. Further, there is a risk in allowing OPO's to assume new service areas under this assumption because we have learned in the collaborative that relationships with donor hospitals are key to the successful functioning of OPO's. If an OPO assumes a new donation service area, begins new relationships with every donor hospital, and is implementing new ways of approaching organ donation, given the amount of change and lack of established relationship, it is more likely donation rates could decrease rather than increase.

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UWHC does not recommend that CMS adopt the limited competition model because * * * *(OR put your discussion about this model right after or in conjunction with how you refute the open competition model).

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UWHCA appreciates the Secretary's desire to rectify differences in OPO performance and create competitive pressure to achieve higher donation rates. However, we have grave concerns with the time and resources required by the proposal to open all OPO services areas for competition at the beginning of each recertification cycle. This will certainly distract OPO's from their core mission of organ recovery and encourage trolling for additional sources of organs.

The proposal estimates that preparing for such a process would only require 16 hours of labor on the part of the OPO bidding for a new donation service area. Based on the preparation time required for recertification in the current state, 16 hours is a woefully inadequate estimate of labor hours. Such a proposal would involve data gathering about foreign donation service areas and the creation of a formal proposal for how the OPO would assume the service area and increase the success. This would likely take a minimum of 80 labor hours.

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Further, the HRSA Breakthrough Collaborative on Organ Donation has increased communication and collaboration among OPO's regarding best practices. This collaboration within the OPO community has resulted in increased donation rates

nationally. Allowing "open" or "limited" competition would stifle, if not eliminate, sharing of best practices and thus negate the progress achieved by the national collaborative on organ donation. Given the enormity of investment made by DHHS, OPO's and donor hospitals in the past two years to carry out the national collaborative on organ donation, open competition would diminish the value of the resources committed by eliminating the foundation of the collaborative, which is an environment that strives to increase donation rates of all OPO's through open sharing of best practices.

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Additionally, the open competition model is based upon a premise that does not consider regional variation in donation service area cultures. UWHCA is known for having a model of partnering with donor hospitals that has been recognized as a best practice within the collaborative, and is unique in the country. Many other hospitals and OPO teams disagree that the UWCHA OPO model would work within the culture of their donation service area. Consequently, because an OPO performs well in their home donation service area and perhaps better than an OPO serving in a different donation service area, it does not necessarily follow that the more successful OPO will be able to improve donation rates in a new service area with a different culture. Further, there is a risk in allowing OPO's to assume new service areas under this assumption because we have learned in the collaborative that relationships with donor hospitals are key to the successful functioning of OPO's. If an OPO assumes a new donation service area, begins new relationships with every donor hospital, and is implementing new ways of approaching organ donation, given the amount of change and lack of established relationship, it is more likely donation rates could and would decrease rather than increase.

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As a result of the aforementioned concerns with the open competition model, we are supportive of "Option One" which allows for highly restricted competition. This option will reduce distraction from the core mission of the OPO, allows the OPO community to continue the collaborative culture that has evolved as a result of National Organ Donation Collaborative (which has proven to increase donation rates), and minimize unnecessary resource utilization involved in the bidding for new areas. Additionally, we suggest that only OPO's with contiguous service areas be allowed to participate in the competition to reduce inefficiencies created by operating multiple service areas that are not geographically proximal. Requiring only contingent OPO's to compete for donation service areas would also ensure a greater chance that the competing OPO's would have greater knowledge of the donation service area, thus support smoother transitions and a greater likelihood of increasing the donation rate.

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Page 3: [17] Deleted Also, this would provide consistency among hospital consent forms and the information provided to all tissue donors. I do not understand what this paragraph is saying. If you want tissue banks to be responsible for the informed consent process how will that be accomplished by adding a COP to hospitals (are all hospitals tissue banks?)	Information Systems	3/22/2005 10:31:00 AM
Page 3: [18] Deleted As an OPO that does not provide tissue services, we wish to continue to collaborate with the tissue bank in the informed consent process and allow the tissue bank to provide the information described in the proposal so that they may address the specifics of their operations with a potential donor family. UWHCA strongly believes that tissue banks should be held accountable for their business practices and operations, and that this should not be the responsibility of the OPO. Moreover, given the controversy around tissue donation in recent years, UWCHA has made great efforts to educate the public on the differences between organ and tissue donation to ensure that life saving organs are not affected by negative media about tissue donation.	System User	3/20/2005 10:32:00 AM
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as the transplant coordinator staff interacting with the OPO on the organ offer is unlikely to be aware of the surgeon's credentials.

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An alternative to this proposal would be to add this requirement the

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Hospital

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ransplant hospitals are ultimately accountable for the patients who may be negatively affected by an will receive the consequences of an organ that is not properly recovered, properly this would seem the most practical way to ensure qualified staff are sent on all recoveries.

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Request for Comments on Related Issues
OPO role in living donation

UWHCA is strongly opposed to OPO's becoming involved in living donation. Though UWHCA is a hospital based OPO within a transplant hospital, the OPO's core mission is to increase deceased organ donation. By requiring or allowing OPO's to expand their operations to encompass elements of living donation only serves to distract the organization. Issues facing living donors and deceased donors and their families are unrelated. OPO's are not skilled in dealing with live patients nor do they traditionally have the resources and expertise to do so. Furthermore, allowing OPO's to become involved in living donation creates a duplication of expertise and resources within transplant overall, as these resources already exist within the transplant program. Additionally, when OPO's have become involved in living donation relationships between transplant hospitals and OPOs have been strained. The relationships are strained when the transplant center perceives that the OPO is not devoting adequate attention to deceased organ donation rates because of the potential revenue associated with living donor program within OPO's.

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Do we agree with the processed process as a whole? If so, start off with something like:

Submitter : Dr. Edward McDonough
Organization : Office of the Chief Medical Examiner
Category : Physician

Date: 04/22/2005

Issue Areas/Comments

Issue

Re-certification and competition

STATE OF CONNECTICUT
OFFICE OF THE CHIEF MEDICAL EXAMINER
11 Shuttle Rd., Farmington, CT 06032-1939
Telephone: (860) 679-3980 Fax: (860) 679-1257

22 April 2005

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

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

Re: CMS-3064-P
?Recertification and competition? ?486.316

Dear Sir / Madam:

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 Department of Health and Human Services (HHS) initiative, and may harm rather than help the almost 90,000 Americans, many of whom are waiting in Connecticut for organ transplants.

The Organ Donation Breakthrough Collaborative has engaged the organ procurement organization (OPO) community and the nation's largest hospitals to increase the number of organs available for transplant. Several New Hospitals are a part of this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. The Collaborative model aims at implementing best practices for increasing the rates of organ donation. The Organ Donation Breakthrough Collaborative has achieved extraordinary results in the past 12-18 months. 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.

CMS is proposing an untested, theoretical, competitive model in which every OPO would be competing every four years to continue to serve its area. This competitive model has the potential of stifling the sharing of best practices between OPOs that have been developed and fostered through the Organ Donation Breakthrough Collaborative.

I am a firm believer in competition in the arena of economics and entrepreneurship. However, I believe that competition between OPO's is detrimental to the ultimate national goal of increasing organ and tissue donation for transplantation. The opportunities for ?conversion? are limited for a variety of reasons not in the least, the highly emotionally charged environment, that do not lend themselves to competition.

I strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Edward T. McDonough, MD
Deputy Chief Medical Examiner Board Member
State of Connecticut Life Choice Donor Services

CMS-3064-P-4-Attach-1.DOC

STATE OF CONNECTICUT
OFFICE OF THE CHIEF MEDICAL EXAMINER
11 Shuttle Rd., Farmington, CT 06032-1939
Telephone: (860) 679-3980 Fax: (860) 679-1257



Attachment #4
22 April 2005

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

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

Re: CMS-3064-P
"Recertification and competition" §486.316

Dear Sir / Madam:

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 Department of Health and Human Services (HHS) initiative, and may harm rather than help the almost 90,000 Americans, many of whom are waiting in Connecticut for organ transplants.

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I strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Edward T. McDonough, MD
Deputy Chief Medical Examiner
State of Connecticut

Board Member
Life Choice Donor Services

Submitter : Mr. Al Patrick

Date: 04/22/2005

Organization : grncsb

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please include Mental Health in the CAP when implemented January 2006.

The current method for billing to Medicare is complicated, confusing and time consuming. An improvement in the billing process would result in better patient access to important injectable mental health medications.

Thank you for help.

Submitter : Mr. Richard Bauer
Organization : Osteotech, INc
Category : Health Care Industry

Date: 04/22/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-3064-P-6-Attach-1.DOC

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.

7

February 20, 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

To Whom It May Concern:

RE: Conditions of Coverage for Organ Procurement Organizations (OPOs)
Proposed Rules – CMS-3064-P

Thank you for allowing this opportunity to provide public comment on such an important issue. I commend the advances in this proposal to continue to address the donation process in this country. As a member of the tissue banking community I have a particular interest in the data collection process for analyzing medical record reviews and referrals calls. As a nurse, I have been involved in Organ and Tissue Donation activities since 1992 and in 1997 I took a position with a large tissue procurement agency. With the advent of the Conditions of Participation (COP's) in 1998, I have always felt strongly that tissue agencies should be responsible for the same reporting standards as OPO's (I will use OPO to describe Organ Only Procurement agencies) even though CMS was not looking to make tissue agencies accountable in the same way they were looking for "organ only" donation data. In discussions with the CMS Organ Coordinators for my region, I was made aware of CMS's desire to create change in how information was reported. In 1998, I began to actively create a reporting process to, QA internal processes of education and coordination as well as, provide information back to hospitals to help identify way to increase compliance and accountability. The COP's were revolutionary and did give all donation agencies greater options to affect change within hospital environments. However, I quickly found that the COP Federal Regulations were not enough. Factual evidence based reporting was a much more effective way to show hospitals specific areas to enhance their donation programs while ultimately increasing compliance to the COP's. With 8 years of experience working with many hospitals and OPO's, I would like to address only specific sections of the proposal that I think might be helpful as you look at creative ways to make these proposals more effective.

Comments:

"Relationship with hospitals/tissue banks" (Proposed 486.322)

- I would like to comment on the section concerning the proposal to *require agreements with 95 percent of the hospitals in their service areas that have both a ventilator and an operating room.* At present I believe that most OPO's try to actively have agreements with most hospitals in their service areas with the exception of psychiatric hospitals (and listed exceptions). I would encourage you to require agreements with 100 percent of the hospitals in their service areas that have both a ventilator and an operating room. If all hospitals have to comply with regulations under the COP's, then all OPO's should have to have maximum compliance as well.
- I regards to the statement *...we do not believe it is advisable to require every OPO to provide designated requestor training in every hospital... we propose requiring OPO's to provide designated requestor training on at least an annual basis...* I agree with this proposal due to the problems created by hospital staffing changes and shortages, however I would encourage language that requires OPO's to include tissue and eye agency staff in the training at any time a training program will be provided to a hospital. This could foster a greater spirit of cooperation amongst all donation agencies. Due to the large volume of referral calls not involving organ donation, most hospital staff work significantly more with tissue and eye agency representatives than organ representatives. Having all agencies represented at any and all training sessions could facilitate communication and donation processes in general.

- I agree that the JCAHO survey process for donation is a low priority and many hospitals have found the surveyors only interested in receiving generic information about donation. During a survey process many hospitals now know the surveyor will not ask about “missed referrals” or “donation compliance statistics”. I encourage publishing statistics of hospitals donation programs and support an annual review of those statistics by CMS and any other credentialing agency such as JCAHO.

“Hospital Accountability” and “QAPI”

- I agree with you statements concerning the problems of reporting referrals in a timely manner by hospitals to a referral line. When the COP’s were established, monetary fines were also established for non-compliance. However, I would ask to view statistics showing how many hospitals have paid fines for not complying with the COP’s. My assumption would be that there have been very few, if any, fines imposed. This has led to the “catch 22” of OPO’s refusing to report hospitals and thus hospitals not being complaint. I would encourage hiring CMS representatives to begin to review results of OPO medical record reviews and reports to hospitals and for CMS to set guidelines on how and when those fines would be established. As many other processes are going to “pay for performance” standards, why not support a system that rewards the highest performing hospitals and OPO’s and penalizes the poorest. In this regard, they would both want to work collaboratively to seek ways to ensure compliance for all parties involved.
- I believe a medical records program can be standardized across the board for OPO’s QAPI process. In essence, there could be a system where certain steps in the donation process could be categorized into donation outcomes.
- I would like to take the opportunity to share an example of the reporting system I have developed to establish compliance statistics for tissue donation. The process starts with compiling information from referral calls, mortality lists and medical records information then subtracting out all the variables for patients who are not eligible for donation. The ultimate goal is to provide the hospital with the number of actual patients who might have been eligible for donation and give the hospital a reason why donation did not take place. This process keeps in line with the COP’s intention that if a patient is eligible to donate the family must be offered the opportunity to donate, if donation is not offered then a reason must be given. This process also allows Hospital Development staff to focus their education on those units and staff where problems exist. I understand that many OPO’s do collect data and provide formalized reports back to hospitals however; I would encourage standardization of outcomes for all OPO’s. By standardizing how information is collected, it could then be posted, by hospital, to provide a detailed report as well as show improvements from month to month then year to year. I hope the examples below of an actual hospital report will provide some suggestions for any reporting structures established for the OPO database. I have provided additional comments (highlighted in blue) next to each section of Table 2 to provide further definition of the categories.
- [See example Table 1 and Table 2 from an actual hospital report next page]

“Human Resources” (Proposed 486.326)

- I would like to comment on the section concerning the proposal...*requiring an OPO to have a medical director who would be responsible*...I applaud this proposal to have a full time medical director but would encourage you to provide a definition of “licensed physician” by including “United States board licensed physician” unless there is no concern of OPO’s hiring physicians licensed abroad.

“Reporting Data” (Proposed 486.328) and

“Quality Assessment and Performance Improvement” (Proposed 486.348)

- I would like to comment on the sections concerning these proposals. I commend the collection of additional data by OPO’s and encourage reporting concerning individual hospital specific data on referrals and organ recovery. I would recommend that the collection of data (or medical record reviews) become standardized (i.e.: every month or every quarter). I know of many OPO’s who submit data without doing actual review of medical records on a consistent basis. I am aware of one OPO that only does annual medical record reviews, and I know of many that are not doing medical record reviews at all. I believe this does a disservice to the hospitals and their staff by not allowing the opportunity for timely feedback to assist in improving their donation programs and providing the opportunity to change any donation processes that are out of compliance with the COP’s. I also question the validity of information submitted to OPTN and SRTR that is not cross-referenced to actual patient records. For instance, if an OPO only provides information on referral received and only reviews medical records annually, or not at all, how are they going to know if an eligible donor was not captured unless they review the medical records of those patients and cross-reference the information to referrals and mortality lists.
- Your current proposal states “ *However, if an OPO determined through death record reviews or by other means that the data it reported to the OPTN was incorrect, we would require the OPO to report the corrected data to the OPTN within 30 days of the end of the month in which the error was identified.* ” If an OPO is providing monthly data to OPTN or SRTR and not consistently reviewing medical records either on a monthly or quarterly basis, what is the statute of limitation on revising the data submitted to the OPTN for incorrect data? For instance, if the OPO reviews medical records in January of 2005 for all referrals and eligible deaths in 2004 and they find a patient was not referred appropriately in January 2004 that would mean an entire year passed without capturing that inappropriate referral. Based on your current proposal, they would have to report the new found information within 30 days of their findings, not 30 days of the missed referral. In the example above, that missed referral would not have been reported or corrected with the OPTN for approximately 14 months, nor education provided in a timely manner back to the hospital on the missed referral. I encourage a statement on the necessity for medical record reviews to be done monthly for hospitals with 200+ beds, that has an ER, ICU and OR, with the option of monthly or quarterly medical record reviews for hospitals between 150-200 beds that have an ER, ICU and OR.
- While hospitals mortality reports should be complete, many are not. Still today, there are many hospitals that do not use computerized systems for their mortality lists and continue to utilize handwritten logs that are often inaccurate. Many hospitals are not providing mortality lists in a timely manner and allowing for review of records in a timely manner. I suggest language to hold hospitals accountable to provide computerized mortality lists within 15 days of the last day of the month and work to provide for timely review of records to all donation agencies.

• Table 1: Table starts at "Total Referrals" and subtracts out referral down to "Actual donors"

	Jan	Feb	Mar	1st Qtr	Apr	May	Jun	2nd Qtr	July	Aug	Sept	3rd Qtr	Oct	Nov	Dec	4th Qtr	Year Totals
Total Referrals	98	98	88	277	88	78	87	253	80	83	80	243	79	78	102	259	1842
Less Non-Potential: Based on FDA and AATB guidelines																	
Age	13	14	15	42	9	8	10	27	10	9	7	26	9	10	7	26	121
Cancer	31	29	27	87	22	22	23	68	22	22	28	72	28	18	27	71	297
Sepsis / Infection	15	10	8	33	6	5	8	19	9	14	5	28	13	12	22	47	127
Other Medical	14	19	22	55	11	15	17	43	20	12	13	45	18	8	22	48	188
Stillborn	9	8	4	21	9	7	10	26	9	14	9	32	5	13	12	30	109
Pending review (8), Duplicates (2) or Referred Not Deceased (7)	0	0	0	0	2	2	3	8	3	0	4	7	1	2	0	3	17
Subtotal Non-Potential:	62	60	78	238	59	68	71	191	73	71	66	210	70	63	90	223	880
Potential Donors	18	13	10	39	10	11	16	37	7	12	14	33	9	12	12	33	142
Difference between Potential Donors and Actual Donors by Outcome:																	
Agency Rule-out for MSSH	1	2	2	5	0	1	0	1	0	0	0	0	0	0	1	1	7
Medical Examiner Declines	0	0	0	0	0	2	1	3	1	0	3	4	1	2	1	4	11
Other: Funeral Home issues, No Legal Next of Kin available	0	0	1	1	0	0	1	1	1	1	0	2	0	0	0	0	4
No Call	1	0	0	1	0	0	0	0	0	0	1	1	0	0	0	0	2
Family Declined (FD) to: OPO (9) /RN (6) EB (11)	4	2	1	7	2	3	1	6	3	0	3	6	2	5	0	7	28
Agency approach - Family Declined	5	5	2	12	4	2	7	13	2	5	4	11	3	3	6	12	48
Hospital -- Prior to call to referral line	2	1	1	4	1	1	0	2	0	1	0	1	0	1	1	2	9
Outcomes Subtotal	13	10	7	30	7	9	10	28	7	7	11	28	6	11	9	28	107
Actual Donors	3	3	3	9	3	2	6	11	0	5	8	5	3	1	3	7	38
Agency conversion rate: (Actual/Potential)	19%	23%	30%	23%	30%	18%	38%	30%	0%	42%	21%	24%	33%	8%	25%	21%	26%
Additional Information: (This information is not subtracted from information above)																	
Total Calls Statline	94	93	88	273	88	69	84	221	78	80	77	233	77	75	98	251	878
No Calls (Total of all calls not received to include potential and non-potential)	1	0	0	1	1	0	2	3	1	1	2	4	0	0	1	1	9
Referred but Not deceased (RND)	0	0	0	0	0	1	2	3	0	0	3	1	1	0	0	1	7
Mort List	95	88	85	268	60	65	78	201	76	74	70	220	74	68	99	239	828
Referrals Not on Mort list	3	5	1	9	9	4	11	24	10	8	7	25	4	9	3	16	74

Table 2: Table subtracts "Potential Donors" down to "Actual Donors" by category.

Difference between Potential Donors and Actual Donors by Outcome of Referral: (*Per the COP's, if a patient is eligible to donate the family must be offered the opportunity, if donation is not offered then a reason must be given - These are the reasons by category)	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	YEAR TOTALS
Potential Donors: (from monthly table)	39	37	33	33	142
Less rule-outs of potentiality created by other situations: * Situations not allowing tissue donation agency the opportunity to approach.					
Tissue Agency rule-out (*Includes but not limited to Med/Soc HX and Inspection of Body)	(5)	(1)	0	(1)	(7)
ME Declines (*Includes decisions based on Medical Examiner jurisdiction for this state)	0	(3)	(4)	(4)	(11)
Other (*Includes but not limited to No LNOK, Funeral Home issues after appropriate referral by hospital staff)	(1)	(1)	(2)	0	(4)
No Call (*Reported to hospitals, as non-compliance of COP's, in a formal report; however these are usually found on review of record after obtaining the mortality lists, long past the opportunity for donation. We provide education based on these missed referrals to ensure all calls are made per COP's)	(1)	0	(1)	0	(2)
Family Decline (FD) to OPO (9) /RN (6) EB (11) (*Includes other trained requestors from donation agencies approaching families and appropriate situations of families declining to staff during)	(7)	(6)	(6)	(7)	(26)
*Donation Based on Actual Potential	(28)	(28)	(20)	(21)	(92)
Subtotal:	25	28	20	21	92
Families approached by trained and non-trained staff: * Situations allowing eligible families to be approached, however we provide education to these nurses on the best practices to maximize the opportunity for donation per the COP's.					
*Tissue Agency Assisted Approach -Family Decline (*Includes the number of families appropriately referred and approached by our trained staff. This is a method to review internal conversion rates for donation)	(12)	(13)	(11)	(12)	(48)
*Hospital Approach Prior to calling Referral Line - FD (*Includes the number of families inappropriately approached by hospital staff prior to calling the referral line, in violation of the COP's and not being "Trained Designated Requestors")	(4)	(2)	(1)	(2)	(9)
*Actual Donors	9	11	8	7	35
Donation % rate: (Donors/Actual Donation Potential)	36%	42%	40%	36%	38%

- Based on the information collected for a hospital (as above) a formalized report is given to the hospital on a quarterly, semi-annual or annual basis (determined by hospital size and donation potential). Our Hospital Services staff provides on-going continuing education for non-compliance to the COP's as well as commendation for excellent compliance. We feel this provides evidence-based data and supports incentives to allow further education to create the highest atmosphere for a successful donation program.

"Public Education"

- I would like to comment on the section concerning this proposal. While I agree that measuring donation results from public education is difficult, and I do agree that education should be primarily focused on research and professional education, I also believe there should be some funding available to support a limited amount of public education.
- Any opportunities to dispel myths and misconceptions may lead to enhanced opportunities for donation. Although, there are many National educational programs, many may not reach their intended audiences without the support of Organ, Tissue and Eye Donation Agencies.

In closing, I would like to express my gratitude for this opportunity to provide public comment. I hope my comments will be of some value as you work towards finalizing these regulations. If you feel further clarification of the information provided above might be useful to this cause, please feel free to contact me via e-mail at any time.

Respectfully submitted,


Ruth I. Cantu, BSN, RN
ruthaida@cablespeed.com



American Board for Transplant Certification

P.O. Box 15
Lenexa, KS 66285-5
(913) 599-0
(913) 599-5340 F
www.abtc

March 21, 2005

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

Dear Messers:

This letter is in response to the Centers for Medicare and Medicaid Services (CMS) Proposed Rulemaking (CMS-3064-P) for Conditions for Coverage for Organ Procurement Organizations (OPOs). The American Board of Transplant Coordinators (now legally incorporated as the American Board for Transplant Certification) recommends that CMS adopt a final rule for OPOs to have qualified procurement transplant coordinators to ensure continuity of care for deceased donors and their organs for transplant. This letter further supports CMS adopting a final rule for OPOs that a qualified procurement transplant coordinator be an individual receiving certification by The American Board for Transplant Certification. Such a rule would require any person functioning in the capacity as a procurement coordinator within an OPO to be required to sit for the Certified Procurement Transplant Coordinator (CPTC) examination offered by the American Board for Transplant Certification. These requirements will ensure that each OPO have available procurement coordinators employed which hold the title of procurement transplant coordinator certified by the American Board for Transplant Certification.

Quality donor and donor organ care is vital to the transplant community, as is the requirement for professional certification of procurement transplant coordinators who perform direct donor care and organ allocation. The proposed standards will aid in ensuring the public's awareness of elevated safeguards to minimize medical errors associated with donation and transplant, and that the organ procurement industry has an objective methodology for assessing the competency level of procurement transplant coordinators. The proposed requirement for a Certified Procurement Transplant Coordinator, through the American Board for Transplant Certification, will also ensure a minimum level of regular continuing education. This rule would also be consistent with the CMS proposed rules for transplant centers (CMS-3835-P), and therefore create similar levels of expected practice between organ procurement and transplant professionals. Supplemental information enclosed fully describes the psychometric methods utilized by the American Board for Transplant Certification for the development of each of its certification examinations and continuing education requirements.

Sincerely,

Richard E. Pietroski, MS, CPTC
President
American Board for Transplant Certification

Enclosure



American Board for Transplant Certification

P.O. Box 153
Lenexa, KS 66285-53
(913) 599-07
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AMERICAN BOARD FOR TRANSPLANT CERTIFICATION

CERTIFICATION PROCESS OVERVIEW

BACKGROUNDER:

American Board for Transplant Certification

The American Board for Transplant Certification (formerly known as the American Board of Transplant Coordinators) is an independent, not-for-profit organization with the mission of awarding voluntary non-governmental certification credentials. Currently, Certified Clinical Transplant Coordinator (CCTC), Certified Procurement Transplant Coordinator (CPTC), and Certified Clinical Transplant Nurse (CCTN) certificates are awarded to qualified transplant professionals that successfully demonstrate a given knowledge threshold based upon a 150 multiple-choice question certification examination. The CCTC examination establishes a national standard baseline competency for transplant center candidates that facilitate pre-transplant care and discharge planning of end-stage organ disease patients, the CPTC examination establishes a national standard baseline competency for organ procurement organization candidates that facilitate donor hospital activities that result in the facilitation of transplantable organs, and the CCTN examination establishes an international standard baseline competency for organ transplant center bedside registered nurses that administer perioperative surgical care to end-stage organ disease patients.

The American Board for Transplant Certification has been an incorporated organization in the states of California and Kansas since 1988. Under this incorporation, the ABTC maintains a board of governors that manage the organization's ongoing operations. In addition to the ABTC board positions of president, vice president, treasurer, and secretary, the ABTC has board positions which chair committees that oversee procurement examination, clinical examination, transplant nurse examination, judiciary, clinical credentials, and continuing certification. Two additional board positions are at-large representatives that are elected annually by the ABTC membership. Furthermore, the ABTC Board of Governors has resolved in January 2005, to add a third elected at-large member to the Board in 2005 as a means of ensuring that all examinations represent current and best practices.

Examination Development

The American Board for Transplant Certification clinical, procurement, and nursing examination committees meet face-to-face annually, and on a regular basis by telephone or Web conference calling, to develop examination items (test questions). Each ten-member committee consists of experts that represent a wide range of national procurement and transplant specialties. Additionally, two CCTN examination committee members represent the international transplant nurse field. The examination committees are structured to provide input into item development

that will ensure broad recognition of practice and limit regional practice variation that could advantage or disadvantage test candidates. All test items are specific to a test matrix which represents job functions consistent with national or international practice. The matrix guides the test development through the formation of items that test within a consistent distribution of practice areas for examination candidates. Equivalent job functions are determined through a job analysis that is typically performed every five to seven years. The national or international job analysis can be performed with greater frequency through the input of the ABTC Board of Governors, examination committees, or through communication from professional membership organizations. The ongoing requirement to perform a periodic job analysis is used as a method to gauge baseline practices nationwide and throughout the international transplant communities. If the job analysis determines that the baseline job functions have changed, or have become specialized to a limited geographic area, relevant examination items are either retired or rewritten to correspond with current and best practices.

Examination Administration

The American Board for Transplant Certification develops candidate examinations in conjunction with its test development contractor, Applied Measurement Professionals (AMP). ABTC has maintained a contractual relationship with AMP since 1988 for ABTC test development and for administrative services. Under the test development contract, AMP employs psychometric item analysis that statistically measures the baseline competency of procurement, clinical, and transplant nurse test candidates. Each test item is reviewed for item performance which allows for substantiating the competency of more proficient examination candidates and qualifying the limited proficiency for less able candidates.

A cut (passing) score is established for each examination based on the normal distribution of more to less qualified candidate scores and a calculated variability and precision index for the examination. Following each examination, Test Analysis Reports demonstrate the level of critical review that each examination receives by the ABTC examination committees and Board of Governors. The Test Analysis Report also validates that ABTC's recent change from paper-based to computer-based test administration has maintained examination reliability. Computer-based testing has allowed ABTC to simultaneously administer multiple 150-question examination forms from an extensive pool of test items to candidates in virtually all metropolitan statistical areas nationwide. Through ABTC's activity associated with the CPTC examination, procedures have been established to administer examinations at any secure location by means of the World Wide Web. Web-base computer examination has been found to be user friendly and cost effective for both the examination candidates and for ABTC.

To-date, the American Board for Transplant Certification has the experience of having administered approximately 4,000 examinations to candidates in the field of organ procurement and transplantation. Candidates that successfully demonstrate competency are conferred with the credentials of Certified Clinical Transplant Coordinator (CCTC), Certified Procurement Transplant Coordinator (CPTC), and Certified Clinical Transplant Nurse (CCTN). While the

overwhelming majority of candidates granted ABTC certification are based in the United States, there is also membership throughout the world.

The ABTC CPTC certification examination is the only certification currently recognized by the Association of Organ Procurement Organizations (AOPO) for meeting the AOPO accreditation administrative standard for demonstrating that OPO coordinators are sufficiently trained. The AOPO administrative standard states:

“Job descriptions should be reviewed. Review OPO’s methods of training organ recovery coordinators and documentation related to training process. The evidence of CPTC credentialing is deemed sufficient to determine that those individuals are trained. For those individuals not CPTC credentialed, look for other evidence of training.”
(www.aopo.org; Administrative Standard AS 2.3).

Recertification

In order to maintain American Board for Transplant Certification credentials, certificants may recertify by demonstrating a sufficient level of continuing education within their field of professional practice. Recertification requires that candidates achieve a minimum of 60 qualifying continuing education contact hours over each three-year period. One third of the contact hours must be in conjunction with ABTC approved programs. There are currently 1,607 persons that hold active CPTC (667), CCTC (778), and CCTN (162) credentials, and a limited number of individuals hold dual certification. Information regarding ABTC certification and recertification is located at www.abtc.net.

3-21-05

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 GABRIEL M. DANOVITCH, MD
 BERTRAM L. KASISKE, MD
 MARY B. LEONARD, MD
 ANDREW S. LEVEY, MD
 ADEERA LEVIN MD, FRCPC
 STUART L. LINAS, MD
 WILLIAM McCLELLAN, MD, MPH
 SHARON M. MOE, MD
 BRUCE A. MOLITORIS, MD
 BARBARA T. MURPHY, MD
 BRIAN J.G. PEREIRA, MD, MBA
 JERRY YEE, MD

March 24, 2005

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

Dear Sir or Madam:

I am pleased to provide comments on the Proposed Rule: Medicare and Medicaid Programs: Conditions for Coverage for Organ Procurement Organizations [CMS-3064-P] that was published in the Federal Register on February 4, 2004, on behalf of the transplant candidates, transplant recipients, living donors, and organ donor families who are members of the following National Kidney Foundation (NKF) groups: Patient and Family Council, transAction Council, and National Donor Family Council. The total membership of these "constituent councils" across the nation is 42,953.

General Comments

The National Kidney Foundation has long advocated the development of performance standards for organ procurement organizations as required by the OPO Certification Act of 2000 and we welcome the provisions of the Proposed Rule because we believe that they should help to increase organ donation and organ placement. Nevertheless, we are concerned that the Proposed Rule is silent with regard to Donation after Cardiac Death (DCD), which many believe could help to relieve the shortage of organs available for transplantation in the United States. We recommend that the Final Rule should require all organ procurement organizations to develop and implement policies and procedures for DCD.

On the other hand, since the Proposed Rule was published in the fourth year of a four-year certification cycle, we urge that the performance requirements proposed in the *Federal Register* on February 4, 2005 not be enforced retroactively.

Recertification and Competition

Competition should play only a limited role in efforts to increase organ donation. Competition could undermine the effectiveness of the Breakthrough Collaborative that has been facilitated by the Health Resources and Services Administration. It would also make OPOs less willing to share best practices. An OPO service area should be opened to competition only if the existing OPO does not meet performance standards. Conversely, if CMS decides to pursue a competitive model, new entities should be permitted to seek OPO designation whereas the Proposed Rule eliminates that possibility.

Outcome Measures

According to the Proposed Rule, OPOs must achieve 75% of the national mean (50% in the case of Hawaii and Alaska) for four out of five outcome measures:

- (1) donors as a percentage of the potential donor denominator;
- (2) number of kidneys procured, as a percentage of the potential donor denominator;
- (3) number of kidneys transplanted, as a percentage of the potential donor denominator;
- (4) number of extra-renal organs procured, as a percentage of the potential donor denominator;
- (5) number of extra-renal organs transplanted as a percentage of the potential donor denominator.

However, the Proposed Rule does not specify how Donation after Cardiac Death (DCD) will be incorporated in these outcome measures. Controlled DCD donors should be included in the numerator for the first three measures.

Instead of the equations proposed in the draft rule to monitor the effectiveness of OPOs, CMS should consider utilizing a model being developed by the Scientific Registry for Transplant Recipients (SRTR), which can track the observed (as opposed to the expected) donation rate in a particular service area. This would parallel the evaluation technique described in the Proposed Rule for transplant centers.

Administration and Governing Body

The National Kidney Foundation has the following comments in regard to the governance provisions in the Proposed Rule. Donor families must be represented on OPO boards. The composition of the OPO Governing Body should provide a balance between lay people and community representatives, on the one hand, and transplant professionals on the other.

At least 50% of the members of the Governing Body should not be connected with user hospitals. One individual should not be allowed to serve as the governing body for an OPO.

Requesting Consent

NKF endorses the principles contained in section 486.342 of the Proposed Rule. That provision addresses the concerns and recommendations expressed in the National Kidney Foundation Donor Family Council's "Position Statement on Tissue Donation," and "Informed Consent Policy for Tissue Donation."

Quality Assessment and Performance Improvement

CMS should require that OPO Quality Improvement programs include goals to enhance the consent rate and the quality of donor management.

OPO Role in Living Donation

OPOs 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 National Kidney Foundation and all kidney patients and transplant candidates and recipients, 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,



David G. Warnock, M.D.
President, National Kidney Foundation, Inc.
Professor and Director, Division of Nephrology
Department of Medicine
University of Alabama at Birmingham

10

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

Dear Sir or Madame:

Please accept this letter as a recommendation to remove the language within the Centers for Medicare and Medicaid Services proposed rulemaking (42 CFR Part 486, Section 486.342), which states that minimum requirements for consent for tissue donation should include "information (such as for-profit or nonprofit status) about organizations that will recover, process and distribute" donated tissue.

Each year, donated tissue is utilized in thousands of musculoskeletal surgeries, which alleviate pain and restore function. This would not be possible without the generous gift of tissue donation, and the enhancement of that gift through the complex technologies developed by the tissue banking community.

A completely not-for-profit system that is capable of meeting the demands and needs of patients requiring musculoskeletal tissue transplantation does not exist. The tissue banking system that exists is inherently a combination of for-profit and not-for-profit companies, and the ability to transplant musculoskeletal tissue extends far beyond recovery, processing and distribution, as defined in the proposed rule.

Inevitably, if the proposed language is adopted, consenting individuals will choose to restrict the use of their loved ones' tissues by for-profit companies, based on the belief that not-for-profit companies, by not generating surplus revenues designated as "profit", are somehow more deserving of the gift of donation. By restricting the amount of tissue sent to for-profit companies, patients will be deprived of the benefit of complex processing technologies that add clinical value to those tissues.

By reducing the volume of tissue available to for-profit companies, such a restriction would reduce the role of such companies in tissue transplantation, eventually resulting in a decrease in the number of tissue banks, a decrease in therapeutic options for physicians, a rise in cost of tissue to hospitals, and a decrease in technological advances that arise from research and development conducted by for-profit companies, with the aim of improving patient outcomes.

The proposed rule, with regard to its inclusion of "such as for-profit or nonprofit" is misleading to consenting individuals, and potentially detrimental to the effectiveness of the tissue banking community and therefore to the medical community which it serves.

I respectfully request that the proposed CMS rule not be adopted in its current form

Sincerely,



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RECEIVED HOTA
OFFICIAL STOP



**THE WESTERN
PENNSYLVANIA HOSPITAL**

**DIVISION OF FOOT AND ANKLE SURGERY
RESIDENCY TRAINING PROGRAMS**

4800 FRIENDSHIP AVENUE
PITTSBURGH, PA 15224
412-688-7578
FAX 412-688-7872

March 22, 2005

Robert Mendicino, DPM, FACEAS
Chief, Division of Foot & Ankle Surgery
Director of Education

Alan Catanzariti, DPM, FACEAS
Director of Residency Training Programs

Clinical Faculty

Philip Carshaj, MD
Chairman, Department of Surgery

Jordan Grossman, DPM, FACEAS

Steven Leers, MD
Chief, Division of Vascular Surgery

Shannon McFeaters, DPM
Clinical Faculty

E. Douglas Newton, MD
Chief, Division of Plastic Surgery

Don Paley, MD
Director, Orthopedics and Limb Deformity
Mt. Sinai Hospital and The Rubin Institute

Karl Sattnick, DPM, FACEAS
Clinical Faculty

Harvey Slater, MD
Director, Burn/Trauma Center

Leslie Walters, DPM, FACEADM
Coordinator, Primary Podiatric Medicine

Andrew Vayonis, MD, FACP
Instructor, Physical Diagnosis

John Mendicino, BS, P.E.M.I.
Business and Practice Management,
Information Management Systems

Beth Sheedy, BS, M.Ed.
Residency Coordinator

Donna Houpt, RN
Clinical Research Coordinator

Debra Hoffman
Residency Assistant

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

Dear Sir or Madame:

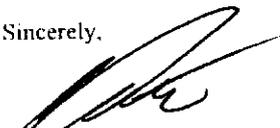
Please accept this letter as a recommendation to remove the language within the Centers for Medicare and Medicaid Services proposed rulemaking (42 CFR Part 486, Section 486.342), which states that minimum requirements for consent for tissue donation should include "information (such as for-profit or nonprofit status) about organizations that will recover, process and distribute" donated tissue.

Each year, donated tissue is utilized in thousands of musculoskeletal surgeries, which alleviate pain and restore function. This would not be possible without the generous gift of tissue donation, and the enhancement of that gift through the complex technologies developed by the tissue banking community, which is inherently a blend of for-profit and not-for-profit companies. In order to contain costs and while advancing technology to improve patient outcomes, not-for-profit companies rely on the services of for-profit companies, and vice-versa.

It is likely that consenting individuals may not understand that both for-profit and not-for-profit companies can generate revenue. Inevitably, some will choose to restrict the use of their loved ones' tissue by for-profit companies based on the belief that not-for-profit companies do not generate revenue. Therefore, because a true not-for-profit option does not exist, this restriction will preclude donation and there will be a decrease in tissue donation rates.

A decrease in tissue donation rates results in a decrease of tissue available for transplantation. At some point, this decrease in supply will result in a decrease in the number of tissue banks, a decrease in therapeutic options for physicians, a rise in cost of tissue to hospitals, and a decrease in technological advances that arise from research and development that is aimed at improving patient outcomes.

The proposed rule, with regard to its inclusion of "such as for-profit or nonprofit" is misleading to consenting individuals, and potentially detrimental to the effectiveness of the tissue banking community and therefore to the medical community which it serves.

Sincerely,


Alan R. Catanzariti, DPM
Director, Residency Training Programs
The Western Pennsylvania Hospital



Orthopaedic Spinal Surgery
PIERCE D. NUNLEY, M.D., Director
EUBY J. KERR, III, M.D.

Orthopaedic Specialist
 Occupational Medicine
AUSTIN W. GLEASON, M.D.

Neurosurgery
DAVID A. CAVANAUGH, M.D.

Physical Medicine & Rehabilitation
 Electromyography
DAVID N. ADAMS, M.D.

Nurse Practitioners
Chris Howard, CFNP
Mike Brandao, CFNP
James Harper, CFNP

Centers for Medicare and Medicaid
 March 22, 2005
 Page 2

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I respectfully request that the proposed CMS rule not be adopted in its current form.

Sincerely,

Pierce D. Nunley MD
 PDN/vramey

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

Dear Sir or Madame:

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A completely not-for-profit system that is capable of meeting the demands and needs of patients requiring musculoskeletal tissue transplantation does not exist. The tissue banking system that exists is inherently a combination of for-profit and not-for-profit companies, and the ability to transplant musculoskeletal tissue extends far beyond recovery, processing and distribution, as defined in the proposed rule.

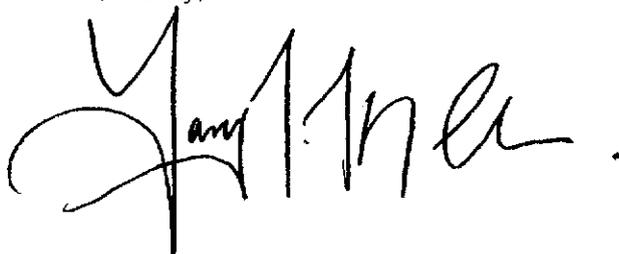
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By reducing the volume of tissue available to for-profit companies, such a restriction would reduce the role of such companies in tissue transplantation, eventually resulting in a decrease in the number of tissue banks, a decrease in therapeutic options for physicians, a rise in cost of tissue to hospitals, and a decrease in technological advances that arise from research and development conducted by for-profit companies, with the aim of improving patient outcomes.

The proposed rule, with regard to its inclusion of "such as for-profit or nonprofit" is misleading to consenting individuals, and potentially detrimental to the effectiveness of the tissue banking community and therefore to the medical community which it serves.

I respectfully request that the proposed CMS rule not be adopted in its current form.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary M. Lee". The signature is written in a cursive style with a large initial "G" and "L".



STATE OF NEW YORK DEPARTMENT OF HEALTH

Coming Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

March 18, 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

To Whom It May Concern:

Please find below our comments to the proposed rule under 42 CFR Parts 413, 441 et.al. Medicare and Medicaid Programs: Condition for Coverage for Organ Procurement Organizations (CMS-3064-P). The Department would like to comment specifically on the proposed rules that relate to re-certification.

Re-Certification and Competition Processes (Proposed § 486.316)

This provision allows the service area of every Organ Procurement Organization (OPO) to be open to competition at the conclusion of every re-certification cycle, regardless of whether they met the performance standards for the prior re-certification cycle.

This provision seems to be contrary to the recent HRSA Collaborative Best Practices effort, in which all four New York State OPOs are participating, and also to our own efforts here in New York State. For many years, the New York State Department of Health has strived to encourage all OPOs, tissue banks, recipients, donors and hospitals- the entire transplant community- to work together to increase donation and provide quality services to New Yorkers. Since the establishment of the NYS Transplant Council in 1991 and the Task Force to Increase Organ and Tissue Donation in 1997 (now the New York Alliance for Donation), the community has worked together on many initiatives- the New York State Organ and Tissue Donor Registry, education for health professionals, establishment of a Donor Medal of Honor, a radio public service campaign to increase organ and tissue donation, live adult liver transplant requirements and many other collaborative efforts to improve quality and increase donation.

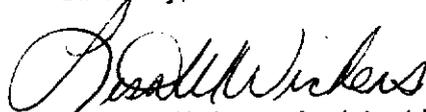
In 2004, New York State saw an eleven percent (11%) increase in overall donation, much of this is thought to be a result of these cooperative efforts. This proposed condition would foster competition amongst OPOs despite an OPO fulfilling its performance measures. This proposal potentially undermines both the HRSA Collaborative and DOH efforts. Why would any OPO, especially one that is meeting its performance standards, share its best practices and resources with a potential competitor?

The provision would also allow an out of state OPO to compete and be assigned New York State service areas. New York State is unique in that it is its own sharing region (Region 9) and shares a single statewide waiting list for livers and hearts. Also, New York State (and in particular the Metropolitan area) has different demographics, different causes of death, therefore different organ donor potential, different expected consent rate and different yields per donor than other regions. For example, NYC donors are older and more likely to die of CVA rather than trauma. Therefore, an out-of-state OPO's unfamiliarity with local practices, systems and demographics could, at least initially, result in a decrease in donation-something NYS cannot afford.

We conclude that these provisions could erode the cooperative initiatives we have worked very hard to accomplish in NYS and could potentially disrupt statewide sharing for hearts and livers, a system which the state Department of Health originally proposed and still strongly supports.

Thank you for this opportunity to comment.

Sincerely,



Lisa M. Wickens, Assistant Director
Office of Health Systems Management

Submitter : Mr. Thomas Asfeldt
Organization : Vesta Therapeutics, Inc.
Category : Health Care Industry

Date: 05/10/2005

Issue Areas/Comments

Issue

Outcome measures

See Attachment

CMS-3064-P-15-Attach-1.DOC

Attachment #15
May 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: "Outcome Measures"

In the February 4, 2005 Federal Register document providing the proposed rule for *Conditions for Coverage for Organ Procurement Organizations* you state: "when compiling outcomes performance measures data and utilizing the data for re-certification of OPOs, we will include pancreata recovered and used for islet cell transplantation or for *research* under the category of extra-renal organs, along with pancreata recovered and used for whole organ transplantation. Also, because researchers and OPOs have suggested that we encourage OPOs to recover other organs for research purposes, we invite comment on whether all organs recovered for research should be included in the outcome measures." (p. 6101)

Without question, the procurement of organs for research purposes should be included in the outcome measures. There is no doubt you have included the procurement of pancreata for research purposes as valuable because the predominant research being performed with these organs may eventually lead to a cure for insulin dependent diabetes. Providing a cure for this disease will provide a great deal of relief in human suffering and financial relief for the expense of treating the long-term complications some patients with diabetes experience. The prevalence of insulin dependent diabetes in the United States also provides a strong case for measuring OPOs performance in contributing to a cure.

Research to find a cure for diabetes is only one of many research efforts that will benefit from access to whole organs unsuitable for transplantation. One of those other efforts is a cellular based treatment for liver disease using human hepatocytes and hepatic stem cells derived from non-transplantable organ donor livers. The research being conducted at the author's institution (Vesta Therapeutics, Inc.) is nearing the clinical trial phase. One of the limiting factors for the speed of entry into human clinical trials is access to tissue.

Access to tissue would not be a limiting factor if every OPO made the same efforts as the highest performing OPOs to request consent for research from the donor family, take the necessary steps to offer organs for research, and be certain the donor surgeon or OPO staff are willing to perform the procurement. According to the OPTN, in 2003, there were 6455 deceased donors and 5348 liver transplants. Of the 1107 livers that were not transplanted, only 168 were submitted for research, and an additional 12 were used for either hepatocyte or extra-corporeal purposes. This organ disposition distribution for livers has been relatively unchanged over the last 5-10 years.

Although the current state of the research is not as advanced as islet transplantation, hepatocellular treatment for liver disease perhaps holds more promise. The predicted volume of cells required to treat one patient will permit multiple patients to be treated with the cells isolated from one liver. In addition, the most promising avenue to treat many patients is the ability to expand adult liver stem cells in culture, thereby increasing the number of cells available from each liver and the number of patients that can be transplanted. Clearly, the more livers the OPOs are able to provide for this therapy, the more quickly the research will reach the patient.

OPOs are strategically positioned to provide the best human organs for research usage. The organs they have access to, provided the family consents, are procured and preserved in the most efficient manner that minimizes warm ischemic damage and cold ischemic times. The organ procurement process is ideally managed to maintain cellular viability in a manner that exceeds any other process. Implementing performance outcome measures for research organs would encourage OPOs to leverage this position.

In addition to the benefits provided to the researcher, the donor family, the OPO, and CMS also benefit from the increased procurement of organs for research. The donor family will benefit from having additional options available, and may benefit from their contribution to a cure that may benefit their children and grand children. The OPO will benefit by increasing the revenue they are able to recoup from an organ that would otherwise not have generated an acquisition charge. The reimbursement available for livers for research far exceeds any additional costs the OPO will incur from a donor that is already going to the OR for the procurement of at least one organ for transplant. This is also a benefit to CMS because the increased revenue available to the OPO from outside CMS will decrease the reimbursement CMS will make to the OPO on a cost allocation basis.

The efforts required by the OPO to submit an organ for research are minimal. The OPO must establish a relationship and negotiate an agreement with the researcher(s) and the organ placement and procurement staff must be educated on the researchers requirements. The time required for this step is very small when allocated incrementally to each organ submitted for research. In addition, most researchers will provide the training required. During the donor phase, the OPO must offer the options of research to the donor family, a process already in common practice. Any organ deemed unsuitable for whole organ transplantation must then be offered to the researcher. Again, a relatively minor time consuming event and much simpler than allocating organs for transplant. The most challenging aspect for some OPOs is to get the donor surgeon to agree to procure organs for research. Two frequent reasons given by surgeons for not procuring research organs is the absence of the same procurement fee as they would receive for recovering an organ for transplant, and the simple lack of interest in the additional effort, albeit minor, required. In the absence of a willing surgeon, several OPOs have their own very capable preservation or perfusion staff perform the research organ procurement. The OPO may incur additional costs for preservation solutions if the organ is not being flushed along with the organs being recovered for transplant.

It is important to note, however, that the reason some OPOs provide to researchers for not procuring organs for research is that they are better off financially to only procure organs for transplant because all costs can be equally allocated to each organ and the resulting acquisition

charge adequately covers their costs. On the other hand, they state that an organ procured for research is cash negative because CMS requires all costs to be allocated to all organs procured, regardless of the available reimbursement from the researcher. Research reimbursement fees are substantially less than the standard acquisition charge for transplant and therefore do not cover their total costs and a research organ becomes an expense. It would be helpful if CMS would provide clarification on reimbursement issues and provide an incentive for the OPO to obtain a research fee as a positive contributor to the OPOs finances, versus the current disincentive some OPOs feel is present.

Outcome measures that would reflect performance in recovering organs for research should include: Research Consent Rate, and Organs Recovered for Research (regardless of whether recovered initially with the intent for transplant). It would also be important to encourage OPOs to participate with researchers whose applications have direct clinical relation to organ replacement therapy like pancreata for islets and livers for hepatocytes. These types of programs are consistent with the mission of the OPOs to facilitate organ donation to directly benefit potential recipients with organ failure.

Procuring organs for research is a common practice for some OPOs, unfortunately, it is an exception for others. Establishing outcome measures for certification and re-certification that include the procurement of organs for research will facilitate an increased effort and performance for OPOs to contribute to the development of new treatments for disease.

Sincerely,

Thomas Asfeldt, RN. BAN. CPTC
Director, OPO/Tissue Bank Relations
Vesta Therapeutics, Inc.
801 Capitola Dr, Suite 8
Durham, NC 27713
tasfeldt@vestatherapeutics.com

Submitter : Mr. Daniel Carney
Organization : National Kidney Foundation of Michigan
Category : Other Association

Date: 05/17/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3064-P-16-Attach-1.DOC

Attachment #16

The National Kidney Foundation of Michigan strongly encourages inclusion of public education in the CMS regulations for organ procurement organizations. In our experience, public education is a key component of the donation and transplantation process, and should be included as a vital component of these regulations.

An example of public education done by the NKFM is a program done in African American beauty salons. Beauty salon stylists have health chats with their clients about their kidneys and organ donation. Because organ donation is low in the African American community, this educational program is essential. Public education is necessary for the many people who still have apprehensive feelings about organ donation.

Organ Procurement Organizations must have education programs in hospitals for staff AND in the public domain. We look forward to the day when the family of a deceased person asks the hospital staff about their loved one becoming an organ donor. This type of behavior will not happen without positive messages continuing to be delivered.

Please include public education in the CMS conditions of participation and conditions for Medicare and Medicaid programs.

Submitter : Ms. Vicki Danner

Date: 05/24/2005

Organization : Tri-State Dialysis

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

I firmly believe that the transplant social worker needs to be a licensed masters social worker. He/she needs to have the clinical skills to screen organ donors & recipients to insure for successful outcome.

Submitter : Ms. Lisa Langley
Organization : Midwest Eye-Banks
Category : Other Health Care Provider

Date: 05/24/2005

Issue Areas/Comments

GENERAL

GENERAL

The Midwest Eye-Banks, with divisions in Illinois and Michigan, strongly encourages the Centers for Medicaid and Medicare Services to incorporate public education activities into the conditions for coverage for Organ Procurement Organizations. While working in collaboration with the Organ Procurement Organizations, Gift of Life Michigan and Gift of Hope Organ and Tissue Donor Network of Illinois, we have found that barriers to donation are reduced if families are given an opportunity to dispel misconceptions and learn facts about donation prior to encountering end of life decisions in a hospital setting. Reduction of these barriers, through education, leads to an increase in affirmative attitudes regarding donation and enrollment in the Michigan and Illinois Organ, Tissue and Eye Donor Registry.

While there may be difficulties in measuring the immediate effectiveness of public education activities, the long-term effects of educating and motivating people to foster a positive local attitude regarding donation will certainly have long-term positive effects on a national level. Funding of public awareness activities will help foster the creation of a "donation-friendly America" where a positive attitude about organ, tissue and eye donation will be the norm rather than just a hope.