

April 26, 2005

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

RE: **CMS-3064-P**
"Recertification and competition" §486.316

To Whom It May Concern:

As President/CEO of Jennie Edmundson Hospital, I am writing to comment on the Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs) proposed rule CMS-3064-P. The proposed rule may severely undermine a critical Department of Health and Human Services (HHS) initiative. The recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90,000 Americans and over 370 people waiting for organ transplants in Iowa.

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. Jennie Edmundson, is represented on the Board of Directors by the service of its Senior Vice President, Karen Stein. This link allows Jennie Edmundson to have a birdseye view into this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. The model aims at implementing best practices for increasing the rates of organ donation.

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

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.

Our hospital is working with Iowa Donor Network (IDN) OPO as a team, implementing what has been learned in the Collaborative hospitals. We know that state-wide, neurosurgeons, intensivists (both pediatric and adult) social workers, nurses, hospital administrators and OPO personnel are working together and achieving a 97% referral rate!

Centers for Medicare & Medicaid Services

April 26, 2005

Page -2-

As a hospital contributing to this referral increase and the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Sincerely,

A handwritten signature in cursive script, appearing to read "David M. Holcomb".

David M. Holcomb
President and Chief Executive Officer

DMH/sh

Stewardship of the Gift of Donation - Organ Versus Tissue Transplantation Systems

 Mixture of "for-profit" and "not-for-profit" companies
 Exclusively "not-for-profit"

Tissue Transplantation System

TPO = Tissue Procurement Organization (musculoskeletal, eye, cardiovascular, and/or skin) other than OPO

The Gift of Donation	Pre-Procurement Screening	Procurement	Post-Procurement Donor Testing/ Screening	Development of Technology	Processing	Storage and Records Management	Packaging Labeling Distribution	Recipient
Hospital or Medical Examiner/ Coroner	OPO, TPO or Donor Screening Service	OPO and/or TPO	Technology Required <ul style="list-style-type: none"> • Safety • Effectiveness • Availability • Ease of Use 			Tissue Processor	Tissue Processor with or without Marketing Company	Hospital or Surgical Center
<p>"For profit" and "not-for-profit" tissue processors often outsource some of these functions to other companies or to one another in order to contain costs and provide a wider range of therapeutic options for patients. As a result, hundreds of forms of tissue are available for patients in need.</p>								

Organ Transplantation System

Hospital	OPO	No Technology Required	No organ Storage - OPO maintains donor file	OPO Organ Sharing per UNOS Guidelines	Hospital
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UNIVERSIDAD DE PUERTO RICO, RECINTO DE CIENCIAS MEDICAS
UNIVERSITY OF PUERTO RICO, MEDICAL SCIENCES CAMPUS
SCHOOL OF MEDICINE, ESCUELA DE MEDICINA

OFICINA DEL DECANO
OFFICE OF THE DEAN



April 29, 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

HARDCOPIES SENT VIA U.S. MAIL

Response Comments Regarding CMS Proposed Regulations On:
"Outcome Measures" (non-contiguous states) §486.318

I am moved to write on behalf of LifeLink of Puerto Rico, to register my support of your proposed regulation regarding OPO performance measures when the OPO is located in non-contiguous States or commonwealths.

42CFR §486.318 states *"With the exception of OPOs operating exclusively in non-contiguous U.S. States, territories, possessions, or commonwealths, we propose an OPO certification threshold of 75 percent of the national mean for four out of five of the following outcome measures...."*

"An OPO operating exclusively in non-contiguous States, territories, possessions, or commonwealths would be required to meet the following outcome measures at 50 percent of more of the national mean, averaged over the 4 calendar years before the year of recertification: 1) Number of kidneys procured as a percentage of the potential donor denominator; and 2) number of kidneys transplanted, as a percentage of the potential donor denominator."

As the Dean of the University of Puerto Rico School of Medicine, I work closely with LifeLink of Puerto Rico and have great respect for the work they do here in Puerto Rico. Since LifeLink of Puerto Rico began operations in 1994, they have overcome many difficulties, both cultural and physical so many of Puerto Ricans have received transplants and this is increasing every year. I understand they work against great difficulties due to a shortage of physical and professional resources in our hospitals. To measure an OPO in this type of environment in the same way a mainland OPO is measured would not be appropriate.

Again, I respect your decision to measure LifeLink of Puerto Rico at a reduced percentage of the national mean and I believe they will continue to meet and even surpass your standards as they continue to increase donation and transplantation in Puerto Rico.

Respectfully,

Francisco M. Joglar, MD
Dean

/cta



Sheila Dixon
President,
Baltimore City Council

100 N. Holliday Street, Room 400 • Baltimore, Maryland 21202
410-396-4804 • Fax 410-539-0647

April 4, 2005

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

Re: Recertification and Competition 486.316

Dear Sir/Madam:

As Board Member of The Transplant Resource Center of Maryland, I am writing to update you about recent regulatory developments that may severely undermine a critical Department of Health and Human Services (HHS) initiative. Recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90, 000 Americans and over 2400 citizens waiting for organ transplants in Maryland.

The Organ Donation Breakthrough Collaborative has engaged the Organ Procurement Organization (OPO) community and the nations' largest hospitals to increase the number of organs available for transplant. The Transplant Resource Center of Maryland is apart of this exciting initiative that relies on joint accountability and an integrated partnership between OPO's and participating hospitals. The 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. Nationally, the number of deceased organ donors has increased by nearly 11%, and contributed to increases of more than 20% in Maryland. In fact, this collaborative model has been widely studied and cited by the greater healthcare quality improvement community for its effectiveness.

As our hospitals and the Transplant Resource Center of Maryland have worked together as a team over the past year and a half, we have accomplished phenomenal things. We have some of the busiest trauma centers in the country and have successful transplant programs that rely on the relationships forged by the OPO and the hospital staff.

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

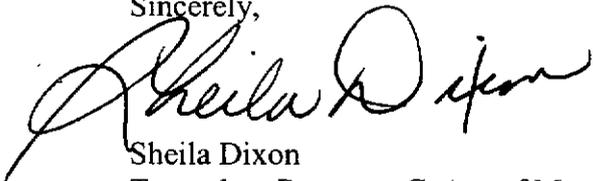
We are proud to say that our team has increased the conversion rates at our OPO to 62%. This success which has saved an addition 100 lives through the provision of addition organs available for transplantation from 2003 to 2004. Some of these gains can be attributed to the exceptional sharing of information across OPO's and hospitals to understand what is working to increase conversion rates in different parts of the country. Sharing best practices is the hallmark of this program. The Transplant Resource Center of Maryland staff has built relationships with hospital, legislative, and regulatory leaders that bridge the gaps that had existed in the past.

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

1. Developed clinical trigger criteria – making referrals more timely and consistent.
2. Increase timely death record reviews so that missed opportunities could be addressed.
3. Identified high level hospital “champions” to put organ donation on the priority list for our hospital.
4. Further developed our DCD protocols
5. Continued to model one of the most effective consent processes in the country

As a Board member of the OPO who has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Sincerely,



Sheila Dixon
Transplant Resource Center of Maryland
Board Member



Methodist • Lutheran • Blank

Eric T. Crowell
President and CEO

1200 PLEASANT STREET
DES MOINES, IA 50309-1453
PHONE 515-241-5891
FAX 515-241-5994

April 21, 2005

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

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

As President and CEO of Iowa Methodist Medical Center and Blank Children's Hospital, I am writing to comment on the Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs) proposed rule CMS-3064-P. The proposed rule may severely undermine a critical Department of Health and Human Services (HHS) initiative. The recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90,000 Americans and over 370 people waiting for organ transplants in Iowa.

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. Iowa Methodist is part of this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. The model aims at implementing best practices for increasing the rates of organ donation.

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

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.

As our hospital and Iowa Donor Network have worked together as a team over the past year and a half, we have seen some phenomenal things. Iowa Methodist is a 600 bed hospital located in Des Moines, Iowa. It is the busiest trauma center in the city and has a successful kidney transplant program. Even though we are a transplant center we were not excelling at referring potential donors to our OPO nor were we a leader in translating consent to an actual donation. Our conversion rate prior to joining the Organ Donation Breakthrough Collaborative was 47%.

We are proud to say that our team has increased the conversion rate at our hospital to 75%, and has met the goal set for the Collaborative participants. This success has been due to the hard work of hospital and OPO staff. It can also be attributed to the exceptional sharing of information across OPOs and hospitals to understand what is working to increase conversion rates in different parts of the country. Sharing best practices is the hallmark of this program. Iowa Methodist Medical Center/Blank Children's Hospital has built relationships with OPO staff that bridge the gaps that had existed in the past.

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

1. Developed clinical trigger criteria - making referrals more timely and consistent
2. Increase timely death record reviews so that missed opportunities could be addresses
3. Identified high level hospital "champions" to put organ donation on the priority list for our hospital
4. Implemented a DCD protocol

As a hospital who has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Sincerely,



Eric Crowell
President and CEO
Iowa Methodist Medical Center

Cc: Suzanne Conrad, CEO
Iowa Donor Network

April 5, 2005

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
April 5, 2005**

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.

§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.

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



Estado Libre Asociado de Puerto Rico
Departamento de Salud

March 30, 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

HARDCOPIES SENT VIA U.S. MAIL

RE: Response comments regarding CMS proposed regulations on outcome measures for non-contiguous states

On behalf of the designated Health Secretary for the Commonwealth of Puerto Rico I would like to strongly endorse the proposed measure for OPO performance applicable to OPOs operating exclusively in non-contiguous States or commonwealths.

42CFR §486.318 states *"With the exception of OPOs operating exclusively in non-contiguous U.S. States, territories, possessions, or commonwealths, we propose an OPO certification threshold of 75 percent of the national mean for four out of five of the following outcome measures...."*

"An OPO operating exclusively in non-contiguous States, territories, possessions, or commonwealths would be required to meet the following outcome measures at 50 percent or more of the national mean, averaged over the past four calendar years before the year of recertification: 1) Number of kidneys procured as a percentage of the potential donor denominator; and 2) number of kidneys transplanted, as a percentage of the potential donor denominator."

LifeLink of Puerto Rico has achieved commendable success since its inception back in 1994. During this time, and despite the difficulties encountered because of our unique cultural barriers among both the general public and health care professionals, our limited resources, and medical infrastructure, an increasing number of organs and tissues have been recovered and benefit hundreds of Puerto Ricans through transplantation therapy.

The Health Department has been very supportive of the struggles of LifeLink and their efforts. LifeLink of Puerto Rico should not be subject to the same performance measures as OPO operating in mainland. Limiting the proposed performance measure to 50% of the national mean for kidneys recovered and transplanted, both as a percentage of the potential donor denominator, is an appropriate outcome measure for LifeLink of Puerto Rico.

If any other outcome performance measure should be selected during the course of the comment period, I would strongly suggest that LifeLink of Puerto Rico be measured at a reduced percentage of the national mean (50%).

Respectfully,

Francisco Alvarado-Ramy, MD
State Epidemiologist
Puerto Rico Department of Health

The Honorable Mike Leavitt

April 5, 2005

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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, UWHCA 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, UWHCA 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.

§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 OPO’s 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 transplants centers be held responsible for verifying a physician’s credentials prior to recovering organs as a “Conditions of Participation:

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

The Honorable Mike Leavitt

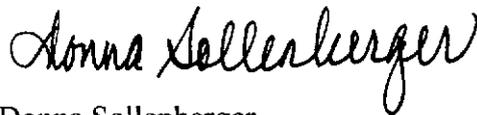
April 5, 2005

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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,

A handwritten signature in cursive script that reads "Donna Sollenberger".

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

Chair - Education, Health, and Environmental Affairs Committee

Chair - Health Subcommittee

Senate Chair

Joint Committee on Health Care Delivery and Financing

Legislative Policy Committee

Executive Nominations Committee

Rules Committee

Management Subcommittee

Special Committee on Substance Abuse

National Conference of State Legislatures



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Baltimore County*

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The Senate of Maryland

ANNAPOLIS, MARYLAND 21401-1991

PAULA C. HOLLINGER
STATE SENATOR

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

“Recertification and Competition” 486.316

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The Organ Donation Breakthrough Collaborative has achieved extraordinary results in the past 12 -18 months. Nationally, the number of deceased organ donors has increased by nearly 11%, and contributed to increases of more than 20% in Maryland. In fact, this collaborative model has been widely studied and cited by the greater healthcare quality improvement community for its effectiveness.

As our hospitals and the Transplant Resource Center of Maryland have worked together as a team over the past year and a half, we have accomplished phenomenal things.

We have some of the busiest trauma centers in the country and have successful transplant programs that rely on the relationships forged by the OPO and the hospital staff.

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

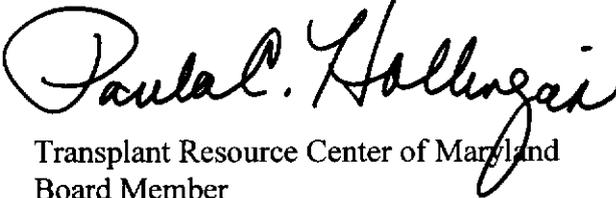
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The Collaborative Team has used strategies and change concepts to create opportunities in the donation process.

1. Developed clinical trigger criteria – making referrals more timely and consistent.
2. Increase timely death record reviews so that missed opportunities could be addressed.
3. Identified high level hospital “champions” to put organ donation on the priority list for our hospital.
4. Further developed our DCD protocols
5. Continued to model one of the most effective consent processes in the country

As a Board member of the OPO who has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Sincerely,


Transplant Resource Center of Maryland
Board Member

March 28, 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

HARDCOPIES SENT VIA U.S. MAIL

Response Comments Regarding CMS Proposed Regulations On:
"Relationships with Tissue Banks" §486.322

I am writing to comment on the proposed CMS regulation regarding relationships with other tissue banks. As a donor family, tissue recipient and Chairperson of LifeLink's Advisory Board, I strongly oppose this rule because I believe that it could have serious implications for the organ procurement organization (OPO) as well as create ethical and legal issues between the OPO and the donor families.

42CFR §486.322 states *"We propose requiring OPOs to have arrangements with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements to cooperate in the following activities, as may be appropriate, to assure that all usable tissues are obtained from potential donors...(2) Obtaining informed consent from families of potential tissue donors in the absence of a donor document; and..."*

I feel strongly that the OPO should only be required to work with those tissue banks with which they have a mutual understanding regarding practices. Since each organization operates under different standards, it raises great concern if the OPO is forced to work with another organization whose practices are not to the highest standards as those practiced by the OPO.

As a family member who has consented to donation, I would not feel comfortable granting consent to one organization knowing there are several other recovery agencies involved in the donation. I would hold the OPO accountable for everything that took place by those other organizations. In addition, since the OPO would not be the only one caring for my loved one, they would have no control over what I could expect from the process such as the appearance of my loved one after the recovery.

I strongly believe that the OPO should only be required to obtain consent or be involved in obtaining a medical/social donor history for a tissue bank with which the OPO has a formal working relationship.

Sincerely,



Ann Sechrist

43

MEDICAL EXAMINER

DEKALB COUNTY

Gerald T. Gowitt, M.D.
Chief Medical Examiner
AP, CP, FP Board Certified

3550 Kensington Road
Decatur, Georgia 30032-1328
Office: (404) 508-3500
Fax: (404) 508-3509
www.dekalbmedicalexaminer.com

March 25, 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

As Medical Examiner for Dekalb County, Georgia, an appointed member of the Georgia Governor's Advisory Board for Anatomical Gifts and long time member of the LifeLink of Georgia's Advisory Board, I am writing to you to voice my concern regarding the proposed CMS regulation that may interfere with Medical Examiner investigations as well as hamper organ procurement operations.

42CFR §486.322 states "*We propose requiring OPOS to have arrangements with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements to cooperate in the following activities, as may be appropriate, to assure that all usable tissues are obtained from potential donors... (2) obtaining informed consent from families of potential tissue donors in the absence of a donor document; and...*"

The Office of the DeKalb County Medical Examiner has honored the wishes of donors and their families for many years and has without reservation, allowed the trained professionals from LifeLink of Georgia to secure informed consent and coordinate the donation process. In calendar year 2004, there were 34 tissue donors that fell under the jurisdiction of the Dekalb ME.

It is very rare when we are unable to give clearance for tissue donation and we take extraordinary steps to assure every suitable organ is made available for transplant. We are able to do this because of a long-standing and trusting relationship with LifeLink. When a request is made for any tissue or organ, we understand their process, know that the family has been counseled and consent secured from the appropriate individual(s) and of utmost importance, we are confident donation will not interfere with the integrity of our investigation or the responsibility of this Office. To date, we only have such a relationship with LifeLink, despite requests by other tissue recovery agencies over the years.

Page 02

My concern with the notion of requiring the OPO to request on behalf of tissue banks other than their own or those they have working relationships with, is twofold. It is my responsibility as medical examiner to ensure integrity of process on behalf of the deceased as described above, also, as an advisor to LifeLink of Georgia, I believe that OPOs should not be forced to work with a tissue bank because the practices of the tissue bank may not be consistent with those of the OPO, particularly as it relates to consent. If the intention of this regulation is to require an OPO to request and obtain an informed consent on behalf of a tissue bank that does not share the same policies/practice, this could place the OPO in a difficult legal and ethical position with the donor family.

To that end, I support the requirement that the OPO function in the role as "gate-keeper" and pass referrals on to the entity the hospital has selected as their tissue provider; however, the OPO should not be required to work with a tissue bank with whom it does not want to work.

Respectfully,

A handwritten signature in cursive script that reads "Gerald T. Gowitt MD". The signature is written in black ink and is positioned above the printed name.

Gerald T. Gowitt, MD
DeKalb County Medical Examiner

44

OFFICE OF THE MEDICAL EXAMINER
GWINNETT COUNTY

Steven F. Dunton, M.D.

Chief Medical Examiner

175 Langley Drive
Suite E-1
Lawrenceville, Georgia 30045
Office: 770-995-5558
Fax: 770-995-6746

March 28, 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

HARDCOPIES SENT VIA U.S. MAIL

Response Comments Regarding CMS Regulations On:
"Relationships with Tissue Banks" §486.322

As Medical Examiner for Gwinnett County of Georgia, I must voice my concern regarding the proposed CMS regulation that may interfere with Medical Examiner investigations as well as potentially adversely effect organ procurement operations.

42CFR §486.322 states *"We propose requiring OPOS to have arrangements with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements to cooperate in the following activities, as may be appropriate, to assure that all usable tissues are obtained from potential donors... (2) obtaining informed consent from families of potential tissue donors in the absence of a donor document; and..."*

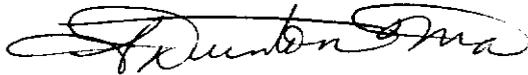
It has been brought to my attention that new regulations proposed by CMS will mandate that OPOs obtain consent from potential donor families and "share" this consent with other agencies, including those they may not have previously signed agreements with. In my opinion, the role in which the OPO is placed, specifically the OPO that I work with, LifeLink of Georgia, will prove detrimental to donation as a whole.

Relationships with medical examiners are built over time fostering integrity and trust, the relationship between Gwinnett County Medical Examiner Office and LifeLink of Georgia is no exception to this rule. This proposed regulation would place the medical examiner in a difficult role as well, we would be asked to "clear" tissue donation to a tissue recovery agency in which no prior relationship has been established. This action could potentially affect the integrity of our investigation where forensic evidence is being gathered. The OPO is placed in a very difficult and litigious position; asking them to

obtain an informed consent for an agency they may not be familiar with or may fundamentally disagree with their procedures/practices. Over the years, other tissue banks have approached us regarding clearance on tissue donation. We have chosen not to collaborate as we do with LifeLink of Georgia, because of the uncertainty of practice and the lack of established relationships.

I would support a requirement where OPOs forward referrals to a tissue bank designated by the hospital however, I would not support any requirement where an OPO is mandated to obtain consent for an agency in which they have no formal or at a minimum "willing" agreement.

Respectfully,

A handwritten signature in black ink, appearing to read "Dr. [Name]", written in a cursive style.



A member of Mercy Health Network

Office of the President

45
801 Fifth Street
Sioux City, IA 51101
P 712.279.2018 F 712.279.2034

APR 25 2005

April 19, 2005

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

CMS-3064-P
“Recertification and competition” §486.316

As President and CEO of Mercy Medical Center – Sioux City, I am writing to comment on the Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs) proposed rule CMS-3064-P. The proposed rule may severely undermine a critical Department of Health and Human Services (HHS) initiative. The recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90,000 Americans and over 370 people waiting for organ transplants in Iowa.

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. Mercy Medical Center – Sioux City is part of this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. The model aims at implementing best practices for increasing the rates of organ donation.

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

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.

APR 25 2005

As our hospital and Iowa Donor Network have worked together as a team over the past six months we have seen some phenomenal things. Mercy is a 300-bed hospital located in Sioux City, Iowa. It is the city's only trauma center and serves many outlying towns and areas. Mercy is the largest non-transplant, donor hospital in Iowa. Yet, we were not satisfied with this status because we knew we had room for improvement. We did a good job of referring potential donors to our OPO but had difficulty translating consent to an actual donation. Our conversion rate prior to joining the Organ Donation Breakthrough Collaborative was 44%.

We are proud to say that our team has increased the conversion rate at our hospital to 61%, and are steadfastly working toward the 75% goal set for the Collaborative participants. This success has been due to the hard work of hospital and OPO staff. It can also be attributed to the exceptional sharing of information across OPOs and hospitals to understand what is working to increase conversion rates in different parts of the country. Sharing best practices is the hallmark of this program. Mercy Medical Center – Sioux City has built relationships with OPO staff that bridge the gaps that had existed in the past.

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

1. Developed clinical trigger criteria - making referrals more timely and consistent
2. Increase timely death record reviews so that missed opportunities could be addresses
3. Identified high level hospital "champions" to put organ donation on the priority list for our hospital
4. Implemented a DCD protocol
5. Created an In-House Coordinator position

As a hospital that has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested, competitive model that CMS proposes in the rule.

Sincerely,



Peter E. Makowski

President/CEO

Mercy Medical Center – Sioux City, IA

51102



EMORY
UNIVERSITY
SCHOOL OF
MEDICINE

Emory Transplant Center
Department of Surgery, Division of Transplantation

Christian P. Larsen, MD PhD
Carlos and Marguerite Mason Professor of Surgery
Director, Emory Transplant Center
404.727.8466

Kenneth A. Newell, MD PhD
Associate Professor of Surgery
404.727.2489

Thomas C. Pearson, MD PhD
Livingston Professor of Surgery
404.727.8464

Paul L. Tso, MD
Assistant Professor of Surgery
404.727.9942

March 30, 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:

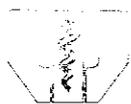
**RE: Response Comments Regarding CMS Proposed Regulations On:
"Outcome Measures" (DCD) §486.318**

As the Chief of Renal Transplantation at Emory University Hospital and Associate Medical Director of LifeLink of Georgia, I would like to address the inclusion of DCD donors in the standardized definition of organ donor potential.

I strongly support the exclusion of donation after cardiac death (DCD) donors in 42CFR §486.318 "*Standardized Definition of Organ Donor Potential*". My reason for opposition regarding the inclusion of DCD is multi-factorial and spans Organ Procurement Organization (OPO) issues as well as transplant center practice.

Specifically, limiting the definition of "donor potential" to include brain deaths only is a more accurate reflection of common OPO practice. DCD donors only represent approximately 5% of the recovered donors in 2004. Locally, LifeLink of Georgia experienced a 21% increase in recovered vascular donors from 2003 to 2004. This increase was achieved without any DCD donors in calendar year 2004 despite the fact they have a DCD policy and evaluate for DCD when appropriate.

While there are transplant centers that successfully recover and transplant organs from DCD donors, this practice is not commonplace throughout the United States and certainly not at a local level here in Georgia. The small number of DCD donors recovered in Georgia since 2003 have been placed outside of the state. Although I believe there will be growth in the area of DCD both locally and nationally, it is premature to include DCD



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1639 Pierce Drive
Atlanta, Georgia 30322

Tel 404.727.8465
Fax 404.727.3660

The Robert W. Woodruff Health Sciences Center
An equal opportunity, affirmative action university

donors in the standardized definition. Once every OPO has maximized growth in the population meeting brain death criteria, then perhaps the standardized definition of organ donor potential should be modified to include DCD. Inclusion prior to such a time may cause donors to be recovered as DCD rather than allowing potential brain-dead donors to be pronounced and the recovery outcome fulfilled to its maximum potential.

Respectfully,

A handwritten signature in black ink, appearing to read 'Tom Pearson', with a long horizontal flourish extending to the right.

Thomas C. Pearson, MD, PhD
Livingston Professor of Surgery
Chief of Renal Transplantation
Emory University Hospital/Emory University School of Medicine
Department of Surgery

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 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,


John Gargaro, M.D.

EMORY HEALTHCARE

The Emory Spine Center

Scott D. Boden, MD
Professor of Orthopaedics
Director, The Emory Spine Center
404-778-7143 Phone
404-778-7117 Fax
Scott_Boden@Emory.Org

May 2, 2005

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

Comment: "Requesting Consent" – Sec. 486.342, proposed consent item 5

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, proposed consent item 5), 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. As an orthopedic surgeon I am regularly involved in helping patients make decisions about tissue transplantation and the use of medical devices to help them lead better lives. My patients and I have come to rely on many of the products that I fear will become too expensive or otherwise unavailable if the current CMS rule goes into effect. Furthermore, the differences in "for profit" and "not for profit" entities have become increasingly blurred and present an unnecessary decision for families at an already difficult time when they have lost a loved one.

Each year, donated tissue is utilized in thousands of musculoskeletal surgeries to alleviate pain and restore a patient's range of motion. This would not be possible without the generous gift of tissue donation, and the enhancement of that gift through the complex technologies developed by for-profit entities in the tissue banking community. This attempted rule change appears to be nothing more than an attempt by one or more of the non-profit processors to "lock up" the already limited supply of donor tissue and shut out the "for profit" competition.

The U.S. does not have a completely not-for-profit system capable of meeting the demands and needs of patients requiring musculoskeletal tissue transplantation. 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 may be forced to restrict the use of their loved ones' tissues to either a for-profit or a non-profit entity. My fear is that the overwhelming majority will choose non-profit entities not knowing that there really is no difference between non-profit and for-profit companies other than federal tax status. By reducing the amount of tissue for-profit companies can obtain, the rule will effectively remove good companies and good products from the market – the same products I rely on weekly during surgery.

I agree with the overall goal of the proposed CMS rule: to increase organ and tissue donation in the U.S. But I fear the rule, as drafted, will lead to confused donors, fewer overall donations, and a vacuum in the market for the kinds of products for-profit companies make using donated tissue. Please remove any discussion of choosing between for-profit and non-profit companies when talking to donors and instead include a statement that *"donated organs and tissue are handled by several entities before they find their way to patients, including a mix of "for-profit" and "non-profit" entities that each add value to make sure your donation is used in the most beneficial way possible."* This would provide the donors with a good deal of information without creating confusion in the hospital or in the marketplace.

I respectfully request that the proposed CMS rule not be adopted in its current form, but rather take the approach I am advocating in this letter.

Sincerely,



Scott D. Boden, MD
Professor, Orthopaedic Surgery
Director, The Emory Spine Center
Emory University School of Medicine
Atlanta, GA

April 26, 2005

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

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

As Vice President at Hartford Hospital, 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. The recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90,000 Americans, many of whom are waiting in Connecticut for organ transplants.

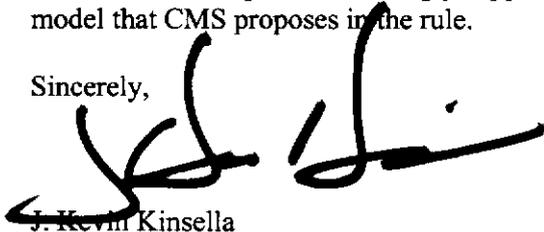
The Organ Donation Breakthrough Collaborative has engaged the organ procurement organization (OPO) community and the nation's largest hospitals to increase the number of organs available for transplant. Hartford Hospital is part of this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. The model aims at implementing best practices for increasing the rates of organ donation.

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. Using this model over the past year, Hartford Hospital has seen a dramatic increase in its conversion rate.

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.

As a hospital who has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

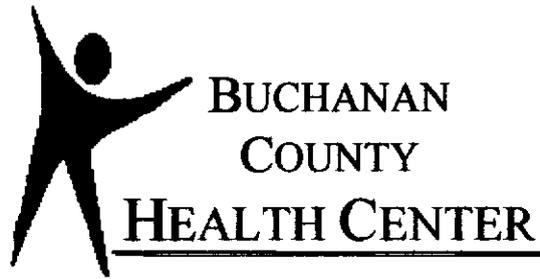
Sincerely,



J. Kevin Kinsella
Vice President

cc: Debra Savaria
Judy Pepe, MD





April 19, 2005

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

RE: CMS-3064-P
"Recertification and Completion" 486.316

Good Morning:

As Administrator/CEO of Buchanan County Health Center in Independence, Iowa, I am writing to comment on the Medicare and Medicaid Program; Condition for Coverage for Organ Procurement Organizations (OPOs) proposed rules CMS-3064-P. The proposed rule may severely undermine a critical Department of Health and Human Services (HHS) initiative. The recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90,000 Americans and over 370 people waiting for organ transplants in Iowa.

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. As a member of Iowa Donor Network's (IDN) Board of Directors, I represent Buchanan County Health Center and the interests of all Iowa hospitals. I am a witness to this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. The model aims at implementing best practices for increasing the rates of organ donation.

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

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.

While Buchanan County Health Center is a Critical Access Hospital and not likely to provide care for a potential organ donor, the citizens of this community do rely on the services of hospitals in Iowa City and Des Moines for organ transplantation. Therefore any effort to promote and increase organ donation is a benefit to this community. Further, Buchanan County Health Center actively works with IDN personnel to promote and facilitate tissue and eye donation. I am proud that by working together, Iowa has achieved a 97% referral rate of potential organ donors! And, on a very personal basis, I am a recipient of a kidney transplant from the University of Iowa, Iowa City in 2000.

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

Sincerely,



Robert J. Richard
Administrator / CEO

cc. Suzanne Conrad
C.E.O.
Iowa Donor Network
550 Madison Avenue
North Liberty, Iowa 52317



DONOR ALLIANCE

Enhancing Lives Through Organ and Tissue Donation

June 3, 2005

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

Re: CMS-3064 Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPO's)

Dear Dr. McClellan:

I am writing in support of the Association of Organ Procurement Organization's (AOPO) response to the proposed CMS regulations. Donor Alliance is the federally-designated organ procurement organization for all of Colorado and Wyoming with the exception of three counties in southwestern Wyoming.

I applaud the many positive aspects of the proposed regulations. In particular, the shift from donors per million to potential based on neurological criteria better reflects the true opportunity for donation. Secondly, the call for continuous quality improvement programs will provide a platform for institutionalizing the analysis of many aspects of the OPO. In support of the recent results of the HRSA Breakthrough Collaborative, I'm pleased that the regulations call for comments related to joint accountability and collaboration between hospitals and organ procurement organizations.

There are, however, several areas that warrant modification. Of most significant concern is decertification based on competition rather than collaboration. The stunning success of the HRSA Breakthrough Collaborative is a testimony to a synergistic process of sharing successful techniques between OPO's. While the performance metric has changed, the performance measures themselves continue to have a high correlation to one another. As proposed, they do not constitute "multiple outcome measures" as required by Congress. Finally, the appeals process, as proposed, is vaguely defined and could allow for uncertainty and unfairness in its application.

720 South Colorado Blvd., Suite 800-N
Denver, Colorado 80246
303-329-4747
Fax 303-321-0366

104 South Cascade Avenue, Suite 107
Colorado Springs, Colorado 80903
719-636-3338
Fax 719-636-1079

518 28 Road, Suite B-106
Grand Junction, Colorado 81501
970-245-9815
Fax 970-245-9818

141 South Center St., Suite 306
Casper, Wyoming 82601
307-577-1700
Fax 307-577-1702

Centers for Medicare and Medicaid Services

June 3, 2005

Page 2

We are supportive of the concept of program accountability and share the commitment to increase organ donation in order to provide transplants for those who wait. From 2003 to 2004, Donor Alliance experienced a 23% increase in donation, and we're on target for a 20% increase in 2005. This can be accomplished by focusing on ways to continue to increase conversion rates rather than facing a competitive environment.

Thank you for the opportunity to comment. If you have any questions about our position, I'm available at 303-329-4747.

Sincerely,

A handwritten signature in cursive script that reads "Sue Dunn".

Susan M. Dunn
President/CEO

SMD/jcm



52

June 1, 2005

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

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

Gentlemen:

The record increases in 2004 organ donation rates followed the launch by HRSA (Health Resources and Services Administration) of the Organ Donation Breakthrough Collaborative. This initiative brought together donation professionals and hospital leaders to identify and share best practices to maximize organ donation rates. The aim was to achieve organ donation rates of 75% at participating hospitals. Staff from HRSA and the OPO's (Organ Procurement Organization) helped participating hospitals identify, adapt, test and implement practices known to produce high donation rates.

Organ donation increased by an unprecedented 11% in 2004, reaching a new annual record of transplants. Results so far for the first four months of 2005 are breaking each of the monthly records established in 2004. In the next phase, the Collaborative seeks to increase the number of transplants by encouraging medical professionals to adopt practices that allow them to maximize the number of transplantable organs from each donor.

As Director of Nursing at Denver Health Medical Center (DHMC), I am writing to you about our concern regarding recent regulatory developments that may severely undermine a critical Health and Human Services (HHS) initiative. CMS is proposing an untested, competitive model in which all OPO's would be competing every four years to continue to serve its area. The above-mentioned progress would not have been possible in a competitive environment.

I am a member of the Board of Directors for Donor Alliance and, as a result, have had the opportunity to interface with other hospitals on how to increase donation in a non-competitive manner.

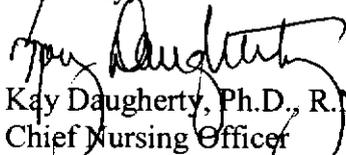
DHMC is a 398 licensed-bed Level 1 trauma center located in Denver, Colorado, the largest trauma center in the state. Our hospital and Donor Alliance have worked collaboratively as a team over the past few years and have experienced some phenomenal results. Our conversion rate prior to joining the Collaborative was below 50% and for 2005 YTD, it is approaching 80%. This success, which has saved at least 30 lives, is mostly attributable to the hard work and persistent efforts of the hospital and OPO staff. Another key to the success of the Collaborative effort has been the genuine willingness of other OPO's and hospitals nationally to share information so we can better understand what is working to increase conversion rates in different parts of the country. Sharing of best practices has played a major role in the success of this program. DHMC staff has helped strengthen these relationships with Donor Alliance staff, and barriers have been removed that existed in the past.

The Collaborative team has used strategies used from Best Practices to create opportunities in the donation process by implementing the following:

- Developed clinical trigger criteria for early referrals
- Developed a referral system through the Emergency Department which has made referrals more consistent and timely
- Developed real-time death record reviews so that missed opportunities could be addressed
- Developed a DCD protocol

The competitive model has the potential of stifling the sharing of best practices between OPO's that have been developed and fostered through the Organ Donation Breakthrough Collaborative. We strongly support the Collaborative model in place of the competitive model that CMS proposes.

Sincerely,


Kay Daugherty, Ph.D., R.N.
Chief Nursing Officer
Denver Health Medical Center

KD:cp

NORTH CAMPUS
700 Potomac Street
Aurora, CO 80011
303.363.7200

MAIN CAMPUS
1501 South Potomac Street
Aurora, CO 80012
303.695.2600

June 1, 2005

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

Re: CMS-3064-P
“Recertification and Competition” §486.316

Gentlemen:

As Chief Nursing Officer of The Medical Center of Aurora, and Chair of the Board of Directors for Donor Alliance, I am writing to comment about recent regulatory developments that may severely undermine a critical Department of Health and Human Services (HHS) initiative; proposed rule CMS-3064-P.

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. While we are making record-breaking progress in organ donation, too many opportunities to donate are missed each year.

The Medical Center of Aurora is a licensed 346-bed general, acute-care hospital located in Aurora, Colorado, and has been one of the participating Collaborative hospital teams in Colorado. I, personally, as well as one of our neurosurgeons, have attended the Collaborative learning sessions. This has been an exciting initiative that relies on joint accountability and partnership with the OPO’s. Being a part of a large hospital system, I have been able to network with my colleagues in Denver as well as other parts of the country on this very important issue.

As a result of some of the best practices generated, we were able to implement a Donation after Cardiac Death (DCD) policy and had our first DCD donor this year without a glitch. This was a positive experience for the family, hospital staff and physicians. We have also implemented the Critical Care Dashboard tool that was developed by one of the participating Collaborative hospitals and use this information to present donation outcomes at our hospital quality committees. This dashboard tool was presented at two of the Collaborative learning sessions and shared with over 20 hospitals/OPO’s nation-wide. We have also developed systems to ensure that expert requestors are involved in family consent and discussions and developed a system to ensure early donor identification and referral to the OPO.

Centers for Medicare & Medicaid Services

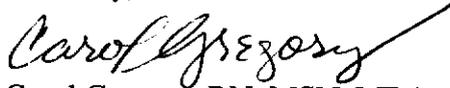
June 1, 2005

Page 2

Drawing from the experiences of practitioners with high donation rates, teams have been working together to learn, adapt, re-design, test, implement and track their organ donation process to achieve donation rates of 75% or higher. This collaboration and sharing of information occurred primarily because of a non-competitive nature.

CMS is proposing an untested competitive model whereby all OPO's 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 OPO's that have been developed and fostered through the Organ Donation Breakthrough Collaborative. We strongly support the Collaborative model in place of the competitive model that CMS proposes.

Sincerely,



Carol Gregory, RN, MSN, MBA

Chief Nursing Officer

The Medical Center of Aurora

CG:ln

ROBERT WOOD JOHNSON
UNIVERSITY HOSPITAL

One Robert Wood Johnson Place
P.O. Box 2601
New Brunswick, NJ 08903-2601/732-828-3000

Office of the President

June 2, 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

RE: **CMS-3064-P**
"Recertification and Competition" §486.316

Dear CMS Officials:

As President and CEO of Robert Wood Johnson University Hospital (RWJUH) in New Brunswick, New Jersey, I am writing to comment on the Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs) Proposed Rule CMS-3064-P. We believe that the proposed rule may severely undermine a critical Department of Health and Human Services (DHHS) initiative. The recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90,000 Americans and over 3,000 New Jerseyans waiting for organ transplants.

The Organ Donation Breakthrough Collaborative has engaged the Organ Procurement Organization (OPO) community and the nation's largest hospitals – including RWJUH – to increase the number of organs available for transplant. We have been a part of this exciting initiative since 2003 and have seen significant improvement in organ donation rates. We believe that this success is related to joint accountability and integrated collaboration between RWJUH and our OPO – the New Jersey Sharing Network. The 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. Nationally, the number of deceased organ donors has increased by nearly 11%. In fact, this collaborative model has been widely studied and cited by the greater healthcare quality improvement community for its effectiveness.

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.

Our hospital and the New Jersey Sharing Network have worked together as a team over the past year and a half with significant success. We are a Level I Trauma Center and have three successful transplant programs. Even though we are a transplant center, we were not excelling at referring potential donors to our OPO nor were we a leader in translating consent to actual donation. Since participating in the Collaborative, our referral and consent rates have improved significantly.

We are proud to say that our team has increased the conversion rate of total potential donors at our hospital to nearly 65% and we expect to reach 75% this year. The success of this initiative can be attributed to the exceptional sharing of information across OPOs and hospitals to understand what strategies are working to increase conversion rates in different parts of the country. Sharing best practices is the hallmark of this program. Robert Wood Johnson University Hospital staff have built relationships with OPO staff that bridge the gaps that existed in the past.

The Collaborative Team has used a number of strategies to create opportunities in the donation process:

1. Developed clinical trigger criteria – making referrals more timely and consistent.
2. Increased timely death record reviews so that missed opportunities could be effectively addressed.
3. Identified high level hospital "champions" to make organ donation a priority for our hospital.
4. Implemented a DCD (donation after cardiac death) protocol.

As a hospital that has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Sincerely,



Clifton R. Lacy, MD
President and CEO

ljr



Oregon Health & Science University

OHSU HOSPITALS AND CLINICS
HOSPITAL ADMINISTRATION

Mail code: CR9-6 • 3181 S.W. Sam Jackson Park Rd. • Portland, Oregon 97239-3098
TEL: 503 494-8744 • FAX: 503 494-8020

May 26, 2005

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

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

As Chief Medical Officer at the Oregon Health & Science University (OHSU), 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. The recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help almost 88,000 Americans and over 400 patients waiting for organ transplants in Oregon.

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. OHSU is part of this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. The model aims at implementing best practices for increasing the rates of organ donation.

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.

As our hospital and the Pacific Northwest Transplant Bank (PNTB) work together, an exciting team has emerged allowing us to accomplish very positive outcomes. Prior to joining the Collaborative, our overall conversion rate for donation was 62%. Currently, as a result of our work together, OHSU's conversion rate exceeds the Secretary of Health and Human Services charge of 75%. OHSU's leadership and team members are motivated to maintain and improve this rate.

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.

Centers for Medicare & Medicaid Services

Page 2

May 26, 2005

As a hospital involved in the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model and discourage the implementation of the untested competitive model that CMS proposes in the rule.

Sincerely,

A handwritten signature in black ink that reads "A. Roy Magnusson, MD." The signature is written in a cursive style.

A. Roy Magnusson, MS, MD, FACEP
Chief Medical Officer, OHSU Hospitals & Clinics
Associate Dean, Health System Affairs



56

JAMES R. TEETER
President and CEO

May 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 Gentlemen and Genteladies of CMS:

The purpose of this letter is to register the Arkansas Hospital Association's concern about the recently proposed rule CMS-3064-P (Conditions for Coverage for Organ Procurement Organizations). We fear this rule could have a detrimental impact on our member hospitals as they work with the Arkansas Regional Organ Recovery Agency (ARORA) to increase organ procurement in our state.

As you may know, our national partner, the American Hospital Association, has taken a leadership role in the HRSA initiative known as the Organ Donation Breakthrough Collaborative. At ARORA's request, we have joined the HHS Workplace Partnership for Life and have provided our board and members with updates on organ donation and the Breakthrough Collaborative.

We are thrilled with the progress we are making in organ donation in Arkansas since ten of our hospitals have joined the Collaborative effort. According to ARORA reports, there was a 45% increase in organ donors from 2003 to 2004 and this trend appears to be continuing.

Since the improvement in Arkansas is obviously linked to collaboration and partnership, we are puzzled and deeply troubled that CMS would emphasize competition between Organ Procurement Organizations as a strategy to increase organ donation. As we understand the proposed rule, each OPO could be subjected to a "takeover" by another OPO at the end of each certification cycle, providing it meets certain eligibility requirements. Such a "takeover" could occur even if the "defending OPO" meets all the standards required by CMS.

We hope you will reconsider what we believe to be a faulty theory of competition. To us, it appears contrary to the spirit of cooperation and partnership fostered through the Organ Donation Breakthrough Collaborative.

Sincerely,

James R. Teeter

JRT/sm



STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning 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

May 23, 2005

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

To Whom It May Concern:

Please find below our comments regarding the proposed rule under 42 CFR Parts 405, 482 and 488 et.al., Medicare Program; Hospital Conditions of Participation: Requirements for Approval of Transplant Centers to Perform Organ Transplants (CMS-3835-P).

As you may be aware, in 2002, New York State Commissioner of Health, Antonia C. Novello, M.D., M.P.H., Dr. P.H., appointed a Committee of experts to review all aspects of living liver donation. In December of that year, the Committee on Quality Improvement in Living Liver Donation released its report, which provided landmark recommendations on all aspects of living liver donation, including donor and recipient selection, informed consent, preoperative evaluation, intraoperative and postoperative care. These recommendations went on to become regulations which took effect in February of 2004. We are pleased to see that many of the provisions of New York State's regulations regarding informed consent and donor rights are being considered on a national level.

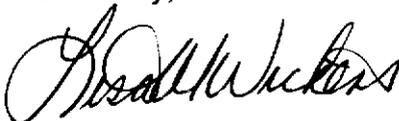
Regarding the proposed requirement, **Conditions of Participation: Patients' and Living Donors' Rights (Proposed § 482.102)**, that transplant centers performing living donor transplants provide the services of an independent donor advocate or advocacy team to potential donors, the New York State Department of Health strongly supports the use of a multi-disciplinary donor advocate team. Currently, all centers performing adult living liver transplantation in New York State are required by regulation to establish such a team.

The independent donor advocate team is required to consist of, at a minimum, an internal medicine physician, a transplant coordinator/nurse clinician, a Licensed Master Social Worker, and a psychiatrist assigned to evaluate the live donor and the participation of an ethicist, as appropriate.

This Regulation was based on the recommendations of the Committee for Quality Improvement of Living Liver Donation, who, in their deliberations, considered the concepts of both a single donor advocate and a multi-disciplinary team. The Committee determined that the interactive nature of a multi-disciplinary team and the broad range of expertise it would provide was essential to protecting the living donor.

Thank you for this opportunity to comment.

Sincerely,



Lisa M. Wickens
Assistant Director
Office of Health Systems Management

KODA

Kentucky Organ Donor Affiliates

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Fax # (304) 523-7649

May 26, 2005

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

Re: CMS 3064-P
Recertification and Competition
Section 486.316

Dear Sir or Madam:

As the President of the Kentucky Organ Donor Affiliates (KODA), the federally certified organ procurement organization for Kentucky and portions of West Virginia and Indiana, I am writing to share with you comments and concerns expressed by KODA's Board of Directors on the Medicare and Medicaid Programs' Accreditation for Coverage for organ procurement organizations (OPOs) proposed by Rule CMS-3064P. It is the opinion of KODA's leadership that the proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90,000 Americans, especially those 600 patients in the Commonwealth of Kentucky waiting for an organ transplant if OPOs which are performing well will become overly vulnerable to replacement by rival OPOs.

The Organ Donation Breakthrough Collaborative has engaged the OPO community and the nations largest hospitals to work together to increase the number of organs available for transplant. KODA, the University of Kentucky Medical Center in Lexington, Kentucky, the University of Louisville Hospital in Louisville, Kentucky, Cabell Huntington Hospital and Saint Mary Medical Center in Huntington, West Virginia, are all part of this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. Further, KODA has joined with other OPOs including LifeLine of Ohio in Columbus, Ohio, The Center for Organ Recovery and Education in Pittsburgh, Pennsylvania, and LifeNet in Virginia Beach, Virginia,



Share Your Life - Share Your Decision

Centers for Medicaid and Medicare Services
May 26, 2005
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in a collaborative effort in the state of West Virginia to enhance organ donor awareness and increase organ donation in this state where four OPOs operate. The West Virginia Organ Donation Collaborative requires all four OPOs to identify best practices that will work for all of West Virginia. Such a process does not allow any of the four OPOs to protect individual leaders of donation or differentiate programs that could give a competitive edge to one of the OPOs. All four OPOs have participated in this process to improve activity without regard to protecting proprietary programs and personnel. Open competition would make future collaborative much less effective or even impossible. Let me share an example of this concern.

Cabell Huntington Hospital, located in Huntington West Virginia, has worked with KODA since 1987 when the statewide OPO was established. Prior to that time, Cabell Huntington Hospital worked with the hospital based OPO located at the University of Kentucky Medical Center. Hoyt Burdick, MD, is the Vice President of Medical Affairs for this busy trauma center, as well as a KODA Board member. Cabell Huntington Hospital has performed so well in the field of organ donation that it is one of the hospitals that will be recognized by the Department of Health and Human Services in May, 2005 for having a consent rate greater than 75%. In the spirit of statewide improvement, Dr. Burdick has further agreed to become the physician advisor to the West Virginia statewide collaborative helping all OPOs and hospitals, by sharing with them the programs that have worked so well at KODA and Cabell Huntington Hospital, for the benefit all of West Virginia. KODA is supportive of making other West Virginia hospitals as good as Cabell Huntington in identifying organ donors. This statewide process eliminates the potential advantage KODA could develop in a competitive environment. Such collaboration would not be possible if competition with neighboring OPOs becomes the primary concern of KODA.

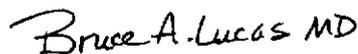
Centers for Medicaid and Medicare Services
May 26, 2005
Page 3

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.

As CMS gives consideration to a broad spectrum of models for OPOs recertification, the KODA Board of Directors favors those models which enhance the kinds of collaborative behavior which are succeeding throughout the country as noted above and promote friendly mergers or partnerships whenever appropriate. Unfriendly takeovers and adversarial posturing among OPOs are counterproductive and risk undermining the public trust in the organ donation process.

The more competitive models CMS is considering may have some questionable theoretical advantage. We believe that sufficient accountability and motivation for improvement can be achieved in a less competitive atmosphere. Open competition for all OPOs every four years is not necessary or desirable. These competitive models have the potential of stifling the sharing of best practices among OPOs that have been developed and fostered over the past two years through the Organ Donation Breakthrough collaborative. As an OPO that has been involved with the important work of increasing the number of organs available for transplantation, KODA and its Board of Directors strongly support a Collaborative model instead of any untested competitive model which CMS might put in place.

Sincerely,



Bruce A. Lucas, MD
President
Chairman of the Board

BAL/cb



**The University of Michigan
Health System**

General and Transplantation Surgery

Jeffrey D. Punch, M.D.
Associate Professor of Surgery

Office: (734) 936-5816
M-Line: (800) 962-3555
FAX: (734) 763-3187
Internet: jpunch@umich.edu

May 25, 2005

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

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

As Associate Professor of Surgery and Chief, Division of Transplantation at University of Michigan Medical Center, 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. The recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90,000 Americans and over 2,700 Michigan patients waiting 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. The University of Michigan Medical Center is part of this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. The model aims at implementing best practices for increasing the rates of organ donation.

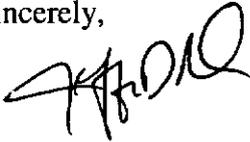
The Organ Donation Breakthrough Collaborative has achieved extraordinary results in the past 12-18 months. The number of deceased organ donors has increased by nearly 11%. In fact, this collaborative model has been widely studied and cited by the greater healthcare quality improvement community for its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

As our hospital and Gift of Life - Michigan have worked together as a team over the past months, we have seen some extraordinary things. We have been able to maintain a Conversion rate of over 75% and we were recently awarded the Department of Health and Human Services Medal of Honor for our work during the Collaborative. We have been instrumental in spreading the practices of the Collaborative to other Michigan hospitals and are often called on from other hospitals and OPOs throughout the nation seeking guidance.

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.

As a hospital who has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeffrey D. Punch". The signature is stylized and cursive.

Jeffrey D. Punch
Associate Professor of Surgery
Chief, Division of Transplantation
University of Michigan



Elizabeth B. Concordia
Senior Vice President
Academic and Community
Hospitals

President
UPMC Presbyterian Shadyside

May 23, 2005

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UPMC Shadyside
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412-623-2010
Fax: 412-623-6400
concordiaeb@upmc.edu

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

“Recertification and Competition” §486.316

As President of UPMC Presbyterian Shadyside Hospital, I am writing to update you about recent regulatory developments that may severely undermine a critical Department of Health and Human Services (HHS) initiative. Recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90,000 Americans waiting for organ transplants, including over 1,800 in the Pennsylvania/West Virginia area.

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. UPMC Presbyterian Shadyside is part of this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. The model aims at implementing best practices for increasing the rates of organ donation.

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

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.

As UPMC Presbyterian Shadyside Hospital and The Center for Organ Recovery & Education (CORE) have worked together as a team over the past year and a half; we have seen some phenomenal things. UPMC Presbyterian, a 578-bed hospital, and UPMC Shadyside, a 467-bed hospital, are located in Pittsburgh, Pennsylvania. We are one of the busiest trauma centers in the country and have a successful transplant program of our own. Our conversion rate prior to joining the Organ Donation Breakthrough Collaborative was 63%.

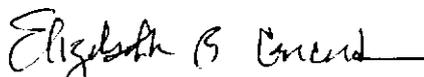
We are proud to say that our team has increased the conversion rate at our hospital to 75%, over and above the goal set for the Collaborative participants. This success, which has saved at least 255 lives, has been due to the hard work of hospital and OPO staffs. It can also be attributed to the exceptional sharing of information across OPOs and hospitals to understand what is working to increase conversion rates in different parts of the country. Sharing best practices is the hallmark of this program. UPMC Presbyterian's and UPMC Shadyside's staffs have built relationships with the OPO staff that bridge the gaps that had existed in the past.

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

1. Developed clinical trigger criteria – making referrals more timely and consistent.
2. Increased timely death record reviews so that missed opportunities could be addressed.
3. Identified high-level hospital “champions” to put organ donation on the priority list for our hospital.
4. Implemented a DCD protocol.

As hospitals that have been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

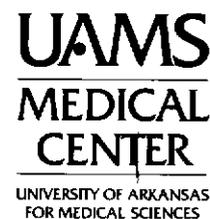
Sincerely,



Elizabeth B. Concordia
President
UPMC Presbyterian Shadyside

61

4301 West Markham
Little Rock, AR 72205-7199
501-686-7000
www.uams.edu/medcenter



May 26, 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 Sirs:

I am writing to provide comments on the recently proposed Conditions for Coverage for Organ Procurement Organizations (proposed rule CMS-3064-P). As the Chief Executive Officer for the UAMS Medical Center, which is a transplant hospital, I am very interested in the impact that this rule may have on our local Organ Procurement Organization (OPO).

UAMS has been rated by the Scientific Registry of Transplant Recipients (SRTR) study to be in the top 100 hospitals in terms of organ donor potential. We are approved to perform heart, kidney, pancreas, and liver transplants. The recent addition of a liver transplant program this year was made possible by the nearly 50% increase in organ procurement over the past two years. This improvement has mainly come about through collaborative partnerships between our local OPO, ARORA, and the three transplant centers in Little Rock. Our own hospital has quadrupled the number of converted organ donors in CY 2004 as compared to CY 2001.

After reviewing the proposed rule, I have the following comments:

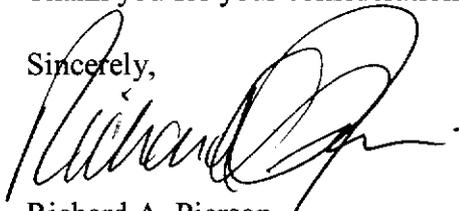
1. Encouraging open competition for OPO service areas at the end of every certification cycle regardless of whether the OPO is recertified runs counter to the spirit of collaboration we have worked so hard to attain. This collaboration comes on both local and national level through the HRSA sponsored Organ Donation Breakthrough Collaborative. We have seen a 10% increase in organ donation nationally through collaboration, not competition. Please revise the proposed rule to allow competition only if an OPO is failing to perform and will be decertified.

2. ARORA has developed a diverse and appropriately involved board of directors since it combined the governing board with the advisory board in 2001. By adding community based members who are not affiliated with the three transplant centers, ARORA now has a balanced group of directors. I understand, and support, the efforts of the proposed rule to thwart undue influence by transplant centers on OPO operations. However, I feel that ARORA's board has properly addressed conflict of interest issues by writing and enforcing a strong conflict of interest policy. If forced to exclude the positions currently required by the Public Health act, I fear we will return to the days of weak board participation, poor attendance, and apathy.

3. I support the intent of the proposed rule to measure OPO performance based on organ donor conversion. However, I do believe that there is still work to be done before we can depend on uniform reporting of potential organ donors. I encourage CMS to work with UNOS to develop a quality assurance program that will protect the integrity of the data used to measure OPO performance.

Thank you for your consideration of these remarks.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard A. Pierson". The signature is fluid and cursive, with a large initial "R" and "P".

Richard A. Pierson
Vice Chancellor for Clinical Programs



LDS HOSPITAL
A Service of Intermountain Health Care

62
Eighth Avenue and C Street
Salt Lake City, Utah 84143
(801) 408-1100

May 26, 2005

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

OR

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

CMS-3064-P

"Recertification and competition" §486.316

As Chief Executive Officer/Administrator at LDS Hospital, 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. The recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90,000 Americans, including over 270 waiting for organ transplants in Utah.

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. LDS Hospital is part of this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. The model aims at implementing best practices for increasing the rates of organ donation.

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.

As our hospital and Intermountain Donor Services have worked together as a team over the past months we have seen some extraordinary things. We have worked together to support families and promote donation by:

1. Developing standard clinical criteria for referral, making referrals timely and encouraging early communication among all members of the care team.
2. Making death record reviews part of the routine paperwork following a death, so the unit manager understands the characteristics of the referral. This has led to nurse-specific, timely education that ultimately improves the donation process.
3. Training new house staff for their role in the donation process.
4. Identifying physician and nurse champions among the critical care and administrative staff.
5. Jointly developing, testing, and implementing a Donation after Cardiac Death protocol that is the model for DCD protocols in the region.

LDS Hospital had donation rates over 65% in September 2003, and donation rates of 71% in 2004. In May, 2004, 32 organs were transplanted, the highest number in one month in our 20 year program. In 2004, LDS Hospital had the largest number of transplants ever (173), which qualified us for a Medal of Honor.

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.

As a hospital who has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Sincerely,

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

Mikelle Moore
CEO/Administrator

Laura L. Forese, M.D., MPH
Vice President & Chief Medical Officer

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foresel@nyp.org

May 15, 2005

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

Re: Re-Certification and Competition Processes (Proposed 486.316)

As VP and Chief Medical Officer of New York Presbyterian Hospital, I am writing to update you about recent regulatory developments that may severely undermine a critical Department of Health and Human Service (HHS) initiative. Recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90,000 Americans waiting nationally, and over 8,400 waiting in New York State for organ transplants.

In 2003, New York-Presbyterian Hospital, in partnership with the New York Organ Donor Network, joined the Organ Donation Breakthrough Collaborative, A HRSA initiative designed to engage the Organ Procurement Organization (OPO) community and the nation's largest hospitals to increase the numbers of organs available for transplant. This exciting initiative has relied on joint accountability and an integrated partnership between OPOs and participating hospitals, a model consistently and aimed at implementing best practices for increasing the rates of organ donation.

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

CMS is proposing an untested, theoretical, competitive model in which every OPO would be competing every four years to continue to service 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.

As our hospital and New York Organ Donor Network have worked together as a team over the past year and a half we have seen some phenomenal things. New York-Presbyterian Hospital is a 2,455-bed hospital located in New York City. Even though we are a transplant center we were not excelling at referring potential donors to our OPO nor were we a leader in translating consent to an actual donation. Prior to the Breakthrough Collaborative one of our campuses has missed a cumulative total of 26 potential organ donors since the year 2000. Since October 2003, after the Collaborative began, this same campus has had 100% referral of potential organ donors.

We are proud to say that our team has helped our hospital to improve in each of the Collaborative measurements, resulting in improvements in the donation process and 36 lives saved in 2004. This success has been due to the hard work of the OPO staff. It can also be attributed to the exceptional sharing of information across OPOs and hospitals to understand what is working to increase conversion rates in different parts of the country. Sharing best practices is the hallmark of this program. New York-Presbyterian staff has built relationships with OPO staff that bridge the gaps that had existed in the past.

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

1. Instituted an in-house Family Services Coordinator position that is devoted specifically to the potential donor families and to work closely with the hospital staff on potential organ donor cases.
2. Increased timely death record reviews so that missed opportunities could be addressed.
3. Identified high level hospital "champions" to put organ donation on the priority list for our hospital and instituted active Donor Councils at each major campus.
4. Developed and will soon implement a DCD protocol.

As a hospital who has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Sincerely,



Laura L. Forese, MD.
VP & Chief Medical Officer
New York Presbyterian Hospital



May 26, 2005

Centers for Medicare & 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: CMS-3064-P
"Recertification and competition" §486.316

As Chief Executive Officer at Primary Children's Medical Center, 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. The recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90,000 Americans, including over 270 waiting for organ transplants in Utah.

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. Primary Children's Medical Center is part of this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. The model aims at implementing best practices for increasing the rates of organ donation.

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.

As our hospital and Intermountain Donor Services have worked together as a team over the past months we have seen some extraordinary things. The Primary Children's Collaborative team has worked to improve communications and the processes related to donation. Specific improvements include:

1. Unit-tested and developed clinical triggers for referral.
2. Improved communication patterns between medical, nursing, social work, and OPO staff that emphasize End-of-Life care.
3. OPO staff presence in M&M conference to review referrals and opportunities for donation.
4. Expanded donation education for house staff, nursing staff, and attendings.

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.

As a hospital who has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Sincerely,



Joseph R. Horton
Chief Executive Officer
Primary Children's Medical Center



Arkansas Regional Organ Recovery Agency
1100 N. University, Suite 200, Little Rock, AR 72207

June 1, 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 Sirs:

I am writing to provide comments on the recently proposed Conditions for Coverage for Organ Procurement Organizations (proposed rule CMS-3064-P). Since I have served as Deputy Director of the DHS Division of Children and Family Services in Arkansas, I have some appreciation for the difficulty inherent in drafting new regulations that are complex and therefore necessarily lengthy. From this perspective, let me tell you that I believe your "first cut" was a very good effort.

Because I took charge of ARORA in the aftermath of it nearly being decertified, I have spent a lot of time thinking about how the standards should be written and how the certification/decertification process should work. I think this gives me some fairly relevant experience from which to frame these comments.

1. Measuring OPO's based on conversion of potential donors is a vast improvement over the old donors per million standard. You will need to put in place some process to assure that all OPO's are interpreting the definition for potential donor in the same way and reporting the data in the same way.
2. I do not believe that the measures for organs recovered and transplanted meet the requirement for multiple outcome measures. Those stats will be so closely linked to donor conversion rates that it is like one measurement standard instead of five.
3. The attempt to address the conflict of interest issues within OPO boards is admirable. However, not all OPO's suffer from that problem. Some, like ARORA, have healthy, thriving boards that are appropriately engaged in governance and have policies for identifying members with such conflicts while preventing them from asserting their agendas in board votes. I hope that you will rethink your requirement to have only one governing board that excludes the PHS act positions from participating by relegating them to an advisory board.
4. I believe it will be a huge mistake to open any OPO service areas for competition regardless of whether it meets CMS standards or not. Collaboration, not competition is the best way for organ procurement to thrive and succeed. HRSA's Organ Donation Breakthrough Collaborative has proved that.

5. It is not clear whether CMS intends to decertify an OPO for failing to meet 75% of the mean for organ donor conversion or if it will decertify an OPO for failing to meet any one of the standards, including the process standards. Please clarify your intent here.

6. If an OPO fails to meet the donor conversion standard but is effectively meeting all of the process standards, I believe this should be taken into account in the appeal process. In this scenario, CMS should have a remedy less severe than outright decertification. Some form of probation combined with a corrective action plan on a tight timetable would be more appropriate. ARORA is a perfect example of an OPO that has turned itself around by reorganizing and implementing multiple new approaches to organ procurement in Arkansas. We have increased our yearly average of organ donors from thirty-four (34) to fifty four (54) during the last three years.

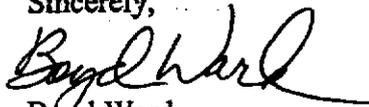
7. The CMS comments call attention (and rightly so) to conflict of interest issues within OPO's and the need to address these. I believe it is a conflict of interest for CMS to select the hearing officer in the appeals process, as proposed in CMS-3064-P. Fairness requires that a neutral third party, qualified to conduct hearings, be used to protect both the integrity of the process and preserve the appearance of impartiality.

8. After reviewing the estimated cost impact of the proposed rule, I find them to be grossly underestimated. I hope CMS will revisit these numbers and include input from people in the OPO field who can provide more accurate figures.

I have participated in the AOPO review of the proposed Conditions of Coverage through my membership on the AOPO Legislative Affairs Committee. I want to state that I am in full agreement with all of their comments and recommendations.

Thank you for making every effort to receive and process feedback on these proposed regulations. I also appreciate the sixty day extension on the public comment period. These are necessarily complex regulations and deserve the extra time and attention you have allowed them.

Sincerely,



Boyd Ward
Executive Director

CC: Bill Fiser
Board of Directors
ARORA staff
Paul Schwab

3609 Saunders Avenue
Richmond, VA 23227
OFFICE: 804-755-6048
FAX: 804-672-8318
OFFICE 24 HRS.: 1-800-847-7839

June 3, 2005

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

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

I am writing on behalf of LifeNet to provide brief comments regarding the proposed CMS rule (CMS-3064-P). LifeNet is the organ procurement organization in Virginia serving the western, central and eastern regions of the Commonwealth.

We fully support the comments included in the June 1, 2005 communication to you from the Association of Organ Procurement Organizations (AOPO). As an accredited member of AOPO, LifeNet actively participated in the consensus process leading to the communication from AOPO, and our comments are fully represented by AOPO's position.

Thank you for the opportunity to add our comments.

Regards,



Kevin A. Myer, MSHA, CPTC
OPO Executive Director

cc: Richard Hurwitz, MD, CEO
Timothy Pruett, MD, Chairman, LifeNet OPO Committee



Administration

May 16, 2005

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

Re: "Recertification and Competition" §486.316

To Whom It May Concern:

As President/CEO at Altoona Regional Health System, I am writing to update you about recent regulatory developments that may severely undermine a Department of Health and Human Services (HHS) initiative. Recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90,000 Americans waiting for organ transplants, including over 1,800 in the Pennsylvania/West Virginia area.

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. Altoona Regional Health System is part of this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. The model aims at implementing best practices for increasing the rates of organ donation.

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 percent. In fact, this collaborative model has been widely studied and cited by the greater healthcare quality improvement community for its effectiveness.

As our hospital and The Center for Organ Recovery & Education (CORE) have worked together as a team over the past months, we have seen some extraordinary things. The consent rate for organ donation at Altoona Regional Health System's Altoona Hospital Campus has increased from 54 percent to 75 percent.

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.

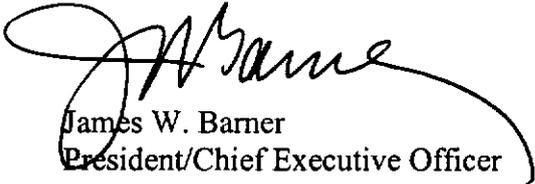
Centers for Medicare & Medicaid Services

May 16, 2005

Page Two

As a hospital who has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Sincerely,



James W. Barner
President/Chief Executive Officer
Altoona Regional Health System

dms

68

ASSOCIATION OF
CRITICAL CARE
NURSES

May 19, 2005

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

Dear Sir or Madam:

The American Association of Critical Care Nurses (AACN) is the world's largest specialty nursing organization and represents the interests of more than 400,000 nurses who care for critically ill patients. We are pleased to have the opportunity to comment on the proposed Rule: Medicare and Medicaid Programs: Conditions for Coverage for Organ Procurement Organizations (CMS-3064-P) that was originally published in the Federal Register on February 4, 2004. Our comments are directed to proposed §486-316, **Re-certification and Competition Processes.**

AACN has been an active member of the Leadership Coordinating Council of the HHS National Organ Breakthrough Collaborative. This major initiative of the Department has engaged the organ procurement organization (OPO) community and the nation's largest hospitals to greatly increase the number of organs available for transplant. Critical care nurses are integral members of the collaborative OPO-hospital teams implementing this exciting collaborative approach. Significantly, this model being pursued across the country is working and is achieving unprecedented increases in deceased donation and most importantly transplantation. This past year alone, the number of deceased donors increased 11 percent in the US, with collaborative team participants achieving even greater increases (i.e. 16 percent).

In our view, the proposed Competitive Framework in the regulation runs a high risk of adversely affecting the continued success of the Collaborative Model. As Improvement Leaders in the US work to spread the best practices identified to date, the value of sustaining and strengthening working relationships between organizations and the importance of widespread sharing of information and technologies need to be supported not imperiled. The application of the proposed Competitive Framework, furthermore, would likely distract OPOs from their core mission, as unproductive attention would be given to competitive scenarios even if the OPOs expected to fully meet stated performance standards.

Thank you for this opportunity to comment. We are committed to sustaining and spreading the success of the Collaborative Framework. For this reason, we believe that an OPO's service area should be open up to competition only if the incumbent OPO fails to meet stated performance standards.

Sincerely,

Kathleen M. McCauley, RN, PhD, FAAN
President



SCHOOL OF MEDICINE
DEPARTMENT OF NEUROLOGICAL SURGERY

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TEL: 503 494-4314 • TOLL FREE: 800 494-4314 • PAGING: 503 494-8311 • FAX: 503 494-7161 • www.ohsu.edu/neurosurgery

Kim J. Burchiel, M.D., F.A.C.S.
John Raaf Professor and Chairman

Neurosurgery

- Stanley L. Barnwell, M.D., Ph.D.
- Phillip C. Berryhill, M.D.
- Kim J. Burchiel, M.D., F.A.C.S.
- Johnny B. Delashaw, Jr., M.D.
- Jorge L. Eller, M.D.
- Edmund H. Frank, M.D., F.A.C.S.
- Kapil Moza, M.D.
- Edward A. Neuwelt, M.D.
- Ahmad M.T. Raslan, M.D.
- Nathan R. Selden, M.D., Ph.D.
- G. Alexander West, M.D., Ph.D.

Neuroendocrinology

- William H. Ludlam, M.D., Ph.D.

Neuroradiology

- Gary Nesbit, M.D.

Neuropsychology

- David Gostnell, Ph.D.
- Richard Kolbell, Ph.D., A.B.P.P.

Otolaryngology

- Sean O. McMenomey, M.D.

Pain Management

- Kim J. Burchiel, M.D., F.A.C.S.
- Beverly Cooke, R.N., B.A.

Physician Assistants

- Margaret Dancan, PA-C.
- Stephen Giles, PA-C.

Nurse Practitioners

- Wendy Domreis, M.S., R.N., C.P.N.P.
- Susan Ferson, M.S.N., C.P.N.P.
- Jane Olsen, R.N., C.R.N.P.
- Chris G. Yedinak, M.N., C.E.N.P.

Research

- Valerie C. Anderson, Ph.D.
- Thomas K. Baumann, Ph.D.
- Mary M. Heinricher, Ph.D.

Emeritus Faculty

- Harold D. Paxton, M.D.

Administration

- Bryce R. Helgerson, M.H.A.
- Shirley McCartney, Ph.D.

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

Comment: "Requesting Consent" – Sec. 486.342, proposed consent item 5

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, proposed consent item 5), 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. As a neurological surgeon I am regularly involved in helping patients make decisions about tissue transplantation and the use of medical devices to help them lead better lives. My patients and I have come to rely on many of the products that I fear will become too expensive or otherwise unavailable if the current CMS rule goes into effect.

Each year, donated tissue is utilized in thousands of surgeries to alleviate pain and restore a patient's range of motion and quality of life, many times enabling them to return to the workforce. This would not be possible without the generous gift of tissue donation, and the enhancement of that gift through the complex technologies developed by for-profit entities in the tissue banking community.

The U.S. does not have a completely not-for-profit system capable of meeting the demands and needs of patients requiring tissue transplantation. 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 may be forced to restrict the use of their loved ones' tissues to either a for-profit or a non-profit entity. My fear is that the overwhelming majority will choose non-profit entities not knowing that there really is no difference between non-profit and for-profit companies other than federal tax status. By reducing the amount of tissue for-profit companies can obtain, the rule will effectively remove good companies and good products from the market – the same products I rely on weekly during surgery.

My surgical colleagues and I agree with the overall goal of the proposed CMS rule: to increase organ and tissue donation in the U.S. But I fear the rule, as drafted, will lead to confused donors, fewer overall donations, and a vacuum in the market for the kinds of products for-profit companies make using donated tissue. Please remove any discussion of choosing between for-profit and non-profit companies when talking to donors and instead include a statement that "donated organs and tissue are handled by several entities before they find their way to patients, including a mix of "for-profit" and "non-profit" entities that each add value to make sure your donation is used in the most beneficial way possible." This would provide the donors with a good deal of information without creating confusion in the hospital or in the marketplace.

Kim J. Burchiel, M.D., F.A.C.S.
John Raaf Professor and Chairman

Neurosurgery

Stanley L. Barnwell, M.D., Ph.D.

Phillip C. Berryhill, M.D.

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Mary M. Heinricher, Ph.D.

Emeritus Faculty

Harold D. Paxton, M.D.

Administration

Bryce R. Helgeson, M.H.A.

Shirley McCartney, Ph.D.

I respectfully request that the proposed CMS rule not be adopted in its current form, but rather take the approach I am advocating in this letter.

Sincerely,



Johnny B. Delashaw, MD
Professor, Dept. of Neurological Surgery
Professor, Dept. of Otolaryngology
Professor, Dept. of Neurology



Hamot Medical Center
201 State Street
Erie, PA 16550
(814) 877-6000
www.hamot.org

May 10, 2005

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

“Recertification and Competition” §486.316

As CEO at Hamot Medical Center, I am writing to update you about recent regulatory developments that may severely undermine a Department of Health and Human Services (HHS) initiative. Recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90,000 Americans waiting for organ transplants, including over 1,800 in the Pennsylvania/West Virginia area.

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. Hamot Medical Center is part of this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. The model aims at implementing best practices for increasing the rates of organ donation.

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.

As our hospital and The Center for Organ Recovery & Education (CORE) have worked together as a team over the past months, we have seen some extraordinary things. The consent rate for organ donation at Hamot Medical Center has increased from 69% to 77%.

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.

Center for Medicare & Medicaid Services

May 10, 2005

Page Two

As a hospital who has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Sincerely,

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

John Malone

CEO

Hamot Medical Center

To Whom It May Concern: RE: OPO Regulations

Administration and governing body

Transplant surgeons and their representatives and related parties should be restricted from any involvement in the business affairs of an OPO. OPOs are required to be not for profit organizations under the IRS code and are often in violation of the code due to the dearth of interested parties from the transplant industry either dominating or dominating influence on the OPO boards. Some OPOs have been able to change their Board structure, but when the transplant community already dominates and does not want to give up power there is no vehicle to make the changes on the board.

Just because the OPO is considered not to be a provider why should the boards be exempt from the fraud and abuse provisions other organizations must follow which are involved in health care and have to deal with the influence of physicians or other health care organizations on their boards? The grip of control on the business affairs, charge structure, financial objectives, professional fees to themselves and their friends is extremely tight and there are often threats and intimidation and harassment used against those who want reform. The high level board committees such as executive committees are often overwhelmingly controlled by transplant surgeons or their proxies. The Stark Amendment and other self-referral rules should apply but often do not because of the strange classification of OPOs. These individuals and organizations, some of which are actually for profit health care organizations, are already planning to circumvent the intent of the proposed OPO governance regulations by simply maintaining control of their executive and finance committees and have their business associates or other colleagues appointed to the boards as members "not representing their centers." For example, Dr. John Doe, a transplant surgeon and politically aligned friend can be on the board but choose to consider his membership as "just another physician." These transplant dominated groups can easily create excess benefit transactions and invite intermediate sanctions based upon the IRS rules for a 501.C.3 organization. Shouldn't the CMS regulations reflect some cognizance with other applicable laws and regulations and specifically prohibit allowing a board structure which could result in these violations?

The OPOs have historically had little standing as independent organizations whether it is at the OPTN level or with regard to transplant center involvement. Too much control and emphasis has been placed on the transplant center's and surgeon's role in the governance process. The aforementioned groups are understandably but overwhelmingly concerned about the volume of organs, and the cost of organs to their centers. This is natural since they are committed to obtaining organs for their transplant patients. What is difficult though is the ability of these groups to maintain a proper fiduciary responsibility to the OPOs as board members. They are often unable to focus on the long term needs and investment requirements of the OPO and lack the motivation and incentive to increase costs to their own organizations for the long term well being of the OPO. Some transplant programs are in arrears on organ acquisition fees or are willing to tolerate dangerously low financial reserves for the OPO while being active board members. This sets up an untenable situation for management and creates an inappropriate management-

board environment. It would be tantamount to forcing hospitals to only have their own insurer customers on their boards, all with their own financial interests and stockholders concerns as a priority.

While it is appropriate to include the transplant community on an advisory board in order to coordinate clinical and operational needs and protocols and placement of organs, etc., it is not necessary or desirable to include them on the board of directors of an OPO. Conflict of interest procedures may give the cosmetic perception that there are safeguards against forcing favorable self dealing but they are not really effective in preventing the improper influence from happening. This is about self interest and the transplant surgeons and center administrative staff have significant financial interest in the OPO business affairs. If things continue as they are and the huge loopholes provided by the CMS regulations stand, it is only logical to assume that national scandals will be reported to the mainstream media, high profile investigations will ensue, and the result on donation could be harmful.

The position of the Association of Organ Procurement Organizations (AOPO) on this issue will most likely be extremely muted because that group and its members are significantly intimidated and cannot speak freely. On the contrary, they will be vocal that there is no significant problem and only very minor changes are necessary in this part of the regulation.

It is hoped that CMS can take advantage of this opportunity and provide regulations which create real reform and make OPOs comply with all relevant regulations regarding real transparency and proper board composition. OPO performance starts with the board. The board needs to really reflect its fiduciary responsibility to the OPO.

Sincerely,

Name Withheld



1305 W. 18th Street
PO Box 5039
Sioux Falls, South Dakota 57117-5039
(605) 333-1000
www.siouxvalley.org

May 13, 2005

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

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

As Chief Clinical Officer at Sioux Valley Hospital, 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. The recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90,000 Americans and over 2500 patients in South Dakota, North Dakota and Minnesota who are waiting 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. Sioux Valley Hospital USDMC is part of this exciting initiative that relies on joint accountability and an integrated partnership between OPOs and participating hospitals. The model aims at implementing best practices for increasing the rates of organ donation.

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

As Sioux Valley Hospital USDMC and LifeSource have worked together as a team over the past months we have seen some extraordinary things. Prior to Sioux Valley USDMC and LifeSource committing to each other and focusing on increasing both the number of deceased organ donors and organ yield per donor through the Organ Donation Breakthrough Collaborative, our hospital had an embarrassing conversion rate of 38%.

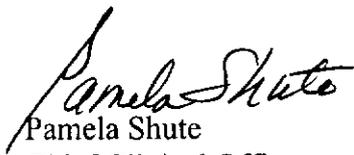
Since October, 2004 when we became part of this national initiative, our conversion rate is 90% with Jan-April of 2005 a remarkable 100%. In addition, the number of organ yield per donor has increased from 3.0 to 5.3 organs per deceased donor. This outcome is because LifeSource and Sioux Valley Hospital USDMC became *transparent* partners with this opportunity to learn and share best practices with other OPOs and Hospitals.

The idea that this firmly established partnership would be reduced to a "supplier/purchaser" relationship, due to the new rule requiring OPOs to compete in a manner similar to the commodities market, flies in the face of logic. If the "desired outcome" is increased organ donations, and we have tangible evidence that the "partnership" approach is working, then why radically change the current model?

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 OPO's that have been developed and fostered through the Organ Donation Breakthrough Collaborative.

As a hospital who has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Sincerely,


Pamela Shute
Chief Clinical Officer

PS/bh

#1 Response to: Federal Register 02/04/2005
HHS, 42CFR, parts 413,441, et.al. OPO Proposed Rule Changes

From: Barbara W. Louck, RN, MEd.
1538 Wildwood Rd.
Toledo, Ohio 43614

CONDITION: Human Resources (proposed 486.326)

RE: STAFF SHORTAGES / TURNOVER— You speak of not wanting to mandate the number of organ procurement coordinators that an OPO should employ:

By NOT doing that, OPO's work their procurement staff to the point of physical and emotional exhaustion, and profound levels of sleep deprivation. Read the studies regarding the effects of sleep deprivation on performance, accuracy, safety, and communication skills. Here are 3 references— of hundreds— on sleep deprivation regarding healthcare workers:

1. *The working hours of hospital staff nurses and patient safety* . Ann E Rogers, Wei-Ting Hwang, et. al., Health Affairs. July/Aug 2004., Vol.23, Issue 4.
2. *An error by any other name*. Ann Freeman Cook, Helena Hoas, et.al., The American Journal of Nursing. June 2004. Vol 104. No.6
3. *Melatonin in Humans*. Amnon Brezeinski,. The New England Journal of Medicine. January 16, 1997., Vol. 336: No.3. P. 186-195.

There are also many studies on sleep deprived medical interns and residents, as well, printed in the last 5 years. Have a look at the Harvard

contend is the point we've all worked toward , is compromised by

I THINK YOU SHOULD LIMIT:

1. THE AMOUNT OF CALL HOURS EACH FULL-TIME COORDINATOR WOULD BE REQUIRED TO TAKE IN A 40-HOUR WEEK. If you want to stop this unbelievable turnover, the first thing you need to do is MANDATE a limit on consecutive on-call hours required for work.

2. THE AMOUNT OF CONSECUTIVE HOURS AN ORGAN PROCUREMENT COORDINATOR MAY WORK, BEFORE BEING RELIEVED FOR A 12 HOUR REST PERIOD.

3. Shift hours :

NO SHIFT LONGER THAN 16 HOURS, ESPECIALLY IF IT INVOLVES BEING AWAKE DURING OR THROUGH THE NIGHT.

Check the info on melatonin .

(*Melatonin in Humans*. Amnon Brezeinski,. The New England Journal of Medicine. January 16, 1997., Vol. 336: No.3. P. 186-195). and circadian rhythms on MEDLINE to see why this is so important.

- Creative staffing can be accomplished to achieve these recommendations. There is plenty of literature out there on that, too, regarding how hospitals have reduced working hours of nursing staff.

ADDITIONAL COMMENTS:

- If it takes 4 years for a coordinator to get "good" at her/his job (according to "Best Practices"), people have to stay at an OPO at least that long.

Do you wonder why you report, later in your document, 15 packaging errors in 6 months? -----look at sleep deprivation.

WE DON'T NEED MORE TRAINING OR EDUCATION TO REMEMBER TO PUT ICE ON KIDNEYS—WE NEED SLEEP!!!!!!! Please try some common sense there within the beltway.....

SLEEP DEPRIVATION severely affects the health of any person – it increases heart disease, causes complications of pregnancy, complications of chronic conditions such as diabetes and bowel disease. Sleep deprivation also causes depression and mood alteration. It depletes the immune system by interfering with interleukin and the production of T-cells, providing for the development of malignancy. ...and on and on and on. Read about melatonin (see the citations listed at the beginning of this letter) and get the whole story. I am NOT making this up!

The Federal Government mandates the working hours of Air Traffic Controllers, Pilots, Nuclear Workers, and Truck Drivers.

Are LOST ORGANS not killing people too, who might have lived otherwise if mistakes were not made in the entire organ donation process from consent to packaging/labeling? Human beings have to have adequate sleep to function safely and effectively. Human beings are not minimal-maintenance machines. Considering the shortage and constant turnover of Organ Procurement Coordinators (OPC's), perhaps someone could realize that OPC's are not expendable.

Using the information from studies on sleep deprivation to guide you

- OPO's diminish the amount of available, and potential, organ procurement coordinators they could hire or retain when coordinators find out they won't see their families / spouse / friends for 3 days when she/he has weekend call from Friday to Sunday. Of course, then it takes 2 days to recover from the call. (See circadian rhythms) I realize there are a myriad of reasons why people leave positions voluntarily, but THIS is a big cause of turnover, in my opinion.
- For many OPO's, **normal operating procedures have work-hour requirements like those seen in a national or regional emergency. This should be the exception, not the rule.** Most humans can't and won't function like that, week after week, year after year, when they have other responsibilities at home, or a "life" other than work that they want to pursue.

Thanks for listening.

Barbara W Couch PhD MEd.

ORIGINAL

74
X-1

#2 Response to: Federal Register 02/04/2005
HHS, 42CFR, parts 413,441, et.al. OPO Proposed Rule Changes

From: Barbara W. Louck, RN, MEd.
1538 Wildwood Rd.
Toledo, Ohio 43614

CONDITION: Organ Preparation and Transport (Proposed 486.346)
ERRORS IN PACKAGING, LABELING, and SHIPPING ORGANS

1. You propose "requiring OPO's to develop and follow a protocol for packaging, labeling, handling and transporting organs in a manner that ensures their arrival without compromise to the quality of the organ or the health of the recipient."
2. You report "15 instances of organ packaging errors that occurred over a period of only 6 months", and that "no one in the OPO community seemed surprised."
3. You say that the OPTN already HAS packaging requirements. But, you say, they are not apparently sufficient.....

When are organs labeled, packaged and shipped?

AT THE END OF THE ORGAN PROCUREMENT PROCESS, RIGHT??

This is also the point where most organ procurement coordinators have been awake for 24 to 40 hours straight, over days and nights, during "call" hours.

YOU ALREADY HAVE GOOD POLICIES—what is lacking is organ procurement coordinators who have had adequate sleep so that they are physically, and mentally able to follow the policies and procedures already standardized.

- A person who has been up for 21 hours straight has the cognitive capacities of someone with a blood alcohol content of 0.08. This is legally drunk in most states.
(Citation: The New England Journal of Medicine; Jan.13,2005. Vol.352:No.2, *Sleep, Science and Policy.*, C. Dennis Wylie.)
- Also see the study: *Shift Work and its Effects on Fire Fighters and Nurses.* By Linda Glazner. Occupational Health and Safety. July, 1992. Vol.61, Issue 7.
- Please look up “Melatonin” and “Circadian Rhythms” on the MEDLINE database.

THE BIG ISSUE HERE IS SLEEP DEPRIVATION, NOT LACK OF EDUCATION OR TRAINING.

The Institute of Medicine, in a 2004 study, concluded:

“there is NO evidence to suggest that any amount of training, motivation, or professionalism is able to overcome the performance deficits associated with fatigue, sleep loss, and the sleepiness associated with circadian variations in alertness.”

(quoted in American Journal of Nursing. *The Perils of Shift Work.* Ronda Hughes, et.al., September 2004. Vol.104.No.9)

- No wonder the OPO's weren't surprised at the numbers of packaging errors-- 15 in 6 months listed in the Federal Register proposals. The coordinators know why, but management does not want to hear about the effects of sleep deprivation. It will require changes in staffing. The funding of more staff is another issue for them and HHS to work out. BUT, Management in OPO's know they have a problem; they don't want to acknowledge it or deal with it.

MY RECOMMENDATIONS:

- If you want to lessen the amount of packaging errors—require OPO's to limit the hours they require Organ Procurement Coordinators to be awake while on call, so that someone whose brain is fully functioning can take care of these critical procedures.
- Many errors are made—organs are lost because of poor donor management by exhausted and sleep-deprived coordinators as well—but packaging and shipping is where the oatmeal REALLY hits the fan.
During this last phase of procurement, the errors of omission and commission are easily seen.
- IF you don't believe the extant studies already done on the effects of sleep deprivation, perhaps you could undertake your own study regarding errors and the amount of wakefulness present in the perpetrator of the error when the error occurred.

Human brains need rest periods from stress, and adequate sleep if they are to optimally function. Please reread the above quote from the Institute of Medicine.

- Your answer for packaging and labeling errors is probably not more education and training for a coordinator to include blood tubes or ice with the correct kidney in a box. Coordinators will remember when she/he has had enough sleep to be able to follow the policy and procedure already in effect. No pun intended, but please "wake-up" to the realities of sleep deprivation that Organ Procurement Coordinators live with.

Thanks for listening.

Barbara W Couch RN, MEd.



A Donate Life Organization

June 1, 2005 via Certified Mail 7003 3110 0000 5254 8607, Return Receipt

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

Dear CMS Officials,

Thank you for the opportunity to comment on the proposed rule under 42 CFR Parts 413, 441, et al., Medicare and Medicaid programs; Conditions for Coverage for Organ Procurement Organizations (the "Proposed Rule").

First, I would like to commend all of the staff of CMS who worked on this Proposed Rule. As written, it is more meaningful than the prior OPO recertification standards. Of particular note is the move away from population-based criteria to an acknowledgement that donor potential is a better metric. Also, the presence of an appeal mechanism is extremely important because of the complexity of the donation process and measuring its success.

I would strongly oppose any application of these rule changes retrospectively, and am working with the understanding that the rule will be applied prospectively.

In general, I support the responses that have been submitted by AOPPO, particularly in the areas of competition, performance measures, transition period, and process measures. I am writing to provide additional comments that are informed by my experience as President & CEO of the New York Organ Donor Network ("NYODN").

Comments on: OPO Service Area Size Designation and Documentation Requirements (Proposed 486.306)

I believe that the development of the proposed rule is an opportunity to reorganize a complex organ donation and allocation system. The area and size designation of OPOs has developed over the years in a manner which may not yield the best results. I believe that CMS should develop a long-term vision for a logical and productive way to divide the country among OPOs and use the new regulations to move toward that goal. OPOs should be designated in a way that optimizes both organ recovery and allocation.

Elaine R. Berg
President & CEO

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This system may be a statewide system, where there is one OPO in each state, or it may be a system that reflects optimal allocation units, based on research, or, it may be a combination of both. In larger states, there could be more than one OPO. In less populous states, there could be a logical consolidation of contiguous states to add up to an "optimal" allocation unit. Such a system would create more of a level playing field, where comparisons between OPOs in the long run would be more meaningful than they are at the present time. The regulations as adopted should reflect these considerations.

The continued existence of *hospital-based OPOs* should be considered. With hospitals under extreme financial pressures, hospital-based OPOs may not be given the resources they need to maximize donation. It is also difficult to imagine a governance structure in a hospital-based OPO that can withstand the conflict of interest test discussed in regard to Section 486.324. The elimination of the hospital-based model should be seriously considered at this time.

Comments on Appeals (Proposed 486.314)

We respectfully suggest that the Proposed Rule does not satisfy the statutory requirement for an OPO to appeal decertification to the Secretary on substantive and procedural grounds or address the finding by Congress that the current system lacks due process to appeal to the Secretary.

Under proposed 42 C.F.R. § 486.312(c), the "appeal" to a CMS hearing officer is the OPO's first and only opportunity to present any evidence in support of its position, and the first opportunity for any measures other than the outcome measures in proposed 42 C.F.R. § 486.318 to be taken into account by the agency. While Congress intended that an "appeal" to the Secretary be provided, there is nothing to suggest that an agency hearing officer should be establishing or implementing agency policy by making judgments on these critical issues in the first instance, before – and indeed as a substitute for – genuine initial agency review and determination. These complex decisions are more appropriately undertaken *before* decertification by someone with specialized training and experience who is intimately involved in the agency's approach to OPO certification. A CMS hearing officer would not have such specialized training, is not policy-oriented and is not in a position to make an initial review of these complex factors as to which no objective standards exist.

OPOs should never be decertified, nor should a competing OPO be allowed to take over a service area, before a detailed and objective death record review for both OPOs is undertaken as a final audit of donor potential. With the small number of instances that this would occur, CMS should be able to manage this process.

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Because the appeals process in Part 498 offers significant procedural protections that the process described at proposed 42 C.F.R. § 486.314 does not (and cannot given the time frame), it should be retained and available to OPOs for use *after* decertification. The two processes are not mutually exclusive.

We recommend that:

- 1. proposed 42 C.F.R. § 486.314 be modified to provide for agency review before decertification by senior staff responsible for OPOs, taking into account process measures and those factors described at 70 Fed. Reg. 6,092 (Feb. 4, 2005) (such as those unique to service areas);*
- 2. the appeals process in 42 C.F.R. Part 498 be retained and available for OPOs after decertification;*
- 3. even if (1) and (2) above are not accepted, that proposed 42 C.F.R. § 486.314 be modified to provide explicitly for judicial review; and*
- 4. wherever possible, quantitative information be used in the appeals process regarding conversion rate and yield measures, and non-quantitative (such as process measure) information considered when relevant.*

Comments on Recertification and Competition (Proposed 486.316)

As discussed above, the Proposed Rule may provide an opportunity to rethink the strategy of starting with 58 current OPOs and continuing to reduce their numbers based on a “pass/fail” system. CMS, in conjunction with various national agencies, may consider developing a long-range plan for systematizing recovery and allocation regions, and work toward that plan.

As one looks at the way OPOs have evolved, it is clear that there are few commonalities among them with respect to the number of transplant programs they work with, the size and type of population that they serve, the demographics of their populations, the geographic area that they cover, the nature of their donor hospitals, and the level of support for donation from their States, both administrative and legislative. This is one reason that I believe that the concept of competition should be eliminated from the proposed regulations. OPOs at this time are too different to make any kind of competitive structure meaningful or fair. Comparing OPOs with each other at this stage is tantamount to comparing hospital death rates without considering case mix. Success in one service area is not an indication of success in another.



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CMS should review the performance of the OPO subject to recertification objectively, taking into consideration measures based on factors in the OPO's service area and, in the event of a denial of recertification, should consider replacements based on historical performance of competitors using the same standard as the recertification review.

The following are further comments about the competitive structure, if it were to be retained:

1. As noted in the "Background" section of the Preamble, the HRSA "Breakthrough Collaborative" has proven that collaboration, rather than competition, is the best methodology for improvement of outcomes.
2. At best, competition should be allowed only in instances where an OPO is decertified. Opening up all OPOs to competition every recertification cycle is destabilizing and unnecessary. I believe that recruitment and retention of OPO management staff would be jeopardized if this open competition were implemented, and it is clear, as recognized in the "best practices" outlined in the Preamble, that stable leadership is one indicator for OPO success.
3. Although the concept of requiring an OPO to have significantly better outcomes in order to compete for a failing OPO's territory is an improvement over the current system, even this concept is troubling. This proposal does not ensure that the "successful" OPO has the ability to be successful in the acquired territory. For example, in New York State, there are four OPOs. NYODN covers a diverse population of 12 million. The other three OPOs cover less diverse populations of approximately 2 million each. I would argue that even if one or more of those OPOs were deemed "successful" enough to compete with NYODN, they do not possess the infrastructure, the knowledge of the varied communities in New York City, or the experience in dealing with a multitude of complex transplant centers in order to be successful in this region. The new regulations should not set up a system whereby failing OPOs are closed and subsumed by another OPO which may not succeed. As noted above, the criteria for allowing an OPO to compete include outcome measures only. I would argue that process measures in this circumstance are extremely important in ensuring that the competing OPO will maintain a stable region because these measures are presumably a proxy for identification of a well-managed organization. ***If the competitive model is retained, part of the designation process should include due diligence in determining whether an OPO competing for a territory has the wherewithal to manage it successfully.***



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Comments on Outcome Measures (Proposed 486.318)

One of the statutory requirements is for the Secretary to establish multiple outcome measures. These measures are particularly important under the Proposed Rule because an OPO can be decertified based *solely* on these outcome measures. I do not believe that the outcome measures proposed fulfill the requirement of “multiple outcome measures,” as they are interdependent variables. The differentiation of kidneys from other organs is irrelevant and should not be counted as two measures.

The criterion of organs procured has no meaning beyond those transplanted and should be eliminated. Those two outcome measures (kidneys and extrarenals procured as two separate measures) lend themselves to manipulation. These measures could lead to some OPOs removing organs which cannot be transplanted with the sole objective of complying with “organs recovered” criteria. The use of organs transplanted, in addition to donors/conversion rates, would be more meaningful, because it is a more adequate reflection of activity and mission.

While potential is a far better denominator than population, there are still significant differences in populations, as was pointed out in the proposed regulations. These factors will affect conversion of potential donors as well as yield per donor. For example, it is known that there are lower consent rates in certain groups of minorities than in the Caucasian population. In order to compare conversion rates, the percentage of minorities, new immigrants, undocumented immigrants, and so on should be considered, and an “expected consent rate” calculated. The OPO should be measured against this rate rather than national averages.

Populations do not all die the same way or in the same clinical condition. For example, deaths by trauma in New York City and in particular, motor vehicle deaths are lower than in other parts of the country. Donors in the NYODN region are older, and even “standard criteria” donors may be sicker than in other parts of the country. These demographics should be taken into consideration when determining both donor potential and potential organ yield per donor. An “expected yield” should be calculated based on the age and medical status of the donor at death, and results should be measured against the expectation rather than national averages. The use of quantitative measures (which can be the sole basis for decertification under the Proposed Rule) is more accurate and reasonable if the data is adjusted for the relevant population.

Trends – Evaluating an OPO based on a point in time or an average of even a few years does not do justice to OPOs who have turned around and are moving in the right direction. Nor does it acknowledge OPOs which meet the averages but may not be moving forward, or which are, in fact, losing ground. Trends are, therefore, are important factors to consider when evaluating outcomes based on average performance over a few years.



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Comments on Process Measures (Proposed 486.320 through 486.348)

The incorporation of process measures into the recertification standards is critical, as the statute instructs. Clearly, fundamental good practices, reflected in these measures, are key to maintaining long-term success. It is not clear, however, how much “weight” the Proposed Rule gives to process rather than outcome measures, given that an OPO could be decertified under proposed 486.312(c) without consideration of any process measures. If CMS believes that good process leads to good outcomes, one must also believe that if process measures are being substantially met, that decertifying the OPO because of outcomes alone will not lead to better outcomes. *Substantial compliance with process measures should be an indicator for recertification.*

If an OPO’s inadequate performance based on outcome measures can be explained by factors specific to the service area, such as donor potential, then it is more important to look to process measures to determine whether that OPO is performing adequately and whether any other OPO could do better. My recommendation would be that unannounced inspections by CMS be carried out to determine compliance with process measures.

If an OPO is well-managed as determined by compliance with process measures, it is likely that no other OPO will be able to improve on the outcome measures given the characteristics of the service area, and decertification will not lead to more donors.

Comments on Administration and Governing Body (486.324)

I strongly concur with the spirit of this section. In 2001, NYODN restructured its governance and bylaws in a very similar manner to the one proposed in this section. The separation of a community-driven governing body from the more provincial focus of a medical board or advisory board is critical in moving OPOs forward.

NYODN chose to incorporate a requirement for each transplant hospital to be represented on its governing body. We feel that this is a very critical factor, in that the entire concept of a DSA is that transplant centers and OPOs are an interdependent unit. In addition to classic governance issues, we would recommend a stronger emphasis on the transplant hospital’s responsibility to the OPO, which would be reflected by a designated seat on the governing body.



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The OPO governing body must deal with issues such as:

1. The aggressiveness of transplant centers in accepting organs (which increases yield)
2. The financial viability of the OPO, which is, to a great extent, dependent on the transplant hospital paying their SAC rates

The conflicts of interest can be overcome by policy and by limiting the percentage of transplant center affiliates and/or physicians who can sit on the Board of Directors.

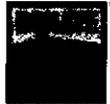
I disagree with the complete separation of the Medical or Advisory Board from the Governing Body. In our structure, the Chair and Vice Chair of the Medical Board serve ex officio as voting members of the Board of Directors. We feel that this is an essential link between the matters considered by the Medical or Advisory Board and the Board of Directors, and a convenient way to bring policy issues recommended by the advisory board to the attention of the governing body.

Comments on Human Resources (Proposed 486.326)

Credentialing - The requirements for OPOs to "maintain credentialing records" for recovery surgeons requires further detail. We suggest that OPOs be allowed to rely on the transplant hospital's extensive credentialing system to determine that recovery physicians are qualified. In this way, the OPOs can maintain records without duplicating complex credentialing systems. The credentialing function should be outlined in the Memorandum of Agreement between the transplant hospital and the OPO.

However, having OPOs responsible for maintaining credentialing records would be very helpful in verifying that recovery surgeons from outside of the region are credentialed. Frequently, organ placements are done in the middle of the night and on weekends, and it would be impossible to get credentialing information from a transplant center in another DSA. Requiring OPOs to maintain credentialing records and therefore being able to rely on other OPOs for verification of credentialing will be helpful, and will make donor hospitals feel more comfortable in their compliance with JCAHO credentialing standards.

Medical Director - NYODN hired a full time medical director one year ago, and as a result of our experience, we strongly support the requirement for a medical director in every OPO, whether full time or part time.



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Comments on "OPO role in Living Donation":

OPOs can play a role in living donation when unrelated parties are involved, and by including living donation in public education efforts, OPOs can also increase deceased donation. However, *OPOs should not be required to play a role in living donation.*

The role of the OPO should not be a medical one; it should, rather be one of placement of organs and referral of donors to the appropriate transplant center (overseen by policies developed in the region). Medical tests and psychiatric workups should be done by the transplant hospitals in a system developed by the DSA.

For example, if there are living donor exchanges (with two willing donors who are not matched with their intended recipients and wish to exchange recipients), the OPO is the ideal organization to identify such potential matches among all of the transplant centers in their regions. Without the OPO's involvement, one transplant hospital may not know of another ideal unmatched pair in another hospital.

Further, OPOs should be responsible for allocating all good Samaritan donor organs in accordance with the UNOS list. These donors should be directed to the OPO rather than going directly to a transplant center.

Thank you for the opportunity to comment on this Proposed Rule.

Sincerely,

Elaine R. Berg
President & CEO

EB:DB

cc: Rocco F. Andriola, Esq., Chairperson, Board of Directors, New York Organ Donor Network
Paul Schwab, Executive Director, Association of Organ Procurement Organizations



Coalition of MICHIGAN

Donate Life Coalition of Michigan
2203 Platt Road
Ann Arbor, MI 48104
1.800.482.4881
www.donatelifemichigan.org

GIVE SO OTHERS CAN LIVE

June 3, 2005

Re: File Code: CMS-3064-P

To Whom It May Concern,

I would like to take this time, as the Marketing/Public Relations Director of the Donate Life Coalition of Michigan to support the importance of public education for the proposed CMS Performance Regulations re: coverage for Organ Procurement Organizations.

As a representative of the Donate Life Coalition of MI, I speak for more than 40 organizations, hospitals, non-profits and individuals dedicated to organ donation. Public Education is extremely important in the field of organ donation. It enables Gift of Life Michigan, as well as the Coalition to educate, raise awareness and familiarize people of all ages and backgrounds of the importance of being a registered organ donor. It's critical that individuals know and understand how they feel about organ donation as well as how their loved ones feel before a tragedy occurs and they are expected to make quick decisions. Education is the key. With only 8 percent of our state's population registered, it is more important than ever to educate and therefore increase the number registered in Michigan as well as nationally.

Public Education makes a difference and it must be recognized for the incredible task it accomplishes in April, National Donate Life Month as well as throughout the entire year.

Sincerely,
Peggy Burkhard
Peggy Burkhard
Marketing and Public Relations Director
Donate Life Coalition of Michigan
(248) 366-6661

Alpena General Hospital

American Liver Foundation

American Red Cross

American Red Cross National Bone Marrow Donor Program

Covenant Health Care System

Detroit Medical Center

Gift of Life Michigan

Gift of Life Minority Organ Tissue Transplant Education Program

Henry Ford Health System

Hurley Medical Center

International Association for Organ Donation

Marquette General Hospital

Michigan Eye-Bank and Transplantation Center

Michigan Department of State

Musculoskeletal Transplant Foundation

National Kidney Foundation of Michigan

Northern Michigan Hospital

Novartis Pharmaceuticals

Oakwood Southshore Medical Center

Roche Laboratories, Inc.

Sparrow Health System

Spectrum Health and DeVos Children's Hospital

St. John Hospital Transplant Specialty Center

St. Mary Mercy Medical Center

University of Michigan Health System

William Beaumont Hospital



May 25, 2005

Texas Organ Sharing Alliance

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

To Whom It May Concern:

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

486.316 Re-certification and Competition Processes:

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

486.324 Administration and Governing Body:

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

486.318 Outcome Measures:

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

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

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

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

Yours truly,

A handwritten signature in cursive script, appearing to read "Patrick J. Giordano".

Patrick J. Giordano, MHA, CHE
Chief Executive



Since 1984 — sharing organs, sharing data, sharing life.

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June 3, 2005

Walter Graham, Executive Director

VIA FEDERAL EXPRESS

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: OSORA - CMS-3064-P
7500 Security Boulevard
Baltimore, MD 21244

RE: Comments Regarding the Centers for Medicare and Medicaid Services (CMS)
Proposed Changes to the Medicare and Medicaid Programs; Conditions for
Coverage for Organ Procurement Organizations (OPOs)

Ladies and Gentlemen:

The enclosed OPTN/UNOS comments on CMS' proposed changes to the Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs) (File Code CMS-3064-P) focus on providing clarification of certain current OPTN/UNOS policies and activities relating to OPOs and on identifying areas in which the national Organ Procurement and Transplantation Network (OPTN) can continue to collaborate and cooperate with CMS to promote continuous quality improvement in organ procurement.

UNOS is a Virginia non-profit corporation that operates the OPTN under contract with the Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS), and pursuant to the National Organ Transplant Act of 1984, as amended (NOTA), and associated regulations. Among the duties assigned to the OPTN are responsibilities for developing and operating a national computer system for matching candidates in need of organ transplants with available donor organs and for establishing the medical criteria by which these donor organs are allocated among all candidates who are registered with the national matching system. UNOS also is tasked with providing input on proposed Federal regulations with potential impact upon the fields of organ procurement and transplantation as deemed relevant and appropriate by the OPTN/UNOS Board of Directors.

In accordance with these charges, OPTN/UNOS has developed organ-specific policies for the allocation of kidneys, livers, thoracic organs, pancreata (including islets), and intestinal organs. Also pursuant to these charges, OPTN/UNOS has established minimum procurement standards for organs that include requirements to assure organ procurement quality, safe packaging, and prevention of infectious disease transmission for diseases

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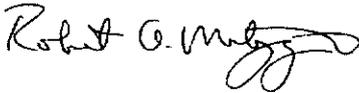
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Gene A. Pierce

Centers for Medicare & Medicaid Services
June 3, 2005
Page 2

such as AIDS and hepatitis. The standards anticipate challenges that result from multiple organ recovery from single donors, and try to maximize the number of transplantable donor organs.

We very much appreciate the opportunity to comment on this important proposal. If you have questions regarding our comments, or if we can provide information that would be useful to you as you reconsider the proposal, please do not hesitate to contact us.

Very truly yours,

A handwritten signature in black ink, appearing to read "Robert A. Metzger". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Robert A. Metzger, M.D.
President

**Comments to
CMS Medicare and Medicaid Programs;
Conditions for Coverage for Organ Procurement Organizations (OPOs)
Proposed Rule**

**42 CFR Parts 413, 441, 486 and 498
Fed. Reg. Vol. 70, No. 23, February 4, 2005**

File Code: CMS-3064-P

OPTN/UNOS Comments

*NOTE: The Proposed Rule text is in **Bold**, and the applicable comments follow in underlined, regular type.*

A. Technical Comments

Donor evaluation and management, organ placement and recovery

§ 486.344 Condition: Donor evaluation and management and organ placement and recovery.

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

- The term “waiting list” as used in this section is not consistent with the language in the Final Rule for the OPTN. The waiting list is a pool of transplant candidates. When a donor organ is available, a match run is generated that ranks and matches potential transplant recipients with the donor’s specific characteristics. In the section of the draft proposal, the term “match run” or match program is a more appropriate and accurate term.

In order to avoid confusion, we suggest that CMS use definitions that are consistent with 42 CFR 121.2. “Waiting list means the OPTN computer-based list of transplant candidates.” We suggest that the term match run or match program also be defined. 42 CFR 121.2 states “OPTN computer match program means a set of computer-based instructions which compares data on a cadaveric organ donor with data on transplant candidates on the waiting list and ranks the candidates according to OPTN policies to determine the priority of allocating the donor organ (s).” Additionally, we suggest adding the words “or electronic” after written since on occasion the OPO verifies this information electronically through the OPTN computer system.

“(b) Evaluation. The OPO must do the following:

(1) Verify that death has been pronounced according to applicable local, state, and federal laws pertaining to organ donation.”

- Federal, state and local laws pertain to the pronouncement of death and not to organ donation. We suggest that “pertaining to organ donation” be deleted and replaced with “pertaining to death and/or declaration of death.”

§ 486.302 Definitions

“Adverse Event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk there of. As applied to OPOs, adverse events include but are not limited to transmission of disease from a donor to a recipient, avoidable loss of a medically suitable potential donor for whom consent has been obtained, or delivery to a transplant center of the wrong organ or an organ whose blood type does not match the blood type of the intended recipient.”

- Clarification is needed for the meaning and scope of the language: “...avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained.” Does this require OPOs to submit justifications and written corrective action plans for any instance in which a donor meets the definitions of a potential organ donor for whom consent for donation is obtained but from whom no organs are actually recovered? Examples of situations where such a “loss” occurs, which may reasonably not be considered an adverse event include: positive immunological tests results which are received post-consent, new medical/social history information that becomes known following consent and intraoperative findings that would preclude donation.
- Clarification is also requested regarding the timeframe for required reporting related to transmission of disease from a donor to a recipient. When considered in conjunction with current OPTN reporting policies (OPTN Policy 4.7 Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, including Malignancies -as approved during the November 18-19, 2005 Board of Directors meeting), it would appear that this means *any time* after transplant even if it is several years.
- We suggest that the portion of the definition that states “...delivery to a transplant center of the *wrong* organ or an organ whose blood type does not match the blood type of the intended recipient...” (emphasis added) be deleted. We recommend replacement with “...delivery to a transplant center of an incorrectly labeled and/or shipped organ.”

We recommend this change because “wrong organ” could be understood as an organ that is less than an optimal organ, e.g., an older donor organ. The recommended change would accommodate instances where non-identical ABO matches and even

incompatible transplants are permitted by OPTN policy such in the allocation of hearts to pediatric candidates under one year old (OPTN Policy 3.7.8).

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

- The definition of organ donor potential in the proposed regulation is different from the OPTN definition of eligible donor in the OPTN computer system. If CMS expects to use data from the OPTN computer system in its calculation of organ donor potential, both definitions should be identical.

<u>CMS proposed definition</u>	<u>Current Definition in the OPTN Computer System</u>
<u>Creutzfeldt-Jacob Disease or any other prion-induced disease</u>	<u>Creutzfeldt-Jacob Disease</u>
<u>Viral septicemia</u>	<u>Herpetic septicemia</u>
<u>Active malignant neoplasms, except primary central nervous system tumors and basal and squamous cell carcinomas</u>	<u>Active malignant neoplasm, except primary CNA tumors and skin cancers</u>
<u>Active viral and systemic fungal infections</u>	<u>Fungal and viral meningitis, viral encephalitis</u>
<u>Chagas Disease</u>	<u>Not specified</u>
<u>Not specified</u>	<u>Hodgkin’s disease, multiple myeloma, leukemia</u>
<u>Not specified</u>	<u>Miscellaneous carcinomas</u>

- The definition of eligible organ donor that is used in data collection by the OPTN is different from the definition of organ donor potential listed in § 486.302. The definition of organ donor potential is used to calculate the potential donor denominator, also listed in § 486.302. This is problematic in that the eligible death data that are currently submitted by the OPOs to the OPTN is in an aggregate from by donor hospital. If the OPTN data are to be used in the calculation of the potential donor denominator, then the two definitions would have to be identical. Once the data are collected under the OPTN definition, it would be impossible to determine which of these reported eligible donors meets the organ donor potential definition as defined in the regulation. Moreover, there is no definition in § 486.302 for the actual donor numerator.
- The goal of the OPTN, under the leadership of the OPTN/UNOS Membership and Professional Standards Committee, is to promote continuous quality improvement in organ procurement and transplantation, with guidance from HRSA. The MPSC is continually refining its system of analysis and feedback to OPOs and transplant

centers. We welcome and encourage CMS to review the current status of MPSC processes before finalizing the proposed amendments to its OPO regulations.

The term "potential donor denominator" used in the five performance measures listed above was very well defined in the proposed CMS regulations. During a conference call of the OPTN/UNOS Executive Committee on March 11, 2005, Virginia McBride, HRSA Public Health Analyst, clarified the definition of donors that would be used in the numerator of the above measures. Ms. McBride stated that all donors, not just those that fit the definition of organ donor potential, would be included in the numerator for all five performance measures. For example, deceased organ transplant donors over the age of 70 would not be included in the potential donor denominator but would be included in the numerator for the percentage of potential donors who become donors, performance measure 1. (As the numerator is no longer a subset of the denominator this measure is no longer strictly speaking a percentage.) Likewise, DCD donors are a growing source of transplantable organs, and recovering organs from these donors could have a significant impact on the number of candidates who get transplants as well as on the numerator in the performance measures.

Outcome Measures

Sec. 486.318 Condition: Outcome measures.

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

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

Potential Donor Denominator (from CMS proposed regulations) –

The number of individuals in an OPO's service area who meet the criteria for organ donor potential, as defined by regulations.

Organ Donor Potential (from CMS proposed regulations) –

The number of patients whose age is 70 or less meeting death by neurological

criteria, based on generally accepted practice parameters for determining brain death, who do not have any of the following clinical indications:

- Tuberculosis.**
- Creutzfeldt-Jacob disease or any other prion-induced disease.**
- Viral septicemia.**
- Rabies.**
- Reactive hepatitis B surface antigen.**
- Any retro virus infection.**
- Active malignant neoplasms, except primary central nervous system tumors and basal cell and squamous cell carcinomas.**
- Aplastic anemia.**
- Agranulocytosis.**
- Active viral and systemic fungal infections.**
- Gangrene of bowel.**
- Extreme prematurity.**
- Positive serological or viral culture findings for HIV.**
- Chagas Disease.**

Table 1 displays a summary of the impact of the two determinations of donors on performance measure 1; donors as a percentage of the potential donor denominator. The following two determinations of donors were used:

1. Deceased donors meeting the definition of potential organ donor
2. Deceased donors meeting the definition of potential organ donor + any other recovered deceased donor (i.e., age > 70 or DCD)

Table 1 includes all donors and eligible deaths reported to the OPTN for the years 2003 and 2004 combined.

Table 1. Deceased Donors and Donor Conversion Rates for Donors Recovered between 2003 and 2004

<u>Determination of a donor</u>	<u>% donors/ potential donors (national mean)</u>	<u>75% of national mean (threshold)</u>	<u># of OPOs failing to meet threshold</u>
<u>Deceased donors with organ donor potential</u>	<u>52.1%</u>	<u>39.1%</u>	<u>2</u>
<u>Deceased donors with organ donor potential + other recovered deceased donors</u>	<u>57.4%</u>	<u>43.1%</u>	<u>4</u>

Table 2 includes further details of these results for the DSAs with the highest and lowest conversion rates using the standard definition (actual donors meeting potential organ donor definition/potential organ donors)

The intent of this redefined numerator was to give credit to OPOs that recover donors outside the standard donor potential, namely DCD donors and older donors. But by changing what is allowed in the numerator, the new definition may also inadvertently affect the OPOs that recover fewer DCD and older donors, specifically with regard to the national threshold. The modification of the definition of the numerator results in an increase in the national mean thereby also increasing the threshold to which all OPOs are compared.

If the number of potential DCD donors and the number of potential brain dead donors over 70 were obtainable, then this issue could be resolved in a more straightforward matter. But in the absence of these data, comparing OPO A that recovers 50 DCD donors to OPO B that recovers 10 is not possible since we do not know how many potential DCD donors were in each service area. OPO A may have had 100 potential DCD donors in their service area (50% conversion) while OPO B may have had 15 potential DCD donors in their service area (67% conversion).

The example below demonstrates how the CMS conversion rate could disadvantage OPO B.

<u>MEASURE</u>	<u>OPO A</u>	<u>OPO B</u>
<u>Eligible donors recovered</u>	<u>150</u>	<u>100</u>
<u>DCD donors recovered</u>	<u>50</u>	<u>10</u>
<u>Potential organ donors (current definition)</u>	<u>300</u>	<u>200</u>
<u>Potential DCD donors (hypothetical)</u>	<u>100</u>	<u>15</u>
<u>Conversion rate #1</u>	$\frac{50\% = 150}{300}$	$\frac{50\% = 100}{200}$
<u>Conversion rate #2 (CMS)</u>	$\frac{67\% = (150+50)}{300}$	$\frac{55\% = (100+10)}{200}$
<u>Actual Conversion rate (if DCD potential were known)</u>	$\frac{50\% = (150+50)}{(300+100)}$	$\frac{51\% = (100+10)}{(200+15)}$

While under the CMS conversion rate, OPO A appears 12 percentage points better than OPO B, OPO B actually did a better job (51% vs 50%) from the standpoint of performance as compared to potential. Unfortunately, the DCD potential in each service area is unknown, so it is not possible to compute the actual conversion rate for all donors. This same logic would also apply when including donors >70 years old in the numerator but not the denominator. An unintended consequence could result from either of these calculations: without knowing the organ donor potential in currently non-eligible donors the use of conversion rate #2 could disadvantage some OPOs that do a superior job of recovering expanded and DCD donors but cannot document it, through no fault of their own.

One possible compromise would be to base the 75% threshold on the conversion rate #1 method, and compare the OPOs to that threshold using conversion rate #2. The national mean would be the total number of actual donors recovered in the US that fit the potential organ donor definition divided by the potential organ donors for the US (12,358/23,701 = 52.1% for 2003-2004). Therefore, 75% of the mean would be 39.1% for 2003-2004. Each individual OPO's conversion rate would then be calculated using conversion rate #2 (including DCD and donors > 70 years of age). This would still provide the incentive to recover DCD donors and donor > 70 years of age without disadvantaging OPOs that may not have the same DCD and or older donor potential.

Concerns have been expressed by ASTS/AST and AOPO regarding the measurement of outcomes for ECD and DCD donor organs. We are confident that OPTN/UNOS and the SRTR will be able to develop an outcomes measurement methodology that fairly takes into account the type of donor.

Table 2

<u>A</u>	<u>B</u>	<u>C</u>	<u>D</u>	<u>E</u>	<u>F</u>	<u>G</u>
<u>OPO</u>	<u>Eligible Donors Recovered</u>	<u>Non-eligible Donors (DCD or > 70)</u>	<u>All Donors Recovered</u>	<u>Eligible Deaths</u>	<u>Conversion Rate #1 (Includes Only Eligible Donors)</u>	<u>Conversion Rate #2 (Includes All Donors - CMS Proposal)</u>
<u>1</u>	<u>68</u>	<u>2</u>	<u>70</u>	<u>90</u>	<u>75.6%</u>	<u>77.8%</u>
<u>2</u>	<u>190</u>	<u>58</u>	<u>248</u>	<u>254</u>	<u>74.8%</u>	<u>97.6%</u>
<u>3</u>	<u>167</u>	<u>5</u>	<u>172</u>	<u>232</u>	<u>72.0%</u>	<u>74.1%</u>
<u>4</u>	<u>132</u>	<u>1</u>	<u>133</u>	<u>196</u>	<u>67.3%</u>	<u>67.9%</u>
<u>5</u>	<u>450</u>	<u>37</u>	<u>487</u>	<u>685</u>	<u>65.7%</u>	<u>71.1%</u>
<u>6</u>	<u>483</u>	<u>19</u>	<u>502</u>	<u>756</u>	<u>63.9%</u>	<u>66.4%</u>
<u>7</u>	<u>200</u>	<u>19</u>	<u>219</u>	<u>315</u>	<u>63.5%</u>	<u>69.5%</u>
<u>8</u>	<u>273</u>	<u>57</u>	<u>330</u>	<u>436</u>	<u>62.6%</u>	<u>75.7%</u>
<u>9</u>	<u>573</u>	<u>158</u>	<u>731</u>	<u>923</u>	<u>62.1%</u>	<u>79.2%</u>
<u>10</u>	<u>279</u>	<u>17</u>	<u>296</u>	<u>450</u>	<u>62.0%</u>	<u>65.8%</u>
<u>*</u>						
<u>*</u>						
<u>*</u>						
<u>49</u>	<u>215</u>	<u>24</u>	<u>239</u>	<u>507</u>	<u>42.4%</u>	<u>47.1%</u>
<u>50</u>	<u>268</u>	<u>50</u>	<u>318</u>	<u>635</u>	<u>42.2%</u>	<u>50.1%</u>
<u>51</u>	<u>414</u>	<u>65</u>	<u>479</u>	<u>984</u>	<u>42.1%</u>	<u>48.7%</u>
<u>52</u>	<u>175</u>	<u>7</u>	<u>182</u>	<u>417</u>	<u>42.0%</u>	<u>43.6%</u>
<u>53</u>	<u>72</u>	<u>24</u>	<u>96</u>	<u>176</u>	<u>40.9%</u>	<u>54.5%</u>
<u>54</u>	<u>84</u>	<u>14</u>	<u>98</u>	<u>212</u>	<u>39.6%</u>	<u>46.2%</u>
<u>55</u>	<u>266</u>	<u>12</u>	<u>278</u>	<u>672</u>	<u>39.6%</u>	<u>41.4%</u>
<u>56</u>	<u>53</u>	<u>2</u>	<u>55</u>	<u>135</u>	<u>39.3%</u>	<u>40.7%</u>
<u>57</u>	<u>88</u>	<u>9</u>	<u>97</u>	<u>245</u>	<u>35.9%</u>	<u>39.6%</u>
<u>58</u>	<u>103</u>	<u>2</u>	<u>105</u>	<u>305</u>	<u>33.8%</u>	<u>34.4%</u>
<u>US</u>	<u>12,358</u>	<u>1,253</u>	<u>13,611</u>	<u>23,701</u>	<u>52.1%</u>	<u>57.4%</u>
<u>75% of National Mean</u>					<u>39.1%</u>	<u>43.1%</u>

Columns

A - OPO

B - The number of actual donors recovered that met the definition of "organ donor potential."

C - The number of actual donors recovered that did not meet the definition of "organ donor potential" (DCD, age > 70).

D - All actual donors recovered = Column B + Column C

E - The number of deaths reported by the OPO that met the definition of "organ donor potential"

F - Conversion Rate #1 - (Column B)/(Column E).

G - Conversion Rate #2 - (CMS Proposed) - (Column D)/(Column E)

B. Strategic Issues

§ 486.320 Condition: Participation in Organ Procurement and Transplantation Network.

- Pursuant to 42 U.S.C. § 273(b)(3)(H), an OPO must “participate in the OPTN.” Those additional words should be added after “member of” in the second line of proposed § 486.320, so that the sentence will read “After being designated, an OPO must become a member of, participate in and abide by the rules and requirements of the OPTN....” Members of the OPTN, pursuant to the Preamble to the OPTN Charter and Bylaws, agree to abide by the voluntary Bylaws and Policies of the OPTN as well as the applicable statutes and the OPTN Final Rule. The voluntary OPTN Bylaws and Policies represent standards of medical practice in organ transplantation, which cannot be kept up-to-date if they are locked into federal regulations. This is the same challenge as CMS describes regarding CDC guidelines to prevent the transmission of disease, which (at p. 6112, Columns 1 and 2) CMS is proposing to remove from its OPO regulations. It is clear that CMS expects OPOs to abide by the standards of practice established from time-to-time by the OPTN. This is essential to the day-to-day relationship between the OPOs and the OPTN. The working relationship goes beyond the “rules” (i.e., federal regulations) approved by the Secretary and referred to in § 1138(b)(1)(D) of the Act.

Donor evaluation and management, organ placement and recovery

§486.344(f) Condition: Donor evaluation and management and organ placement and recovery.

OPOs must “participate in the OPTN” and have a system to allocate donated organs that is consistent with OPTN “standards of practice” and rules and requirements. See §486.320 for the reasoning behind this comment. All of the OPTN’s organ allocation policies are voluntary standards of practice, as they must be to allow the policies to be kept up-to-date.

Organ preparation and transport

§ 486.346 Condition: Organ preparation and transport.

- We agree that organ packaging and labeling errors are unacceptable. However, there have been recent changes in organ packaging requirements and monitoring of compliance implemented since the apparent data was collected as referenced by CMS.

In the preamble CMS reports that the “OPTN/UNOS OPO Committee recently documented 15 instances of packaging errors that occurred over a period of only 6 months.” This in reference to a letter sent to the OPTN/UNOS OPO Committee by an

OPO in which the OPO provides anecdotal information regarding instances of organ shipped with incomplete labeling involving six different OPOs. This was discussed at the OPTN/UNOS Committee meeting in March 2001. Since this time, UNOS Department of Evaluation and Quality (DEQ -- formerly Policy Compliance) has grown significantly and currently evaluates and report to the MPSC any instances involving incorrect packaging and shipping of labels that are reported by members. In September 2003, DEQ sent a memo to the OPO Committee that documented six instances of improper packaging in a two year period. DEQ's analysis of these errors identified the root cause of many of these errors involved the reuse of organ shipping boxes. DEQ recommended and the OPTN/UNOS Board of Directors approved policy revisions that now prohibit the reuse of organ shipment boxes. Similarly, the OPTN has already implemented requirements for double checking of ABO, organ packaging and labeling as those requirements are proposed by CMS.

I. Things Which Cause Concern for Members

A. Technical Comments

B. Strategic Issues

Reporting Data

§ 486.328 Condition: Reporting of Data

(a) The proposed regulation language calls for OPOs to provide “individually-identifiable hospital specific organ donation and transplantation data to the OPTN and Scientific Registry.”

There needs to be clarification about which data need to be “individually-identifiable.” Currently OPOs provide individually-identifiable data on actual donors, that is, data in which individual donors are identified separately. There would be no change required in the current method of OPOs reporting these data about actual donors. However, data about *eligible* donors, i.e, those constituting the “organ donor potential” are currently collected from the OPOs on an aggregate basis for each hospital. If it is intended that all data reported by the OPO be “individually- identifiable” as it pertains to the potential donors as well as actual donors, a change would be required in the data collection process, which would result in a significant increase in the data reporting burden on OPOs.

Donor evaluation and management, organ placement and recovery

§ 486.344 Condition: Donor evaluation and management and organ placement and recovery.

Donor evaluation and management, organ placement and recovery

§ 486.344 Condition: Donor evaluation and management and organ placement and recovery.

“(d) Standard: Collaboration with transplant programs.

(1) ...The protocol for organ placement must include procedures to ensure that the blood type of the donor is compared with the blood type of the recipient by two OPO staff members before organ recovery takes place and that documentation of the donor’s blood type accompanies the organ to the hospital where the transplant will take place.”

- This may not always be logistically possible. OPO staff does not always know the recipient prior to recovery (as in the case of kidneys). Additionally, the UNOS Organ Center is sometimes used as a verification point when additional OPO staff is not present for re-verification (late nights, remote donor hospitals, etc). There are not always two OPO staff members in the Operating Room at recovery. We suggest that “prior to recovery” be DELETED and replaced with “prior to placement of the organ for transplantation”. We make this suggestion to cover situations in which an organ is allocated for a candidate located at a transplant center outside the recovering OPO’s service area and may need to be reallocated once it arrives at its destination. In such a case the OPO that recovered the organ may distribute the organ to another OPO for a particular candidate at a transplant center in the second OPO’s service area. In the event the organ is not suitable for that candidate, the second OPO may need to allocate the organ within its service area using the OPTN match system. In this instance, it would have been impossible for the recovering OPO to know the identity of the eventual recipient prior to organ recovery.

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

- In many cases, especially related to recovery of kidneys, due to requirements for prospective crossmatching of potential recipients’ blood with the donor’s blood, the identity of the intended recipient is not known to the OPO prior to recovery. In other cases, the condition of the organ at recovery affects the final placement of the organ, such as post recovery biopsy results. We suggest that “prior to recovery” be DELETED and replaced with “prior to placement of the organ for transplantation”. We make this suggestion to cover situations in which an organ is allocated for a candidate located at a transplant center outside the recovering OPO’s service area and may need to be reallocated once it arrives at its

destination. In such a case the OPO that recovered the organ may distribute the organ to another OPO for a particular candidate at a transplant center in the second OPO's service area. In the event the organ is not suitable for that candidate, the second OPO may need to allocate the organ within its service area using the OPTN match system. In this instance, it would have been impossible for the recovering OPO to know the identity of the eventual recipient prior to organ recovery.

II. Issues We Want to Address on Behalf of Our Members

A. *Technical Comments*

B. *Strategic Issues*

§ 486.306 Condition: Public Education

“While we believe that systematic efforts by OPOs to identify specific barriers to donation, along with public education programs designed to address these barriers, may result in increased rates of consent to donation among targeted populations, the OPO community appears to lack consensus about this issue. Therefore, we have not included requirements for public education in this proposed rule.”

Public education is one of the three components that have been shown to increase donation across the country: effective requesters, in the immediate term, professional education in the mid-term, and public education in the long term. Consequently, CMS should continue to support and endorse public education as an investment in the continued growth of organ donation and transplantation, even if it does not make public education a requirement for OPOs.

National surveys report general public support for the concept of organ donation; however, there is a significant gap between this general support and the national average consent rate for organ donation. The role of public education is to assess and implement strategies to move target populations from general support of organ donation to an intention to donate their own organs or the organs of their loved ones.

The specific effect of public education campaigns is difficult to measure with scientific precision, particularly since there may be a delay of years between the time a member of the public hears a donation message and actually becomes a donor. However, anecdotal evidence and the results of publicly funded initiatives repeatedly have demonstrated the value of carefully designed and targeted communications efforts. Public education does not replace the value of other efforts such as professional education and OPO-hospital collaboratives; instead it enhances and supports the effectiveness of these complementary approaches by predisposing the public to consent to donation.

§ 486.328 Condition: Reporting of Data.

“(a) The OPO must provide individually-identifiable, hospital-specific organ donation and transplantation data to the OPTN and the Scientific Registry of Transplant Recipients (SRTR), as directed by the Secretary.”

- Subsection (a) has been expanded to require the OPO to provide hospital specific organ donation and transplantation data to the OPTN and Scientific Registry. Also, there needs to be clarification on which data need to be “individually-identifiable.” Currently OPOs provide individually-identifiable data on actual donors. There would be no change required in the reporting of these data. However, the eligible donor or “organ donor potential” data is collected on an aggregate basis. If it is intended that all data reported by the OPO be “individually- identifiable” then this would require in a change in the data collection process and a significant increase in the data reporting burden on the OPO.

Sec. 486.330 Condition: Information Management

1. The following modification is recommended:

An OPO must establish and use an electronic information management system to maintain the required medical, social and identifying information for every donor and transplant recipient and develop and follow procedures to ensure the confidentiality and security of the information.

2. The following modification is recommended:

(a) Donor information. The OPO must maintain a record for every donor. The record must include, at a minimum, information identifying the donor (for example, name, address, date of birth, social security number or other unique identifier, such as Medicare health insurance claim number), organs and (when applicable) tissues recovered, date of the organ recovery, donor management data, all test results, current hospital history, past medical and social history, the pronouncement of death, and consent and next-of-kin information.

- i. Donor information must be maintained in an electronic format that provides for communication of the donor data with federal agencies and contractors, such as CMS, OPTN and SRTR, and provides for the transfer of donor information to a successor OPO as described in § 486.330 (d).
- ii. OPOs must include in their memorandums of understanding (MOU) with each hospital within their assigned service area, a mutually agreed upon method for electronic access to the Internet or virtual private networks to allow for donor information to be communicated during the donation process to the OPTN, their own data systems, and to any other organizations that are approved by the OPO to receive this information.

3. Recommend inserting the following new subsection:

(e) Data Confidentiality and Security. The OPO must adhere to federally published data confidentiality and security standards, and follow security and confidentiality requirements established by the OPTN. In maintaining data within its physical control, the OPO should consider and include patient data confidentiality measures, outlined in federally published regulations and guidelines from the National Institute of Standards and Technology and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), to protect the identities of potential donors, donors, donor next-of-kin, transplant candidates, and transplant recipients.

4. Recommend inserting the following new subsection:

(f) Technology Standards. The OPO must maintain basic technology standards as published by CMS and the OPTN, to provide for donation information access, communication, storage, redundancy, privacy and security.

OPO Survey

The OPTN/UNOS, in conjunction with the Association of Organ Procurement Organizations (AOPO), developed and distributed the AOPO/UNOS OPO Technology Assessment in late May of 2004. The survey was key in determining baseline information related to how OPOs and their local transplant centers currently utilize technology in their business operations. The primary goal of obtaining this information was to determine feasible approaches to enhance donor data collection and sharing, and improve the organ placement process using technology. Of secondary value, the information will assist in the analysis of the value of information technology and telecommunications to support the clinical operations of OPOs, as referenced in the recently enacted Organ Recovery and Improvement Act of 2004.

The web-based survey of thirty questions was implemented on May 24, 2004 and was available to OPOs through June 9, 2004. All 59 OPOs completed the survey. The results of the technology assessment (Attachment A) were distributed to the OPO community, and have subsequently been used by AOPO, UNOS, and other interested parties to evaluate future strategies for utilizing technology for donor data collection and organ placement.

AOPU/UNOS OPO Technology Assessment Results

Demographics

1. Number of OPO office locations:

1	22
2	9
3	13
4	9
5	4
Greater Than 5	2

2. Total Number of OPO employees:

0-10	1
11-20	9
21-30	13
Greater Than 30	36

Procurement Coordinators:

0	0
1-5	9
6-10	24
11-15	15
Greater Than 15	11

Placement Coordinators:

0	34
1-5	14
6-10	8
11-15	2
Greater Than 15	1

Procurement/Clinical Managers:

0	4
1	30
2	13
3	4
4	4
5	2
Greater Than 5	2

Hospital Development staff:

0	8
1-5	31

6-10	12
11-15	5
Greater Than 15	3
Data Coordinators:	
0	15
1-5	43
6-10	0
11-15	1
Greater Than 15	0
Dedicated Information Technology staff:	
0	21
1	18
2	9
3	6
4	2
5	3
Greater Than 5	0
Quality Assurance staff:	
0	15
1	19
2	13
3	8
4	3
5	1
Greater Than 5	0
3. Do you have a 24-hour organ placement or call center?	
Yes	24
No	35
Take donor referral calls?	
Yes	24
No	0
Enter/communicate donor data for procurement coordinators at the donor center?	
Yes	15
No	9
Maintain waiting list data for local transplant centers?	
Yes	2
No	22
If yes:	
Does the OPO manage the candidate data from adds to removals?	0

Are your transplant centers responsible for certain aspects of maintaining this data, i.e. changing statuses? 2

4. Do you utilize a third-party referral call center/answering service?

Yes 47

No 12

If yes, please describe how your OPO interacts with this third-party center:

Please Refer To Comments Section.

5. Does your OPO typically contact centers directly when making organ offers?

	Local Offers				Regional/National Offers			
	Yes	No	Yes	No	Yes	No	Yes	No
Heart	57	2	52	7	49	10	36	27
Heart/Lung	52	7	52	7	49	10	36	27
Intestine	44	15	49	10	36	27	51	8
Kidney	56	3	23	36	32	27	51	8
Kidney/Pancreas	55	4	32	27	51	8	52	7
Liver	54	5	51	8	39	20	41	18
Lung	51	8	52	7	39	20	41	18
Pancreas	56	3	39	20	41	18		
Pancreas Islets	49	10	41	18				

6. Does your OPO take organ offers on behalf of any of your local transplant centers?

Yes 51

No 8

If yes, indicate organ type below:

Heart 39

Heart/Lung 24

Intestine 18

Kidney 49

Kidney/Pancreas 42

Liver 39

Lung 27

Pancreas 39

Pancreas Islets 19

7. Does your OPO recover tissues?

Yes 45

No 14

8. Does your OPO recover eyes?

Yes 15

No 44

OPO Technology Use

9. Do you record/store/maintain donor data in a data system?

Yes 57

No 2

How many computer systems other than Unet does your OPO use?

0 1

1 36

2 12

3 4

4 4

Provide the system's name(s)

Please Refer To Comments Section.

Describe the type of system(s) (i.e. web based, Lotus Notes, MS Access...)

Please Refer To Comments Section.

10. Are procurement coordinators provided with:

Cell Phones?

Yes 56

No 3

Laptop/tablet-top PCs?

Yes 26

No 33

PDA's?

Yes 20

No 39

Fax machines at home?

Yes 41

No 18

High speed internet connection?

Yes 18

No 41

Portable printer?

Yes 6

No 53

Portable scanner?

Yes 4

No 55

Other?

Yes 13

No 46

Explain (Other):

2-way pager

2-way pagers

2-way pagers

2-way pagers

Digital camera to provide photos of organs prior to shipment.

Digital Pagers

Digital Pagers

Digital pagers.

monthly allowance for cell phone; text pagers provided; allowance for PDA if requested by coordinators and specialists

Pagers

paggers

Wireless Cards

Wireless internet connection PCMCIA cards from Sprint.

11. Donor information collected in the donor hospital is recorded on:

Paper forms?

Yes 54

No 5

Laptop/tablet-top PC software?

Yes 10

No 49

Internet application?

Yes 9

No 50

PDA?

Yes 0

No 59

Other?

Yes 1

No 58

Explain (Other):

Donor information is back entered in our database, but is not utilized realtime.

If you use an electronic collection method, what is your fallback method in the event of equipment failure?

Daily backup tapes

No realtime entry of donor information currently, hence, no backup system.

Paper

Paper

Paper

Paper

paper and fax

Paper chart based on the AOPO standard donor form

Paper form

Paper forms

Paper Records

Paper, but never needed in 2 years of full time operation

Paper. But again, our application (OTIS) can run on any computer, or locally on the TRC laptop provided to staff

The OPO will have an electronic CDF within the next couple of months. If that fails they will revert to manually completing the CDF, fax, & DonorNet.

We use a paper system for the most part, but we have 24/7 service support on IT equipment with a 4 hour on-site service response

12. How frequently does your OPO use a fax machine or telephone to communicate donor-related information when contacting a center to make an organ offer?

a. Voice only

Always 15

Frequently 28

Infrequently 1

Never 4

Sometimes 11

b. Fax only

Always 5

Frequently 7

Infrequently 17

Never 16

Sometimes 14

c. Combination voice & fax

Always 16

Frequently 20

Infrequently 8

Never 3

Sometimes 12

13. Do your coordinators communicate donor data electronically from the donor hospital while on site?

Yes 20

No 39

If Yes, how if this information communicated:

Other	3
Through a placement center?	4
Through an OPO data system?	6
Through DonorNet?	12
Through fax/phone by coordinators?	9
14. What impediments has your OPO identified in communicating data/information electronically from the donor hospital?	
Please Refer To Comments Section.	
15. What strategies have worked well for your OPO in communicating data/information electronically from the donor hospital?	
Please Refer To Comments Section.	
16. Are your coordinators able to access the Internet while on site at the donor hospital?	
Yes	31
No	28
If Yes, Please explain how.	
Dial-up connection	9
Hospital computer/network	25
Other	3
Wireless connection from a laptop	11
Specify (Other):	
Only sometimes available and only at some hospitals.	
We only have access at certain hospitals. Not all hospitals allow us access.	
Wireless internet connection via Sprint cellular network. This is NOT an 802.11x connection.	
17. Are your coordinators able to use wireless technologies (cell phone, laptop connection...) in the donor hospital?	
Yes	27
No	32
What types of problems have your coordinators experienced when using wireless technologies in the donor hospital?	
Please Refer To Comments Section.	
What successful strategies have you applied to overcome some of these issues?	
Please Refer To Comments Section.	
Are there limitations that prevent you from using wireless technologies in the donor hospitals?	
Please Refer To Comments Section.	
18. Do your coordinators use document scanning technology in the donor hospital?	
Yes	5
No	54
If Yes, please provide more detail.	
Fax machines and copiers	

Portable scanners with proprietary software to upload lab reports, consent forms, med/soc history

The basic chart is entered directly. All other documents are scanned into MS Word documents.

We scan death notes and death certificates.

we use a scanner with OTRS

19. What technologies are of most interest to your OPO?

Connectivity options	50
Laptop / tablet-top PCs	47
Other	5
PDAs	31
SmartPhones	24

Explain (Other):

a direct connection to centers that are listed and be able to page as many as you wish all at the same time, download, and update data from one docking station, compact and user friendly

N/A

Scanners so that photos of organs can be transmitted.

The most helpful thing for us would be a seamless way to upload and view (remotely) the various imaging studies used in donor evaluation - CXRs, echos, caths, etc. Since these primary data need to be viewed and interpreted by clinicians, and this process is somewhat subjective, it would be very helpful if the responsible clinicians (accepting tx surgeon) could view these primary data themselves

We are interested in information systems that allow integrated communication - the specific instrument (e.g. PDAs) are not the issue.

20. Does your OPO use DonorNet on a frequent basis?

Yes	46
No	13

Does your OPO post donor information as attachments on DonorNet?

Yes	34
No	12

Does your OPO fax donor information to the Organ Center to post on DonorNet?

Yes	42
No	4

Has DonorNet been beneficial to your organization?

Yes	44
No	2

21. Should technology play a greater role in the communication of donor information and the placement of organs?

No Opinion	1
Yes	57
No	1

22. Please provide any comments or suggestions related to utilization of technology in the organ procurement and placement process.

Please Refer To Comments Section.

23. What other types of information would you like to see shared amongst OPOs across the US in terms of technology and methodologies used for organ allocation operations?

Please Refer To Comments Section.

Local Transplant Center Technology Use

24. Who from your local transplant centers take organ offers from your coordinators?

Clinical coordinators	47
Lab personnel	1
Other	2
Surgeons/physicians	52

Explain (Other):

non-clinical coord take initial referral and info on organ offers at one center varies by center; either clinical coordinators or tx ctr procurement/perfusion staff

25. Through what means does your OPO contact these individuals?

Cell phone	39
Email	4
Hospital operator / answering service	34
Pager	54
Telephone	47

26. Do any of your local transplant centers accept donor information electronically?

Yes	18
No	41

If yes, through what method?

after verbal description, then faxed copy of AOPO chart for more info

Donor Net

DONORNET

donornet

DonorNet

DonorNet attachments

Fax

Fax and UNet

For the most part the answer is no, but on rare occasion we have sent digital photos of kidneys with unusual anatomy for example by e-mail attachment to accepting surgeon. We have only done this a handful of times.

LDT-OTRS for 75% of our offers, locally, regionally, and nationally

Lifeguard America, donor net

OPO has provided a wireless laptop to the local transplant centers for placement use.

OTIS

PDF

POAP, DonorNet

some via internet at home and office; some are limited to daytime only...all with desktops and/or laptops

UNet

Websites

- 27. What means of electronic communication do you think would work best for transplant centers to retrieve donor information (web based system, email, instant messaging, PDA, etc)?**
Please Refer To Comments Section.
- 28. What objections would your transplant centers raise to electronic communication of donor information?**
Please Refer To Comments Section.
- 29. Would you like for your transplant center(s) to:**
- | | |
|---|----|
| Enter their own refusal codes | 33 |
| Review donor information electronically | 56 |
| Take their own organ offers directly | 21 |
- 30. Please provide any comments or suggestions related to transplant center adoption and use of technology for taking organ offers and reviewing donor information.**
Please Refer To Comments Section.



1149 Bethel Street, Suite 801 • Honolulu, HI 96813

June 2, 2005

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

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

Dear CMS Officials:

The Hawaii Organ Procurement Organization, dba Organ Donor Center of Hawaii (ODCH), wishes to provide comment and feedback on the proposed CMS Rule CMS-3064-P regarding Conditions for Coverage for Organ Procurement Organizations (OPOs). We applaud CMS for its initiative to update federal requirements regulating OPOs to enhance quality services and address current trends in the industry. As a member of the Association of Organ Procurement Organizations (AOPO), we have participated in developing a full and complete response to the entire proposed Rule and ODCH endorses the recommendations made to CMS by AOPO. However, there are several aspects of the proposed rule that we would like to provide additional comment:

- "OPO service area size designation and documentation requirements (proposed §486.306)":

ODCH recommends that the 24-donor exception be retained for Hawaii. Hawaii is an island state with a population of approximately 1.21 million and has only one transplant center (St. Francis Transplant Institute) which only transplants kidneys, liver, pancreas, and heart. The nearest alternative transplant center to St. Francis is over 2,000 miles away making organ placement outside Hawaii challenging, at times, frustrating. In addition to isolation issues, Hawaii also has limited availability of transplant surgeons. There is only one liver transplant surgeon, one pancreas transplant surgeon, and one heart transplant surgeon on the islands. When these surgeons are out of state, pancreas and heart are not recovered for transplant.

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

ODCH opposes the proposed competition framework that would allow the takeover of a certified OPO's service area by another OPO during re-certification. ODCH agrees with the option included in the proposed rule, identified as the "highly restricted competition process," with competition occurring among OPOs only in cases where an incumbent OPO has been de-certified.

We believe that the competitive approach will have a negative impact on the successful work of the national Organ Donation Breakthrough Collaborative. HHS has demonstrated and publicized the effectiveness and success of its investment in the collaborative model approach of the Collaborative. The successes of this Breakthrough Collaborative are largely due to the cooperation of all 58 federally designated OPOs, the nation's largest hospitals, and the US government to achieve unprecedented organ donation results through active pursuit of best practices established through collaboration and information sharing.

There is a unique willingness to share within the OPO community. Establishing a competitive approach during the recertification cycle will result in an unwillingness to share data and information and to assist other OPOs, resulting in lowered performance at a national level.

- “Outcome Measures (proposed §486.318)”:
 - 3. Standardized Definition of Organ Donor Potential

While a definition of Organ Donor Potential is necessary, we have concerns about listing clinical indications for medical rule-out in the regulation, as additions and deletions to this list would require a change through the regulatory process. We propose that CMS refer to UNOS and designate their guidelines as the clinical indicators for OPOs to follow.

- 6. Outcome Performance Standards and Thresholds

ODCH agrees with CMS in replacing the former population-based model with outcome related performance indicators. However, we request that in establishing outcome performance thresholds, CMS continue to recognize the isolation, distance, and transplant limitations that are particular to an OPO such as Hawaii that operates exclusively in a non-contiguous state and that thresholds for Hawaii be at a lower rate than OPOs in the contiguous states.

We concur with the AOPO proposal to use “overall conversion rate” and “organs transplanted per donor ratio” as performance standards in assessing OPO performance and that thresholds for Puerto Rico and Hawaii be for kidneys only at 50 percent of the national mean.

- “Relationships with tissue banks (proposed §486.322)”:
ODCH does not agree with the requirement for OPOs to have arrangements with tissue banks that have formal agreements with hospitals with which the OPO has agreements. While we agree with the concept of cooperation in retrieval, processing, preservation, storage, and distribution of tissues, OPOs should have the option of deciding not to have an arrangement with a tissue bank that the OPO has quality and professionalism concerns. There are also liability concerns if we have an arrangement with a tissue bank that may not have good tissue practices and the patient’s well being as a primary concern. We believe it is reasonable that the only requirement that should be imposed upon the OPO is that it must pass along notice of a potential donor to the tissue bank, and only in the event the OPO is not to be involved in the recovery of an organ.
- “Administration and Governing Body (proposed §486.324)”:
We do not agree with the requirement to have a governing board of directors and a separate advisory board. Organ Donor Center of Hawaii has only one board, with members that meet required PHS positions. Conflict of interest is not an issue and review and disclosure by all board members is performed annually. The proposed rule would unnecessarily force ODCH to revert to multiple boards and create difficulties in recruiting adequate numbers of qualified board members from the various proposed backgrounds and specialties.

ODCH agrees that representation from other stakeholders should be considered, but we do not agree that such representation should be required and that we have the discretion to add stakeholders to the advisory boards consistent with ODCH needs and priorities. Constituents such as research facilities, donor family members, transplant recipients, coroners or medical examiners, social workers, and chaplains can all add valuable input and bring considerable influence, however OPOs must have the flexibility to bring those resources to bear as needed in each community.

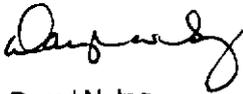
ODCH also opposes the requirement to have one tissue bank on the Advisory Board as the representative of all tissue bank(s) within the donation service area. We believe that the individual would, by the very nature of the appointment, appear to have primary responsibilities back to the tissue bank, especially if there is competition for tissue recovery or banking services. It would be inappropriate to put a competitor on its board.

We propose that CMS allow an OPO to have one governing board which includes positions required by the PHS Act with the requirement that the OPO have by-laws and/or policies addressing conflicts of interest of and among governing and/or advisory board members. This policy must include conflict of interest disclosure statements and shall be consistent with both state corporate law and Internal Revenue Service (IRS) requirements and practices.

- "Human Resources (proposed §486.326)."
ODCH does not agree with the new requirement that OPOs maintain credentialing records of their recovery personnel, particularly if the recovery personnel are transplant surgeons. If transplant surgeons from local transplant hospitals are used to recover organs, credentialing has already been performed by the transplant hospital and an OPO would be duplicating the credentials verification process.

Thank you for this opportunity to comment on the proposed CMS rule on Conditions for Coverage for Organ Procurement Organizations (OPOs) and your consideration of Organ Donor Center of Hawaii's concerns. If you have any questions, please feel free to contact me by phone at (808)599-7630 or e-mail at ding@organdonorhawaii.com

Sincerely



Darryl N. Ing
Executive Director
Organ Donor Center of Hawaii

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