

February 20, 2005

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

To Whom It May Concern:

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

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

Comments:

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

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

- In regards to the statements ... *we propose requiring OPO's to maintain collaborative relationships with their tissue banks in their service areas...* I would suggest allowing the local tissue and eye banks to provide comment about an OPO. Utilize comments made by these organizations to assess the working relationships. This could be easily done by sending an annual questionnaire to the tissue and eye agencies (T&E) working in conjunction with an OPO. Although subjective, the information obtained from these agencies can be compiled and used as part of the inspection process for certification. As the federally mandated OPO, they have a responsibility to provide a service to all their customers in a community, which includes tissue and eye agencies. The answers received from the questionnaires would provide specific information relative to the cooperation for a collaborative donation relationship in a community. Many OPO's have not been held accountable for their poor behavior and unwillingness to work collaboratively,
- Since the COP's effectively made the OPO's the "gatekeepers" of referral calls, while I agree that all agencies need to pay for their referral costs, some OPO's do not provide the opportunity to review the referral information in a timely manner. Those OPO's utilizing the referral service *Statline* have allowed timely access while other OPO's using private services such as *LifeLink* have refused timely access to referral calls and provide general information only after a month or more. This has created a situation in which tissue and eye agencies have had to seek ways to have access to the referrals in a timelier manner. The only alternative was for T&E agencies to independently contract with *Statline*, to receive information in a timely manner and obtain some control of their referrals. Clearly, this has generated considerable additional expenses for T&E agencies. Effectively, for those OPO's not willing to provide access to timely referral information, T&E agencies have had to pay not only the OPO referral fees but also additional fees to have their own access to the referral information. Although this is a complex issue, it is one that continues to create ongoing frustration and expense for T&E agencies. I would encourage looking at this issue when determining if an OPO is creating "a spirit of cooperation and collaboration".
- In regards to the statement...*ensure that all usable tissues are obtained from potential donors: ...obtaining informed consent from families of potential tissue donors...* I would encourage you to consider making this a measurable process by tracking the percentage of consents for tissue and eye agencies and making this information public. There continues to be the perception by some OPO coordinators that they will not jeopardize organ consent by listing out tissues for donation. Effectively, these OPO coordinators are making the decision for families regarding tissue donation by claiming that the "laundry list" for donation will harm their changes to get any organs. While I agree that organ donation is a priority, there should be some method to hold OPO's accountable for conversion rates for consents obtained for all donation agencies.

"Administrative and governing body" (Proposed 486.324)

- I would like to comment on the section concerning the proposal to ...*have on its advisory board a tissue bank representative from a facility no affiliated with the OPO, unless the only tissue bank in the service area is affiliated with the OPO...* I applaud this proposal and would like to see further clarification of this proposal. For instance, if an OPO is in an area with multiple tissue and eye banks, should all T&E agencies be represented on the advisory board? How does the OPO choose which agency to invite in their service area to not show favoritism? Please provide clarification on the statement "*include representatives from tissue banks that are not affiliated with the OPO (pg 6104)*". My assumption is that you mean a tissue agency combined with the OPO versus a tissue agency within that OPO's service area. Please consider the above when making this recommendation in order to avoid possible conflict or interest and favoritism of one tissue and eye agency over another.

“Human Resources” (Proposed 486.326)

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

“Reporting Data” (Proposed 486.328) and

“Quality Assessment and Performance Improvement” (Proposed 486.348)

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

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

“Hospital Accountability” and “QAPI”

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

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

	Jan	Feb	Mar	1st Qtr	Apr	May	Jun	2nd Qtr	July	Aug	Sept	3rd Qtr	Oct	Nov	Dec	4th Qtr	Year Totals
Total Referrals	89	93	86	277	69	70	87	228	80	83	80	243	79	76	102	258	1602
Less Non-Potential: Based on FDA and AATB guidelines																	
Age	13	14	15	42	9	8	10	27	10	9	7	26	9	10	7	26	121
Cancer	31	29	27	87	22	22	23	68	22	22	28	72	26	18	27	71	297
Sepsis / Infection	15	10	8	33	6	5	8	19	9	14	5	28	13	12	22	47	127
Other Medical	14	19	22	55	11	15	17	43	20	12	13	45	16	8	22	46	169
Stillborn	9	8	4	21	9	7	10	26	9	14	9	32	5	13	12	30	109
Pending review (8), Duplicates (2) or Referred Not Deceased (7)	0	0	0	0	2	2	3	8	3	0	4	7	1	2	0	3	17
Subtotal Non-Potential:	82	80	76	238	69	59	71	197	73	71	66	210	70	63	90	223	860
Potential Donors	16	13	10	39	10	11	16	37	7	12	14	33	9	12	12	33	142
Difference between Potential Donors and Actual Donors by Outcome:																	
Agency Rule-out for MSSH	1	2	2	6	0	1	0	1	0	0	0	0	0	0	1	1	7
Medical Examiner Declines	0	0	0	0	0	2	1	3	1	0	3	4	1	2	1	4	11
Other: Funeral Home issues, No Legal Next of Kin available	0	0	1	1	0	0	1	1	1	1	0	2	0	0	0	0	4
No Call	1	0	0	1	0	0	0	0	0	0	1	1	0	0	0	0	2
Family Declined (FD) to: OPO (9) /RN (6) EB (11)	4	2	1	7	2	3	1	6	3	0	3	6	2	5	0	7	26
Agency approach - Family Declined	5	5	2	12	4	2	7	13	2	5	4	11	3	3	6	12	48
Hospital - Prior to call to referral line	2	1	1	4	1	1	0	2	0	1	0	1	0	1	1	2	9
Outcomes Subtotal	13	10	7	30	7	9	10	26	7	7	11	25	6	11	9	28	107
Actual Donors	3	3	3	9	3	2	6	11	6	5	3	8	3	1	3	7	38
Agency conversion rate: (Actual/Potential)	19%	23%	30%	23%	30%	18%	38%	30%	0%	42%	21%	24%	33%	8%	25%	21%	26%
Additional Information: (This information is not subtracted from information above)																	
Total Calls Statline	94	93	86	273	68	69	84	221	76	80	77	233	77	76	99	251	978
No Calls (Total of all calls not received to include potential and non-potential)	1	0	0	1	1	0	2	3	1	1	2	4	0	0	1	1	8
Referred but Not deceased (RND)	0	0	0	0	0	1	2	3	0	0	3	1	1	0	0	1	7
Mort List	95	88	85	268	60	65	76	201	76	74	70	220	74	66	99	239	928
Referrals Not on Mort list	3	5	1	9	9	4	11	24	10	6	7	25	4	9	3	16	74

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

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

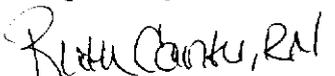
- Based on the information collected for a hospital (as above) a formalized report is given to the hospital on a quarterly, semi-annual or annual basis (determined by hospital size and donation potential). Our Hospital Services staff provides on-going continuing education for non-compliance to the COP's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

“Public Education”

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

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

Respectfully submitted,


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American Board for Transplant Certification

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March 21, 2005

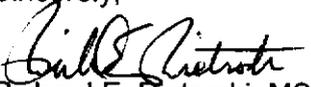
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, Maryland 21244-8015

Dear Messers:

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

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

Sincerely,


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

Enclosure

AMERICAN BOARD FOR TRANSPLANT CERTIFICATION

CERTIFICATION PROCESS OVERVIEW

BACKGROUNDER:

American Board for Transplant Certification

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

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

Examination Development

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

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

Examination Administration

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

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

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

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

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

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

Recertification

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

3-21-05

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 Baltimore, MD 21244-8015

Dear Sir or Madam:

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

General Comments

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

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

Recertification and Competition

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

Outcome Measures

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

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

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

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

Administration and Governing Body

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

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

Requesting Consent

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

Quality Assessment and Performance Improvement

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

OPO Role in Living Donation

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

On behalf of the members of the National Kidney Foundation and all kidney patients and transplant candidates and recipients, I wish to thank CMS for its efforts to increase the supply of organs available for transplantation and for the opportunity to respond to the Proposed Rules for Conditions of Coverage for Organ Procurement Organizations.

Sincerely,



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

4

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

Dear Sir or Madame:

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

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

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

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

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

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

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

Sincerely,

David Karanich AD, FACP

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4800 FRIENDSHIP AVENUE
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412-688-7578
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**DIVISION OF FOOT AND ANKLE SURGERY
RESIDENCY TRAINING PROGRAMS**

March 22, 2005

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

Alan Catanzariti, DPM, FACFAS
Director of Residency Training Programs

Clinical Faculty

Philip Caushaj, MD
Chairman, Department of Surgery

Jordan Grossman, DPM, FACFAS

Steven Leers, MD
Chief, Division of Vascular Surgery

Shannon McFeaters, DPM
Clinical Faculty

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

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

Karl Saltrick, DPM, FACFAS
Clinical Faculty

Harvey Slater, MD
Director, Burn/Trauma Center

Lisa Walters, DPM, FACFAOM
Coordinator Primary Podiatric Medicine

Andrew Vayons, MD, FACP
Instructor Physical Diagnosis

John Mendicino, BS, PE, MT
Business and Practice Management
Information Management Systems

Beth Sheedy, BS, M.Ed
Residency Coordinator

Donna Houpt, RN
Clinical Research Coordinator

Debra Hoffman
Residency Assistant

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

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

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

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

Sincerely,

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



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

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

Neurosurgery
DAVID A. CAVANAUGH, M.D.

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

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

March 22, 2005

Centers for Medicare and Medicaid
Department of Health and Human Services
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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.

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Centers for Medicare and Medicaid
March 22, 2005
Page 2

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Sincerely,

A handwritten signature in black ink that reads "P. Nunley, MD". The signature is written in a cursive style with a large, looped initial "P".

Pierce D. Nunley, MD
PDN/vramey

7

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

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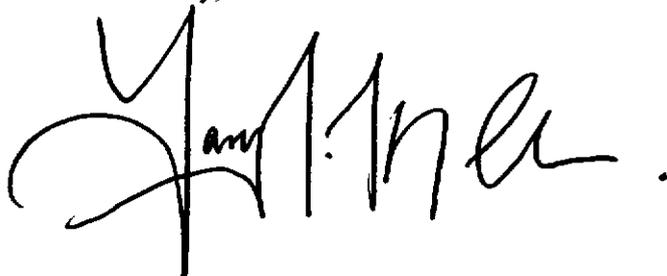
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Sincerely,

A handwritten signature in black ink, appearing to read "Gary M. Miller". The signature is fluid and cursive, with a period at the end.



STATE OF NEW YORK DEPARTMENT OF HEALTH

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

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

Dennis P. Whalen
Executive Deputy Commissioner

March 18, 2005

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

To Whom It May Concern:

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

Re-Certification and Competition Processes (Proposed § 486.316)

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

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

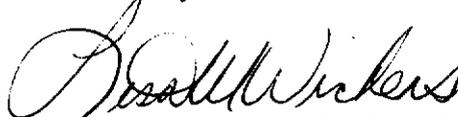
In 2004, New York State saw an eleven percent (11%) increase in overall donation, much of this is thought to be a result of these cooperative efforts. This proposed condition would foster competition amongst OPOs despite an OPO fulfilling its performance measures. This proposal potentially undermines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

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

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

Thank you for this opportunity to comment.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa M. Wickens". The signature is fluid and cursive, with the first name being the most prominent.

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