October 28, 2013

VIA ELECTRONIC MAIL AND FACSIMILE

Howard Shelanski, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: Unaddressed Implications of the Proposed Changes to the Conditions for Coverage for Organ Procurement Organizations (HHS/CMS Rule 0938-AR54)

Dear Administrator Shelanski:

Since its inception 35 years ago, New York Organ Donor Network ("NYODN") has been dedicated to the recovery of organs and tissue for transplantation in the greater New York metropolitan area and is the second largest organ procurement organization ("OPO") in the United States. We are writing to express our serious concerns about the Centers for Medicare & Medicaid Services ("CMS") proposed rule pursuant to which certification, and therefore reimbursement under Medicare and Medicaid programs for organ procurement costs, will remain dependent on performance metrics that are illegal under the authorizing statute and which CMS acknowledges are flawed. The imminent 2014 certification cycle will be the first time in which these metrics will be implemented to decertify OPOs. The proposed rule fails to meet its objective of protecting OPOs against arbitrary decertification and, therefore, will not avert an acute destabilization of the organ donor process. If the proposed rule is not modified to delay the implementation of the flawed performance metrics, the outcome will be devastating, both in terms of human suffering—more transplant patients will wait longer for organ donors and more will die—and dollars, through significantly increased costs to the healthcare system. At the same time, the proposed rule will provide no benefit at all.

The proposed rule was prompted by CMS's concerns about the propriety of the performance metrics set forth in the current regulations and its concern that their enforcement could result in OPOs being arbitrarily decertified. Instead of changing these metrics, or suspending their application, however, the proposed rule purports to reduce the burden on OPOs to meet the flawed metrics by requiring that OPOs satisfy only two out of the three metrics in order to qualify for recertification, i.e., remain eligible for coverage. Given that the outcomes of at least two of the metrics are in part dependent on each other, this proposed change amounts to almost no change at all and falls far short of establishing quality-based performance outcome measures that satisfy the requirements of the authorizing statute and that the OPO community supports. A better alternative would be to provide for a formal transition period, as was

informally accomplished through non-enforcement during the first recertification cycle in 2010. During the suggested transition period, recertification could continue to be based on the process review standards contained in the regulations, without consideration of the flawed performance outcome metrics. CMS also should call for further comment on the outcome metrics and continue to work to develop appropriate measures, which then can be applied during the next recertification cycle. This solution will avert a public health crisis, while promoting good government practices, creating transparency for the public and establishing certainty in this regulated industry.

**NYODN is a Dedicated and Well Performing OPO Serving a Uniquely Challenging Service Area**

NYODN is a nonprofit, federally designated OPO. Our designated service area, within which we operate to facilitate donations, consists of 13 million people, 10 transplant centers and more than 90 hospitals. We also strive to raise awareness in our service area for organ, eye, and tissue donation and transplantation, educate the public, and encourage residents to enroll in the New York State Donate Life Registry. NYODN is accredited by the Association of Organ Procurement Organizations and a member of the United Network for Organ Sharing ("UNOS"), which oversees the organ transplant waiting list throughout the United States.

NYODN’s service area presents at least three unique challenges to obtaining organ and tissue donors, all of which are outside of NYODN’s control:

- NYODN’s service area is more diverse than any other, in terms of race, ethnicity, culture and religion. For example, in some parts of our service area, almost 50% of the population does not speak English as a first language. We also have the largest Chinese population outside of mainland China and largest Asian Indian population of all OPOs. In addition, NYODN serves the largest Jewish community and one of the highest non-Christian communities. These racial, ethnic, cultural and religious groups can present resistance to organ donation and traditionally lower overall consent rates in areas in which they live.

- New York has the second lowest percentage of its potential donors enrolled in a donor registry, the Donate Life Registry. Having potential donors participate in such consent registries in greater numbers increases donation consent rates.

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2 At present, there are 58 OPOs in the United States, each of which serves a particular geographic “service area,” as designated by CMS.

3 All hospitals in the greater New York metropolitan area are required by law to notify NYODN of in-hospital deaths or imminent deaths. NYODN has highly trained staff whose primary role is to ensure that families carry out the legally binding consent decisions of their loved ones to be donors. If the potential donor was not enrolled in the New York State Donate Life Registry, NYODN seeks authorization for donation from family members or other authorized individuals. NYODN works closely with hospital personnel to recover suitable organs (including hearts, kidneys, livers and lungs) and tissues (such as heart valves, cardiovascular tissue, bone and skin), and to seek or confirm consent for cornea donation. We offer follow-up care and referrals to all families who consent to donation or whose loved ones had legally consented to donation.

4 The New York Donate Life Registry is a registry run by the New York State Department of Health, which records a person’s legal consent to organ, tissue and eye donation upon his or her death. If a potential donor is signed up in this registry, his or her family will be informed of the decision to donate and given information about the donation process, but their consent is not required to proceed with donation. See Organ Donation Frequently Asked Questions, New York State Dept. of Health, http://www.health.ny.gov/professionals/patients/donation/organ/frequently_asked_questions.htm (last visited Oct. 25, 2013).

5 Donate Life Annual Report, 2011
As documented by the Centers for Disease Control ("CDC"), the donor potential in NYODN's designated service area has been decreasing annually. We have the fifth lowest death rate from gunshot wounds, the third lowest death rate from stroke, and a life expectancy for men of 86. Indeed, 49.2% of donors in NYODN's service area are relatively old, at over 50. Although good news overall, these statistics result in fewer organs being available for transplantation.

For many years, and despite prior management changes, NYODN has experienced below national average donation rates (data that impacts the first two performance metrics maintained in the proposed rule). These relatively lower donation rates are due in large part to the above-listed factors, and are not attributable to NYODN's quality of operation or its processes. Indeed, NYODN always has successfully satisfied the process review requirements to remain certified. Significantly, despite its older donor pool, NYODN also is in compliance with the third performance metric, relating to organs transplanted per donor.

To meet the donation rate challenge, however, two years ago NYODN assembled a new top-notch management team. This team is assisted by a renowned medical advisory board, which includes the best regarded transplant surgeons and other doctors in our service area. These doctors have strong relationships with the hospitals with which they are affiliated and best position NYODN to effectively meet its objectives. Through the use of process improvement and strategic initiatives, NYODN has established best practices to help address the barriers to donation that its service area presents. For example, although not responsible for enrolling potential donors in the New York State Department of Health's Donate Life Registry, NYODN recently embarked on an aggressive marketing and educational campaign to increase awareness and enrollment. As a result, New York has one of the fastest growing donor registries in the country.

The Outcome Measures Fail to Meet the Act's Requirements and Are Fundamentally Flawed

As CMS states in the preamble to the proposed rule, § 371(b)(1)(D)(ii) of the Public Health Service Act, as amended by the Organ Procurement Organization Certification Act of 2000 (the "Act"), requires that regulations be established for the certification and/or recertification process, which (1) "rely on outcome and process performance measures that are based on empirical evidence obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations," and (2) "use multiple outcome measures as part of the certification process."

Thus, the Act requires that the regulations governing the certification and recertification process weigh empirical evidence that reflects not only donor potential in a service area, but also other factors that impact the relative performance of each OPO.

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7 Scientific Registry for Transplant Recipients: http://www.srtr.org
Regulations establishing the Conditions for Coverage ("CfCs") were promulgated in 2006.\(^{12}\) The three outcome measures that were adopted and that currently are required to be met in order for an OPO to be certified or recertified under these regulations are set forth at 42 C.F.R. § 486.318.\(^{13}\) The outcome measures all are clinically-based and depend on consents to donation. The regulations also provide a system where each OPO's performance is judged in relation to the performance of the others. In fact, OPOs must perform within 1.5 standard deviations of the mean national rate.\(^{14}\) Therefore, some always will fall short and decertification will be inevitable. All three of these outcome measures must be satisfied in order for an OPO to be certified or recertified.\(^ {15}\) The regulations also require that OPOs satisfy eight separate process requirements.\(^{16}\)

Because certification reviews are performed every four years, the 2006 regulations, with the three then new performance metrics, should have been part of the recertification process in 2010. At that time, however, OPOs had not collected sufficient data for CMS to use to assess their performance under the three outcome measures. As a result, CMS did not enforce this aspect of the regulation, creating an unofficial reprieve. In 2010 CMS determined eligibility for recertification based exclusively on the eight process requirements. The 2014 certification cycle is set to be the first cycle during which the 2006 performance metrics will be applied.

\(^{12}\) See 42 C.F.R. §§ 486.1-486.348.

\(^{13}\) "Condition: Outcome measures.

(a) With the exception of OPOs operating exclusively in non-contiguous U.S. states, commonwealths, territories, or possessions, an OPO must meet all 3 of the following outcome measures:

1. The OPO’s donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle. Both the numerator and denominator of an individual OPO’s donation rate ratio are adjusted by adding 1 for each donation after cardiac death donor and each donor over the age of 70;

2. The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by the SRTR;

3. At least 2 out of the 3 following yield measures are no more than 1 standard deviation below the national mean, averaged over the 4 years of the re-certification cycle:

(i) The number of organs transplanted per standard criteria donor, including pancreata used for islet cell transplantation;

(ii) The number of organs transplanted per expanded criteria donor, including pancreata used for islet cell transplantation; and

(iii) The number of organs used for research per donor, including pancreata used for islet cell research."

\(^{14}\) 42 C.F.R. § 486.318(a)(1).

\(^{15}\) 42 C.F.R. § 486.316.

\(^{16}\) 42 C.F.R. §§ 486.303, 486.320-486.348.
The Proposed Regulatory Change Does Not Address the Acknowledged Flaws in the Outcome Measures

Prompted by concerns over the legality and appropriateness of the performance metrics, CMS proffered the proposed rule. Its attempt to avoid arbitrary decertifications – and the havoc and human suffering that would ensue – however, fails miserably, as the proposed rule will not avert the disastrous impact of the metrics. The proposed rule does not include any changes to the outcome measures. Instead, pursuant to the proposed rule, OPOs will be required to satisfy only two, rather than all three, of the flawed measures in order to qualify to be certified or recertified. As explained more fully below, this rule is wholly inadequate to address the fundamental defects inherent in the performance measures or otherwise to implement a change that will protect the public from their imminent and devastating effects. More fundamentally, because the first two performance metrics depend on the same data, i.e., donation rate, suggesting that an OPO need meet only two of the three criteria is effectively making no change at all, since it is highly likely that an OPO either will satisfy both the first and second performance measures or will satisfy neither.

1. The Evidence Relied on as Part of the Certification Process is Not "Empirical," as the Act Requires

As CMS acknowledges, there are “differences in how the definition of ‘eligible death’ is being clinically interpreted and implemented,” as well as how the determination is made. As a result of these differences in practices among different OPO service areas, CMS admits to being “concerned that this apparent variance may be adversely affecting the performance of some OPOs on the outcome measures.” Since the definition of eligible death is so critical to the calculation of the outcome measures, these discrepancies discredit the use of the outcome measures as a comparative review. The proposed rule does not address this flaw.

In addition, under the current and proposed rule, the data that OPOs submit to CMS in connection with the outcome measures is self-reported and unaudited. Not surprisingly, errors have been found in the data on which CMS has relied as the basis for judging OPO performance. Clearly, this type of “evidence” fails to meet any reasonable definition of “empirical.” The proposed rule does not address this defect in the current regulation.

2. Contrary to the Act’s Requirements, the Outcome Measures Fail to Consider “Other Related Factors” in Each Service Area

The outcome measures do not adequately adjust for various factors related to demographics. CMS acknowledges that a lack of adjustment for demographic factors may negatively impact the first performance measure, but does not – because it cannot – explain how the proposed rule addresses this significant issue.

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18 Id. at 43,672.
19 Id. at 43,671.
20 Id.
21 Id.
While organ donor registries are an integral element of an OPO’s infrastructure, they are not within the OPO’s control, and enrollment participation does not reflect the quality of an OPO’s operations. Therefore, CMS’s failure to provide a metric that adjusts donation rates based on donor registry enrollment across service areas improperly measures OPOs against each other while they stand on wholly unequal playing fields. The importance of this adjustment cannot be overstated. Indeed, enrollment rates in donor registries vary dramatically across OPO service areas, ranging from as low as 20% to over 75%.22 This difference in donor registry enrollment dramatically impacts an OPO’s relative ability to obtain consent for organ donation, yet is not accounted for in the proposed rule.

Mortality and co-morbidity data from the CDC clearly demonstrates that regional disparities in health demographics exist. In fact, the incidence of disease in certain populations may have an even more significant impact on CMS’s second performance measure than age, race, sex or cause of death.23 While these variations in health demographics can significantly impact the performance metrics, they are not considered in the performance metrics, and this flaw is not corrected in the proposed rule.

In addition, health demographics also limit the number of organs transplanted per donor (impacting the third performance metric), another way in which this variable causes relative OPO performance to be judged improperly under the current performance metrics.24 Once again, nothing in the proposed rule addresses this flaw.

If the Proposed Rule Becomes Final in Its Current Form, It Will Have Devastating Consequences and Provide No Benefit

While NYODN wholeheartedly agrees that outcome measures should be utilized to improve overall OPO performance, the existing metrics are not legally acceptable or sensible, as they fail to accurately evaluate OPOs’ quality. Even as CMS acknowledges, the current outcome measures are “unnecessarily stringent” and “of concern.”25 The proposed rule does not correct the fundamental flaws in the metrics or protect against the harm that will result from their application. Indeed, the proposed rule does not address the defective structure of the regulations, which necessarily will lead to decertification of at least two OPOs every review cycle. These mandatory decertifications will occur because to be recertified OPOs must perform within 1.5 standard deviations of the mean national rate.26 Therefore, some always will fail short.

22 Donate Life Annual Report, 2011
23 Center for Disease Control: http://www.cdc.gov/nchs/fastats/death.htm
24 While the second performance measure in the current regulation (§ 486.318(a)(2)), which remains unchanged in the proposed rule, purports to consider certain demographic factors, the data relied on for the adjustment has changed since the regulations became effective and the new criteria are even less effective in making a reasonable adjustment than the prior criteria. While the expected donation rate is, by regulation (§ 486.302), defined to reflect an adjustment based on certain enumerated hospital characteristics (e.g., trauma center level, size of community, number of ICU beds, etc.), as calculated by Scientific Registry of Transplant Recipients (SRTR), SRTR no longer obtains or uses the hospital data and instead applies different adjustment criteria based on the characteristics of patient (e.g., age, gender, sex and an outmoded concept of “race”). CMS was notified of this change to the SRTR criteria, yet failed to adjust the regulation accordingly.
26 42 C.F.R. § 486.318(a)(1).
CMS acknowledged that if its metrics are faulty, which it also acknowledged they could be, it "may take inappropriate enforcement action."\textsuperscript{27}

The performance metrics also have created a sad and well recognized irony: OPOs are incentivized to pursue only high yield donors, as opposed to single organ donors, so as to maintain a high organ per donor metric and minimize any negative impact single donations have on the performance measures. CMS has acknowledged this problem as well, which the performance metrics are causing, and stated: "[t]his could have a significant impact on the potential transplant recipient waiting for transplants nationwide."\textsuperscript{28}

1. **It Is Better from a Cost/Benefit Perspective to Work With an Existing OPO to Improve Performance, Rather than Have an Outside OPO Take Over a Service Area**

Decertifying an OPO, particularly one as large as NYODN, should not be undertaken lightly, as it will result in significant costs, in terms of both human lives and dollars. For example, any new OPO covering NYODN's service area will face the very same challenges to donation rates that NYODN faces. There is no reason to believe that a new OPO will be able to achieve a higher donation rate, especially in light of the appointment of NYODN's new management team, which recently has put new strategic processes in place. In fact, there is a high risk that at least for a significant transition period, there will be a decrease in the donation rate, as the newly designated OPO builds up good will, makes connections and develops the knowledge required to achieve the current donation rate, let alone a better rate. In the meantime, an already challenged transplant system will be strained even further.

Reallocating service areas also will create additional expenses associated with organ sharing and allocation procedures. OPOs share organs based on the "local" service area so that those in need closest to the donor receive the organ offer first.\textsuperscript{29} Any OPO taking over a service area will be required to share organs with a greater number of transplant centers and throughout their full combined service area. Corresponding changes also would have to occur within the national sharing system. In addition, UNOS would have to redefine service areas, operating regions and the collections of SRTR data. Each one of these changes will be expensive to implement, further burdening our healthcare system.

Incurring the burdens of decertifying an OPO would be an unfortunate necessity if it were properly determined that an OPO were underperforming. Here, however, the dramatic consequences that would result from such decertifications – the loss of life and expenditure of scarce resources – would be based on what even CMS acknowledges are flawed metrics.\textsuperscript{30} Formally suspending the application of the performance metrics, as occurred informally through non-enforcement in 2010, and allowing OPOs who satisfy the process review criteria to remain certified until new metrics can be developed, will allow CMS to continue to work with existing OPOs to improve donation rates, taking into account matters outside of an OPO's control. At the same time, such a transition period would allow CMS to call for further comments on performance metrics and develop criteria that will properly evaluate OPO performance. This approach will not create any added burden on patients or the health care reimbursement system and will result in the creation of appropriate outcome measures that can be utilized in the future.

\textsuperscript{27} 78 Fed. Reg. at 43,672.

\textsuperscript{28} Id.

\textsuperscript{29} This approach reduces expense and ensures a short cold ischemic time due to less travel and well documented better outcomes for the recipient.

\textsuperscript{30} 78 Fed. Reg. at 43,672.
2. **The Immediate Impact of Adopting the Proposed Rule Will Be to Leave Service Areas of Decertified OPOs with No Means of Procuring Donors**

If the proposed rule is adopted, OPOs, including NYODN, will be decertified on August 31, 2014. The proposed rule includes no transition plan and, therefore, there are no provisions for organ donation services in New York while CMS determines the reassignment of the service area. Under the current regulations, neighboring OPOs will be encouraged to submit proposals to acquire NYODN's service area. Given the inherent challenges that this service area has in satisfying the donation rate metrics, it would not be surprising if no OPO volunteered to take it on, for fear of bringing down their own metrics. In the absence of any volunteers, CMS would assign the service area to a neighboring OPO.

While the reassignment and reestablishment of an OPO in one of the largest service areas in the country is being sorted out, service will suffer, if it continues at all. The same consequences, of course, would play out with equal devastation in other service areas where OPOs are decertified. Decertifications will exacerbate the existing hardships for transplant patients, which are caused by a lack of sufficient donor organs, causing a true crisis.

**The Proposed Rule Should Be Modified To Temporarily Suspend the Application of the Performance Metrics and Allow CMS To Call For Further Comment**

We suggest changing the proposed rule to provide that 42 CFR § 486.316(a)(1) and 42 CFR § 486.318 become effective on January 1, 2017.

The imminent decertification of the NYODN and other OPOs based on metrics that CMS acknowledges are flawed will result in an acute healthcare crisis. This disaster only can be averted by postponing the implementation of the performance metrics for the 2014 review cycle and providing CMS with an opportunity to call for further comment and continue to develop new quality-based metrics that satisfy the requirements of the Act and that accurately assess OPO performance. We understand from CMS that it does not intend to suspend the application of the performance metrics in 2014, as it did in 2010. In any event, relying on non-enforcement as a cure for flawed regulatory requirements undermines transparency, accountability, and public participation, as well as the principles codified in the Administrative Procedure Act and Executive Orders 12866 and 13653.

We look forward to discussing these issues with your colleagues at our meeting on October 29, 2013.

Very truly yours,

Helen M. Irving
President & CEO

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31 42 C.F.R. § 486.316.

32 *Id.*
POSITION STATEMENT OF THE ASSOCIATION OF ORGAN PROCUREMENT ORGANIZATIONS (AOPO) ON CMS PROPOSED MODIFICATIONS OF OPO PERFORMANCE MEASURES

OVERVIEW:

The Association of Organ Procurement Organizations (AOPO) is grateful for the opportunity to comment on the proposed modifications for Organ Procurement Organization (OPO) requirements in 42 §§ 486.316(a) (1) and (b) and the introductory text of §§ 486.318(a) and (b). AOPO also acknowledges the considerable thought given by CMS to the issues outlined by AOPO, and recognizes the challenges regarding proposed revisions of the OPO performance outcome measures.

After nearly a year of formal meetings and collaborative dialogue between AOPO and a range of CMS representative levels, CMS has not put forth within the most recent CMS Proposed Rule to revise the Medicare hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system (July 17, 2013), the essential changes which had been delineated:

1. Replace the requirement that [CMS] "will not voluntarily renew its agreement with an OPO if the OPO fails to meet" the performance standards ", with "may voluntarily not renew its agreement with an OPO if the OPO fails to meet the performance standards", and

2. Allow CMS to adopt an option to require an OPO to develop a corrective action plan, or similar improvement process, as determined by CMS, similar to the process currently in place for organ transplant centers.

AOPO has identified seven key concerns with the existing CMS measures and proposed principles. AOPO also wishes to emphasize the urgency to which AOPO's recommendations are to be considered due to CMS's plan to issue a decertification notice to certain OPOs not meeting the flawed measures by the end of the data cycle period, December 31, 2013.

SUMMARY OF CONCERNS:

1. The current OPO outcome measures and their proposed modifications are not based on empirical evidence. CMS acknowledges the empirical flaws in the existing measures and proposed modifications.

2. The accuracy and consistency of data cannot be assured as definitions are inconsistent with OPO industry standards, data are self-reported and regional differences are not accounted for in the model.

3. Performance Measure 3 is based on outdated concept as ECD (Extended Criteria Donor) is no longer a recognized term or measurement within the policies of the federal Organ Procurement and Transplantation Network (OPTN).
4. The CUJTent system has created a disincentive for OPOs to pursue organ recovery when there may be a lower yield of organs transplanted per donor. This is in direct conflict with the mission of OPOs to pursue every viable organ for transplant to save even one life.

5. The current OPO regulations are in direct conflict with CMS transplant center regulations, encouraging recovery of transplantable organs that are subsequently refused by centers for transplant.

6. The current regulations and methods incorporated by CMS use inconsistent time periods for evaluating OPO performance.

7. The timing of recertification process may result in decertification of OPOs which performed within measurement guidelines in 2013.

PROPOSAL:

Given the above noted concerns, we propose this principle for short term reform:

That CMS adopt the ability to decide whether to terminate an OPO which fails one of the performance measures by modifying §486.312(c), “[CMS] will not voluntarily renew its agreement with an OPO if the OPO fails to meet” the performance standards “

The sentence should be modified to read:

“[CMS] may voluntarily not renew its agreement with an OPO if the OPO fails to meet the performance standards”.

This proposed short term reform recognizes that there are true empirical issues with the performance measures and their timeliness. This will permit CMS flexibility in the certification process in order to assess any mitigating circumstances which may come to bear on whether an OPO should or should not be decertified and prevent any subsequent harm to the procurement and transplantation system.

The proposed modifications do nothing to ensure that the regulations meet the express requirements of the Organ Procurement Organization Certification Act of 2000 (the “Act”). CMS does not identify low or high-performing OPOs, increase the number of organs available for transplant, nor allow CMS to assist OPOs with corrective action plans or other process improvement programs. AOPO has not changed its strong opposition to these performance measures. We still agree with the position of the DHHS Secretary’s Advisory Committee on Organ Transplantation (ACOT)¹, a position referenced in this notice for public comment, that the “performance measures are fundamentally flawed.” The application of these proposed modifications as written (or the application of the current measures without change), puts Organ

¹ Advisory Committee on Organ Transplantation (ACOT): Recommendation 35: The ACOT recognizes that the current CMS and HRSA/OPTN structure creates unnecessary burdens and inconsistent requirements on transplant centers (TCs) and organ procurement organizations (OPOs) and that the current system lacks responsiveness to advances in TC and OPO performance metrics. The ACOT recommends that the Secretary direct CMS and HRSA to confer with the OPTN, SRTR, the OPO community, and TC representatives, to conduct a comprehensive review of regulatory and other requirements, and to promulgate regulatory and policy changes to requirements for OPOs and TCs that unify mutual goals of increasing organ donation, improving recipient outcomes, and reducing organ wastage and administrative burden on TCs and OPOs. These revisions should include, but not be limited to, improved risk adjustment methodologies for TCs and a statistically sound method for yield measures for OPOs. The ACOT recommends that this review be completed within one year and that action be taken within two years.
Procurement Organizations, Transplant Centers, and the nearly 120,000 patients waiting for transplant at needless risk. CMS is proposing to use fatally flawed measures to potentially decertify qualified organ procurement organizations (OPOs) from continuing to serve their communities. The application of these measures will create disruption and distraction that will erode certain OPOs’ viability and may dramatically decrease the supply of organs, organs desperately needed by potential recipients.

While proper, valid, audited measures are essential requirements to any regulated medical process, these measures meet none of those requirements. Neither the existing measures nor proposed modifications accurately identify OPOs that fail to meet neither an acceptable level of performance, nor conversely, those which may be performing well.

ANALYSIS:

AOPO’s Seven Key Concerns with the Existing Measures

1. Neither the original measures nor the proposed modifications meet the statutory requirements that the measures be based on empirical evidence, and CMS itself identifies the empirical flaws in the existing measures and proposed modifications.

   a. As noted by CMS in the Preamble to this proposed regulation, Congress required “outcome...measures that are based on empirical evidence obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified [OPOs]”.

   b. CMS goes on to note (strongly supported by evidence provided by AOPO in the last year) that there are “differences in how the definition of ‘eligible death’ is being clinically interpreted and implemented,” and as a result CMS admits to being “concerned that this apparent variance may be adversely affecting the performance of some OPOs on the outcome measures.”

   c. CMS also notes that, critically, it is “concerned that the current measures may not be accurately allowing for adjustment of various factors” related to demographics (again, strongly supported by evidence provided by AOPO in the last year). CMS discusses how a lack of adjustments for demographic factors may negatively impact the first measure, but neither addresses how the measure could be improved nor considers the relevance to the other standards.

   d. And finally, without proposing a method to control this flaw, CMS notes (as has been reported to CMS by a number of OPOs) that the regulations may be causing OPOs to “game” the process of meeting the third standard by only targeting “high-yield” organ candidates.

2. Accuracy and Consistency of Data Cannot be Assured.

   The performance regulations are based on an OPO’s performance as compared to the mean performance of all OPOs (Measures 1 & 3), or as compared to the expected performance of a “typical” OPO (Measure 2). Therefore it is essential that the performance metrics be validated, that there be precise definitions of all measurements, that these definitions are consistently applied by all OPOs, that there be some way of verifying the accuracy of the data, and that the performance metrics are validated. Unfortunately, this is not currently the case.
a. Definitions are Imprecise:

i. Definition of Eligible Death
This definition is the foundation essential for determining the denominator for Measure 1, the donor conversion rate. The Organ Procurement and Transplantation Network (OPTN), which established the definition of eligible death and collects the data, has repeatedly acknowledged that there are problems with the definition. An alternate definition for imminent and eligible death has been vetted and approved by the OPTN in June 2013. However, audits of data as currently submitted (and as will be used for the 2014 recertification cycle) factually demonstrate significant inconsistencies in the application of the Eligible Death definition.

ii. Definition of Donor
This definition is essential for determining the numerator of Measure 1, and for determining the denominator for Measure 3. The OPTN provides this definition of a deceased donor in the UNet reporting system:

"A patient declared dead using either brain death or cardiac death criteria, from whom at least one vascularized solid organ (kidney, liver, pancreas, heart, lung, or intestine) was recovered [emphasis added] for the purpose of organ transplantation”

However, there is no clear definition of “recovered” within CMS language, nor OPTN language. This becomes an issue on a potential single organ donor where a decision is made to not transplant the organ for which the recovery was initiated. If the organ is biopsied in situ, but never actually removed, it is fairly clear that this would not count as a donor. However, what if the organ was removed, biopsied on the back table and then found to be unacceptable for transplant? Essentially it is the exact same situation - decision made in the operating room that an organ was not transplantable - but two possible reporting outcomes: no donor, or donor and no organs transplanted. OPOs, having received no instruction from CMS, are widely using both of these definitions (or variations thereof), creating a system in which no uniform measure may be derived, and thus providing an inaccurate measurement.

This lack of definitional precision stands in contrast to that which is used to measure transplant center performance. For example, in determining the number of transplants the OPTN uses a definition that can be consistently applied without interpretation biases.

“7.1.1 For form submission purposes, an organ transplant has occurred once either: any initiation of anastomosis has taken place during the intended transplant, or the initiation of an islet cell infusion has occurred. The transplant procedure shall be considered complete when either (1) the chest and/or abdominal cavity is closed and the final skin stitch and/or staple is applied or (2) the islet cell infusion is complete. For the purposes of this definition, solid organ transplants and islet cell infusions are all considered to be transplants. Extracorporeal transplants are not considered organ transplants for the purposes of this definition.”
As noted, the ramifications of multiple interpretations of some of these critical definitions used to calculate performance measures can be devastating, not just as it may impact a single OPO which may be interpreting and thus reporting information such that it negatively impacts them, but again, because the data of the entire community of OPOs is used to comparatively evaluate all OPOs.

b. Data Accuracy Cannot Be Assured:

i. Data are Unaudited and Self-Reported
There is no provision for even random audits of the data submitted by OPOs to assess the accuracy of the data reporting. All data are self-reported and unverified. Again, given that each OPO is compared against the performance of all other OPOs, this is problematic and ultimately a fatal flaw in the regulation.

ii. SRTR Subcontractor & CMS Data Contain Inconsistencies
A review of the data set released by CMS for the period 1/01/2011 – 6/30/2012 indicated that there were significant differences from the data as reported to the OPTN and verified by the Scientific Registry of Transplant Recipients (SRTR) subcontractor. As reported to CMS, this included donors recovered as Donors after Cardiac Determination of Death (DCDD) which were incorrectly shown in the CMS data as eligible donors. By definition, DCDDs are not eligible donors. Failure to correctly transfer or interpret data can obviously also result in the inappropriate determination of an OPO’s performance.

c. Validity of Performance Measures Not Established

Even if the metrics were uniformly defined and applied, there is no indication that any of the performance measures have been validated to demonstrate that they actually distinguish between an OPO at which performance is acceptable, and an OPO at which performance is unacceptable. Further, it appears that the performance measures were designed to ensure that a certain number of OPOs would be found to be out of compliance with performance standards on each recertification cycle, in order to reduce the number of OPOs in the US. In fact, the Final Regulations note that CMS expects that 9 OPOs were expected to fail to meet the performance standards. (Federal Register/Vol. 71, No. 104, May 31, 2006, Page 31036). Furthermore, there will be cuts in every survey cycle because this type of measurement, where there are standard deviations below the national mean, would always generate OPOs that do not meet the standard, until there were a few OPOs performing nearly identically to each other.

In one example of the validation problem, Measure 2 is based only on the four characteristics of Age, Sex, Race and Cause of Death of a potential donor, and assumes that everyone in the entire United States will have similar beliefs, behaviors and desire to donate their organs for transplant characterized only by these four characteristics. Furthermore, it falsely and incorrectly assumes that other characteristics such as religion, generation within the US (foreign born vs. 2nd or 3rd generation), education, etc. have no relationship to an individual’s decision to donate.

These measures were crafted more than a decade ago, and do not take into account other factors that have changed within that time frame. For example, they do not take
into consideration the effects of donor registries, which vary from state to state in terms of the number or percentage of people within those service areas who have registered as donors. The range of difference between state registries with the highest percentage of adults over 18 who have registered to donate and states with the lowest is more than 60 percent of their respective adult populations. Put another way, the highest state donor registry percentage rate, is more than three times as high as the lowest state donor registry percentage rate.


Performance measure 3 (in part) measures an OPO’s organs transplanted per donor (OTPD) on Standard Criteria Donors (SCD) and Extended Criteria Donors (ECD). ECD was a concept developed by the OPTN to facilitate the placement of kidneys from less than ideal donors. It was never intended to apply to extra-renal organs. Moreover, the yes/no nature of donor ECD classification has proven to be too crude. Many years’ worth of data demonstrate that many ECDs yield more organs per donor transplanted than certain SCDs, e.g. SCD with positive serologies. The OPTN recently passed policy changes that entirely eliminate the ECD definition and substitute the Kidney Donor Profile Index (KDPI), which is a continuous scale that more accurately reflects the likelihood that a specific transplanted kidney will be successful. CMS must not use definitions to decertify an OPO based on data from a concept that the OPTN has rejected as invalid.

4. Performance Measures Provide Disincentive to Organ Recovery.

Measure 3 can be a disincentive to pursue marginal organ donors that generally yield fewer organs (or no organs) transplanted per donor. If an OPO is in jeopardy of decertification based on OTPD, and for example, that OPO has a high percentage of “marginal” donors (whether due to age, propensity for disease, or other factors, which in turn may be due to geographic, cultural or other influences), the OPO is incentivized (for fear of being decertified) to not pursue, or even evaluate the potential for donation of these types of donors. This practice results in fewer organs being transplanted, and more lives lost. Furthermore, current performance measures do not fully reflect an OPO’s successful efforts to recover organs from “non-eligible” donors in that they are not counted and credited to the OPO’s donation rate in all of the measures. For example, a non-eligible, brain dead 25-year-old liver only donor who is in multi-system organ failure is not counted in the SCD OTPD rate, but neither are the OPO’s efforts on this donor reflected in the OPO’s Donation Rate. Conversely, a brain dead 65-year-old liver only donor who is in multi-system organ failure is included in the ECD OTPD calculation. These donors adversely affect an OPO’s ECD OTPD rate without any offsetting benefit to their donation rate. Finally, donors over the age of 70 who are not “eligible” are not calculated in the OPO’s donation rate, but depending on their designation as SCD vs. ECD, they may or may not be calculated in the OTPD rate. These examples are offered to illustrate potential disincentives to pursuing certain donors and reflect the incompleteness and inconsistencies of the performance measures in reflecting the entirety of an OPO’s contributions to transplanting patients.
5. Performance Measures Conflict with CMS Transplant Center Regulations.

Except as noted above, OPOs are incentivized to recover as many organs from as many donors as possible, even if the organ quality may be less than ideal. Transplant centers are required to meet stringent one year transplant outcome requirements with insufficient risk adjustment for the quality of the donor and donor organs. Without an adequate risk adjustment provision, many transplant programs, especially smaller ones, are driven to be more conservative about the organs they will accept for transplant. Studies have shown that transplant centers cited for below expected outcomes become more selective in organ acceptance practices, resulting in a decrease in the number of transplants performed. Organs that are more marginal are generally harder to place at non-local transplant centers, especially after local centers have declined them. Thus OPO performance is impacted, differentially and substantially, by the clinical acceptance practices of its local transplant programs. The OPO performance measures do not make any adjustment for this phenomenon, which is entirely out of the OPO's control.

6. Final Regulations Use Inconsistent Time Periods for Evaluation.

Section 486.318 of the OPO regulations is internally inconsistent on the dates of data to be used in measuring OPO performance for recertification. (a)(1) requires the data to be “...averaged over the 4 years of the recertification cycle.” (a)(3) requires the data to be “...averaged over the 4 years of the re-certification cycle.” (c)(1) Indicates that an OPO's performance will be “based on 36 months of data, beginning with January 1 of the first full year of the recertification cycle and ending 36 months later on December 31, 7 months prior to the end of the re-certification cycle.”

CMS has indicated that it will follow section (c)(1) and ignore sections (a)(1) and (a)(3) in calculating the performance measures for the 2014 recertification cycle. However, CMS only came to this decision, and announced it to the OPOs, in mid-2012, halfway through the certification cycle. Further, AOPO has not received any analysis of the basis for CMS’ decision. Given the inherent year to year variability in a relatively infrequent event such as donation, the exclusion of the data from 2010 may cause an OPO to fail to meet the performance measures, which it otherwise would have not failed. This is especially true of OPOs which have fewer donors and organs recovered for transplant. The smallest OPOs with smaller service areas and lesser potential for organ donors recover organs from as few as 40 donors each year. Any number of the above mentioned or other variables, that reduce the number of donors or organs even by a few, result in significant percentage changes.

7. Timing of Recertification Process will be Disruptive to Organ Donation and Transplantation.

The data to be used in determining OPOs’ compliance with the performance measures includes activity through 12/31/2013. CMS staff has indicated they expect to receive the calculation of OPO performance in late January 2014 from its contractor, UMKECC. However, data for the end of 2013 will not yet be complete or subject to even the most basic verification by the OPO, OPTN or SRTR. Based on this data report, CMS intends to notify OPOs in March that fail to meet the performance standard that they will be decertified and their donation service area (DSA) assigned to another OPO. This notification is likely to create great concern to the staff of notified OPOs, and likely will lead to staff departures and a decrease in the local organ supply. Yet a few months later,
once the data set is finalized and means and standard deviations adjusted, it is possible
that one or more of the notified OPOs who were close to meeting the performance
standards will, in fact, qualify and have their decertification notice rescinded. However,
the damage will already have been done. Even worse, other OPOs may then be subject to
decertification based on final data, and will receive a decertification notice with even less
time to respond. This staffing projection has actually already been demonstrated in an
OPO that received their most recent letter from CMS about their interim failure to meet
these flawed measures. This, despite the fact that according to the much more rigorous
quality performance model of observed versus expected organs recovered, this particular
OPO was performing as expected.

AOPO’s Principles for Short Term Reforms:

AOPO believes that addressing the concerns above, and others that have been expressed
elsewhere and by others in the transplant and patient communities, will take the commitment
of time and resources to develop and validate new measures. We appreciate CMS's desire to
engage in that dialogue and stand ready to assist CMS in those efforts. In conceptualizing
those measures, it is important to ensure that the measures and the process reliably
differentiate between acceptable and unacceptable OPO performance in a statistically valid
manner. AOPO believes it is important to develop a process that moves the performance
measurement strategy outside of the current regulatory text so that future changes in practice
and technology can be more rapidly incorporated into CMS's evaluation of OPO
performance.

Likewise, AOPO believes significant improvements can be made to better align the measures
that influence the behavior and performance for OPOs with the measures that influence the
behavior and performance of transplant centers. The current misalignment, as well as and
surgeon and/or physician preferences, appear to strongly influence whether a transplant
program is more or less conservative in their acceptance of organs. Recognizing that some of
these issues are locally-determined strategies while others are more global responses to
performance incentives, AOPO urges CMS to ensure that performance measures for OPOs
reflect activities over which they have direct control and for which they should be held
accountable, and that OPOs are not penalized for actions and activities and geographic and
demographic realities over which they have no control.

Unfortunately, development of a fully revised and validated set of performance measures is
not possible in time for the 2014 recertification cycle. In the near term, AOPO remains most
cconcerned about the limited appeals process (CMS noted repeatedly to AOPO that no appeal
on "substantive" issues may be allowed) and stringent rules mandating termination of an
OPO's participation in Medicare if it fails one or more of the existing measures. Our short
term recommendations are as follows:

- That CMS adopt the ability to decide whether to terminate an OPO which fails one of the
performance measures by modifying §486.312(c) from "[CMS] will not voluntarily
renew its agreement with an OPO if the OPO fails to meet" the performance standards
to "... may voluntarily not renew ..." or "... may voluntarily not renew ... provided
that..." (See below for suggestions regarding “provided that”).
• That CMS adopt the ability to look behind the existing measures to be sure that an OPO’s failure to meet a performance measure is not reflective of variations in the application of definitions, data collection and documentation and any other operational factors which may affect past or future compliance with the measures. A separate consideration is that under current regulations, the tolerance for variations in performance is inappropriately strict, and perhaps the use of 1.5 standard deviations needs to be reconsidered.

• That CMS adopt the ability to take into account statistically significant information from any OPO which initially “fails” recertification to divert that OPO from decertification to certified or provisionally certified status [perhaps through a corrective action plan (CAP) or systems improvement agreement (SIA) process], including, for example, review and application of:
  - the rigor with which the OPO has (or all OPOs have) applied the definitions;
  - the unique attributes of the OPO’s potential donor population, and other DSA factors like geography;
  - the impact of the OPO’s aggressive pursuit of single organ donors; and,
  - the organ acceptance practices of the transplant centers in the OPO’s DSA.

• That CMS adopt the ability to identify and utilize alternative metrics and/or principles which can be used as supplementary information to evaluate OPO performance or, help with the interpretation of data of existing metrics. For example:
  - The OPTN expected yield metric is an alternative that may help support the information available to CMS in evaluating performance;
  - Demographic information may be compared to performance data to understand variations in performance which reflect the underlying population characteristics in an OPO’s DSA; and,
  - Consideration of the full 48 months of data in the current certification cycle.

• That CMS adopt the ability to develop an intermediate path before a decision is made to terminate a program that can include progressive discipline and/or performance improvement activities that can help an organization meet CMS expectations. The termination of an OPO will be highly disruptive, and may not be necessary if performance can be improved through operational changes, similar to demonstrated successes with transplant programs that were initially found to be challenged. It is important that a process differentiate between OPOs for whom the measure(s) are not an accurate and valid reflection of performance from those in which actual performance is substandard.

CONCLUSION:

AOPO believes the benefits of pursuing the above recommendations for this current survey cycle offer significant improvement and outweigh the deficits of holding firm to the faulty current measures and process. All 58 organ procurement organizations are comprised of individuals and communities that include a spectrum of thoughtful and committed men and women whose inherent mission, and often deep passion, is to maximize the donation of lifesaving organs and tissues for transplantation. A portion of CMS’s role is to ensure the safety and adequate performance of OPOs, which thus translates to the rate of donation and the volume of organs
transplanted. However, the single fact alone that in some circumstances the current performance measures encourage OPOs to NOT perform their responsibilities of maximizing the recovery of organs from donors so that they can stay compliant, and thus remain certified, is contradictory enough to the mission and role of CMS that the entire paradigm of performance evaluation for this community should be re-evaluated.

As stated by Dr. Cassel, the President of the National Quality Forum to the Senate Finance Committee Hearing this past June 26th on “Health Care Quality: The Path Forward”, “…focusing on quality will only be effective if the tools we use to measure are themselves “high quality.”” Further, Dr. Cassel wrote that for quality measurement to have the intended impact, the measures must be understandable, actionable by providers, meet high medical and scientific standards, and that it is critical that a range of stakeholders agree on what is important to measure and that there is evidence that the measures selected can drive improvements in care. In Dr. Cassel’s expert testimony, there were points made identical to those we raise above, for example, that the scientific acceptability of measure properties are based on criteria that “evaluate whether the measure will generate valid conclusions about quality; if measures are not reliable (consistent) and valid (correct), they may be improperly interpreted and providers may be misclassified.”

The application of invalidated, arbitrary standards which will only damage the lifesaving practices for which we are all responsible, is not consistent with the intent of the ACOT recommendations to the Secretary, recommendations by the National Quality Forum, the current performance evaluation process for transplant centers, nor CMS’s similar efforts to identify and implement performance review of hospitals, as is demonstrated in its commissioned white paper “Statistical Issues in Assessing Hospital Performance”, and therefore these existing and proposed invalid, arbitrary standards for OPOs are unacceptable.

Thank you again for your thoughtful consideration. AOPO stands ready to assist CMS to improve the process and tools used to evaluate OPO performance.

Respectfully Submitted,

Susan Stuart
President, AOPO
The proposed modifications released this past July do not ensure that the regulations meet the requirements of the Organ Procurement Organization Certification Act of 2000 (the “Act”). Neither by the current, nor proposed revisions of the regulations, is CMS able to identify low or high-performing OPOs, or increase the number of organs available for transplant. AOPO has not changed its opposition to these performance measures. We agree with the position of the DHHS Secretary’s Advisory Committee on Organ Transplantation (ACOT), a position referenced in this notice for public comment, that the “performance measures are fundamentally flawed.” The application of these proposed modifications as written (or the application of the current measures without change), puts Organ Procurement Organizations, Transplant Centers, and patients waiting for transplant at needless risk. CMS is proposing to use fatally flawed measures to potentially decertify qualified organ procurement organizations (OPOs) from continuing to serve their communities. The application of these measures will create disruption and distraction that will erode affected OPOs’ viability and may dramatically decrease the supply of organs needed by waiting recipients.

AOPO has identified several key concerns with the existing CMS measures and proposed principles. AOPO also wishes to emphasize the urgency to which AOPO’s recommendations are to be considered due to CMS’s plan to issue a decertification notice to OPOs not meeting the flawed measures by the end of the data cycle period, December 31, 2013 (or soon thereafter).

SUMMARY OF CONCERNS:

1. The current OPO outcome measures and their proposed modifications are not based on empirical evidence. CMS acknowledges the empirical flaws in the existing measures and proposed modifications.
2. The accuracy and consistency of data cannot be assured as definitions are inconsistent with OPO industry standards, data are self-reported and regional differences are not accounted for in the model.
3. Performance Measure 3 is based on outdated concept as ECD (Extended Criteria Donor) is no longer a recognized term or measurement within the policies of the federal Organ Procurement and Transplantation Network (OPTN).
4. The current system has created a disincentive for OPOs to pursue organ recovery when there may be a lower yield of organs transplanted per donor. This is in direct conflict with the mission of OPOs to pursue every viable organ for transplant to save even one life.
5. The current OPO regulations are in direct conflict with CMS transplant center regulations, encouraging recovery of transplantable organs that are subsequently refused by centers for transplant.
6. The current regulations and methods incorporated by CMS use inconsistent time periods for evaluating OPO performance.
7. The timing of recertification process may result in decertification of OPOs which performed within measurement guidelines in 2013.

PROPOSAL:

Given the above noted concerns, we propose this principle for short term reform:

That CMS adopt the ability to decide whether to terminate an OPO which fails one of the performance measures by modifying §486.312(c), “[CMS] will not voluntarily renew its agreement with an OPO if the OPO fails to meet” the performance standards “

The sentence should be modified to read: “[CMS] may voluntarily not renew its agreement with an OPO if the OPO fails to meet the performance standards”.

This proposed short term reform recognizes that there are true empirical issues with the performance measures and their timelines. This will permit CMS flexibility in the certification process in order to assess any mitigating circumstances which may come to bear on whether an OPO should or should not be decertified and prevent any subsequent harm to the procurement and transplantation system.

While proper, valid, audited measures are essential requirements to any regulated medical process; these measures meet none of those requirements. Neither the existing measures nor proposed modifications accurately identify OPOs that fail to meet neither an acceptable level of performance, nor conversely, those which may be performing well.
March 9, 2000: Organ Procurement Organization Certification Act of 2000. ...(ii) is defined through regulations that are promulgated by the Secretary by not later than January 1, 2002, that—
   (I) require recertifications of qualified organ procurement organizations not more frequently than once every 4 years;
   (II) rely on outcome and process performance measures that are based on empirical evidence of organ donor potential and other related factors in each service area of qualified organ procurement organizations;
   (III) use multiple outcome measures as part of the certification process;
   (IV) provide for the filing and approval of a corrective action plan by a qualified organ procurement organization that fails to meet the performance standards and a grace period of not less than 3 years during which such organization can implement the corrective action plan without risk of decertification; and
   (V) provide for a qualified organ procurement organization to appeal a decertification to the Secretary on substantive and procedural grounds.


May 31, 2006: Final Rule published in Federal Register with effective date of July 31, 2006;
FR 30982 / Vol. 71; 42 CFR Parts 413, 441, 486 and 498.

The Final Rule stated that CMS was recertifying all the OPOs through July 31, 2010. "In this final rule, we re-certify the 58 currently certified OPOs from August 1, 2006 through July 31, 2010. Each OPO will retain its currently designated service area. Since the OPOs' current agreements with the Secretary expire July 31, 2006, prior to that date, we will request each OPO to sign a new agreement with an ending date of January 31, 2011." Therefore, the performance measurements within the May 31, 2006, regulations were not utilized for the 2006 – 2010 period for recertification. All 58 OPOs recertified.

February to July 2010: CMS surveyors performed 58 individual site surveys of OPOs under the May 31, 2006, final rule for the 2010 – 2014 OPO recertification cycle. All 58 OPOs recertified based on review of all other portions of the regulation. The performance measure components were not utilized for the recertification process at this point.

November 2009 to July 2013: AOPO and CMS communicated extensively, through phone calls/conferences and face to face meetings to review and discuss the CMS regulations, interpretive guidance, and performance measures. There were discussions between AOPO and CMS regarding the faults and possible solutions of the final rule performance measures, as well as other of the requirements in the final rule and draft interpretive guidance.

AOPO and CMS recognized the faults and challenges of the performance measures as required by the May 31, 2006, regulations and language of the final rule. In discussions with CMS, an option for a short term solution to modify final rule language that would allow the CMS Survey and Certification Group the ability to review supplemental information to evaluate OPO performance was identified. It was presented that a logical and acceptable alternative would be to change the final rule regulation language from the absolute “shall”, to “may”, and to allow for an OPO appeals process if outcome measures were not met. It was offered by CMS that this proposed regulatory language could possibly be attached to the annual (November 2013) Medicare Physician Fee Schedule final rule.

Released July 8 and published July 19, 2013: Proposed revised language for OPO regulations became public (FR 43533 / Vol. 78; Page: 43533 – 3707; 42 CFR Part 486) and did not incorporate the changes both CMS and AOPO discussion previously.

September 6, 2013: AOPO and the OPOs responded to the CMS proposed regulation public comment period with the same recommendations and fault points noted in previous discussions.

November 1, 2013: Medicare Physician Fee Schedule final rule will be issued that can incorporate the final rule language sought by AOPO to change “shall”, to “may”, and to allow for an OPO appeals process if outcome measures were not met.

February or March through July 2014: CMS Survey and Certification group will perform on-site surveys of all 58 OPOs. The performance measure data period will be January 1st 2011 through December 31st 2013. It will take a few months before all of the data for that period can be reviewed and finally be analyzed by CMS to determine compliance with the measures as defined. CMS notifications to the OPOs regarding compliance with these measures (independent of the other regulatory requirements reviewed during the onsite surveys) will likely be made in March.
Appendix Y - Organ Procurement Organization (OPO)
Interpretive Guidance

Regulation

§486.301 Basis and Scope

(a) Statutory basis. (1) Section 1138(b) of the Act sets forth the requirements that an organ procurement organization (OPO) must meet to have its organ procurement services to hospitals covered under Medicare and Medicaid. These include certification as a "qualified" OPO and designation as the OPO for a particular service area.

(2) Section 371 (b) of the Public Health Service Act sets forth the requirements for certification and the functions that a qualified OPO is expected to perform.

(3) Section 1102 of the Act authorizes the Secretary of Health and Human Services to make and publish rules and regulations necessary to the efficient administration of the functions that are assigned to the Secretary under the Act.

(4) Section 1871 of the Act authorizes the Secretary to prescribe regulations as may be necessary to carry out the administration of the Medicare program under title XVIII.

(b) Scope. This subpart sets forth –

(1) The conditions and requirements that an OPO must meet;

(2) The procedures for certification and designation of OPOs;

(3) The terms of the agreement with CMS and the basis for and the effect of decertification; and

(4) The requirements for an OPO to be re-certified.

§486.302 - Definitions

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. 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 for donation 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.

The "unintentional" transmission of a disease through organ transplantation would be considered an adverse event. There are limited instances where disease transmission may occur with the knowledge of the recovery personnel and the recipient. (See 486.344 (b)(2)).

Instances where the donor has a transmittable disease (e.g., Human Immune Deficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV)) and the recovered
§486.302 – Definitions. (con't.)

organ is transplanted into a recipient with the same transmittable disease; with the informed consent of the recipient, this would not be considered an adverse event.

Agreement cycle refers to the time period of at least 4 years when an agreement is in effect between CMS and an OPO.

Brain death (as defined by State law) is the irreversible cessation of cerebral and brain stem function; characterized by absence of electrical activity in the brain, blood flow to the brain, and brain function as determined by clinical assessment of response. A brain-dead person is dead although his/her cardio pulmonary functioning may be artificially maintained for some time.

Certification means a CMS determination that an OPO meets the requirements for certification at §486.303.

Death record review means an assessment of the medical chart of a deceased patient to evaluate potential for organ donation.

Decertification means a CMS determination that an OPO no longer meets the requirements for certification at §486.303.

Designated requestor or effective requestor is an individual (generally employed by a hospital), who is trained to handle or participate in the donation consent process. The designated requestor may request consent for donation from the family of a potential donor or from the individual(s) responsible for making the donation decision in circumstances permitted under State law, provide information about donation to the family or decision-maker(s), or provide support to or collaborate with the OPO in the donation consent process.

Designation means CMS assignment of a geographic service area to an OPO. Once an OPO is certified and assigned a geographic service area, organ procurement costs of the OPO are eligible for Medicare and Medicaid payment under section 1138(b)(1)(F) of the Act.

Donation service area (DSA) means a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area or does not include any part of such an area and that meets the standards of this subpart.

Donor means a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is recovered for the purpose of transplantation.

Donor after cardiac death (DCD) means an individual who donates after his or her heart has irreversibly stopped beating. A donor after cardiac death may be termed a non-heart beating or asystolic donor.
**Donor document** is any documented indication of an individual’s choice in regard to donation that meets the requirements of the governing state law.

**Eligible death** for organ donation means the death of a patient 70 years old or younger, who ultimately is legally declared brain dead according to hospital policy independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice, who exhibits none of the following:

(1) **Active infections** (specific diagnoses).
   
   (i) **Bacterial:**
      (A) Tuberculosis.
      (B) Gangrenous bowel or perforated bowel and/or intra-abdominal sepsis.

   (ii) **Viral:**
      (A) HIV infection by serologic or molecular detection.
      (B) Rabies.
      (C) Reactive Hepatitis B Surface Antigen.
      (D) Retroviral infections including HTLV I/II.
      (E) Viral Encephalitis or Menigitis.
      (F) Active Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia.
      (G) Acute Epstein Barr Virus (mononucleosis).
      (H) West Nile Virus infection.
      (I) Severe acute respiratory syndrome (SARS).

   (iii) **Fungal:**
      (A) Active infection with Cryptococcus, Aspergillus, Histoplasma, Coccidioides.
      (B) Active candidemia or invasive yeast infection.

   (iv) **Parasites:**
      Active infection with Trypanosoma cruzi (Chagas’), Leishmania, Strongyloides, or Malaria (Plasmodium sp.).

   (v) A history of Creutzfeldt-Jacob Disease.

(2) **General:**
   
   (i) Aplastic Anemia.
   (ii) Agranulocytosis.
   (iii) Extreme Immaturity (<500 grams or gestational age of <32 weeks).
   (iv) Current malignant neoplasms except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease.
   (v) Previous malignant neoplasms with current evident metastatic disease.
   (vi) A history of melanoma.
   (vii) Hematologic malignancies: Leukemia, Hodgkin’s Disease, Lymphoma, Multiple Myeloma.
(viii) Multi-system organ failure (MSOF) due to overwhelming sepsis or MSOF without sepsis defined as 3 or more systems in simultaneous failure for a period of 24 hours or more without response to treatment or resuscitation.

(ix) Active Fungal, Parasitic, viral, or Bacterial Meningitis or encephalitis.

(3) The number of eligible deaths is the denominator for the donation rate outcome performance measure as described at §486.318(a)(1).

Eligible donor means any donor that meets the eligible death criteria. The number of eligible donors is the numerator of the donation rate outcome performance measure.

Entire metropolitan statistical area means a metropolitan statistical area (MSA), a consolidated metropolitan statistical area (CMSA), or a primary metropolitan statistical area (PMSA) listed in the State and Metropolitan Area Data Book published by the U.S. Bureau of the Census. CMS does not recognize a CMSA as a metropolitan area for the purposes of establishing a geographical area for an OPO.

Expected donation rate means the donation rate expected for an OPO based on the national experience for OPOs serving similar hospitals and donation service areas. This rate is adjusted for the following hospital characteristics: Level I or Level II trauma center, Metropolitan Statistical Area size, CMS Case Mix Index, total bed size, number of intensive care unit (ICU) beds, primary service, presence of a neurosurgery unit, and hospital control/ownership.

Observed donation rate is the number of donors meeting the eligibility criteria per 100 deaths.

Open area means an OPO service area for which CMS has notified the public that it is accepting applications for designation.

Organ means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine).

Organ procurement organization (OPO) means an organization that performs or coordinates the procurement, preservation, and transport of organs and maintains a system for locating prospective recipients for available organs.

Re-certification cycle means the 4-year cycle during which an OPO is certified.

Standard criteria donor (SCD) means a donor that meets the eligibility criteria for an eligible donor and does not meet the criteria to be a donor after cardiac death or expanded criteria donor.

Transplant hospital means a hospital that provides organ transplants and other medical and surgical specialty services required for the care of transplant patients. There may be one or more types of organ transplant centers operating within the same transplant hospital.
Urgent need occurs when an OPO’s non-compliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or an organ recipient.

The term “Urgent Need” should be considered to be synonymous with the Survey and Certification definition of “Immediate Jeopardy.” (See §489.3). Follow procedures in the State Operations Manual (Appendix Q) for notification of the OPO and termination procedures when urgent need is identified.

§486.303 Requirements for certification. In order to be certified as a qualified organ procurement organization, an organ procurement organization must:

§486.303(a) Have received a grant under 42 U.S.C. 273(a) or have been certified or re-certified by the Secretary within the previous 4 years as being a qualified OPO.

Interpretive Guidelines §486.303(a)

No on-site activity is necessary. The CMS Regional Office (RO) maintains a current signed copy of the Designation/Certification (Form CMS-576) for the OPO on file and should review this document before going on-site.

§486.303(c) Be a non-profit entity that is exempt from federal income taxation under section 501 of the Internal Revenue Code of 1986.

Interpretive Guidelines §486.303(c)

During the on-site review, check the organization’s most current IRS 501C approval documentation to validate non-profit status. This will usually be in the form of a letter from the IRS stating that the status is approved or renewed. The documentation should be no more than 5 years old as the Internal Revenue Service (IRS) reviews non-profit status every five years. If the approval is more than 5 years old, the OPO may produce IRS website information to indicate a more recent approval.

Deficient practice found at this regulation should be cited at §486.324(e).

§486.303(c) Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant hospitals.

Interpretive Guidelines §486.303(c)

The OPO must have written policies to ensure that fiscal affairs are conducted in accordance with generally accepted accounting procedures to maintain the fiscal stability of the organization. The policies should address, at a minimum, a-d below:
a) Use of a balance sheet(s) which indicate assets, liabilities and fund balance(s);  
b) The annual operating budget (preparation and approval by the governing body);  
c) Cost report submission and responses from the fiscal intermediary/Medicare Administrative Contractor (MAC); and  
d) Procedures to obtain payment for all renal and non-renal organs from transplant hospitals.

Verify that the organization’s policies in regards to fiscal affairs address the above. Deficient practice found at this regulation should be cited at §486.324(e).

§486.303(d) Have an agreement with CMS, as the Secretary’s designated representative, to be reimbursed under title XVIII for the procurement of kidneys.

Interpretive Guidelines §486.303(d)  
See Interpretive Guidance for §486.303(a).

§486.303(e) Have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005.

§486.303(f) Have procedures to obtain payment for non-renal organs provided to transplant centers.

Interpretive Guidelines §486.303(f)  
See Interpretive Guidance for §486.303(c).

§486.303(g) Agree to enter into an agreement with any hospital or critical access hospital in the OPO’s service area, including a transplant hospital that requests an agreement.

§486.303(h) Meet the conditions for coverage for organ procurement organizations, which include both outcome and process performance measures.

Interpretive Guidelines §486.303(h)  
This regulation should be co-cited with any citation of a condition.

§486.303(i) Meet the provisions of titles XI, XVIII, and XIX of the Act, section 371(b) of the Public Health Services Act, and any other applicable Federal regulations.
§486.304 Requirements for designation.

§486.304(a) Designation is a condition for payment. Payment may be made under the Medicare and Medicaid programs for organ procurement costs attributable to payments made to an OPO by a hospital only if the OPO has been designated by CMS as an OPO.

§486.304(b) An OPO must be certified as a qualified OPO by CMS under 42 U.S.C. 273(b) and §486.303 to be eligible for designation.

Interpretive Guidelines §486.304(b)
See Interpretive Guidance at §486.303(a)

§486.304(c) An OPO must enter into an agreement with CMS in order for the organ procurement costs attributable to the OPO to be reimbursed under Medicare and Medicaid.

Interpretive Guidelines §486.304(c)
This agreement is completed at each recertification cycle.

§486.306 OPO service area size designation and documentation requirements.

§486.306(a) General documentation requirement. An OPO must make available to CMS documentation verifying that the OPO meets the requirements of paragraphs (b) through (d)* of this section at the time of application and throughout the period of its designation.

*subsection (d) referenced above is a misprint and should be (c) as there is no subsection (d).

Interpretive Guidelines §486.306(a)
At the time of the on-site review, the surveyor verifies that:

a) The OPO's policies incorporate the information required by (§486.306(b) and (c));

b) The OPO is operating consistently with the information as stated in their policies; and
c) The OPO donation service area corresponds to the information on file at the applicable CMS Regional Office.

Deficient practice found at this regulation should be cited at §486.324(e).

§486.306(b) Service area designation. The defined service area either includes an entire metropolitan statistical area or a New England county metropolitan statistical area as specified by the Director of the Office of Management and Budget or does not include any part of such an area.

§486.306(c) Service area location and characteristics. An OPO must define and document a proposed service area’s location through the following information:

§486.306(c) (1) The names of counties (or parishes in Louisiana) served or, if the service area includes an entire State, the name of the State.

§486.306(c) (2) Geographic boundaries of the service area.

§486.306(c) (3) The number and the names of all hospitals and critical access hospitals in the service area that have both a ventilator and an operating room.

§486.308 Designation of one OPO for each service area. §486.308 (a) CMS designates only one OPO per service area. A service area is open for competition when the OPO for the service area is de-certified and all administrative appeals under §486.314 are exhausted.

§486.308 (b) Designation periods

§486.308 (b) (1) General. An OPO is normally designated for a 4-year agreement cycle. The period may be shorter, for example, if an OPO has voluntarily terminated its agreement with CMS and CMS selects a successor OPO for the balance of the 4-year agreement cycle. In rare situations, a designation period may be longer, for example, a designation may be extended if additional time is needed to select a successor OPO to an OPO that has been de-certified.

§486.308 (b) (2) Re-Certification. Re-certification must occur not more frequently than once every 4 years.

Interpretive Guidelines §486.308(a) and (b)
A donation service area is only open for competition in the event of de-certification or voluntary withdrawal from the program. As a result, a current OPO may only change the boundaries of their donation service area (outside of re-designation by CMS resulting from an open competition) as a result of a merger, (approved in advance by CMS), with another OPO. OPOs must compete for an entire service area.

§486.308(c) Unless CMS has granted a hospital a waiver under paragraphs (d) through (f) of this section, the hospital must enter into an agreement only with the OPO designated to serve the area in which the hospital is located.

§486.308(d) If CMS changes the OPO designated for an area, hospitals located in that area must enter into agreements with the newly designated OPO or submit a request for a waiver in accordance with paragraph (e) of this section within 30 days of notice of the change in designation.

Interpretive Guidelines §486.308(d)
Requests for waiver should be submitted to: The OPO should submit their request for a waiver to:
Director of the Division of Technical Payment Policy
Chronic Care Policy Group
Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

§486.308(e) A hospital may request and CMS may grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. To qualify for a waiver, the hospital must submit data to CMS establishing that:
1) The waiver is expected to increase organ donations; and
2) The waiver will ensure equitable treatment of patients listed for transplants within the service area served by the hospital’s designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement.

§486.308(f) In making a determination on waiver requests, CMS considers:
1) Cost effectiveness;
2) Improvements in quality;
3) Changes in a hospital’s designated OPO due to changes in the definitions of metropolitan statistical areas, if applicable; and
4) The length and continuity of a hospital’s relationship with an OPO other than the hospital’s designated OPO.

Interpretive Guidelines §486.308(e) and (f)

The OPO should submit their request for a waiver to:

Director of the Division of Technical Payment Policy
Chronic Care Policy Group
Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Waiver requests are processed by the Division of Payment Policy, Center for Medicare

§486.308(g) A hospital may continue to operate under its existing agreement with an out-of-area OPO while CMS is processing the waiver request. If a waiver request is denied, a hospital must enter into an agreement with the designated OPO within 30 days of notification of the final determination.

§486.309 Re-certification from August 1, 2006 through July 31, 2010.
An OPO will be considered to be re-certified for the period of August 1, 2006 through July 31, 2010 if an OPO met the standards to be a qualified OPO within a 4-year period ending December 31, 2001 and has an agreement with the Secretary that is scheduled to terminate on July 31, 2006. Agreements based on the August 1, 2006 through July 31, 2010 re-certification cycle will end on January 31, 2011.

§486.310 Changes in control or ownership or service area.

§486.310(a) OPO requirements.
§486.310(a)(1) A designated OPO considering a change in control (see §413.17(b)(3)) or ownership or in its service area must notify CMS before putting it into effect. This notification is required to ensure that the OPO, if changed, will continue to satisfy Medicare and Medicaid requirements. The merger of one OPO into another or the consolidation of one OPO with another is considered a change in control or ownership.

Interpretive Guidelines §486.310(a)(1)
When the CMS RO receives notification of a prospective change in control or ownership for a designated OPO, the CMS RO must determine, based upon the documents submitted, that the operation of the OPO will continue uninterrupted during and following the changeover of ownership or control. Review all the documents submitted by the OPO in response to the elements on Form CMS-576. The OPO should show evidence of transition planning to ensure continuity. With change of ownership a new CMS Form 576 must be signed. Confirm with the Fiscal Intermediary/MAC that the OPO has submitted a revised CMS Form-855 and that the information has been accepted by the Fiscal Intermediary/MAC.

Refer to Chapter 2 of the SOM, 2814 - Organ Procurement Organizations (OPOs) - Change in Control/Ownership or Service Area

§486.310(a) OPO requirements.

§486.310(a)(2) A designated OPO considering a change in its service area must obtain prior CMS approval. In the case of a service area change that results from a change of control or ownership due to merger or consolidation, the OPOs must resubmit the information required in an application for designation. The OPO must provide information specific to the board structure of the new organization, as well as operating budgets, financial information, and other written documentation CMS determines to be necessary for designation.

Interpretive Guidelines §486.310(a)(2)

The OPO must inform the applicable CMS RO of their intent to change the ownership of the designated OPO or participate in a merger, which will require the re-designation of one or more current OPO donation service areas. This information must be submitted prior to the effective date of the change in ownership or merger and must include, as a minimum, all the information required by Form CMS-576.

If during the on-site visit it is discovered that the OPO completed a change of ownership, a change in control, or merger and the CMS RO did not receive prior notification with submission of the required documents, cite a deficiency at §486.324(e)

§486.310(b) CMS requirements.

§486.310(b)(1) If CMS finds that the OPO has changed to such an extent that it no longer satisfies the requirements for OPO designation, CMS may de-certify the OPO and declare the OPO’s service area to be an open area. An OPO may appeal such a decertification as set forth in §486.314. The OPO’s service area is not opened for competition until the conclusion of the administrative appeals process.

Interpretive Guidelines §486.310(b)

See State Operations Manual (SOM) Chapter 2, Section 2812.3 for discussion regarding procedures for opening of a Donation Service Area for competition.
§486.310(b) CMS requirements

§486.310(b)(2) If CMS finds that the changed OPO continues to satisfy the requirements for OPO designation, the period of designation of the changed OPO is the remaining portion of the 4-year term of the OPO that was reorganized. If more than one designated OPO is involved in the reorganization, the remaining designation term is the longest of the remaining periods unless CMS determines that a shorter period is in the best interest of the Medicare and Medicaid programs. The changed OPO must continue to meet the requirements for certification at §486.303 throughout the remaining period.

§486.312 De-Certification.

§486.312(a) Voluntary termination of agreement.

If an OPO wishes to terminate its agreement, the OPO must send the applicable CMS RO written notice of its intention to terminate its agreement and the proposed effective date. The CMS RO may approve the proposed date, set a different date no later than 6 months after the proposed effective date, or set a date less than 6 months after the proposed effective date if it determines that a different date would not disrupt services to the service area. If the CMS RO determines that a designated OPO has ceased to furnish organ procurement services to its service area, the cessation of services is deemed to constitute a voluntary termination by the OPO, effective on a date determined by the RO. The CMS RO will de-certify the OPO as of the effective date of the voluntary termination.

Interpretive Guidelines §486.312(a)

See SOM Chapter 2, Section 28.17 for discussion regarding the procedures for voluntary termination of an OPO.

§486.312(b) Involuntary termination of agreement.

During the term of the agreement, CMS may terminate an agreement with an OPO if the OPO no longer meets the requirements for certification at §486.303. CMS may also terminate an agreement immediately in cases of urgent need, such as the discovery of unsound medical practices. CMS will de-certify the OPO as of the effective date of the involuntary termination.

Interpretive Guidelines §486.312(b)

If at any time during the certification period the OPO is determined by the CMS RO to be out of compliance with one or more of the conditions for coverage (CFC) and fails to make corrections sufficient to regain compliance, the CMS RO will begin de-certification procedures per the SOM at Chapter 2 Section 2818. For de-certification due to urgent need refer to §486.302.
§486.312(c) Non-renewal of agreement.

CMS will not voluntarily renew its agreement with an OPO if the OPO fails to meet the requirements for certification at §486.318, based on findings from the most recent re-certification cycle, or the other requirements for certification at §486.303. CMS will decertify the OPO as of the ending date of the agreement.

Interpretive Guidelines §486.312(c)

If the OPO is found to be out of compliance with CfCs at §486.318 or §486.303, provide the OPO the opportunity to develop and implement an acceptable plan of correction prior to the end of their current provider agreement. If the OPO is not able to regain compliance prior to the end of the current provider agreement begin non-renewal procedures per the SOM Chapter 2 Section 2818.

§486.312(d) Notice to OPO.

Except in cases of urgent need, CMS gives written notice of de-certification to an OPO at least 90 days before the effective date of the de-certification. In cases of urgent need, CMS gives written notice of de-certification to an OPO at least 3 calendar days prior to the effective date of the de-certification. The notice of de-certification states the reasons for de-certification and the effective date.

§486.312(e) Public notice.

Once CMS approves the date for a voluntary termination, the OPO must provide prompt public notice of the date of de-certification and such other information as CMS may require through publication in local newspapers in the service area. In the case of involuntary termination or non-renewal of an agreement, CMS provides public notice of the date of de-certification through publication in local newspapers in the service area. No payment under titles XVIII or XIX of the Act will be made with respect to organ procurement costs attributable to the OPO on or after the effective date of de-certification.

Interpretive Guidelines §486.312(e)

In cases where an OPO voluntarily terminates their provider agreement they must publish notification to the public in the local newspapers of their service area and on their website. Request that the OPO include in the notice:

a) Date they will cease operation;

b) The hospitals and CAHs located within their service area; and

c) An OPO telephone contact number for inquiries to their notice.

Request that the OPO provide CMS with copies of all publications, include the copies of the notices in the provider's file.
Public notice is considered prompt when the notice of voluntary termination appears in local newspapers within three (3) business days of the date that CMS approved the OPO termination date.

§486.314 Appeals.

If an OPO's de-certification is due to involuntary termination or non-renewal of its agreement with CMS, the OPO may appeal the de-certification on substantive and procedural grounds.

Interpretive Guidelines §486.314

This regulation addresses the reconsideration and appeal process. There is no pre-survey or on-site survey activity required by the surveyor. Do not make a compliance determination for this regulation as a component of the survey process.

§486.314(a) Notice of initial determination.

CMS mails notice to the OPO of an initial de-certification determination. The notice contains the reasons for the determination, the effect of the determination, and the OPO's right to seek reconsideration.

Interpretive Guidelines §486.314(a)

See §486.312(d).

§486.314(b) Reconsideration.

§486.314(b)(1) Filing request. If the OPO is dissatisfied with the de-certification determination, it has 15 business days from receipt of the notice of de-certification to seek reconsideration from CMS. The request for reconsideration must state the issues or findings of fact with which the OPO disagrees and the reasons for disagreement.

Interpretive Guidelines §486.314(b)(1)

The de-certification notice should be sent to the provider by registered mail. Add three days (for mail delivery) to the date on the notice and then the provider has until the close of 15 business days from that date to submit any request for reconsideration of the de-certification notice.

General statements of disagreement with the final decision, concerns about the financial situation of the provider, or general access concerns are not sufficient additional information to support reconsideration. The provider must include specific, factual information concerning each finding with which they disagree and reasons for disagreeing with the CMS determination, including any supporting evidence. The submitted information is then evaluated by CMS to determine if the de-certification decision may be reversed in light of the additional information submitted.

§486.314(b)(2) An OPO must seek reconsideration before it is entitled to seek a hearing before a hearing officer. If an OPO does not request reconsideration or its request is not made timely, the OPO has no right to further administrative review.
Interpretive Guidelines §486.314(b)(2)

When the CMS RO receives notice that the provider has filed a request for hearing, inform the hearing officer if the provider failed to submit a request for reconsideration prior to his/her request for hearing or did not file the request for reconsideration timely (see §486.314(b)(1) above).

§486.314(b)(3) Reconsideration determination.

CMS makes a written reconsidered determination within 10 business days of receipt of the request for reconsideration, affirming, reversing, or modifying the initial determination and the findings on which it was based. CMS augments the administrative record to include any additional materials submitted by the OPO, and a copy of the reconsideration decision and sends the supplemented administrative record to the CMS hearing officer.

Interpretive Guidelines §486.414(b)(3)

If the reconsideration request is received timely by the RO, review the submitted information. The reconsideration process should be conducted by staff not involved in the original de-certification decision. Within 10 business days from the date of receipt of the reconsideration request, make a determination as to whether sufficient information and documentation was received to justify reversing the decision to terminate the provider agreement. If the de-certification decision is reversed, notify the provider in writing and forward a revised Form CMS-2567 to reflect the revised findings.

If the de-certification decision is not reversed, notify the provider in writing of the decision including what materials were reviewed and why the materials did not provide substantive information to reverse the decision. Inform the provider that when the service area is “opened for competition” they will not be permitted to compete for that service area or any other service area in the future.

Incorporate all notifications to the provider into the provider file. If the provider seeks further administrative review (hearing officer review), provide the reconsideration request and supporting documentation that was received from the provider and the written reconsideration determination to the hearing officer.

§486.314(c) Request for hearing.

An OPO dissatisfied with the CMS reconsideration decision, must file a request for a hearing before a CMS hearing officer within 40 business days of receipt of the notice of the reconsideration determination. If an OPO does not request a hearing or its request is not received timely, the OPO has no right to further administrative review.

Interpretive Guidelines §486.314(c)

See Interpretive Guidance at §486.314(b)(2)
§486.314(d) Administrative record. The hearing officer sends the administrative record to both parties within 10 business days of receipt of the request for a hearing. The administrative record consists of, but is not limited to the following:

i) Factual findings from the survey(s) on the OPO conditions for coverage.

Interpretive Guidelines §486.314(d)(1)(i)

Upon notification that the OPO has requested an administrative hearing, forward the following information related to the survey in question to the hearing officer for inclusion into the administrative record:

(a) Copies of Forms CMS-2567 (including any plans of correction);
(b) Methodology for donor record selection during the survey;
(c) Survey Observation Notes (Form CMS-807 if used);
(d) Documentation of interviews with staff or families;
(e) Portions of the donor records copied during the survey (redacted);
(f) Donation Service Area description;
(g) OPTN membership status;
(h) OPO staff qualifications as applicable;
(i) Waivers granted;
(j) List of hospitals and CAHs in the service area;
(k) Member name and position represented on record for Advisory Board and Governing Body;
(l) Evidence of compliance/non-compliance with OPTN regulations on reporting data (CMS OPO Database report).

§486.314(d)(1)(ii) Data from the outcome measures.

Interpretive Guidelines §486.314(d)(1)(ii)

Provide the hearing officer with copies of the CMS OPO Database report, which include the measurement of provider performance with the three OPO regulatory data requirements. Provide sufficient historical Database information to encompass the survey period.

§486.314(d)(1)(iii) Rankings of OPOs based on the outcome data.
Interpretive Guidelines §486.314(d)(1)(iii)
Provide the hearing officer with a copy of the CMS OPO Database report ranking of all OPO(s) utilizing the most recent data collection period, based upon compliance with the regulatory data requirements at §486.318 and §486.328.

§486.314(d)(1)(iv) Correspondence between CMS and the affected OPO.

Interpretive Guidelines §486.314(d)(1)(iv)
Provide the hearing officer with:
(a) Copies of all written correspondence between the OPO and the CMS RO relevant to the certification action under appeal;
(b) All relevant e-mail correspondence between the OPO and the RO;
(c) Any pertinent entries from a correspondence log if utilized; and
(d) Relevant Survey and Certification Memoranda.

§486.314(d)(2) The administrative record will not include any privileged information.

Interpretive Guidelines §486.314(d)(2)
Privileged information includes those documents of communication between attorney and client. In this instance, all associated communications which were intended to be confidential between CMS and the Office of General Counsel are considered privileged and should not be included in the administrative record forwarded to the hearing officer.

§486.314(e) Pre-Hearing conference. At any time before the hearing, the CMS hearing officer may call a pre-hearing conference if he or she believes that a conference would more clearly define the issues. At the pre-hearing conference, the hearing officer may establish the briefing schedule, set the hearing date, and address other administrative matters. The hearing officer will issue an order reflecting the results of the pre-hearing conference.

Interpretive Guidelines §486.314(e)
This regulation addresses the reconsideration and appeal process. There is no pre-survey or on-site survey activity required by the surveyor. Do not make a compliance determination for this regulation as a component of the survey process.

§486.314 (f) Date of hearing.
The hearing officer sets a date for the hearing that is no more than 60 calendar days following the receipt of the request for a hearing.

Interpretive Guidelines §486.314(f)
This *regulation* addresses the reconsideration and appeal process. There is no pre-survey or on-site survey activity required by the surveyor. Do not make a compliance determination for this *regulation* as a component of the survey process.

§486.314(g) Conduct of Hearing

(1) The hearing is open to both parties, CMS and the OPO.

(2) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(3) The hearing officer provides the parties with an opportunity to enter an objection to the inclusion of any document. The hearing officer will consider the objection and will rule on the document's admissibility.

(4) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(5) The hearing officer rules on the admissibility of evidence and may admit evidence that would be inadmissible under rules applicable to court procedures.

(6) The hearing officer rules on motions and other procedural items.

(7) The hearing officer regulates the course of the hearing and conduct of counsel.

(8) The hearing officer may examine witnesses.

(9) The hearing officer takes any action authorized by the rules in this subpart.

Interpretive Guidelines §486.314(g)

This *regulation* addresses the reconsideration and appeal process. There is no pre-survey or on-site survey activity required by the surveyor. Do not make a compliance determination for this *regulation* as a component of the survey process.

§486.314(h) Parties' rights. CMS and the OPO may:

(1) Appear by counsel or other authorized representative, in all hearing proceedings.

(2) Participate in any pre-hearing conference held by the hearing officer.

(3) Agree to stipulations as to facts which will be made a part of the record.

(4) Make opening statements at the hearing.

(5) Present relevant evidence on the issues at the hearing.
(6) Present witnesses, who then must be available for cross-examination, and cross-examine witnesses presented by the other party.

(7) Present oral arguments at the hearing.

Interpretive Guidelines §486.314(b)

This regulation addresses the reconsideration and appeal process. There is no pre-survey or on-site survey activity required by the surveyor. Do not make a compliance determination for this regulation as a component of the survey process.

§486.314(i) Hearing officer's decision.
The hearing officer renders a decision on the appeal of the notice of the de-certification within 20 business days of the hearing.

(1) Reversal of de-certification.
If the hearing officer reverses CMS' determination to de-certify an OPO in a case involving the involuntary termination of the OPO's agreement, CMS will not terminate the OPO's agreement and will not de-certify the OPO.

(2) De-certification is upheld.
If the de-certification determination is upheld by the hearing officer, the OPO is de-certified and it has no further administrative appeal rights.

§486.314(j) Extension of agreement.
If there is insufficient time prior to expiration of an agreement with CMS to allow for competition of the service area and, if necessary, transition of the service area to a successor OPO, CMS may choose to extend the OPO’s agreement with CMS.

Interpretive Guidelines §486.314(j)

No extension will be granted to an OPO de-certified for an unabated Urgent Need (Immediate Jeopardy) finding. During any extension that is granted for non-urgent need findings, the applicable CMS RO must monitor the OPO’s performance in the areas which resulted in the de-certification.

§486.314(k) Effects of de-certification.
Medicare and Medicaid payments may not be made for organ procurement services the OPO furnishes on or after the effective date of de-certification. CMS will then open the de-certified OPO’s service area for competition as set forth in §486.316(c).

Interpretive Guidelines §486.314(k)

See SOM Chapter 2, Section 2812.3 for discussion regarding opening a donation service area for competition.

§486.316 Re-certification and competition processes.
§486.316(a) Re-certification of OPOs.
An OPO is re-certified for an additional 4 years and its service area is not opened for competition when the OPO:

§486.316(a)(1) Meets all 3 outcome measure requirements at §486.318; and

§486.316(a)(2) Has been shown by survey to be in compliance with the requirements for certification at §486.303, including the conditions for coverage at §486.320 through §486.348.

Interpretive Guidelines §486.316(a)(2)
The OPO may not be re-certified with uncorrected deficiencies at the condition level. The OPO may be re-certified with standard level deficiencies with an acceptable plan of correction.

§486.316(b) De-certification and competition.
If an OPO does not meet all 3 outcome measures as described in paragraph (a)(1) of this section or the requirements described in paragraph (a)(2) of this section, the OPO is de-certified. If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs. The de-certified OPO is not permitted to compete for its open area or any other open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

§486.316(c) Criteria to compete.
To compete for an open service area, an OPO must meet the criteria in paragraph (a) of this section and the following additional criteria:

(1) The OPO's performance on the donation rate outcome measure and yield outcome measure is at or above 100 percent of the mean national rate averaged over the 4 years of the re-certification cycle; and

(2) The OPO's donation rate is at least 15 percent points higher than the donation rate of the OPO currently designated for the service area.

(3) The OPO must compete for the entire service area.
§486.316(d) Criteria for selection. CMS will designate an OPO for an open service area based on the following criteria:

§486.316(d) (1) Performance on the outcome measures at §486.318;

Interpretive Guidelines §486.316(d)(1)
The applying OPO must currently be in compliance with all outcome measures at §486.318 and have been in compliance with all measures throughout the current certification cycle. For each data measure, consider the level of compliance (i.e., position above the national mean). This data performance of the OPO should be considered as one of the factors for selection and should be utilized in association with the OPO's performance with the requirements of §486.316(d)(2) through §486.316(d)(4).

§486.316(d)(2) Relative success in meeting the process performance measures and other conditions at §486.320 through §486.348;

Interpretive Guidelines §486.316(d)(2)
"Relative success" is defined as compliance during the current re-certification cycle and the prior re-certification cycle at a Condition level with §486.320-§486.348.

§486.316(d)(3) Contiguity to the open service area;

Interpretive Guidelines §486.316(d)(3)
Consider the proximity to and timely access of the applying OPO to the donor hospitals in the open service area.

§486.316(d)(4) Success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

Interpretive Guidelines §486.316(d)(4)
Review the deficiencies that led to the opening of the service area. Review the information submitted by the applying OPO to determine what experiences that the applying OPO has had in addressing and successfully correcting similar concerns.

§486.316(e) No OPO applies.
If no OPO applies to compete for a de-certified OPO's open area, CMS may select a single OPO to take over the entire open area or may adjust the service area boundaries of two or more contiguous OPOs to incorporate the open area. CMS will make its decision based on the criteria in paragraph (d) of this section.

Interpretive Guidelines §486.316(e)
See SOM Chapter 2, Section 2812.3 for discussion regarding opening of a donation service area.

Organ Procurement Organization Outcome Requirements

(Cond) §486.318 Condition: Outcome measures.
§486.318 (a) With the exception of OPOs operating exclusively in non-contiguous U.S. states, commonwealths, territories, or possessions, an OPO must meet all 3 of the following outcome measures:

Interpretive Guidelines §486.318(a)
Currently, the only OPOs in non-contiguous areas are located in Hawaii and Puerto Rico.

(Std) §486.318(a)(1) The OPO's donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle. Both the numerator and denominator of an individual OPO's donation rate ratio are adjusted by adding a 1 for each donation after cardiac death donor and each donor over the age of 70;

Interpretive Guidelines §486.318(a)(1)
Prior to going on site, refer to the most recent CMS OPO Database report. The database report will record the OPO's compliance level with this measurement as computed on an annual basis and then averaged over the three full calendar years of the re-certification cycle (aggregate 36 months). Utilize the most recent calculated compliance results for the aggregate calculation. During the re-certification survey, inform the OPO of the report findings (compliance/non-compliance) and include any non-compliance in the exit interview.

(Std) §486.318(a)(2) The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by the SRTR;
The SRTR is the Scientific Registry of Transplant Recipients. Because CMS performs review of OPOs on a four year cycle it is necessary to rely upon data to verify consistent compliance by the OPO with the requirements for “observed donation rate vs. expected donation rate.” In order to verify consistent compliance with the requirements for observed donation rate vs. expected donation rate, CMS expects the OPO to show, at a minimum, of 18 months consecutive compliance within the 36 month period between re-certification cycles.

Prior to going on site, refer to the most recent CMS OPO Database report. Determine that the OPO has been in compliance with any 18 consecutive months of the 36 months of data utilized for the reports. CMS will use a rolling average methodology to calculate compliance.

(Std) §486.318(a)(3) At least 2 out of the 3 following yield measures are no more than 1 standard deviation below the national mean, averaged over the 4 years of the re-certification cycle:

**Interpretive Guidelines §486.318(a)(3)**
Prior to going on-site, refer to the CMS OPO Database report. The Database report will record the OPO level of compliance with (i) – (iii) below for each full calendar year of the re-certification cycle as well as the aggregate compliance level for the three full years. Utilize the most recent calculated compliance results (36-month aggregate) to evaluate compliance with the Standard. During the re-certification survey inform the OPO of the report findings (compliance/non-compliance) and include any non-compliance in the exit interview.

(Std) §486.318(a)(3)(i) The number of organs transplanted per standard criteria donor, including pancreata used for islet cell transplantation;

(Std) §486.318(a)(3)(ii) The number of organs transplanted per expanded criteria donor, including pancreata used for islet cell transplantation; and

**Interpretive Guidelines §486.318(a)(3)(ii)**

*Definition: Expanded Criteria Donors (ECD) This group includes donors who meet the expanded criteria and whose organs were recovered prior to cardiac death. Donors who meet the expanded criteria are those over 60 years of age and those between 50 and 59 years of age meeting two of the following three conditions: died of a stroke, had a history of hypertension or had a serum creatinine of greater than 1.5.*
§486.318(a)(3)(iii) The number of organs used for research per donor, including pancreata used for islet cell research.

Interpretive Guidelines §486.318(a)(3)(iii)
Self explanatory.

§486.318(b) For OPOs operating exclusively in non-contiguous U.S. states, commonwealths, territories, and possessions, the OPO outcome measures are as follows:

Interpretive Guidelines §486.318(b)
Non-contiguous areas include the geographical areas of Hawaii and Puerto Rico.

§486.318(b)(1) The OPO's donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle. Both the numerator and denominator of an individual OPO's donation rate ratio are adjusted by adding 1 for each donation after cardiac death donor and each donor over the age of 70.

Interpretive Guidelines §486.318(b)(1)
Same as §486.318(a)(1) above.

§486.318(b)(2) The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36-months of data used for re-certification, as calculated by the SRTR;

Interpretive Guidelines §486.318(b)(2)
Same as §486.318(a)(2) above.

§486.318(b)(3) At least 2 out of the 3 following are no more than 1 standard deviation below the national mean:

Interpretive Guidelines §486.318(b)(3)
The data measured for §486.318(b)(3)(i) and (ii) are based exclusively on kidneys. However, the surveyor will follow the same survey procedure as for §486.318(a)(3).

Z012

(Std) §486.318(b)(3)(i) The number of kidneys transplanted per standard criteria donor;

**Interpretive Guidelines §486.318(b)(3)(i)**

Self explanatory.

Z013

(Std) §486.318(b)(3)(ii) The number of kidneys transplanted per expanded criteria donor; and

**Interpretive Guidelines §486.318(b)(3)(ii)**

Self explanatory.

Z014

(Std) §486.318(b)(3)(iii) The number of organs used for research per donor, including pancreata recovered for islet cell transplantation.

**Interpretive Guidelines §486.318(b)(3)(iii)**

Self explanatory.

Z015

(Std) §486.318(c) Data for the outcomes measures. §486.318(c)(1) An OPO's performance on the outcome measures is based on 36 months of data, beginning with January 1 of the first full year of the re-certification cycle and ending 36 months later on December 31, 7 months prior to the end of the re-certification cycle.

**Interpretive Guidelines §486.318(c)(1)**

Self explanatory.

Z016

(Std) §486.318(c)(2) If an OPO takes over another OPO's service area on a date later than January 1, of the first full year of the re-certification cycle so that 36 months of data are not available to evaluate the OPO's performance in it's new service area, we will not hold the OPO accountable for it's performance in the new area until the end of the following re-certification cycle when 36 months of data are available.
Interpretive Guideline §486.318(c)(2)

Self explanatory.

Z036

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

After being designated, an OPO must become a member of, participate in, and abide by the rules and requirements of the OPTN established and operated in accordance with section 372 of the Public Health Service Act (42 U.S.C. 274). The term "rules and requirements of the OPTN" means those rules and requirements approved by the Secretary. No OPO is considered out of compliance with section 1138(b)(1)(D) of the Act or this section until the Secretary approves a determination that the OPO failed to comply with the rules and requirements of the OPTN. The Secretary may impose sanctions under section 1138 only after such non-compliance has been determined in this manner.

Interpretive Guidelines §486.320

Prior to going on-site, review the CMS OPO Database report to confirm that the OPO is a member of the OPTN. A membership status will be listed on the database report for the OPO. Only two OPTN membership statuses result in a non-compliance finding for this Condition. They are:

1) "Withdrawal of OPTN membership;" and
2) "Not an OPTN Member."

If the OPO is currently listed in either of these statuses, do not perform an on-site survey and notify the OPO that their Medicare certification will not be renewed.

Z056

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

Interpretive Guidelines §486.322

Note: For review purposes the requirements of this Condition consider tissue banks and eye banks as separate entities.

Z057

(Std) §486.322(a) Standard: Hospital agreements.

An OPO must have a written agreement with 95 percent of the Medicare and Medicaid participating hospitals and critical access hospitals in its service area that have both a ventilator and an operating room and have not been granted a waiver by CMS to work...
with another OPO. The agreement must describe the responsibilities of both the OPO and hospital or critical access hospital in regard to donation after cardiac death (if the OPO has a protocol for donation after cardiac death) and the requirements for hospitals at § 482.45 or §485.643. The agreement must specify the meaning of the terms “timely referral” and “imminent death.”

Interpretive Guidelines §486.322(a)

Request the written agreements for a percentage of the hospitals in the donation service area.
Less than 100 hospitals in the service area ............ 10%
More than 100 hospitals in the service area.......... 05%
If during the review of the sample, the surveyor determines that the OPO does not have a current agreement with one or more hospitals in their service area, request additional information to determine whether the hospital(s) has a ventilator and operating room. If the hospital(s) does not meet these criteria disregard the hospital(s) for the sample. If the hospital(s) does meet these criteria expand the sample to a 100% review to verify that the OPO has an agreement with at least 95% of the Medicare and Medicaid participating hospitals/CAHs in the donation service area that have both a ventilator and an operating room.

Do not cite a deficiency if the OPO has made a good faith effort to obtain the hospital/CAH agreement. Notify Central Office to make a referral to the Division of Acute Care Services within The Survey and Certification Group of CMS.

If the OPO for a donation service area has changed since the last survey, due to a CMS change of designation or CMS approval of a merger of two OPOs, verify that the OPO has effected new agreements with the Medicare certified hospitals and CAHs in the service area. In those instances where there is no agreement and there is no pending request for waiver (submitted within 30 days of the notice of change of designation), look for written documentation to show effort by the OPO to obtain a new agreement. If such documentation is available but the hospital or CAH refuses to enter into an agreement with the newly designated OPO and there is no waiver request pending, do not cite the deficiency but make a referral to the applicable State Survey Agency for possible investigation per §482.45 or §485.643. The Regional Office may elect to perform the hospital complaint investigation in conjunction with the OPO survey.

If the OPO has a written agreement with any facility outside their service area and cannot provide evidence of a waiver for that facility, either currently pending with CMS or approved by CMS, (see approval requirements under §486.308(e)), cite a deficiency at 486.322(a). Inform the OPO that the agreement must be terminated and the facility must be given any necessary assistance to secure an agreement with their designated OPO. Refer the finding to the applicable State Survey Agency for possible investigation under §482.45 or §485.643.

Prior to going on-site, check the CMS OPO Database report to identify:
1. any waiver denials issued, or
2. any pending hospital request to return to its designated OPO after its previous waiver approval.
During the on-site review, verify that there is an agreement in place between the OPO and any hospital or CAH within the OPO’s donation service area which requested a waiver and the waiver was subsequently denied by CMS.

Review the agreements to ensure that they include the responsibilities of both the OPO and the hospital/CAH and describe how they will work together collaboratively. Deficiencies found at §486.303(g) should be cited at this regulation.

The hospital/CAH responsibilities should address at a minimum:

Note: The terms Designated Requester and Effective Requester are used interchangeably in the OPO community.

a) Hospital/CAH may elect to have the OPO staff serve as their Designated Requester, or the hospital may provide Designated Requestors or hospital Designated Requestors may work in conjunction with the OPO staff. The hospital/CAH must provide sufficient coverage for all shifts, and the designated staff must have completed an OPO approved training for Designated Requestors. The hospital/CAH must notify the OPO when their Designated Requestor staff is changed.

b) Appropriate hospital staff participation in training provided by or approved by the OPO;

c) Staff roles/expectations for approaching the families regarding possible donation;

d) Parameters for timely notification of the OPO of an imminent death (Agreement should define “timely referral” and the clinical triggers which would indicate an “imminent” death.) Cardiac arrest which occurs during transport from one hospital to another should be reported by the receiving hospital;

e) Access by the OPO to hospital services such as laboratory services, radiological services, operating room availability or anesthesia services on a 24/7 basis;

f) OPO access to hospital medical records and what are the arrangements for copies to be made of the hospital medical records requested by the OPO;

g) Hospital/CAH staff role/responsibilities for management of organ viability;

h) Hospital/CAH staff role/responsibilities for procedures during Donation after Cardiac Death (DCD), if applicable. (The hospital may elect to opt out of DCD);

i) Hospital/CAH requirements for the qualifications that must be provided by the OPO for organ recovery team members upon request;

j) Notification of the OPO of any change in hospital privileges for any surgeon or other recovery personnel from the hospital routinely recovering organs for the OPO; and

k) Roles and responsibilities of surgeons and other personnel recovering for an OPO.

The OPO responsibilities should address at a minimum:
The parameters for OPO interaction with hospital/CAR staff and families or the legally authorized representative:

a) The provision for:
   1. timely communication and prompt response by the OPO on a 24/7 basis;
   2. orientation training for new Designated Requestors and annual training for all Designated Requestors;
   3. hospital specific organ donation data annually.

b) The determination of the suitability of the donor;

c) The parameters for OPO interaction with hospital/CAR staff and families or the legally authorized representative;

d) Use of sensitivity in discussions with families or with the legally authorized representative;

e) The notification to the hospital/CAR of any OPO policy changes that affect recovery, perfusion or transport;

f) The assurance that:
   1. the proper composition and qualifications of organ recovery teams are available to the hospital;
   2. proper documentation is prepared for the transplant program about the recovered organ(s) including blood type and other identifying information;

h) The roles of the OPO staff;
   1. in organ tissue management within the hospital/CAR; and
   2. with the interactions with the family or the legally authorized representative in cases of first person consent.

i) OPO roles, responsibilities and collaboration with the hospital staff on DCD, if applicable.

Z058

(Std) §486.322(b) Standard: Designated requestor training for hospital staff.
The OPO must offer to provide designated requestor training on at least an annual basis for hospital and critical access hospital staff.

Interpretive Guidelines §486.322(b)

According to the hospital regulations at 42CFR 482.45(a)(3), the individual designated by the hospital to initiate the request to the family or to the legally authorized representative must be an organ procurement representative or a Designated Requester. According to regulations at 42CFR 485.643 for CAHs, the individual designated by the CAH to initiate the request to the family or to the legally authorized representative must be a Designated Requester. However, the CAH may designate the OPO staff to function as the Designated Requestor. In both cases the Designated Requestors must have completed a training course provided or approved by the OPO. Hospital/CAR staff assigned to be the Designated Requestor(s) must successfully complete an OPO approved training program prior to beginning their duties. The training course does not have to be presented in person by the
OPO staff. The course may be presented by the hospital staff utilizing OPO approved materials.

Review any Designator Requestor training programs to evaluate the role of the OPO in the development or approval of the programs and whether the programs were developed in conjunction with the tissue bank and eye bank communities. If the Designated Requestor approaches the family or the legally authorized representative on behalf of the tissue banks or eye banks, the tissue banks or eye banks must participate directly in their training or indicate their approval of their training course.

Review the OPO training records for each hospital/CAH to ensure that training was provided or offered to Designated Requestors at each hospital/CAH on an annual basis. A hospital or CAH may provide their own Designated Requestor training. If the hospital/CAH provides the Designated Requestor training, the training content must be approved by the associated OPO per §482.45 (a)(3). The OPO should maintain records of these training presentations and evidence that they approved the programs. Training, offered by the OPO or hospital/CAH, must show participation by the tissue bank and eye bank communities or be approved by the tissue and/or eye bank if the OPO is performing recoveries for the banks.

Designated Requester training programs should include, at a minimum, information on:

a) Communication with the appropriate hospital staff to determine the approach with the family or with the legally authorized representative of the potential donor;

b) The appropriate timing for approaching the family;

c) The appropriate method for initially approaching the family or with the legally authorized representative including identification of the entity they represent (i.e., hospital, OPO, tissue bank);

d) Sensitivity to varying family or legally authorized representative situations;

e) Support staff that should be included when the family or the legally authorized representative is approached to ensure they receive adequate information;

f) Accepting decisions by the family or the legally authorized representative to decline donation in the absence of first person consent;

g) 24/7 coverage; and

h) The process to obtain informed consent from the family or the legally authorized representative in the absence of first person consent if applicable;

i) Interactions with OPO staff; and

j) Any limitations of Designated Requesters.
In those instances where the hospital/CAH and OPO agree that the OPO will perform the Designated Requestor role exclusively in lieu of hospital/CAH staff, this arrangement must be stipulated in the agreement between the OPO and the hospital/CAH. In these cases the OPO will not be required to provide annual Designated Requestor training to the hospital staff.

Z059

(Std) §486.322(c) Standard: Cooperation with tissue banks.

§486.322(c) (1) The OPO must have arrangements to cooperate with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements. The OPO must cooperate in the following activities, as may be appropriate, to ensure that all usable tissues are obtained from potential donors:

Interpretive Guidelines §486.322(c)(1)

Verify that the OPO has identified the eye bank and tissue bank agreements between each hospitals/CAHs and tissue banks and eye banks also located in the service area. The OPO should have written arrangements (either signed agreement or Memorandum of Understanding (MOU)) with each identified tissue bank and eye bank to address tissue recovery by the OPO in conjunction with organ recovery in the hospitals/CAHs (unless the OPO has written documentation that the tissue bank or eye bank refused a written arrangement); the arrangements must address §486.322(c)(1) (i)-(iv) below. The tissue bank and eye bank may elect to perform portions of §486.322(c)(1) (i) - (iv) themselves as delineated by the written arrangements. This coordination facilitates the recovery of usable tissues and eyes and limits the number of people who will approach the family or the legally authorized representative regarding donation.

Z060

(Std) §486.322 (c)(1)(i) Screening and referral of potential tissue donors.

Interpretive Guidelines §486.322 (c)(1)(i)

If the OPO has made arrangements to perform the screening for the tissue banks and eye banks, the arrangements between the two entities should include current written protocols for screening procedures and referral procedures. Review the screening and referral protocols.

Tissue bank and eye bank screening criteria can vary from bank to bank and may change periodically. Therefore, the OPO should annually verify that they are using current screening criteria for their work for the tissue banks and eye banks.
The OPO must maintain documentation of all screening, referral and/or recovery activities performed for tissue banks and eye banks. Select a sample of donor records where screening and/or recovery was conducted by the OPO for a tissue bank or eye bank. Verify that the protocols agreed upon with the tissue banks and eye banks were followed.

Z061

(Std) §486.322(c)(1)(ii) Obtaining informed consent from families of potential tissue donors.

Interpretive Guidelines §486.322(c)(1)(ii)

The written agreement/MOU between the tissue banks or eye banks and the OPO for securing informed consent from the family or the legally authorized representative of the potential donor in the absence of a donor document (living will, advance directive, driver’s license) should include the expectations of the tissue banks and/or eye banks for obtaining “informed consent,” from the family or the legally authorized representative of the potential donor. The arrangements should address the extent of information that should be shared with the family or the legally authorized representative regarding:

a) What procedures will be performed;
b) Where the procedures will be performed;
c) Who will perform the procedures (generally);
d) When the procedures will be performed (generally);
e) What impact the procedures will have on the donor’s body (e.g., disruption of funeral viewing); and
f) The associated documentation requirements including specific requirements for telephone consents.

If the OPO utilizes the same informed consent form or procedure to obtain informed consent for both organs and tissue/eye, the documentation on the consent form must verify that the OPO provided information specific to tissue, eye or organ donation.

The OPO should have a written protocol in place with the tissue banks and eye banks regarding telephone consent. The telephone consent protocol should require a witness to all telephone consents unless the individual State law specifically allows a verbal record of the informed consent over the telephone without the need for a witness. In these cases, the consent recording should be maintained per medical record retention requirements. The telephone protocol should also address the OPO staff who may take the consent, persons who may provide consent, and how the OPO verifies the identity of the person providing consent.

Z062

(Std) §486.322(c)(1)(iii) Retrieval, processing, preservation, storage, and distribution of tissues.
Interpretive Guidelines §486.322(c)(1)(iii)
The written arrangements between the OPO and the tissue banks and eye banks should delineate the specific procedures the OPO may perform as a representative of the tissue bank and/or eye bank in the retrieval of tissues, what measures the OPO must follow to preserve the tissues or eyes, and the role the OPO will play in the storage and distribution of tissues.

Note: In the case of eye banks, recovery must be accomplished by a certified eye bank technician. Depending upon written arrangements, the OPO may be expected to perform primary screening and obtain informed request for consent from the family or the legally authorized representative (dependent upon the written arrangements) in eye donation cases.

(Std) §486.322(c)(1)(iv) Providing designated requestor training.

Interpretive Guidelines §486.322(c)(1)(iv)
The written arrangements between the OPO and the tissue banks and eye banks should specify whether the OPO or tissue or eye bank will provide Designated Requestor training (in those instances where a hospital has employees assigned as Designated Requestors), what the training must include, and how the tissue banks and eye banks participate in training programs or approve any training programs presented by the OPO. See §486.322(b) for discussion of documentation requirements.

(Std) §486.322(c)(2) An OPO is not required to have an arrangement with a tissue bank that is unwilling to have an arrangement with the OPO.

Interpretive Guidelines §486.322(c)(2)
Self explanatory.

(Cond) §486.324 Condition: Administration and governing body.

(Std) §486.324(a) While an OPO may have more than one board, the OPO must have an advisory board that has both the authority described in paragraph (b) of this section and the following membership:

Interpretive Guidelines §486.324(a)
Verify that there are written bylaws for the designated Advisory Board. The bylaws must grant the Advisory Board, as a minimum, the authority described in (b) of this section and require (as a minimum) the membership as listed in §486.324(a)(1)–(6) below. Review the
written policies, which describe the process the OPO will follow for initial and/or annual verification of Advisory Board member qualifications. Request a list of the current Advisory Board members, their positions, professional qualifications and the corresponding OPO documentation of the verification of their qualifications.

Review the Advisory Board minutes to ensure that the designated membership is active. While there will always be instances when not all members are able to attend a meeting, the OPO should make every effort to schedule meetings at a time that the majority can attend. There should be written documentation that the members do attend most meetings. Consistently absent members should be replaced by the OPO per their written bylaws.

Z086

(Std) §486.324(a)(1) Members who represent hospital administrators, either intensive care or emergency room personnel, tissue banks, and voluntary health associations in the OPO's service area.

Interpretive Guidelines §486.324(a)(1)
There are four (4) individual member requirements listed within this Standard.

(a) hospital administrator;
(b) either intensive care or emergency room personnel;
(c) tissue banks, if the OPO is the only tissue bank in their DSA they may represent the tissue bank; and
(d) voluntary health associations in the OPO's service area.

Voluntary health associations are those organizations primarily engaged in raising funds for health related research such as disease prevention and treatment and providing health education and patient services.

The tissue bank representative may be from any tissue bank in the service area.

Z087

(Std) §486.324(a)(2) Individuals who represent the public residing in the OPO's service area.

Interpretive Guidelines §486.324(a)(2)
This representative should not be the family member of a donor. This representative provides the "general public" perspective on organ donation to the Board.

Z088
§486.324(a)(3) A physician with knowledge, experience, or skill in the field of human histocompatibility, or an individual with a doctorate degree in a biological science and with knowledge, experience, or skills in the field of human histocompatibility.

Interpretive Guidelines §486.324(a)(3)
Individual should be an MD/DO or a PhD (in a science that studies living organisms) with knowledge and experience working with the genetics that influence acceptance or rejection of grafts.

§486.324(a)(4) A neurosurgeon or other physician with knowledge or skills in the neurosciences.

Interpretive Guidelines §486.324(a)(4)
This position on the Advisory Board should be filled by a neurosurgeon or a neurologist.

§486.324(a)(5) A transplant surgeon representing each transplant hospital in the service area with which the OPO has arrangements to coordinate its activities. The transplant surgeon must have practicing privileges and perform transplants in the transplant hospital represented.

Interpretive Guidelines §486.324(a)(5)
A transplant surgeon representing a transplant hospital may not simultaneously fulfill the requirements for any other role on the Advisory Board. Prior to going on-site, identify the transplant hospitals in the donation service area (information available on the CMS OPO Database report). During the on-site review, verify that the Advisory Board membership has transplant surgeon representation from each transplant hospital in the OPO service area.

§486.324(a)(6) An organ donor family member.

Interpretive Guidelines §486.324(a)(6)
The person fulfilling this role on the board may be an organ donor’s family member or a living organ donor.

§486.324(b) The OPO board described in paragraph (a) of this section has the authority to recommend policies for the following:

(1) Procurement of Organs.
(2) Effective agreements to identify potential organ donors with a substantial majority of hospitals in its service area that have facilities for organ donation.

(3) Systematic efforts, including professional education, to acquire all useable organs from potential donors.

(4) Arrangements for the acquisition and preservation of donated organs and provision of quality standards for the acquisition of organs that are consistent with the standards adopted by the OPTN, including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immunodeficiency syndrome (AIDS).

(5) Appropriate tissue typing of organs.

(6) A system for allocation of organs among transplant patients that is consistent with the rules and requirements of the OPTN, as defined in §486.320 of this part.

(7) Transportation of organs to transplant hospitals.

(8) Coordination of activities with transplant hospitals in the OPO's service area.

(9) Participation in the OPTN.

(10) Arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors.

(11) Annual evaluation of the effectiveness of the OPO in acquiring organs.

(12) Assistance to hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

Interpretive Guidelines §486.324(c)(1)-(12)

The Public Health Service Act limits the authority of the OPO Advisory Board to recommendations only. This regulation further limits the scope of recommendations appropriate for the Board to (1) through (12) above. Review the minutes of the Advisory Board for any 12-month period during the current certification cycle. Ensure that the topics placed before the Advisory Board and the recommendations from the Advisory Board are consistent with (1) through (12) above. Advisory Board recommendations should be made to the Governing Body of the OPO.

(Std) §486.324(e) The advisory board described in paragraph (a) of this section has no authority over any other activity of the OPO and may not serve as the OPO's governing body or board of directors. Members of the advisory board described in paragraph (a) of this section are prohibited from serving on any other OPO board.
Interpretive Guidelines §486.324(c)

Review the membership of the Governing Body or Board of Directors and the Advisory Board to ensure that these are separate and distinct bodies with no cross membership.

Review the bylaws of the Advisory Board for a notation disallowing cross membership and stipulating that the Advisory Board may make recommendations to the OPO Governing Body in the listed areas (1)-(12) above but has no authority over other OPO activities (such as financial, administrative and personnel matters).

Review the minutes of all OPO boards other than the Advisory Board to ensure that if Advisory Board members are in attendance at other board meetings the minutes confirm that their attendance is purely in an advisory capacity (i.e., non-voting) and upon request. While OPO staff certainly are in attendance at Advisory Board meetings and respond to or provide additional information to the members, they should not be voting members.

(Std) §486.324(d) The OPO must have bylaws for each of its board(s) that address potential conflicts of interest, length of terms, and criteria for selecting and removing members.

Interpretive Guidelines §486.324(d)

Ensure that the written bylaws for each of the currently operating boards of the OPO address as a minimum:

a) Potential or appearance of conflict of interest for Board members (define conflict and measures to identify and prohibit conflicts);

b) Length of terms for members; and

c) Criteria for selecting and removing members.

d) Attendance criteria (e.g., number of meetings that may be missed before replacement);

e) Quorum; and

f) Frequency of meetings.

(Std) §486.324(e) A governing body must have full legal authority and responsibility for the management and provision of all OPO services and must develop and oversee implementation of policies and procedures considered necessary for the effective administration of the OPO, including fiscal operations, the OPO's quality assessment and performance improvement (QAPI) program, and services furnished under contract or arrangement, including agreements for these services. The governing body must appoint an individual to be responsible for the day-to-day operation of the OPO.
**Interpretive Guidelines §486.324(c)**

Review Governing Body minutes to verify their oversight activities regarding the development and implementation of policies, the annual budget, other fiscal concerns, personnel matters, and the QAPI program.

Verify that the OPO Governing Body has appointed an individual in writing to be responsible for the day-to-day operation of the OPO. This individual must have his/her role defined by the Governing Body and there should be written documentation that his/her activities are shared with or reported to the Governing Body on a routine basis. If the Governing Body has not defined the role of this individual and there are associated deficiencies with day-to-day oversight of the OPO, cite a deficiency for the lack of such definition.

The Governing Body is also responsible for the OPO's fiscal responsibilities at §486.303(b) and (c). Non-compliance with those regulations should be cited here.

**Interpretive Guidelines §486.324(f)**

The OPO must have procedures to address potential conflicts of interest for the governing body described in paragraph (d) of this section.

**Interpretive Guidelines §486.324(g)**

The OPO must include a statement in its policies as to whether or not it recovers organs from donors after cardiac death.

**Condition: Human resources.**

All OPOs must have a sufficient number of qualified staff, including a director, a medical director, organ procurement coordinators, and hospital development staff to obtain all usable organs from potential donors, and to ensure that required services are provided to families of potential donors, hospitals, tissue banks, and individuals and facilities that use organs for research.
§486.326(a) Standard: Qualifications.

(1) The OPO must ensure that all individuals who provide services and/or supervise services, including services furnished under contract or arrangement, are qualified to provide or supervise the services.

Interpretive Guidelines §486.326(a)(1)

Review the written position descriptions for clinical and family support positions. These descriptions should describe the requirements for licensure as applicable, educational background and work experience. Review the files for a sample of clinical and family support personnel to determine:

a) If employees meet the requirements of the position description within which they are working;

b) If licensure is applicable, the employee has a current license on file; and

c) In the case of contract employees, the OPO maintains the same information in (a)-(b) above.

§486.326(a)(2) The OPO must develop and implement a written policy that addresses potential conflicts of interest for the OPO's director, medical director, senior management, and procurement coordinators.

Interpretive Guidelines §486.326(a)(2)

The OPO must have written policies and procedures for the identification, investigation and resolution of potential conflicts of interest (financial or personal) for the OPO director, medical director, senior management, and procurement coordinators.

Confirm during review of employee files that a potential conflict of interest is evaluated at the time of employment. Also, be alert in the employee files to any indication of a potential conflict of interest (consistent with the OPO written policy). If noted, discuss the observation with the OPO Director to learn whether the situation was identified and what follow-up action was taken.

§486.326(a)(3) The OPO must have credentialing records for physicians and other practitioners who routinely recover organs in hospitals under contract or arrangement with the OPO and ensure that all physicians and other practitioners who recover organs in hospitals with which the OPO has agreements are qualified and trained.

Interpretive Guidelines §486.326(a)(3)

The OPO should indicate in their operational policies what qualifications are required for recovery personnel who recover organs under contract or arrangement with the OPO. They
should also detail in their procedures how recovery personnel's qualifications will be verified prior to any recovery.

For surgeons or other qualified practitioners who do not routinely recover organs on behalf of the OPO, the OPO must have protocols in place for quick verification of their qualifications and training prior to any recovery. Documentation of the verification must remain on file and confirm that verification was done before recovery.

CMS will utilize the transplant program's outcome measures to periodically identify significant sentinel events which may indicate issues with recoveries by OPOs.

Z121

(Std) §486.326(b) Standard: Staffing.
(1) The OPO must provide sufficient coverage, either by its own staff or under contract or arrangement, to assure both that hospital referral calls are screened for donor potential and that potential donors are evaluated for medical suitability for organ and/or tissue donation in a timely manner.

Interpretive Guidelines §486.326(b)(1)

Review the OPO written policy on the screening of incoming hospital referral calls. Policies should include who may conduct the screening, the screening process to be followed, the timeframe for completing the screening and the documentation that must be entered into the intake record. Also, review the OPO written policy on the timeframes for subsequent OPO staff arrival at the hospital and evaluation.

As a part of the donor record review verify that the OPO policies for screening are being followed.

Z122

(Std) §486.326(b)(2) The OPO must have a sufficient number of qualified staff to provide information and support to potential organ donor families; request consent for donation; ensure optimal maintenance of the donor; efficient placement of organs; and conduct QAPI activities, such as death record reviews and hospital development.

Interpretive Guidelines §486.326(b)(2)

Review of donor records and results of QAPI activities should confirm that the OPO is:

- responding promptly (consistent with OPO policies) to the notification of a potential donor through screening and evaluation;
- performing optimal, clinical maintenance of the donor through correct use of management protocols;
- providing complete information to enable the donor's family or legally authorized representative to make an informed decision in the absence of first person consent;
- initiating timely communication with the transplant community;
- facilitating an effective and timely recovery process; and
• transporting donated organs consistent with current OPTN requirements.

Verify that the staff performing QAPI review of a particular case did not actively participate in the recovery for that case. Verify that there is sufficient staff assigned to ensure that death record reviews conducted for the QAPI program are completed on a timely basis (monthly).

Z123

(Std) §486.326(b)(3) The OPO must provide a sufficient number of recovery personnel, either from its own staff or under contract or arrangement, to ensure that all usable organs are recovered in a manner that, to the extent possible, preserves them for transplantation.

Interpretive Guidelines §486.326(b)(3)

If the OPO does not employ surgeons or other qualified practitioners to perform recoveries, it should have written arrangements in place with such personnel (most likely a group of surgeons from the transplant hospitals in its service area) who are available on call 24/7 to travel to the donor hospitals and recover organs for the OPO. Review these written agreements. Ensure that current call schedules are available from the hospitals. Review the sample of donor records to determine whether there were any unnecessary delays in organ recovery due to the unavailability of a recovery surgeon or other qualified practitioner. Review the minutes of the QAPI program to determine if there have been any aborted recoveries due to the lack of availability of a surgeon or other qualified practitioner.

When surgeons or other qualified practitioners are performing recoveries for the OPO they are functioning as OPO representatives and must follow the OPO policies and procedures. The OPO is ultimately responsible for ensuring that every surgeon or other qualified practitioner that performs a recovery is qualified and trained and have sufficient experience in recovery to preserve the organs properly. See also §486.326(a)(3).

Prior to going onsite for the CMS survey review the transplant hospitals’ outcome data reports for each transplant hospital in the OPO DSA. If outcomes for both patient and graft are good, no other steps should be taken. If outcomes are not good, investigation of the qualifications of the recovering surgeon should be reviewed for the last 30 days.

Z124

(Std) §486.326(c) Standard: Education, training, and performance evaluation.

The OPO must provide its staff with the education, training, and supervision necessary to furnish required services. Training must include but is not limited to performance expectations for staff, applicable organizational policies and procedures, and QAPI activities. OPOs must evaluate the performance of their staffs and provide training, as needed, to improve individual and overall staff performance and effectiveness.

Interpretive Guidelines §486.326(c)
Verify that there is a written position description for each OPO employee that includes the expectations for the employee. Review a minimum of five (5) employee files for the clinical and family support staff at the OPO including contract employees in those positions. Select the files at random from a list of all OPO employees and expand the samples as indicated to ensure that:

a) A standardized orientation to the OPO philosophy and company, and an individualized orientation (per their performance expectations listed in their position descriptions including policies, procedures, and QAPI expectations) were provided and successfully completed;

b) Training opportunities are provided for OPO employees who require continuing education credits (e.g., CEUs) to maintain their licensure/certification; and

c) Periodic evaluations are conducted of employee performance and recommendations for improvement and plans to achieve that improvement are developed.

Verify that the OPO has an operational methodology for the identification of training needs for each employee and that these identified needs are addressed promptly.

Review the general training schedule for the OPO employees. Ensure that the training is appropriate (based upon the identified needs of employees, training requests from employees or updates on standards of community practice), occurs on a regular basis and includes all OPO staff and contract staff as applicable.

Z125

(Std) §486.326 (d) Standard: Medical director.
The OPO's medical director is a physician licensed in at least one of the States or territories within the OPO's service area or as required by State or territory law or by the jurisdiction in which the OPO is located. The medical director is responsible for implementation of the OPO's protocols for donor evaluation and management and organ recovery and placement. The medical director is responsible for oversight of the clinical management of potential donors, including providing assistance in managing a donor case when the surgeon on call is unavailable.

Interpretive Guidelines §486.326(d)

Review the administrative file for the OPO medical director to verify that:

a) He/she is currently licensed as a physician in one of the States within the OPO donation service area or as required by State law (do the State laws of other States in the Donation Service Area require that any physician practicing within that State be licensed by that State); and

b) The position description for the medical director clearly delineates his/her role in the implementation of protocols for donor evaluation and management, determination of donor suitability for donation, organ recovery and placement in increased risk cases.

Interview the medical director to determine:
a) His/her familiarity with the OPO protocols;

b) The extent of his/her involvement in the implementation of protocols (especially protocols for the evaluation for suitability and donor management);

c) His/her role in donor management (either on-site or consultation);

d) His/her process for verifying whether the OPO is following its written protocols and ensuring the protocols are consistent with current standards of practice;

e) Documentation of periodical evaluations of compliance with protocols (d above); and

f) His/her role in the determination of donor suitability (e.g., donor of increased risk).

Generally, the OPO organ procurement coordinator performs donor management per protocols approved by the OPO medical director without his/her on-site participation. However, the OPO medical director must be available for consultation on any case where a procurement coordinator requires additional guidance. Verify through interview and review of donor records that the medical director is available for consultation 24/7 or has back-up coverage by another MD or DO.

§486.328 Condition: Reporting of data

Prior to going on-site, review the CMS OPO Database report to ensure that the OPO is submitting data to the OPTN and SRTR as required by OPTN by-laws (7.0-7.9) for the data elements (1)-(9) above. No on-site review activity is required.
CMS will consider a submission rate of 95% and above to meet the requirements of this standard.

§486.328(b) An OPO must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.

Interpretive Guidelines §486.328(b)
From the sample of transplant hospitals and CAHs selected in §486.322(a) request the reports that have been provided to the hospitals/CAH facilities by the OPO since the last re-certification visit. These reports should have provided information to the individual hospital or CAH for (1)-(9) above on an annual basis.

§486.328(c) Data to be used for OPO re-certification purposes must be reported to the OPTN and must include data for all deaths in all hospitals and critical access hospitals in the OPO's donation service area, unless a hospital or critical access hospital has been granted a waiver to work with a different OPO.

Interpretive Guidelines §486.328(c)
Self explanatory.

§486.328(d) Data reported by the OPO to the OPTN must be reported within 30 days after the end of the month in which a death occurred. If an OPO determines through death record review or other means that the data it reported to the OPTN was incorrect, it must report the corrected data to the OPTN within 30 days of the end of the month in which the error is identified.

Interpretive Guidelines §486.328(d)
See §486.328(a) above.

§486.328(e) For the purpose of determining the information to be collected under paragraph (a) of this section, the following definitions apply:

1) **Kidneys procured**. Each kidney recovered will be counted individually. En bloc kidneys recovered will count as two kidneys procured.

2) **Kidneys transplanted**. Each kidney transplanted will be counted individually. En bloc kidney transplants will be counted as two kidneys transplanted.

3) **Extra-renal organs procured**. Each organ recovered is counted individually.
(4) **Extra-renal organs transplanted.** Each organ or part thereof transplanted will be counted individually. For example, a single liver is counted as one organ procured and each portion that is transplanted will count as one transplant. Further, a heart and double lung transplant will be counted as three organs transplanted. A kidney/pancreas transplant will count as one kidney transplanted and one extra-renal organ transplanted.

**Interpretive Guidelines §486.328(e)**

See §486.328(a) above.

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**Condition §486.330**

**Condition: Information management.**

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.

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**Standard §486.330(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 tissues recovered, date of 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.

**Interpretive Guidelines §486.330(a)**

For each donor the OPO maintains, in electronic format, a copy of the above information and documentation of consent and family or legally authorized representative information.

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**Standard §486.330(b) Disposition of organs.**

The OPO must maintain records showing the disposition of each organ recovered for the purpose of transplantation, including information identifying transplant recipients.

**Interpretive Guidelines §486.330(b)**

See Interpretive Guidelines for §486.330(a)
§486.330(c) Data retention.
Donor and transplant recipient records must be maintained in a human readable and reproducible paper or electronic format for 7 years.

Interpretive Guidelines §486.330(c)
Verify that the OPO policies require that donor records will be maintained for a minimum of seven (7) years. Verify that the OPO policies are being followed through the donor record sample.

For purposes of this regulation, transplant recipient records are any transplant recipient information received from the institution from the transplant hospital and subsequently included in the donor record.

Request that the OPO locate the sampled donor records either electronically or in hard copy. If electronic records are located, verify that the entire record is maintained and that the record can be printed in a readable format. Ask the OPO to print one page to verify.

§486.330(d) Format of records.
The OPO must maintain data in a format that can readily be transferred to a successor OPO and in the event of a transfer must provide to CMS copies of all records, data, and software necessary to ensure uninterrupted service by a successor OPO. Records and data subject to this requirement include donor and transplant recipient records and procedural manuals and other materials used in conducting OPO operations.

Interpretive Guidelines §486.330(d)
The OPO should have written policies which outline the procedures which will be followed, if necessary, to make available its Electronic Information Management System (EIMS) software to allow a successor OPO to operate the program.

The policies and procedures of the OPO should also be in a format which can be forwarded electronically.

Other OPO operations (e.g., material budgets, governing body minutes, personnel files, QAPI minutes, etc.) may be transferred via paper or electronic format.

§486.342 Condition: Requesting consent.
An OPO must encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of potential donor families.

Interpretive Guidelines §486.342
Before going on-site, review the Aspen Complaint/Incident Tracking System (ACTS) to determine if any complaints have been filed against the OPO for inappropriate or insensitive behavior during the process of obtaining consent. If so, determine if there is any additional follow-up required or were the complaints resolved sufficiently?

While it may be assumed by the OPO that, in general, all persons, regardless of religious or personal beliefs, may be approached for organ donation, the OPO must be sensitive to any factors (from record review, hospital staff information, their own knowledge regarding religious beliefs or information received) which indicate that the OPO should not pursue consent. The OPO must respect the decisions by the family or the legally authorized representative as determined by State law of legal residence regarding donation. Declination must be respected. Review the staff orientation program for discussions on sensitivity with donor families and legally authorized representatives.

Review the QAPI minutes to determine if the OPO program conducted analysis on any complaints received from family members or legally authorized representatives reporting insensitive behavior or lack of discretion on the part of the OPO staff. Review OPO documentation of subsequent counseling and increased training that was provided to any staff member involved in such a complaint.

ZZ65

(Std) §486.342(a) An OPO must have a written protocol to ensure that, in the absence of a donor document, the individual(s) responsible for making the donation decision are informed of their options to donate organs or tissues (when the OPO is making a request for tissues) or to decline to donate. The OPO must provide to the individual(s) responsible for making the donation decision, at a minimum, the following:

1. A list of the organs and/or tissues that may be recovered.
2. The most likely uses for the donated organs or tissues.
3. A description of the screening and recovery processes.
4. Information about the organizations that will recover, process, and distribute the tissue.
5. Information regarding access to and release of the donor’s medical records.
6. An explanation of the impact the donation process will have on burial arrangements and the appearance of the donor’s body.
7. Contact information for individual(s) with questions or concerns.
8. A copy of the signed consent form if a donation is made.

Interpretive Guidelines §486.342(a)
In the absence of a donor document (e.g., living will, advance directive, driver’s license declaration in those States where informed consent is provided and State donor registries),
the family or legally authorized representatives must give informed consent for the donation of organs.

Review the donor record sample (for donors without first person consent) to verify that in each case the family or legally authorized representatives was provide with the information listed in (1)-(8) above and indicated an understanding of the information. The confirmation that the informer assessed the level of understanding by the family or legally authorized representatives may be incorporated into the consent form or may appear as a summary note by the informer in another part of the record. Any documentation of the level of understanding should include what information was provided, the method used to determine the level of understanding and the actual level of understanding exhibited. The documentation should also include any specifics that were repeated for clarification.

At the time that informed consent is acquired, the OPO may not know definitively how the organ will be used. In these cases, the informed consent must provide the family or legally authorized representatives with the range of most likely possibilities for usage (transplant or research).

The OPO should list its contact information on the consent form to include a specific point of contact at the OPO.

Copies of the consent are shared with the family or legally authorized representatives at the time the consent is signed. In instances where the recovery does not ultimately go forward, there would be no need to include a copy of the consent with any letter of explanation sent to the family or legally authorized representatives.

Z166

(Std) §486.342(b) If an OPO does not request consent to donation because a potential donor consented to donation before his or her death in a manner that satisfied applicable State law requirements in the potential donor’s State of residence, the OPO must provide information about the donation to the family of the potential donor, as requested.

Interpretive Guidelines §486.342(b)

Request the OPO’s written protocol for contacting family or legally authorized representatives in the case of first person donation. Ensure that the OPO is following their written protocol.

Review a sample of records in the donor record sample of donors where no, who did not require family or legally authorized representatives consent was required (e.g., living will, advance directive, driver’s license declaration with informed consent and State donor registries).

Verify that the OPO followed applicable State laws regarding first person consent. Documentation in the donor record should confirm that the OPO made every attempt to make contact with family or legally authorized representatives to provide additional information to
them regarding the expected process of donation. Instances where the OPO attempted but was unable to make contact should be documented. Look for any instances where a donor family or legally authorized representatives requested additional information and verify that the OPO provided the information.

Z167

(Cond) §486.344 Condition: Evaluation and management of potential donors and organ placement and recovery.

The OPO must have written protocols for donor evaluation and management and organ placement and recovery that meet current standards of practice and are designed to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor.

Interpretive Guidelines §486.344

The OPO should have written protocols for:

A. Donor Evaluation (per organ) which addresses at a minimum:
   - Chart review required;
   - Laboratory testing required (standard and additional as indicated);
   - Other testing as indicated (echo, chest x-ray, etc.);
   - Required timeframes for donor protocol activities;
   - Documentation required;
   - OPO staff member interactions with family or legally authorized representatives to collect information; and
   - OPO staff roles.

(Note: The above protocol is not developed to determine organ suitability for a certain recipient, but to determine the medical suitability of a potential donor.)

While the OPO may review the potential donor’s hospital record without consent, in the absence of a donor document, consent from family or legally authorized representatives, or specific state law which allows invasive testing prior to consent, the OPO should not conduct invasive testing prior to consent.

B. Donor Management (per organ) to include at a minimum:
   - Testing (such as cardiac);
   - Laboratory testing;
   - Drug administration parameters;
   - Ventilation management;
   - Optimal vital signs; and
   - Fluid levels;

C. Organ Placement to include at a minimum:
   - UNET match list review;
   - Communication with transplant hospitals.
D. Organ Recovery to include at a minimum:

- Scheduling;
- Qualified staff;
- Documentation of verification of blood type;
- Documentation required during recovery;
- Organ packaging;
- Organ transport; and
- Documentation accompanying the organ; and,
- Any subsequent follow-up with transplant hospital.

The above OPO protocols must be consistent with current standards of community practice for organ procurement. If practices are used outside current standards of practice, they may only be carried out under an Institutional Review Board (IRB) or Western Institutional Review Board (WIRB) approved research program.

As current clinical practices continue to evolve at a fairly rapid pace, advances are made in the science of organ procurement to improve the outcomes of transplantation. Therefore, the individual OPO is ultimately responsible for updating its own clinical policies and protocols as necessary but at least annually.

Z168

(Std) §486.344(a) Potential donor protocol management.

1) The medical director is responsible for ensuring that potential donor evaluation and management protocols are implemented correctly and appropriately to ensure that potential donors are thoroughly assessed for medical suitability for organ donation and clinically managed to optimize organ viability and function.

Interpretive Guidelines §486.344(a)

The OPO must have a written procedure for and must be able to provide evidence that the medical director reviews donor records (either periodically or in real time) to ensure that the OPO approved protocols for donor management are being followed. Any failure by the OPO staff to follow the written OPO protocols should be documented by the medical director, promptly addressed and shared with the QAPI program. There must be evidence that the medical director is conducting periodic (consistent with OPO policy) reviews consistent with OPO policy to ensure that staff are following the protocols.

Verify in the sample of donor records that:

a) OPO staff consistently followed the written protocols for management;

b) Appropriately trained staff performed all procedures; and

c) The medical director was notified promptly with any concerns.
§486.344(a)(2) The OPO must implement a system that ensures that a qualified physician or other qualified individual is available to assist in the medical management of a potential donor when the surgeon on call is unavailable.

Interpretive Guidelines §486.344(a)(2)

During the time period following the onset of brain death, it is critical that the potential donor’s vital signs be maintained by aggressive medical management. This is a complex process that may involve a number of different recovery personnel in various capacities, including the OPO Procurement Coordinator, the OPO medical director, transplant surgeon(s), hospital critical care specialists, intensivists or anesthesiologists, and other OPO experts and consultants. Actual practice varies with individual OPOs and transplant surgeons. However, it is imperative for the OPO to make sure a qualified physician, physician’s assistant, clinical nurse specialist or nurse practitioner (as allowed by State law) is readily available at all times to assist the primary OPO Coordinator with direct medical management of the potential donor as the transplant surgeon on call may not be immediately available.

The OPO may elect to utilize physicians in the donor hospital per its written agreement with the hospital or maintain a separate agreement with surgeons for call from one or more transplant hospitals in its service area.

Z170

(Std) §486.344(b) Potential donor evaluation.

The OPO must do the following:

Z171

(Std) §486.344(b)(1) Verify that death has been pronounced according to applicable local, State, and Federal laws.

Interpretive Guidelines §486.344(b)(1)

The OPO does not make the actual determination of death (whether brain death or cardiac death). Rather, the OPO must verify and document that the potential donor has been pronounced dead in accordance with applicable legal requirements of local, State, and Federal laws with supporting documentation.

The OPO should be able to produce a copy of and have familiarity with the applicable, current, State law on pronouncement.

Review the sample of donor records (brain death) to verify that the OPO confirmed the pronouncement of death as part of the evaluation of the possible donor.

A copy of the death pronouncement must be included in the OPO donor record.

Z172
§486.344(b)(2) Determine whether there are conditions that may influence donor acceptance.

Interpretive Guidelines §486.344(b)(2)

Ask the OPO for a list of those medical conditions which they consider as elimination criteria for a possible donor and which are included in its screening and evaluation processes. Verify during the review of donor records that the policies of the OPO are being followed.

The OPO must be alert to and identify those characteristics, findings, and conditions in the potential donor that may exclude consideration of that patient's solid organs for transplant (except in limited cases) per the recommended donor exclusion criteria of the Centers for Disease Control and Prevention.

In all instances where there are factors which result in the donor being designated as a donor with increased risk, the OPO must have documented evidence that they provided notification to the transplant surgeon/transplant coordinator that the organ was from a donor with increased risk and provided specific findings. The OPO must maintain additional information to confirm that the transplant surgeon or transplant coordinator was notified of all the pertinent information.

§486.344(b)(3) If possible, obtain the potential donor's medical and social history.

Interpretive Guidelines §486.344(b)(3)

Due to the compressed time frame for deceased donor evaluation, there is a possibility that certain infections, such as HIV, HBV, and or HCV, may be present at an early stage, prior to the development of specific antibodies. Thus, considerable weight is placed on the donor's social and medical history in identifying potential risks that might not be reflected in serologic testing. The potential donor's medical and social history provides invaluable information that might clarify or explain ambiguous and/or discordant diagnostic test results that could eliminate an otherwise suitable organ donor or could include an otherwise unsuitable organ donor. It is crucial that the OPO closely review the medical and social history for the potential donor, identify any factors which may exclude the donor from donation or indicate extra restrictions on the type of recipient who may be allowed to receive the organ. The OPO must consider the reliability of the informant for the social history and the likelihood the informant has sufficient knowledge of the potential donor to provide a definitive response to questions, especially questions associated with increased risk behavior.

In all instances on the social history where there are either questions answered in the affirmative regarding increased risk behavior or there is inadequate information to definitively respond on questions regarding increased risk behavior, confirm that the OPO immediately recorded this information to provide sufficient information to transplant surgeons or transplant coordinators before proceeding with the donation.

In any instance where a social history or medical history revealed a condition or behavior that makes donation increased risk in most cases, there must be written documentation in the donor record to verify that the conditions and behaviors were completely discussed with the
transplant surgeons at the time the organ offer was made. The documentation should also include the basis of the transplant surgeon's decision to accept the organ in these circumstances.

In the absence of a social or medical history, the OPO should elevate the potential donor to an increased risk status and notify transplant surgeons of such.

Z174

(Std) § 486.344(b)(4) Review the potential donor's medical chart and perform a physical examination of the donor.

Interpretive Guidelines § 486.344(b)(4)

The OPO Coordinator, or other appropriately qualified OPO staff, must review the hospital chart, perform a physical examination of the potential donor, and document all findings. Documentation from both reviews must be included in the OPO donor record. Simply charting that a record review was completed does not provide sufficient verification of a thorough review.

Chart reviews should include as a minimum:

a) Social history, if possible;
b) Physical examination;
c) Medical history;
d) Laboratory results;
e) Physician progress notes;
f) Death pronouncement (e.g., DCD case); and
g) Donor documents.

The donor physical examination performed by the OPO should not be confused with the physical examination performed by the hospital physician. The OPO examination is primarily performed to determine if there are any conditions that may indicate a compromised organ (e.g., masses or observations that could indicate the possibility of infection such as tattoos, ear piercing, etc. and which require additional investigation).

The hospital medical chart review is conducted not only to gain information from the medical and social history but also to review the course of the hospitalization. Events occurring throughout the hospitalization could impact the suitability for organ donation.

Review the sample of donor records to confirm that the OPO completed a physical examination and medical record review as a part of their evaluation for organ suitability. Ensure that all findings were documented and considered in the determination to proceed with donation.

Z175

(Std) § 486.344(b)(5) Obtain the potential donor's vital signs and perform all pertinent tests.
Interpretive Guidelines §486.344(b)(5)

The OPO must have written protocols for the required laboratory and other clinical testing required per organ to enable the OPO to make a determination on donor suitability. (See §486.344(a))

Review the sample of donor records to confirm that the potential donor’s vital signs (e.g., temperature, oxygen saturation, blood pressure, heart rate, respiratory rate) were obtained during the evaluation and additional testing as required by OPO protocol was performed and utilized in the evaluation process.

§486.344(c) Testing. The OPO must do the following:

§486.344(c)(1) Arrange for screening and testing of the potential donor for infectious disease according to current standards of practice, including testing for the human immunodeficiency virus.

Interpretive Guidelines §486.344(c)(1)

The goals of pre-transplant infectious disease screening are:

- To identify conditions which disqualify the potential donor;
- To identify and treat active infection pre-transplant; and
- To define the level of infection risk in order to determine strategies for preventing post-transplant infection.

The timeframe for deceased donor evaluation is typically hours. Because of the short timeframe, there is a possibility that certain infections, such as HIV, HBV, and/or HCV, may be present at an early stage, prior to the development of the specific antibody. Thus, considerable weight must be placed on the donor’s social and medical history in identifying potential risks that might not be reflected in serologic testing.

Also, certain infections (e.g., donor bacteremia) may come to light only after the transplant has been performed.

The OPO must have arrangements in place to perform the necessary screening and testing for infectious diseases on a 24/7 basis. The arrangements must be with a Clinical Laboratory Improvement Amendments (CLIA) approved laboratory willing to perform STAT testing.

OPTN Rules Policy Number 2.2.3.2 states, “All potential donors are to be tested by use of a serological screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (Anti-HIV-1 and Anti-HIV-2).

If the sample is qualified, the screening test for HIV is negative, and blood for subsequent transfusions has been tested and found to be negative for HIV, retesting the potential donor for HIV is not necessary.”

The OPO must develop and implement procedures for the types and the number of tests that will be performed for HIV, using the FDA’s most sensitive approved test available, for potential donors who:
a) Test positive on the initial HIV, HBV, and/or HCV;

b) Received transfusions during the current hospitalization and for whom there is insufficient pre-transfusion blood to perform an initial HIV, HBV, and/or HCV screening test; or

c) Have a social history that reveals increased risk.

The OPO must make full disclosure of the results of all HIV, HBV, and HCV screening tests and subsequent confirmation tests. This disclosure is crucial to enable the transplant surgeon to request additional testing of the donor and/or to allow the potential transplant recipient to give informed consent for transplantation.

Review the OPO policies for infectious disease testing to ensure they are consistent with current standards of practice (e.g., HIV, HBV, and HCV). Verify in the sample of donor records that the OPO follows its policies for testing.

If the OPO makes print screen copies of laboratory results from the donor hospital, those copies should be appropriately identified for inclusion in the donor record with the patient name, medical record number and the date of the test.

Interpretive Guidelines §486.344(c)(2)

The OPO may accomplish laboratory testing in one of three ways.

a) The hospital laboratory of the donor hospital;

b) An agreement with an off-site laboratory;

c) Point of Care Testing (POCT); and/or

Verify through the Regional CLIA staff that all laboratories performing tests for the OPO are appropriately CLIA certified. Ensure that if the OPO uses POCT (as identified in donor records), the testing is performed by an OPO staff member who has received training from laboratory personnel.

Interpretive Guidelines §486.344(c)(3)

Ensure that the potential donor’s blood is typed using two separate blood samples.
Verify through the sample of donor records that two distinct samples of blood (e.g., during current patient admission and/or OPO evaluation) were collected from the donor at two different times and submitted as separate specimens for blood typing. If one test was already performed by the hospital the OPO need only perform one additional test. "Split samples" (that is, submitting two specimens from a common sample derived from a single blood sample collection) do not meet this requirement.

Interpretive Guidelines §486.344(c)(4)
Review the sample of donor records to confirm that the results of all tests ordered or performed by the OPO during its evaluation for donor suitability are included in the donor record. The documentation may be in the form of actual laboratory test reports or the results may be documented in narrative in the OPO Coordinator notes.

Interpretive Guidelines §486.344(d)(1)
The OPO should have a written agreement or Memorandum of Understanding (MOU) in place with every Medicare certified transplant program in its donation service area (separate from its agreement with the hospital portion of the transplant program). These documents should describe the type of collaboration that will occur between the two entities on an ongoing basis as well as protocols for any assistance the transplant program will provide for donor management and organ recovery. Protocols should be reviewed annually by the OPO and the transplant hospitals to ensure they maximize organ donation and transplantation.

Interpretive Guidelines §486.344(d)(2)
See § 486.344(c)(3)
If the *identify* (sic) of the intended recipient is known, the OPO has a procedure to ensure that prior to organ recovery, an individual from the OPO's staff compares the blood type of the donor with the blood type of the intended recipient, and the accuracy of the comparison is verified by a different individual; (*identify is a misprint in the regulation text and should be identity.)

Interpretive Guidelines §486.344(d)(2)(ii)

The OPO must have policies in place for compliance with OPTN requirements for two separate persons to verify the potential donor's ABO type. At least one verification must be performed by an OPO staff person. Comparison of the recipient ABO to the potential donor is done through the UNET data match run.

Interpretive Guidelines §486.344(d)(2)(iii)

Review the sample of the donor record to confirm that the OPO forwarded documentation of the donor blood type to the transplant hospital with the organ. This documentation should use the UNET assigned identification number in lieu of the donor's name.

Interpretive Guidelines §486.344(d)(3)

See §486.344(d)(1)

Interpretive Guidelines §486.344(e)

If the intended recipient has been identified prior to recovery of an organ for transplantation, the OPO must have written documentation from the OPTN showing, at a minimum, the intended organ recipient's ranking in relation to other suitable candidates and the recipient's OPTN identification number and blood type.

Interpretive Guidelines §486.344(e)
suitable candidates. If the recipient has not yet been identified, the OPO cannot obtain such documentation.

Z186

(Std) §486.344(f) Donation after cardiac death.
If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following:

Interpretive Guidelines §486.344(f)

If it is the OPO’s policy to recover DCD organs, it must have protocols specifically for the evaluation of the donor, management of the organs, and recovery of the organs for DCD donors as these procedures may need to be carried out somewhat differently from those utilized with brain death donation. These protocols must clearly delineate how the OPO will work with the donor’s hospital to maintain the donor until recovery.

Z187

(Std) §486.344(f)(1) Criteria for evaluating patients for donation after cardiac death;

Interpretive Guidelines §486.344(f)(1)

The criteria for the evaluation of organ suitability for DCD donors are the same as the evaluation of brain death donors. However, there is a need for additional evaluation of organ suitability in the operating room post-extubation for the DCD donor. The OPO protocols must address what evaluations will be done during this period (from extubation to declaration of death) and at what frequency.

The OPO should include documentation in their donor record of WIT; and the OPO should include documentation in the DCD donor records of declaration of death in accordance with State and local laws.

Z188

(Std) §486.344(f)(2) Withdrawal of support, including the relationship between the time of consent to donation and the withdrawal of support;

Interpretive Guidelines §486.344(f)(2)

Once informed donation consent is obtained, or in the case of first person consent, the OPO should work in collaboration with the donor hospital staff to prepare the family or the legally authorized representative for withdrawal of support and honor the family’s or the legally authorized representative’s desire to be included as much as possible consistent with hospital policies and protocols.

The OPO must have written protocols for its collaboration with the donor hospital staff regarding withdrawal of life support including clear directives as to the responsibilities of the donor hospital staff and the OPO staff in the period of time between extubation and declaration of death. The protocol should state that recovery personnel (surgeons and other
recovery practitioners) may enter the operating room to prep and drape the donor, but then must leave the operating room until declaration of death. OPO personnel may be in the operating room prior to the actual recovery pursuant to OPTN policy 2.1 and 2.3 which requires that they maintain complete information on any and all organs recovered.

§486.344(f)(3) Use of medications and interventions not related to withdrawal of support;

Interpretive Guidelines §486.344(f)(3)
Medications and interventions may be used to maintain perfusion of organs until the time of transplant. The OPO should have written protocols on the types of drugs that may be used, the dosages and frequency of administration, the persons who may administer the drugs and collaboration with the hospital staff on the administration of medications. The protocol should be consistent with current standards of practice and should include those situations that would require notification of the OPO medical director. Review the sample of donor records to verify that the OPO followed its approved protocols for these administrations.

§486.344(f)(4) Involvement of family members prior to organ recovery;

Interpretive Guidelines §486.344(f)(4)
The OPO must have written protocols for their involvement with families prior to the recovery. The protocol should indicate that the OPO is not involved in the family’s or the legally authorized representative’s decision to withdraw life support. Throughout the informed consent process the OPO should work in tandem with the donor hospital staff to support the family or the legally authorized representative by allowing them the opportunity to ask questions and to make decisions such as when the withdrawal will occur, who will be present for the withdrawal and whether there are any religious implications to consider.

§486.344(f)(5) Criteria for declaration of death and the time period that must elapse prior to organ recovery.

Interpretive Guidelines §486.344(f)(5)
The OPO staff cannot make a death pronouncement. The person making the declaration must be a person authorized to do so by the donor hospital and applicable State laws. The declaration must be made in conformance with State laws and the OPO must include a copy of the declaration in the donor record. The OPO must have written protocols that discuss the wait time between declaration and the beginning of recovery (consistent with current expert recommendations).

Review the sample of DCD donor records to verify that the OPO followed its protocols.
(Std) §486.344(g) Organ allocation. The OPO must have a system to allocate donated organs among transplant patients that is consistent with the rules and requirements of the OPTN, as defined in §486.320 of this part.

Interpretive Guidelines §486.344(g)
If the OPO is a member in good standing with the OPTN (per the CMS OPO Database report) assume this is met.

(Std) §486.344(h) Organ placement. The OPO must develop and implement a protocol to maximize placement of organs for transplantation.

Interpretive Guidelines §486.344(h)
As timing is crucial to the donation process, the OPO should have a written protocol to ensure there is no unnecessary delay of the process from the time that consent is received or confirmed for organ donation to the time of donor cross-clamp and transport.

The components of the protocol should include a minimum, timeliness for entering information into UNET, responsibilities of each staff member throughout the process, timeframes for each process and the documentation that is required to verify that each process was completed.

(Cond) §486.346 Condition: Organ preparation and transport.

(Std) §486.346(a) The OPO must arrange for testing of organs for infectious disease and tissue typing of organs according to current standards of practice. The OPO must ensure that testing and tissue typing of organs are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter.

Interpretive Guidelines §486.346(a)
See §486.344(c)

(Std) §486.346(b) The OPO must send complete documentation of donor information to the transplant center with the organ, including donor evaluation, the complete record of the donor's management, documentation of consent, documentation of the pronouncement of death, and documentation for determining organ quality. Two
individuals, one of whom must be an OPO employee, must verify that the documentation that accompanies an organ to a transplant center is correct.

**Interpretive Guidelines §486.346(b)**

Review the sample of donor records to verify OPO documentation that the following information was transported with each organ:

- (a) ABO typing source documents;
- (b) Serology results;
- (c) Medical/social history form;
- (d) Donor evaluation (documentation that donor met the OPO donation criteria);
- (e) Records of donor management (monitoring, drug administration, testing etc. done by the OPO from the time of death to recovery);
- (f) Copy of signed informed consent form or documentation of first person consent;
- (g) Copy of pronouncement of death;
- (h) Documentation of organ quality (size, appearance, etc).

The records should also include a notation that all the information that was sent with the organ was confirmed by two individuals. One of the individuals must be an OPO employee.

These activities should also be completed in those cases where an organ is recovered and transplanted within the same hospital.

**Z197**

(Std) §486.346(c) The OPO must develop and follow a written protocol for packaging, labeling, handling, and shipping organs in a manner that ensures their arrival without compromise to the quality of the organ. The protocol must include procedures to check the accuracy and integrity of labels, packaging, and contents prior to transport, including verification by two individuals, one of whom must be an OPO employee, that information listed on the labels is correct.

**Interpretive Guidelines §486.346(c)**

The OPO should develop their protocols for packaging, labeling, handling and shipping organs to be consistent with OPTN rule 5.0 Standardized Packaging and Transporting of Organ and Tissue Typing Materials.

The protocols should also require that an OPO staff member verify in writing that the ABO indicated on the container label and the donor information documents being sent with the organ are accurate. A second person, other than the person originally performing verification of the labeling and documentation requirements, should also verify their accuracy in writing.

Review the sample of donor records to verify that the OPO has documentation to confirm that this double confirmation occurred and was documented.

**Z198**
§486.346(d) All packaging in which an organ is transported must be marked with the identification number, specific contents, and donor’s blood type.

Interpretive Guidelines §486.346(d)
See §486.346(c)

§486.348 Condition: Quality assessment and performance improvement (QAPI).
The OPO must develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all donation services, including services provided under contract or arrangement.

Interpretive Guidelines §486.348
A focus on continual improvement of procedures, processes, responsibilities, and approaches to care and the provision of services—This typically involves system level changes to promote sustained improvement. A comprehensive, data-driven program should include the following:

1. A mechanism by which the OPO identifies events (such as complaints or adverse events) that need to be investigated to determine the underlying causes. As a result of this identification and investigation the OPO's comprehensive QAPI program includes a system that:
   - develops an action plan,
   - implements the action plan,
   - evaluates the effectiveness of the plan utilizing a data-driven system, and
   - revises the plan or continues with the plan based on the outcomes of the evaluation.

2. Performance indicators that are monitored on an on-going basis. These performance indicators are measured against established benchmarks or thresholds. Results from the on-going monitoring and evaluation of these performance measures will determine whether the OPO has met their goals or require some type of corrective action plan.

3. A governance or leadership function (e.g., a steering committee, QA committee, and/or senior leadership) that ensures that the OPO has a QAPI program, a written QAPI plan, and appropriate resources to carry out QAPI activities. The role of this function is to establish priorities for the QAPI program, authorize performance improvement projects and action plans, and assure there is a designated, qualified QAPI program coordinator.

See also §486.348(a).
Standard: Components of a QAPI program.
The OPO's QAPI program must include objective measures to evaluate and
demonstrate improved performance with regard to OPO activities, such as hospital
development, designated requestor training, donor management, timeliness of on-site
response to hospital referrals, consent practices, organ recovery and placement, and
organ packaging and transport. The OPO must take actions that result in performance
improvements and track performance to ensure that improvements are sustained.

Interpretive Guidelines §486.348(a)
The OPO QAPI program must include a comprehensive plan that encompasses each phase of
an organ procurement process (i.e., pre-organ procurement: procurement of the organ(s),
and post-organ procurement).

This plan should include:

a. QAPI Committee or organizational structure (the plan should delineate lines of
   communication, committee composition, roles and responsibilities);

b. Objective measures by which the quality-related data will be collected and analyzed;

c. Established frequencies for review of program performance and reporting to the
   QAPI Committee or governance/leadership structure;

d. Designation of person or persons responsible for monitoring the QAPI program and
description of their role(s) and responsibilities;

e. Evidence of systemic approaches that are focused on changes and promote sustained
   improvements;

f. Evidence of implementation of recommendations and continuing compliance for
   improvement;

g. Evaluation of missed opportunities for donation identified through death record
   reviews;

h. Analysis of complaints/investigations;

i. Measurement of the level of compliance with OPTN policies;

j. Evaluation of infectious disease;

k. Staff training requirements (sensitivity and family interactions);

l. Measurement of effectiveness with relationships to tissue banks and eye banks;

m. Measurement of effectiveness with relationships to hospitals;

n. Data collection, analysis, and reporting;
o. Evaluation of potential for Advisory Board, Governing Body conflicts of interest;

p. Evaluation of staff compliance with approved protocols; and

q. Analysis of adverse events reported to the OPO by a transplant center.

Z201

(Std) §486.348(b) Standard: Death record reviews.
As part of its ongoing QAPI efforts, an OPO must conduct at least monthly death record reviews in every Medicare and Medicaid participating hospital in its service area that has a Level I or Level II trauma center or 150 or more beds, a ventilator, and an intensive care unit (unless the hospital has a waiver to work with another OPO), with the exception of psychiatric and rehabilitation hospitals. When missed opportunities for donation are identified, the OPO must implement actions to improve performance.

Interpretive Guidelines §486.348(b)
OPO Policies must address the components that will be included in the monthly death record review (including how records are identified for each hospital) and the timeframes for summarization of the reviews and submission of summarization to the QAPI Committee. The policies must delineate how these findings will be shared with the involved hospital/CAB.

For a sample of hospitals in the service area meeting the above criteria, select a consecutive three (3) month period within the previous four (4) years and request the following information for each hospital in the sample meeting the above criteria:

a) A list of hospital deaths each of the three months;

b) A sample of the completed OPO reviews from each hospital in the sample each of the months; and

c) OPO documentation for each review.

Look for evidence that death record review findings are reported to the Governing Body, corrective actions are implemented, as appropriate, and there is evidence that corrective actions are tracked for compliance.

Z202

(Std) §486.348(c) Standard: Adverse events.
(1) An OPO must establish written policies to address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events that occur during the organ donation process.

Interpretive Guidelines §486.348(c)(1)
The OPO policies should address as a minimum:
a) Procedure for OPO reporting of adverse events to OPTN/CDC/CMS/and local authorities as indicated by the OPO staff and the hierarchy for reporting;

b) The required time frame for reporting, investigating and analyzing adverse events;

c) The timeframes for corrective action following the analysis and recommendations; and

d) Use of analysis in prevention of future adverse events.

Std §486.348(c)(2) The OPO must conduct a thorough analysis of any adverse event and must use the analysis to affect changes in the OPO's policies and practices to prevent repeat incidents.

Interpretive Guidelines §486.348(c)(2)
Request the OPO's log of all adverse events occurring over the current re-certification cycle. Verify that the program followed its written procedures for timely investigation, reporting and analysis and utilized the findings to effect changes in their operation as indicated.

During the review of donor records, be alert to any adverse event incidents. Verify that these events were investigated promptly and appropriate follow-up action was taken including OPO policy changes, if indicated.