

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01P001	<b>(X3) Date Survey Completed</b>  04/18/2014
<b>Name of Provider or Supplier</b>  Legacy Of Hope	<b>Street Address, City, State</b>  516 20th Street South, Birmingham, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>  (Each deficiency should be preceded by full regulatory or LSC identifying information)
<b>Z0000</b>	An unannounced Organ Procurement Organization (OPO) certification survey was conducted on-site at the Alabama Organ Center (AOC) on 4/14-18/2014. The OPO was found to be out of compliance at the following Condition levels at 486.324 (Z084): Administration and Governing Body and 486.326 (Z117): Human Resources.
<b>Z0057</b>	<p>HOSPITAL AGREEMENTS CFR(s): 486.322(a)</p> <p>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."</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the OPO Governing Body failed to ensure hospital designated requestor (HDR) training was provided according to the criteria established in 125 of 125 Hospital Agreements reviewed. The findings include: Review of the OPO's 125 Hospital Agreements (Organ Procurement Organization Agreements) was conducted on 4/14-15/14. The agreements stated the OPO, upon request of the Donor Hospital, would provide HDR training for Donor Hospital staff. The agreements further stated the Donor Hospital would ensure, (in collaboration with the OPO), the family of each potential donor was informed of their options to donate or decline to donate organs, or tissue, by a HDR or by a trained AOC employee or agent. During review of the Donor Records on 4/16/14 at 10:30 a. m. and 1:30 p.m., the Certified Procurement Transplant Coordinator (CPTC) was</p>

interviewed regarding prompt response to the hospital regarding referral time for potential donation of an organ and the date and time that the OPO designated requestor (OPO DR) would arrive on site. The CPTC stated all OPO DRs were designated requestors and were trained regarding approaching family members; however, sometimes the HDRs have to make the request if the OPO DRs were detained. Further interview of the CPTC on 4/18/14 at approximately 9:30 a.m., and review of HDR Training Records at that time, revealed the OPO had not maintained records of training for the HDRs to identify those who had discontinued employment with the hospitals since 2010, could not identify those who were in need of current training, or included data to indicate the training had occurred per the agreements.

**Z0058**

**DESIGNATED REQUESTOR TRAINING - HOSP STAFF**  
CFR(s): 486.322(b)

The OPO must offer to provide designated requestor training on at least an annual basis for hospital and critical access hospital staff.

This STANDARD is not met as evidenced by:  
Based on interview and record review of OPO Staff, training of Hospital Designated Requestors (HDRs) was not offered on an annual basis to those who required such training. The findings include: Interview of the Certified Procurement Transplant Coordinator (CPTC) on 4/18/14 at approximately 9:30 a.m., and record review of the HDR Training Lists provided on 4/18/14 at 9:00 a.m., revealed HDR training was not offered on an annual basis to all HDRs. The interview revealed there was no system in place to indicate training was offered on an annual basis for all HDRs. The CPTC stated training for the OPO trainers had been completed for the OPO designated requestors but stated HDR training had not been offered on an annual basis.

**Z0084**

**ADMINISTRATION AND GOVERNING BODY**  
CFR(s): 486.324

Administration and governing body.

This CONDITION is not met as evidenced by:  
Based on record review and staff interview, the OPO's Governing Body/Board of Directors (BOD) did not ensure effective administration of the organization took place in the following areas: (1) Clarity of the OPO's role in the training of Hospital Designated Requestors, (2) Ensuring the Advisory Board had established and documented Bylaws and (4) that Quality Improvement initiatives that affected the OPO were either established, reviewed or effective. The OPO's cumulative lack of compliance at Standards Z085, Z092 & Z095 rose to the Condition Level of non-compliance.. The findings include: Cross Refer to Z085: Based on interview and record review, the Governing Body/ Board of Directors (BOD) failed to ensure the Advisory Board had established Bylaws. Cross Refer to Z092: Based on record review and interview, the BOD did not ensure there were systematic efforts in place to educate the hospital designated requestors (HDRs) in order to increase the potential of the OPO to acquire useable organs and tissue from potential donors and per the Hospital Agreements. Cross Refer to Z095: Based on interview, the BOD did not define the duties of the Executive Director to address all aspects of Quality Improvement in the OPO.

**Z0085**

**ADMINISTRATION AND GOVERNING BODY**

CFR(s): 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:

This STANDARD is not met as evidenced by:

Based on interview and record review, the Organ Procurement Organization (OPO) failed to ensure there were written bylaws for the Advisory Board (AB). The findings include: Interview conducted with the Certified Procurement Transplant Coordinator (CPTC) on 4/18/14 at 9:28 a.m. and record review of the AB activities revealed there were no Advisory Board Bylaws.

**Z0092**

**ADMINISTRATION AND GOVERNING BODY**

CFR(s): 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.

This STANDARD is not met as evidenced by:

Based on record review and interview, the Governing Body/Board of Directors (BOD) did not ensure there were systematic efforts in place to educate the hospital designated requestors (HDRs) to increase the potential of the OPO to acquire useable organs and tissue from potential donors. The findings include: Cross Refer to Z057 and Z058. The BOD did not ensure the education of HDRs took place according to the Organ Procurement Organization Agreement (Version 8/1/12) for 125 of 125 hospitals in the designated service area. According to interview of the Certified Procurement Transplant Coordinator (CPTC) on 4/18/14 at approximately 9:30 a.m., and record review of the Governing Body Bylaws, HDR Training needs were not addressed. Review of the OPO's 125 Hospital Agreements (Organ Procurement Organization Agreements) was conducted on 4/14-15/14. The agreements stated the OPO, upon request of the Donor Hospital, would provide HDR training for Donor

Hospital staff. The agreements further stated the Donor Hospital would ensure, (in collaboration with the OPO), the family of each potential donor was informed of their options to donate or decline to donate organs, or tissue, by a HDR or by a trained AOC employee or agent. The BOD did not ensure the HDRs were trained according to the Hospital Agreements, or that there was a system in place to identify those HDRs who were in need of training.

**Z0095**

**ADMINISTRATION AND GOVERNING BODY**  
CFR(s): 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.

This STANDARD is not met as evidenced by:  
Based on interview, the Governing Body/Board of Directors (BOD) did not define the duties of the Executive Director to address all aspects of Quality Improvement in the OPO. The findings include: Cross Refer to Z200. Document review revealed there was no QAPI plan that included objective measures which evaluated and demonstrated improved performance of the OPO activities since the last recertification in 2010. During interview with the OPO's Executive Director, Chief Operating Officer, Senior Manager of Professional Education and the Manager of Professional Development & [and] Process Improvement on 4/17/14 at approximately 5:00 p.m., they confirmed there currently was no QAPI Director, no QAPI Plan since 2010, and the OPO was in the process of redeveloping their QAPI program.

**Z0117**

**HUMAN RESOURCES**  
CFR(s): 486.326

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.

This CONDITION is not met as evidenced by:  
Based on interview and record review, the OPO failed to ensure all employees met the criteria established in their job descriptions (Employee #'s 1 & 2), (2) that Conflict of Interests Policies were established for the Executive Director, the Medical Director, Senior Management and the Procurement Coordinators and (3) that there was sufficient staff to request or document whether or not requesting of organs/tissue of potential donor families/qualified significant others, was done in a timely manner. The cumulative lack of compliance at the Standard levels of Z118, Z119 and Z121 rose to the Condition Level of non-compliance.. The findings include: 1. Cross Refer to Z118: Based on record review and staff interview, the Organ Procurement

Organization (OPO) failed to maintain current evidence of qualifications as required by employee job descriptions in two (2) of eight (8) employee files reviewed (Employee #1 and 2). 2. Cross Refer to Z119: Based on interview, the Organ Procurement Organization did not 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. 3. Cross Refer to Z121: Based on record review, the facility failed to ensure there was sufficient staff to request or document whether or not requesting of organs/tissue of potential donor families/qualified significant others, was done in a timely manner.

**Z0118**

**QUALIFICATIONS**  
CFR(s): 486.326(a)

(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.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the Organ Procurement Organization (OPO) failed to maintain current evidence of qualifications as required by employee job descriptions in two (2) of eight (8) employee files reviewed (Employee #1 and 2). The findings include: Employee #1 worked as the Assistant Tissue Manager for the OPO. During record review of Employee #1's file, the Assistant Tissue Manager (ATM) job description documented, ". . . Experience as an Operating Room (OR) Scrub Nurse or OR Technician . . ." as a requirement for the position. According to the job description, the ATM is responsible for tissue procurement for training of tissue recovery staff in assigned regions. Review of Employee #1's file documented no experience as an OR Scrub Nurse or an OR Technician. Employee #2 worked in one of the OPO's Procurement Transplant Coordinator II positions. During record review of the employee's file, the Procurement Transplant Coordinator II job description documented, ". . . Completion of BCLS and/or ACLS [Basic Cardiac Life Support and/or Advanced Cardiac Life Support] . . ." as a requirement for the position. BCLS is a certification for providing basic medical interventions and ACLS is certification in the clinical interventions for the urgent treatment of cardiac arrest, stroke and other life threatening medical emergencies, as well as knowledge and skills to deploy those interventions. There was no evidence of current BCLS and/or ACLS documented in Employee #2's file. During interview with the OPO's Manager of Professional Development & [and] Process Improvement on 4/17/14 at approximately 4:20 p.m., she confirmed Employee #1 did not have experience as an OR Scrub Nurse or an OR Technician as well as Employee #2 did not have a current BCLS and/or ACLS in the file.

**Z0119**

**QUALIFICATIONS**  
CFR(s): 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.

This STANDARD is not met as evidenced by:

Based on interview, the Organ Procurement Organization did not 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. The findings include: Interview with the Certified Procurement Transplant Coordinator (CPTC) on 4/17/14 at 10:30 a. m., revealed the OPO did not have policies or procedures to address conflicts of interest for the OPO director, medical director, senior management and procurement coordinators. 28555 Based on interview, the Organ Procurement Organization did not 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. The findings include: Interview with the Certified Procurement Transplant Coordinator (CPTC) on 4/17/14 at 10:30 a.m., revealed the OPO did not have policies or procedures to address conflicts of interest for the OPO director, medical director, senior management and procurement coordinators.

**Z0121**

**STAFFING**  
CFR(s): 486.326(b)(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.

This STANDARD is not met as evidenced by:  
Based on record review, the facility failed to ensure there was sufficient staff to request or document whether or not requesting of organs/tissue of potential donor families/qualified significant others, was done in a timely manner. The findings include: Based on interview of the Senior Manager of Professional Education (SMPE) on 4/18/14 at 1:45 p.m., and review of the OPO's response time documents, the information provided to demonstrate compliance with sufficient staff coverage to ensure timely response was not defined or consistently evaluated by the OPOs . The Call /Response Time Log was requested on 4/17/14 (Thursday), at 2:00 p.m. On 4/18 /14 (Friday), at 1:30 p.m., prior to the Exit Conference, some of the staff response data was provided on 4/18/14 at 1:45 p.m.; however, it was incomplete. The data was not reviewed or evaluated by the OPO staff to ensure there was sufficient staff to address approaching families/qualified significant others of potential donors in a timely manner. During the interview of the SMPE, she stated the OPO staff realized they would have to address the response times as related to staffing needs.

**Z0147**

**REPORTING OF DATA**  
CFR(s): 486.328(b)

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

This STANDARD is not met as evidenced by:  
Based on document review and staff interview, the Organ Procurement Organization (OPO) failed to include all of the required elements in their Hospital-Specific Organ Donation annual data reports for three (3) of three (3) transplant hospitals (Hospital #s 1, 2 and 8). The findings include: Document review revealed there was no

	<p>documentation of the number of organs recovered by type of organ and the number of organs transplanted by type of organ in the Hospital-Specific Organ Donation annual data reports provided to the OPO's transplant hospitals. During interview with the OPO's Senior Manager of Professional Education on 4/17/14 at approximately 3:03 p.m., she confirmed these elements were not present in the annual data reports provided to the transplant hospitals.</p>
<p><b>Z0148</b></p>	<p><b>REPORTING OF DATA</b> CFR(s): 486.328(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on document review and staff interview, the Organ Procurement Organization (OPO) failed to submit data to the Organ Procurement and Transplantation Network (OPTN) for one (1) of eight (8) hospitals reviewed (Hospital #8) since the last OPO recertification. The findings include: Document review revealed the OPO did not submit data on deaths which occurred at Hospital #8 to OPTN between 2011 - present. During interview with the OPO's Senior Manager of Professional Education and the OPO's Manager of Professional Development &amp; [and] Process Improvement on 4/17/14 at approximately 4:50 p.m., they confirmed the OPO did not submit data to OPTN for this hospital due to problems encountered collecting data from Hospital #8. When the surveyor inquired if the OPO developed a process improvement plan to address this problem, both the Senior Manager of Professional Education and the Manager of Professional Development &amp; [and] Process Improvement said "No."</p>
<p><b>Z0162</b></p>	<p><b>DATA RETENTION</b> CFR(s): 486.330(c)</p> <p>Donor and transplant recipient records must be maintained in a human readable and reproducible paper or electronic format for 7 years.</p> <p>This STANDARD is not met as evidenced by: Based on the facility's "Record Retention" policy review and staff interview, the Organ Procurement Organization (OPO) failed to define the time frame for record retention of OPO donor records. The findings include: The facility's "Record Retention" policy, dated 6/15/13, documented "PURPOSE: To establish guidelines for the retention period of records, to identify specific records to be retained and the language of the documentation . . ." Although this was defined as the purpose, the policy review revealed there was no time frame defined for record retention of the OPO's donor records. During interview with the OPO's Senior Manager of Professional Education on 4/17/14 at approximately 3:03 p.m., she confirmed their "Record Retention" policy did not include a time frame.</p>
<p><b>Z0168</b></p>	<p><b>POTENTIAL DONOR PROTOCOL MANAGEMENT</b> CFR(s): 486.344(a)(1)</p>

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.

This STANDARD is not met as evidenced by:

Based on interview and record review, the Organ Procurement Organization (OPO) failed to have a written procedure for and provide evidence that the Medical Director reviewed Donor Records for assessment for medical suitability for organ donation and for clinical management to optimize organ viability and function. The findings include: Interview conducted during Donor Record reviews on 4/17/14 at 9:20 a.m., with the Certified Procurement Transplant Coordinator (CPTC), revealed the Medical Director did not review the Donor Records. The CPTC stated, "The Medical Director does not review the donor records."

**Z0180**

**COLLABORATION WITH TRANSPLANT PROGRAMS**

CFR(s): 486.344(d)(1)

The OPO must establish protocols in collaboration with transplant programs that define the roles and responsibilities of the OPO and the transplant program for all activities associated with the evaluation and management of potential donors, organ recovery, and organ placement, including donation after cardiac death, if the OPO has implemented a protocol for donation after cardiac death.

This STANDARD is not met as evidenced by:

Based on document review and staff interview, the Organ Procurement Organization (OPO) failed to establish written agreements or Memorandum of Understanding (MOU) with three (3) of the three (3) certified transplant hospitals within the OPO's designated service area (Hospital #s 1, 2 and 8) that was separate from its agreement with the hospital portion of the transplant program. The findings include: Document review revealed there was no written agreement or MOU between the OPO and the certified Transplant Hospital #s 1, 2 and 8 located in the OPO's designated service area which defined the role and responsibilities of the transplant program as well as defined donation after cardiac death. During interview with the OPO's Certified Procurement Transplant Coordinator on 4/17/14 at approximately 4:10 p.m., he confirmed there was no agreement or MOU with the OPO's three transplant hospitals that defined the transplant program's role and responsibilities that was separate from the OPO's contract with the hospital.

**Z0189**

**DONATION AFTER CARDIAC DEATH**

CFR(s): 486.344(f)(3)

[If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following:] Use of medications and interventions not related to withdrawal of support;

This STANDARD is not met as evidenced by:

Based on document review and staff interview, the Organ Procurement Organization (OPO) failed to include: 1) Persons who might administer drugs, and 2) Evidence of

Collaboration with the hospital staff on the administration of medications who were included in their written protocols for Organ Donor Management. The OPO also failed to follow their own Standard Operating Procedures (SOPs) to ensure all donors received some type of prophylactic coverage, and that a paralytic drug was given at the beginning of the surgical recovery for three (3) of five (5) Donor Records, (#&#x27;s 1, 2 & 3) for antibiotics and paralytics. The findings include: Review of the " Standard Operating Procedures (SOPs) " for " Organ Donor Management" with the effective date of 1/30/2014, revealed two components were missing from the protocol: (1) The protocol failed to include the staff who might administer drugs in collaboration with the hospital staff on the administration of medications. In addition, (2)The SOP 7.16 Antibiotic Therapy and 7.17 Paralytics, documented the following, " 17.16.1, "All donors should receive some type of prophylactic coverage ...7.17.4 A paralytic is always given at the beginning of the surgical recovery ... " Donor record review conducted on 4/18/14 with the Certified Procurement Transplant Coordinator (CPTC) revealed antibiotics and paralytics were not administered for 3 of 5 records reviewed for Donor #&#x27;s 1, 2 & 3.

**Z0200**

**COMPONENTS OF A QAPI PROGRAM**  
CFR(s): 486.348(a)

The OPO&#x27;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.

This STANDARD is not met as evidenced by:  
Based on document review and staff interview, the Organ Procurement Organization (OPO) failed to develop a Quality Assurance Performance Improvement (QAPI) Plan since their last Recertification Survey in 2010. The findings include: Document review revealed there was no QAPI Plan that included objective measures which evaluated and demonstrated improved performance of the OPO activities since the last recertification in 2010. During interview with the OPO&#x27;s Executive Director, Chief Operating Officer, Senior Manager of Professional Education and the Manager of Professional Development & [and] Process Improvement on 4/17/14 at approximately 5:00 p.m., they confirmed there currently was no QAPI Director, no QAPI plan since 2010 and the OPO was in the process of redeveloping their QAPI program.

**Z0201**

**DEATH RECORD REVIEWS**  
CFR(s): 486.348(b)

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.

This STANDARD is not met as evidenced by:

Based on document review, the facility's "Medical Record Review" Policy review and staff interview, the OPO failed to obtain lists to conduct complete monthly death record reviews from three (3) of eight (8) donor hospitals reviewed within the OPO's designated service area (Hospital #'s 8, 3 and 4). The findings include: Document review revealed there was no death lists obtained for Hospital # 8. Further review revealed there was incomplete information documented during death record reviews for Hospital #'s 3 and 4. During July 2012 - September 2012, the OPO failed to document the following for Hospital #3 during death record reviews: UNOS [United Network for Organ Sharing] Eligible Donor Potential, Missed Referral, DCD [Donation after Cardiac Death] Potential, Timely Referral, Late Referral, Effective Requestor, Requests before Referral, OPO Approaches, and Organ Donors. The OPO failed to document the same data for Hospital #4 during April 2011 - June 2011 as well as the following: Time of Death, Date/Time OPO contacted and documentation if the donor Family was approached. Review of the OPO's "Medical Record Review" policy, dated 12/1/13, documented, "PURPOSE: To assess the potential organ donor pool and ongoing effectiveness of organ recovery and marketing efforts, medical record reviews (MRR) are conducted . . . The goal of the review is to determine whether any potential donors were missed and to ensure that the hospital's policy is followed regarding the timing of the referral and the use of effective requestors . . . " During interview with the OPO's Senior Manager of Professional Education and the OPO's Manager of Professional Development & [and] Process Improvement on 4/17/14 at approximately 4:50 p.m., they confirmed the OPO did not complete death record reviews for Hospital #8 due to problems encountered collecting data from this hospital as well as confirmed death record reviews were not complete for Hospital #'s 3 and 4 during 2011 and 2012.