

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01P001	(X3) Date Survey Completed 03/29/2018
Name of Provider or Supplier Legacy Of Hope	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies (Each deficiency should be preceded by full regulatory or LSC identifying information)
E0000	An unannounced Emergency Preparedness recertification survey was conducted onsite at Alabama Organ Center on 3/29/18. Alabama Organ Center is in compliance with Requirements for Emergency Preparedness of Organ Procurement Organizations.
Z0000	An unannounced Organ Procurement Organization (OPO) recertification survey was conducted on-site at the Alabama Organ Center (AOC) on 3/26-29/2018. The OPO was found to be out of compliance at the following Condition level at 486.324 (Z084): Administration and Governing Body.
Z0084	<p>ADMINISTRATION AND GOVERNING BODY CFR(s): 486.324</p> <p>Administration and governing body.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview, the Organ Procurement Organization's (OPO's) Governing Body (Operating Committee) failed to ensure effective administration of the organization took place in the following areas: 1) Verification of Advisory Board members qualifications, 2) Ensured the Advisory Board had a Transplant Surgeon from each Transplant Hospital as a member, 3) Established bylaws of the OPO's Operating Committee (OC), 4) Defined the timeframe for OPO staff initial response onsite at the Donor Hospital, 5) Validated written Donor Record review was completed by the Medical Director and 6) that Quality Improvement measured and evaluated the timeliness of chart review and initial response onsite after hospital referral. The OPO's cumulative lack of compliance at Standards Z085, Z090, Z094, Z121, Z168 & Z200 rose to the Condition Level of non-compliance. The OPO had a high likelihood of missed donations due to lack of oversight by the Governing Body (Operating Committee) as evidenced by: onsite response times after hospital referral that ranged from 5 hours to 4 days for 7 of</p>

10 donor records reviewed and tissue processing delays of at least 90 days for at least 60 Tissue donor records due to staffing and delays in completing chart audits. The findings include: Cross Refer to Z085: Based on staff interview and review of the Advisory Board Bylaws the Organ procurement Organization (OPO) failed to verify qualifications of the Advisory Board members. Cross Refer to Z090: Based on staff interview, document review and review of the Advisory Board Membership, the Organ Procurement Organization (OPO) failed to ensure a transplant surgeon was on the Advisory Board from each of the three (3) transplant hospitals. Cross Refer to Z094: Based on document review and staff interview, the Organ Procurement Organization (OPO) failed to have bylaws for it's Governing Body (Operating Committee) for four of four (4 of 4) years. Cross Refer to Z121: Based on donor record review, staff interview and review of the "Responding to a Potential Donor" policy, the Organ Procurement Organization (OPO) failed to arrive promptly onsite for seven (7) of 10 donors and failed to define the timeframe for initial response onsite at the donor hospital within their policy. Cross Refer to Z168: Based on staff interview, donor record review and review of the "Quality Assurance Review/Audit of Donor Records" policy, the Organ Procurement Organization (OPO) failed to ensure donor records were reviewed by the Medical Director for nine of nine (9 of 9) Donors. Cross Refer to Z200: Based on document review and staff interview, the Organ Procurement Organization (OPO) failed to include measures to evaluate and improve 1) the timeliness of on-site response to hospital referrals and 2) delays in completing chart audits required prior to tissue donation processing. The OPO had a high likelihood of missed donations due to lack of oversight by the Governing Body (Operating Committee) as evidenced by: onsite response times after hospital referral that ranged from 5 hours to 4 days for 7 of 10 donor records reviewed and tissue processing delays of at least 90 days for at least 60 Tissue donor records due to staffing and delays in completing chart audits.

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 staff interview and review of the Advisory Board Bylaws the Organ Procurement Organization (OPO) failed to verify qualifications of the Advisory Board members for 13 of 14 members. The findings include: Review of the OPO document entitled, "Advisory Board Policies and Bylaws," dated 6/2/14, revealed, "Members of the Advisory Board will provide a signed and dated copy of their curriculum vitae (CV) confirming their qualifications to serve in the so designated position for which they were appointed." Further review revealed there was no content concerning the process for initial and/or annual verification of Advisory Board (AB) member qualifications. During an interview on 3/27/18 at 10:47 A.M., the Director of Quality Management (DQM) acknowledged that the OPO did not have a policy or procedure for verifying the qualifications of the OPO members and that this was not addressed in the Advisory Committee Bylaws. She also stated that while the OPO did obtain a copy of the CV for each member, they did not take steps to verify the stated qualifications.

Z0090

ADMINISTRATION AND GOVERNING BODY

CFR(s): 486.324(a)(5)

[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:] 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.

This STANDARD is not met as evidenced by:

Based on staff interview, document review and review of the Advisory Board Membership, the Organ Procurement Organization (OPO) failed to include transplant surgeons from three of three (3 of 3) transplant hospitals (Transplant Hospitals A, B and C) as members of the Advisory Board. The findings include: Review of the OPO document entitled, "Advisory Board Policies and Bylaws," dated 6/2/14, revealed the Advisory Board was to include the following members: "A transplant surgeon representing each transplant hospital in the DSA (Designated Service Area) with which the OPO has arrangements to coordinate its activities. The transplant surgeon must have practicing privileges and perform transplants in the hospital represented." A review of the OPO Advisory Board Membership List, dated 2014 - 2018, revealed all 3 transplant hospitals had members on the Advisory Board but none of these members were identified as being a transplant surgeon. During an interview on 3/29/18 at 12:00 P.M., the Director of Quality Management (DQM) verified that the transplant hospital representatives on the Advisory Board were not transplant surgeons. She also said that the Advisory Board did not have any transplant surgeons on the Board other than the OPO's own Medical Director.

Z0094

ADMINISTRATION AND GOVERNING BODY

CFR(s): 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.

This STANDARD is not met as evidenced by:

Based on document review and staff interview, the Organ Procurement Organization (OPO) failed to have bylaws for its Governing Body (Operating Committee) for four of four (4 of 4) years (2014 - 2018). The findings include: During an interview on 3/26/18 at 9:30 A.M., the Director Quality Management (DQM) stated that the OPO's Operating Committee was the Governing Body. She also revealed that this OPO was a University Based OPO and the University gave the OC the role of Governing Body via a Charter document dated 6/5/14. Review of the Charter document revealed the Executive Vice President of the University's Health Services Foundation appointed the OC with the responsibility for the management and provision of all OPO services and required an annual report to the University's Health Services Foundation Board every year. Further review of the Charter revealed there was no reference made to OC Bylaws, potential conflicts of interest for the OPO OC/Governing Body members or criteria for seeking or removing OC members. The OC members were identified in the Charter and included three (3) University Health Services Foundation Board members and the OPO Medical Director. The Charter also listed the OPO Executive Director as an ex-officio member, however the OPO Executive Director's participatory rights were not

defined. Lastly the Charter revealed that appointments to the OC were to be for a period of three (3) years. Review of the Meeting sign-in sheets from 2014 - 2018 for the OC as well as the OC membership list revealed that the Medical Director did not participate as a member of the OC as indicated in the Charter document. In addition, the review indicated that appointments to the OC had not been reviewed since 6/5/14. During an interview on 3/29/18 at 12:00 P.M., the DQM confirmed that the OPO's Governing Body did not have Bylaws or OPO specific policies regarding conflicts of interest and criteria for seeking and removing OC members.

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 donor record review, staff interview and review of the "Responding to a Potential Donor" policy, the Organ Procurement Organization (OPO) failed to arrive promptly onsite for 7 of 10 donors (Donor #s 6, 10, 4, 7, 8, 5 and 3) and failed to define the timeframe for initial response onsite at the donor hospital within their policy. The findings include: Review of Donor #s 6, 10, 4, 7, 8, 5 and 3 records revealed the following: 1. Donor #6 was referred on 6/25/15 (no time indicated). The onsite arrival of OPO staff was documented as 6/29/15 at 11:40 A.M. The response time was approximately 4 days. 2. Donor #10 was referred on 12/23/17 at 12:50 A.M. The onsite arrival of OPO staff was documented as 12/24/17 at 1:15 P.M. The response time was 1 day, 12 hours and 25 minutes 3. Donor #4 was referred on 3/8/15 at 2:24 P.M. The onsite arrival of OPO staff was documented as 3/9/15 at 1:30 P.M. The response time was 23 hours and 6 minutes. 4. Donor #7 was referred on 2/22/17 at 12:14 P.M. The onsite arrival of OPO staff was documented as 2/23/17 at 11:10 A.M. The response time was 22 hours and 46 minutes. 5. Donor #8 was referred on 1/31/18 at 5:58 P.M. The onsite arrival of OPO staff was documented as 2/1/18 at 9:20 A.M. The response time was 15 hours and 32 minutes. 6. Donor #5 was referred on 5/16/16 at 5:55 P.M. The onsite arrival of OPO staff was documented as 5/17/16 at 09:00 A.M. The response time was 15 hours and 5 minutes. 7. Donor #3 was referred on 7/13/16 at 5:08 A.M. The onsite arrival of OPO staff was documented as 7/13/16 at 10:00 A.M. The response time was 4 hours and 52 minutes. Review of the OPO's policy entitled "Responding to a Potential Donor," dated 12/5/14, documented, ". . . Timely response to donor hospital referrals is vital to a successful organ procurement effort, and to providing good customer service to the hospital. . ." During an interview on 3/28/18 at 4:40 P.M, Family Support Coordinator #1 (FSC #1) explained that once a referral came in, the FSC called the hospital Nurse to gather information and then discussed the case with the OPO Administrator On-Call (AOC). At that time, the AOC made the determination of when the FSC went onsite (e.g. immediately or delayed pending further developments). FSC #1 also confirmed that there was no specified timeframe within which the initial onsite hospital arrival and onsite evaluation needed to occur and that it was determined on a case by case basis. During an interview on 3/29/18 at 10:00 A.M., the Clinical Director stated after a Donor referral was made, the OPO staff onsite arrival time was not tracked or monitored because there was no policy in place.

Z0168

POTENTIAL DONOR PROTOCOL MANAGEMENT

CFR(s): 486.344(a)(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.

This STANDARD is not met as evidenced by:

Based on staff interview, donor record review and review of the "Quality Assurance Review/Audit of Donor Records" policy, the Organ Procurement Organization (OPO) failed to ensure donor records were reviewed by the Medical Director for nine of nine (9 of 9) Donors (Donor #s 2, 3, 4, 5, 6, 7, 8, 9, and 10) The findings include: Review of Donor Records for Donor #s 2, 3, 4, 5, 6, 7, 8, 9 and 10 revealed no evidence that records were reviewed and signed by the Medical Director. Records for Donor #s 2, 3, 4, 5, 6, 7 and 9 revealed they were reviewed and signed by a non-OPO physician. The Donor Records for Donor #s 8 and 10 revealed a typed and unsigned Medical Director Review dated 2/19/18 for Donor #8 and dated 12/27/17 for Donor #10. Review of the OPO's policy entitled, "Quality Assurance Review/Audit of Donor Records," dated 9/13/17, revealed, " ...The Medical Director (or designee) will document the review on FO 1.0 MDRR Medical Director Review of Donor Record and provide details of any actions that were contrary to the effective evaluation and management of potential donors ..." During an interview on 3/29/18 at 10:00 A.M., the Clinical Director (CD) stated to her knowledge the physician who signed the aforementioned Donor records, was not the Medical Director. The CD confirmed the physician that signed the Donor records, had no formal agreement with the OPO.

Z0200

COMPONENTS OF A QAPI PROGRAM

CFR(s): 486.348(a)

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.

This STANDARD is not met as evidenced by:

Based on document review and staff interview, the Organ Procurement Organization (OPO) failed to include measures to evaluate and improve 1) the timeliness of on-site response to hospital referrals and 2) delays in completing chart audits required prior to tissue donation processing. The findings include: Cross Refer: Z121 1) The OPO's "Responding to a Potential Donor" policy, dated 12/5/14, did not address or specify a timeframe for staff arrival at the hospital. Review of Appendix A of the QAPI Plan revealed that "Timely Response" was one of the indicators being monitored. The percent of time the response was timely for 2017 was listed as 99.55% of the time. During an interview on 3/29/18 at 10:00 A.M., the Clinical Director stated after a Donor referral was made, OPO staff onsite arrival time was not tracked or monitored because there was no policy in place. During an interview on 3/29/18 at 12:00 P.M., the Director of Quality Management (DQM) stated that the 99.55% figure noted in the QAPI Plan Appendix A, regarding timely response, was in reference to

how often the Family Support Coordinator (FSC) met the requirement to call the hospital within an hour of the referral. She said that the QAPI Plan did not include any measures to determine how timely the onsite response was. 2) The OPO's Complaint Log revealed that they received a complaint in March 2018 from their Tissue Processing partner regarding delays in receiving Tissue Donor charts, which resulted in tissue processing delays. The Complaint Log revealed that 60+ (over 60) charts were late in being audited and that this resulted in tissue processing delays of 90+ (over 90) days. The Complaint Log also revealed that the auditing delays were due to a lack of staff. During an interview on 3/29/18 at 12:00 P.M., the Director of Quality Management (DQM) revealed that the OPO had staffing issues at the time of the above complaint and the lack of sufficient staff caused the delay. She acknowledged that while the OPO did take actions to improve the timeframe; these improvements were not implemented proactively. When the complaint was received the turnaround time was at least 90 days. The DQM stated the implemented improvements had reduced this time to 45 days but said staffing continued to be an issue and was being addressed. She added that at full staffing, prior to the complaint, turnaround time for these chart audits had been 23 days. Review of the document entitled, "Quality Assessment and Performance Plan for the (name of OPO)," dated 1/22/18, revealed the following, "The (name of OPO) will establish annually through its strategic planning process, key performance measures and targets that will be incorporated in Appendix A Quality Assessment and Performance Improvement (QAPI) Goals of the QAPI Plan". Further review of the QAPI Plan Appendix A revealed that the number of complaints from Tissue Processing partner was one of the indicators monitored. The number of complaints from Tissue Processing partner for 2017 was five (5). However, there were no indicators regarding timeliness of Tissue Donor record quality audits or delays in sending Tissue Donor records and tissues for processing.