

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Approved PSEC OPTN Hearing 12/18/2019
01/07/2020 FORM APPROVED
Exhibit L 120 OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: [REDACTED]	(X2) MULTIPLE CONSTRUCTION A. BUILDING [REDACTED] B. WING [REDACTED]		(X3) DATE SURVEY COMPLETED C 12/04/2019
NAME OF PROVIDER OR SUPPLIER LIFE ALLIANCE ORGAN RECOVERY AGENCY			STREET ADDRESS, CITY, STATE, ZIP CODE [REDACTED] [REDACTED]		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
[REDACTED]	<p>INITIAL COMMENTS</p> <p>An unannounced Organ Procurement Organization (OPO) complaint survey was conducted on-site at Life Alliance Organ and Recovery Agency of Miami on December 2-4, 2019. The OPO was found to be out of compliance at the following Standard Level: Z0165 Informed Consent.</p> <p>REQUESTING CONSENT CFR(s): 486.342(a)</p> <p>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:</p> <ol style="list-style-type: none"> (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 	[REDACTED]	<p>Donation is family-driven, in this case the mother had a change of heart after inside the OR. The Life Alliance Organ Recovery Agency ("LAORA") team supported the family, the team members were sensitive to the family's fragile state of mind, and honored their wishes. This course of conduct was the cause behind how this particular donation process unfolded. Despite the rarity of such cases, LAORA recognizes the need to review and update its policies and procedures to address this type of case.</p> <p>1) How the corrective action will be accomplished:</p> <ol style="list-style-type: none"> a. LAORA conducted a root cause analysis ("RCA") and held leadership meetings to discuss the results. The discussions resulted in LAORA modifying its BD/DCD policy along with creating an addendum to the authorization form. 		

LABORATORY REPRESENTATIVE'S SIGNATURE [REDACTED]

(X6) DATE

1/7/2020

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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[REDACTED]	<p>Continued From page 1 appearance of the donor's body.</p> <p>(7) Contact information for individual(s) with questions or concerns.</p> <p>(8) A copy of the signed consent form if a donation is made. This STANDARD is not met as evidenced by: Based on staff interview and donor record review the Organ Procurement Organization (OPO) failed to obtain written informed consent from the Legal Next of Kin (LNOK) when a Donor's status changed from "will be proclaimed dead due to cardiac death" to "has been declared brain dead." The OPO also failed to have evidence that the LNOK changed their "Authorization for Donation of Organs/Tissues" consent from Donation after Cardiac Death (DCD), to organ recovery immediately after extubation. These failures affected 1 (one) of 6 (six) donors (Donor #1).</p> <p>The findings include:</p> <p>Donor #1 was admitted to the hospital following a motor vehicle accident on 11/19/18.</p> <p>Review of the "Criteria for the Determination of Brain Death in Adults" form revealed that Donor #1 had the first of two examinations required by the State of Florida Statutes for a legal pronouncement of brain death, on 11/24/18 at 10:29 a.m. Examination #1 found that Donor #1 was brain dead. A second examination showing the same result was still needed to pronounce Donor #1 legally dead.</p> <p>Review of the Referral Notes revealed that on 11/26/18 the family had elected to withdraw life support (WDLs).</p>	[REDACTED]	<p>b. LAORA contacted three other OPOs and learned that although they do not have a formal policy addressing the scenario at issue, they do obtain consent for both BD and DCD and work with the hospitals if the family wishes to proceed as a DCD even though their loved one has been declared BD.</p> <p>c. LAORA modified its policies and procedures (see attached exhibit A). Pursuant to the new policy, in cases where the family wishes to proceed as a DCD for a BD donor, LAORA will ensure that family signed authorizations for both BD and DCD donation. An additional authorization addendum is added for those rare cases where a verbal authorization is given by the family that is different from the signed authorization. In addition, in such circumstances, two LAORA team members must document in the medical records the verbal authorization. LAORA will also verify that the hospital is in agreement with proceeding as a DCD on a BD declared donor.</p>		12/23/2019

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Z 165	<p>Continued From page 2</p> <p>A Referral Note dated 11/27/18 at 3:36 a.m. revealed the family wanted to proceed with donation however they wanted the donation to proceed as a Donation after Cardiac Death (Donation after the donor's heart has irreversibly stopped beating), so they could be present for the withdrawal of life support and the determination of cardiac death (at this time Donor #1 had not yet been proclaimed dead since a second examination for Brain Death had not yet taken place). Regarding time constraints the Referral Note read, "Yes, to be in the OR (Operating Room) by Wednesday at noon."</p> <p>Review of the "Authorization for the Donation of Organs/Tissues" form revealed that on 11/26/18 at 11:30 p.m. the Legal Next of Kin (LNOK) consented to organ Donation after Cardiac Death (DCD) for Donor #1. The consent specified that Donor #1 "will be pronounced dead as a result of Cardiac Death." The form also included an option for death pronouncement as a result of Brain Death but this option was not selected.</p> <p>Further review of the "Criteria for the Determination of Brain Death in Adults" form revealed that Donor #1 had the second examination required by the State of Florida Statutes for pronouncement of brain death, on 11/24/18 at 10:29 a.m. Examination #2, which was completed by a different physician than Examination #1, as required, also found that Donor #1 was brain dead. The Certification section of the form revealed the "Date and Time of Death Pronouncement" was 11/27/18 at 6:00 a.m.</p> <p>A Late Entry Referral note written on 11/28/18 at 12:17 a.m. revealed that on 11/27/18 at 7:55 p.m.</p>	[REDACTED]	<p>What measures or mechanisms will be put into place to ensure that the deficient practice will not recur.</p> <p>a. The modified policy and authorization addendum was emailed to all DFA staff (Exhibit B) and will be also distributed through our document control system (Q-Pulse) to be acknowledged by all staff.</p> <p>b. A refresher training for DFA staff is scheduled on January 16, 2020 during the next DFA meeting.</p> <p>c. The Pre-OR huddle is expanded to ensure that all documentation for BD as DCD are included in the medical record (Exhibit C)</p> <p>d. The new Pre-OR guideline was emailed to staff who participate in the Pre OR huddle i.e DMC, OAC, SRC (Exhibit D)</p>	<p>12/23/2019</p> <p>1/16/2020</p> <p>1/16/2020</p> <p>12/23/2019</p> <p>12/23/2019</p>	

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[REDACTED]	<p>Continued From page 3</p> <p>OPO Staff #1 witnessed a conversation between the LNOK and OPO Staff #2 where the following was discussed "(LNOK) understands (Donor #1) is brain dead and has a time of death.... (LNOK) wishes to move forward with organ donation but will only do so if she witnesses asysole (absence of electrical activity of the heart seen as a flatline on an electrocardiogram / cardiac standstill). (LNOK) understands gift of life will not be maximized as a result of running a BD (Brain Dead) potential donor as a DCD (Donation after Cardiac Death) and continues to firm on her decision for emotional closure. Leadership was made aware... Case will be ran as a DCD due to family dynamics, despite BD."</p> <p>Review of the Donor Record revealed no evidence that a new or updated "Authorization for the Donation of Organs/Tissues" form was completed to reflect Donor #1's change in status from "will be pronounced dead as a result of cardiac death" to "has been declared brain dead."</p> <p>A Referral Note dated 11/28/18 at 9:17 a.m. revealed that the LNOK agreed to push back the OR (operating Room) time two hours as more time was needed to obtain the liver biopsy results. The new OR time was 11/28/18 at 2:00 p.m.</p> <p>A Referral Note dated 11/29/18 at 7:42 p.m., written as a Late Note addendum, revealed that prior to entering the OR the LNOK said, "she understood that (Donor #1) had gone already when she was declared BD, however she would like to be present at the time of the final moment for emotional closure." The note also indicated that Donor Family Advocate (DFA) #1 was with the LNOK prior to entering the OR to provide support and go over the procedure again as the</p>	[REDACTED]	<p>e. The new Pre-OR huddle will also be distributed through our document through Q-Pulse, our document control system to be acknowledged by staff.</p> <p>f. LAORA will conduct a refresher simulation of a DCD/BD case during the next Clinical Meeting scheduled on January 16, 2020.</p> <p>3) How the organization will monitor its corrective action to ensure that the deficient practice is being corrected and will not recur (i.e., what program will be put in place to monitor the continued effectiveness of the systemic changes).</p> <p>a. LAORA will discuss the dynamics of a BD/DCD case during the Pre OR huddle as well as in the weekly case review.</p> <p>b. Albeit rare, LAORA will conduct an after action review for BD/DCD cases to ensure all policies, procedures, and documentation protocols were followed.</p>	<p>1/16/2020</p> <p>1/16/2020</p>	

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11	<p>Continued From page 4</p> <p>LNOK had requested. The note also read, "We proceeded to get into OR, Personalized Moment of Honor was read and then patient was extubated. We exited the OR quietly, however when we got to the private room (the LNOK) became very emotional."</p> <p>Review of the Intraoperative Management documentation dated 11/28/18 revealed that the procedure was not a DCD procedure. The comment section read, "patient was extubated in presence of the family members in OR immediately after first incision took place and recovery done as a regular donor No waiting time since patient was completely declare brain death. No warm ischemia (a restriction of blood supply to tissues causing a shortage of oxygen) time recorded. Heart beating stop at Xclamp (cross clamp) time 4:19 p.m."</p> <p>Further review of the Donor Record from 11/28/18 through the last entry on 12/4/18 revealed there was no documented indication of whether the LNOK had consented to having the recovery initiated immediately after extubation, instead of after extubation and naturally occurring cardiac standstill as per the signed DCD "Authorization for the Donation of Organs/Tissues."</p> <p>During an interview on 12/3/19 at 2:00 p.m. with Donor Management Coordinator (DMC) #1 he stated that while the LNOK was waiting to go into the OR he went over the procedure with her one more time and she was adamant to see Donor #1's cardiac arrest. Once in the OR and after extubation the LNOK was emotional and crying and asked to leave. He said that after she left the OR hospital team, OPO team and surgeons huddled and determined that recovery should</p>	11	<p>c. LAORA's auditor will audit BD/DCD cases quarterly and report compliance with policies and procedures.</p> <p>d. LAORA policies, work instructions, checklist, and forms associated with DCD will be reviewed annually by an independent OPO quality consultant.</p>		

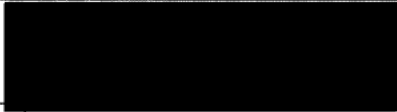
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[REDACTED]	<p>Continued From page 5</p> <p>process immediately since Donor #1 was brain dead and DCD was planned only because the LNOK had wanted to be present. He stated that it was his understanding that the LNOK was aware recovery would proceed immediately but he was not sure who told her.</p> <p>During an interview on 12/3/19 at 2:30 p.m. with Donor Family Advocate (DFA) #1, she stated that while she was waiting to go into the OR the LNOK was again informed of the procedure and still wanted to stay till the end. DFA #1 said that after they went into the OR they had the moment of honor and the OR staff proceeded to extubate Donor #1. She added that the LNOK seemed overwhelmed by the setting of the OR and witnessing the extubation. The DFA revealed it was at that moment the LNKO asked to leave the OR and said, "proceed as planned." The DFA said she thought the LNOK was aware the recovery procedure would start right after she left the OR but that the DFA did not specifically discuss that with her.</p> <p>During an interview on 12/4/19 at 9:15 a.m. with the Executive Director (ED) he indicated that at the time this case occurred the OPO did not have an informed consent procedure related to a change in donor status from DCD to BD. In addition, they did not have a procedure to address a BD donor whose LNOK would only authorize a DCD recovery, but then might later change their mind once in the OR during the DCD process. He added that these were rare circumstances but they needed to have a procedure in place. The ED said they had worked on a procedure to address these issues but acknowledged that it needed to be developed further.</p>	[REDACTED]			

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