STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	42P001	A. BUILDING _____ B. WING _____	C 05/09/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WE ARE SHARING HOPE SC	**3950 FABER PLACE DRIVE CHARLESTON, SC 29405**

(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
Z 000	INITIAL COMMENTS An unannounced Organ Procurement Organization (OPO) complaint survey was conducted on-site at the We are Sharing Hope SC on May 8-9, 2019. The OPO was found to be out of compliance at the following Standard Levels: Z125: Medical Director, Z168: Potential Donor Protocol Management and Z202: Adverse Events.	Z 000		
Z 125	MEDICAL DIRECTOR CFR(s): 483.326(d) 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. This STANDARD is not met as evidenced by: Based on staff interview, review of the procedure entitled "Specimens Drawn for Donor Evaluation" and review of Organ Procurement Transplant Network Policies the Organ Procurement Organization (OPO) failed to have a policy, procedure or protocol regarding discrepancies in donor blood type test results which had the potential to affect all recipients. The findings included: During an interview with the Quality Systems Auditor on 05/09/19 at 11:00 AM, she revealed	Z 125		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 05/28/2019

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Z 125	Continued From page 1 that the OPO did not have a policy, procedure or protocol to guide staff when a donor's blood type test results were not consistent. During an interview with the Chief Executive Officer on 05/09/2019 at 5:45 PM, he acknowledged that the Organ Procurement and Transplant Network (OPTN) required OPO's to have a protocol regarding discrepancies in donor blood type results. He also acknowledged that having such a policy was an expected standard of practice for OPO's as indicated by the OPTN rquirement. Review of the Standard Operating Procedure (SOP) entitled "Specimens Drawn for Donor Evaluation", revised 06/14/2018 revealed there was no guidance within the SOP regarding primary blood type discrepancies. Review of the OPTN Policy number "2.6 C: Deceased Donor Organ Procurement - Reporting of Deceased Donor Blood Type and Subtype", revealed, "If there are conflicting primary blood type test results, the host OPO must follow its protocol for resolving the discrepancy and must re-execute the match run if the final ABO result is different from the initial ABO on the original match run."	Z 125		
Z 168	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	Z 168		

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Z 168	Continued From page 2	Z 168		

organ donation and clinically managed to optimize organ viability and function.
This STANDARD is not met as evidenced by:
Based on Medical Director Interview, staff interview and review of the procedure entitled "Medical Director Responsibilities" the Organ Procurement Organization (OPO) failed to ensure all donor records were reviewed by the Medical Director.

The findings included:

During an interview with the Medical Director on 05/09/2019 at 5:04 PM, she stated that during her work hours she reviewed the donor records of all the donors she was involved with, in real time. She acknowledged that she had not been reviewing the donor records for donor's she did not work with. The Medical Director indicated that the Associate Medical Director did review some donor records but that there was no procedure in place to ensure the all donor records were reviewed to determine if OPO protocols were followed by staff and to take action as needed.

During an interview with the Quality Systems Auditor on 05/09/2019 at 5:20 PM, she acknowledged the OPO did not have evidence that all donor records were reviewed by the Medical Director or Associate Medical Director either in real time or periodically.

Review of the Standard Operating Procedure entitled "Medical Director Responsibilities", revised 06/01/2017, revealed the Associate Medical Director was responsible for the following: "Perform a chart review on all organ donor cases to ensure that potential donor

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Z 168	Continued From page 3 evaluation and management protocols are implemented correctly." The procedure indicated this review was to be completed within 30 days.	Z 168		
Z 202	ADVERSE EVENTS CFR(s): 486.348(c)(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. This STANDARD is not met as evidenced by: Based on staff interview, review of the procedure entitled "Adverse Events" and review of a Non-Conformance Report and the Adverse Event Log the Organ Procurement Organization (OPO) failed to report an Adverse Event to Centers for Medicare and Medicaid Services. The findings included: Review of a Non-Conformance Report dated 11/28/18 revealed the following blood typing concern "the vessel and blood labels that accompanied the Pancreas has a blood type of 'O" but when he runs the blood in the lab the blood type results yields an 'A'." Further notes regarding this case revealed that this non-conformance was determined to be an Adverse Event and that the root cause was "failure to escalate indeterminate results from (name of Serology Lab) to Medical Director." Review of the Adverse Event Log for 10/01/2018 - 12/31/2018 revealed the above Adverse Event was not listed. During an Interview with the Director Quality	Z 202		

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Z 202	Continued From page 4 Systems on 05/08/2018 at 4:30 PM, she stated that when the incident was initially reported she thought it was a non-conformance issue as she had not yet determined that it was going to become an Adverse Event. She stated that when she determined it was an Adverse Event she had neglected to re-categorize it in the data base. During an Interview with the Director Quality on 05/09/2019 at 10:45 AM, she said that she was aware Adverse Events needed to be reported to Centers for Medicare and Medicaid Services (CMS) but that she did not make this report. She stated that she had reported the Adverse Event to the United Network for Organ Sharing (UNOS) Organ Procurement Transplant Network and had been so involved with the root cause analysis and corrective actions that she forgot to report to CMS. Review of the Standard Operating Procedure entitled "Adverse Events", revised 02/09/17, revealed that all Adverse Events were to be reported to the United Network for Organ Sharing (UNOS) via the OPTN Improving Patient Safety Portal. The procedure did not indicate reporting to CMS was required, although the CMS regulation requiring reporting was referenced in the document.	Z 202		

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
61 Forsyth St., SW, Suite 4T20
Atlanta, Georgia 30303-8909

Division of Survey & Certification

Important Notice – Please Read Carefully
(Receipt of this notice is presumed to be May 28, 2019 – Date Notice Emailed)

05/28/2019

Mr. David DeStefano, Chief Executive Officer/President
We are Sharing Hope
3950 Faber Place Drive, Suite 400
Charleston, SC 29405

RE: We are Sharing Hope-CCN: 42-P001

Dear Mr. David DeStefano:

On 05/08/2019 – 05/09/2019 a complaint survey was conducted at We are Sharing Hope to determine whether the organization had maintained compliance with the provisions of §1138 (b) of the Social Security Act applicable to Organ Procurement Organizations (OPO) and the Conditions for Coverage for Organ Procurement Organizations found at 42 CFR Part 486, Subpart G; related to the complaint. This survey found deficiencies that are not Urgent Need as evidenced by the attached Form CMS-2567.

You must submit a Plan of Correction (PoC) for these deficiencies within ten (10) days of receipt of the Form CMS-2567, or not later than 06/07/2019. The PoC must be returned, signed and include dates of correction. An acceptable PoC must contain the following elements:

1) How the corrective action will be accomplished;
2) What measures or mechanisms will be put into place to ensure that the deficient practice will not recur; and
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).

Please email your plan of correction to:

Kathy Brazil: Kathy.brazil@cms.hhs.gov

We may accept the plan of correction and presume compliance has been/will be achieved until substantiated by a revisit or other means.

In the event your organization does not regain compliance, we will recommend to CMS Central Office that your Medicare provider agreement be terminated in accordance with 42 CFR 486.325. You will be given at least 90 days' notice. We are required to provide the public with a notice of termination and will publish a notice in a local newspaper before the effective date.

If you have any questions, please contact Kathy Brazil at (404) 562-7448.

Sincerely,

 for Linda Smith

Linda Smith
Associate Regional Administrator

Enclosures: CMS-2567 – Deficiency Report

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{Z 000}	INITIAL COMMENTS On 7/1/201 a Desk Review follow-up for the Plan of Correction (POC) submitted on June 7, 2019 was conducted. The following Standard level tags were reviewed and found to be corrected: Z125: Medical Director, Z168: Potential Donor Protocol Management and Z202: Adverse Events. It was determined that We Are Sharing Hope SC was in substantial compliance with the requirements at 42 CFR § 486, Requirements for Organ Procurement Organizations. The date of correction was 6/29/20.	{Z 000}		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 07/01/2019

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
61 Forsyth St., SW, Suite 4T20
Atlanta, Georgia 30303-8909

Division of Survey & Certification

Important Notice – Please Read Carefully
(Receipt of this notice is presumed to be July 1, 2019 – Date Notice Emailed)

7/1/19

Mr. David DeStefano, Executive Director
We are Sharing Hope
3950 Faber Place Dr.
Charleston, NC 29405

RE: We are Sharing Hope-CCN: 42-P001

Dear: Mr. DeStefano:

The Centers for Medicare & Medicaid Services (CMS) received your Plan of Correction on 6/7/19, which alleged compliance with Medicare and Medicaid regulations related to Organ Procurement Organizations (OPOs). All of the documents supplied by We are Sharing Hope were carefully reviewed related to the deficiencies issued in the May 9, 2019, Complaint Survey.

CMS determined that We are Sharing Hope has attained substantial compliance with requirements contained with the provisions of §1138 (b) of the Social Security Act applicable to Organ Procurement Organizations (OPO) and the Conditions for Coverage for Organ Procurement Organizations found at 42 CFR Part 486, Subpart G. If you have any questions, please feel free to contact Kathy Brazil, RN at (404) 562-7448.

Sincerely,

Adriane J. Saunders
Health Quality Review Specialist