

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Dallas Regional Office
1301 Young Street, Room 827
Dallas, Texas 75202



DIVISION OF SURVEY & CERTIFICATION, REGION VI

July 16, 2018

Our Reference: CCN 459805

Macon Woodard, MHSM, BSN, RN
Director Transplant Services, Cardiothoracic
CHI St Luke's Health Baylor College of Medicine Center
6720 Bertner
Houston, TX 77030

RE: Adult Heart Only

Dear Ms. Woodard:

On December 1, 2017, the Centers for Medicare & Medicaid Services (CMS) contractor, Healthcare Management Solutions, Inc., conducted a Reapproval survey of the CHI St Luke's Health Baylor College of Medicine Center. Based on data from the Scientific Registry of Transplant Recipients (SRTR) Center Specific Report we have determined that the facility's Adult Heart Only (AHO) transplant program did not meet the Federal requirements for participation as a Medicare-approved transplant program.

Under 42 CFR § 488.61, a transplant program located within a hospital that has a CMS certification number must comply with the Conditions of Participation (CoP) set forth in 42 CFR § 482.72 through 482.104. CMS determined that the AHO program did not meet the patient/organ survival outcome requirements contained in the following CoP:

42 CFR §482.82 Data Submission, Clinical Experience and Outcome Requirements.

The results of the survey were sent to the program on January 19, 2018. Since that time, St. Luke's Baylor has been given an opportunity to demonstrate compliance with the CoPs for organ transplant centers by correcting deficiencies cited during the December 1, 2017, survey. After review, CMS Central Office denied your request for approval based on mitigating factors under 42 CFR § 488.61(a)(4). **Accordingly, Medicare approval for the AHO program will be revoked effective August 17, 2018. No Medicare payment will be made for AHO transplant services furnished by the center on or after that date.** This action does not affect the Medicare hospital provider agreement for CHI St. Luke's Baylor College of Medicine; the action also does not affect the Medicare approval for the Adult Kidney Only, Adult Liver, Adult Lung Only, and the Adult Pancreas programs. We will publish public notice of this revocation action on the CMS Survey & Certification website at:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Termination-Notices.html>

No later than July 17, 2018, (i.e., 30 days before the effective date of your loss of Medicare re-approval), you must inform Medicare beneficiaries on the waiting list that Medicare will not pay for AHO transplants performed by the transplant center after August 17, 2018, as outlined in 42 CFR § 482.102(c)(2)(ii). You must also assist waiting list patients who choose to transfer to another Medicare-approved transplant center without loss of time accrued on the waiting list as outlined in 42 CFR § 482.102(c)(2)(i).

The transplant program may seek re-entry into the Medicare program at any time by following the initial approval procedures described in 42 CFR § 488.61(d). More specific information on the application and approval process may be found at:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Transplant.html>.

Appeal Rights

If you believe this determination is not correct, you or your legal representative may request a hearing before an administrative law judge of the U.S. Department of Health and Human Services, Departmental Appeals Board. Procedures governing this process are set out in 42 CFR §498.40, *et seq.* A request for a hearing should identify the specific issues, and the findings of fact and conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. You may have counsel to represent you at a hearing (at your own expense). Requests for a hearing submitted by U.S. mail or commercial carrier are no longer accepted unless you do not have access to a computer or internet service. **You must file your hearing request electronically by using the Departmental Appeals Board's Electronic Filing System (DAB E-File) at <https://dab.efile.hhs.gov> no later than September 14, 2018 (60 days from the date of receipt of this letter via fax).**

When using DAB E-File for the first time, you will need to create an account by a) clicking Register on the DAB E-File home page; b) entering the requested information on the Register New Account form; and c) clicking Register Account at the bottom of the form. Each representative authorized to represent you must register separately to use the DAB E-File on your behalf.

The e-mail address and password given during registration must be entered on the login screen at: https://dab.efile.hhs.gov/user_sessions/new to access DAB e-File. A registered user's access to DAB e-File is restricted to the appeals for which he/she is a party or an authorized representative. You can file a new appeal by a) clicking the *File New Appeal* link on the Manage Existing Appeals screen; then b) clicking *Civil Remedies Division* on the File New Appeal screen; and c) entering and uploading the requested information and documents on the File New Appeal-Civil Remedies Division form.

The Civil Remedies Division (CRD) requires all hearing requests to be signed and accompanied by the notice letter from CMS that addresses the action taken and your appeal rights. All submitted documents must be in Portable Document Format (PDF). Documents uploaded to DAB e-File on any day on or before 11:59 p.m. EST will be considered to have been received on that day. You will be expected to accept electronic service of any appeal-related documents filed by CMS or that the CRD issues on behalf of the Administrative Law Judge (ALJ) via DAB e-File. Further instructions are located at: https://dab.efile.hhs.gov/appeals/to_crd_instructions. Please contact the Civil Remedies

Division at 202-565-9462 if you have questions regarding the DAB e-Filing System. If you experience technical issues with the DAB e-Filing System, please contact E-File System at OSDABImmediateOffice@hhs.gov or call 202-565-0146 before 4:00 p.m. EST.

If you do not have access to a computer or internet service, you may call the Civil Remedies Division at (202) 565-9462 to request a waiver from e-filing and provide an explanation as to why you cannot file electronically or you may mail a written request for a waiver along with your written request for a hearing. A written request for a hearing must be filed no later than September 14, 2018 (60 days from the date of receipt of this letter via fax), by mailing to the following address:

U.S. Department of Health and Human Services
Departmental Appeals Board, MS 6132
Director, Civil Remedies Division
330 Independence Avenue, SW
Cohen Building, Room G-644
Washington, D.C. 20201

In addition, please forward a copy of your request to:

CMS Associate Regional Administrator
Centers for Medicare & Medicaid Services
Division of Survey and Certification
ATTN: Karen Hillman
1301 Young Street; Room 827
Dallas, Texas 75202

In lieu of CMS revocation of the approval for your AHO transplant program, the program may voluntarily withdraw from Medicare prior to the effective date of the loss of Medicare approval. If the program elects this option, you must notify Jacque Smith at jacque.smith@cms.hhs.gov no later than July 19, 2018. Please note that if the program elects to voluntarily withdraw from Medicare, such withdrawal waives your right to appeal CMS' decision to deny continued approval of the hospital's AHO transplant program.

You may contact Jacque Smith at 214-767-4436 or jacque.smith@cms.hhs.gov if you have questions regarding this matter.

Sincerely,

Gerardo Ortiz
Associate Regional Administrator

cc: CMS CO
State Medicaid Agency