

STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

JOHN G. ROWLAND
GOVERNOR

CRISTINE A. VOGEL
COMMISSIONER

March 30, 2004

Mr. Norman G. Roth
Senior Vice President, Administration
Yale-New Haven Hospital
20 York Street
New Haven, CT 06504

RE: Certificate of Need Determination; Report Number 03-23013-DTR
A reconsideration of the Certificate of Need Determination issued under Report Number 02-03 regarding the temporary suspension of Liver Transplant Program

Dear Mr. Roth:

On November 12, 2002, the Office of Health Care Access ("OHCA") issued a Certificate of Need ("CON") Determination under Report Number 02-03 regarding the inactive status of the Yale-New Haven Hospital ("Hospital") Liver Transplant Program. In that CON Determination, OHCA determined that a CON was required for termination of services pursuant to Section 19a-638. On February 27, 2003, the Hospital requested that OHCA reconsider its CON Determination under Report Number 02-03 indicating that it was not the Hospital's intention to terminate its Liver Transplant Program. OHCA has received periodic updates since the February 27, 2003 request for reconsideration, the most recent update filed with OHCA on March 26, 2006. Below are the pertinent findings regarding this matter:

1. Effective the end of December 2000, Yale-New Haven Hospital's Liver Transplant Program lost its primary transplant hepatologist.
2. The Hospital has not performed liver transplant surgery since January 28, 2000.
3. On January 17, 2001, Dr. Marc I. Lorber, the Chief of the Section of Organ Transplantation and Immunology of Yale University sent a letter to the United Network for Organ Sharing ("UNOS"), which described the situation as regards the liver transplant program. It stated that due to personnel changes in the Anesthesia Department a decision was made to curtail liver transplant activities during early 2000. The letter indicated that an enhanced transplant team might be in place by summer, 2001. At that time, the Hospital was recruiting for a primary liver transplant surgeon and senior liver transplant anesthesia faculty as well as hepatology and transplant pathology.
4. On February 21, 2001, Dr. Lorber sent a follow-up letter to UNOS, which formally requested that the Hospital's liver transplant program be considered voluntarily inactive.

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5. On May 29, 2001, Dr. Lorber sent a letter to HCFA (*now the Centers for Medicare and Medicaid Services*), which notified HCFA of the voluntarily inactive status of the program since January 28, 2000.
6. On July 3, 2001, the Hospital filed a letter with OHCA in response to an OHCA inquiry in June of 2001 related to the inactive Liver Transplant Program. Prior to that point in time, OHCA was unaware of the inactivity of this program. The July 3, 2001 letter states that the “temporary suspension” was due to the loss of a few of the program’s key individuals that had been recruited away from the Yale School of Medicine Liver Program” and that patients on the programs waiting list were transferred to other transplant programs. The letter further states that “Nationwide recruitment efforts are currently underway and it is expected that the program will be reconstituted this Fall” (*Fall of 2001*).
7. On November 15, 2001, at OHCA’s request, the Hospital filed a status update on the Liver Transplant Program, indicating that a “nationwide recruitment effort is aggressively being pursued to identify a strong clinical leader to restore this program” and the Hospital anticipates that “this recruitment effort will be completed by July 1, 2002 with the renewed program activity occurring within six months of that date.”
8. On June 28, 2002, at OHCA’s request, the Hospital filed a status update on the Liver Transplant Program, indicating that the Hospital has continued to “aggressively recruit a liver surgeon in a market where there are only a few viable candidates ...” and such recruitment requires “coordination with the Yale University School of Medicine (YSM) and relies on YSM’s support of the recruit’s academic and research efforts.” The Hospital states that it “has every intention to continue to recruit for a viable liver transplant surgeon and there are no plans to abandon this program.”
9. On November 4, 2002, at OHCA’s request, the Hospital filed a status update on the Liver Transplant Program, indicating that the Hospital continues “actively recruiting a liver transplant surgeon.”
10. On November 12, 2002, OHCA issued a CON determination under Report Number 02-O3, which informed the Hospital that OHCA determines that the Hospital has terminated a health care service and that CON authorization would be necessary.
11. On February 27, 2003, the Hospital filed a letter with OHCA which requested OHCA to reconsider its determination made under Report Number 02-O3 as it is not the Hospital’s intention to terminate the Program and the Hospital continues to “actively recruit a liver transplant surgeon.
12. On September 15, 2003, the Hospital informed OHCA that David Cronin, M.D., a liver transplant surgeon would be joining the medical staff on November 1, 2003 to reestablish the Liver Transplant Program.
13. On November 5, 2003, the Hospital informed OHCA that Dr. Cronin received his Connecticut license to practice medicine on October 8, 2003.

14. On March 26, 2003, the Hospital informed OHCA that Dr. Cronin began employment on December 1, 2003 and the Hospital submitted its UNOS application for reinstatement of the liver transplant program on February 11, 2004. The Hospital anticipates that the application will be formally reviewed by UNOS at its Membership and Professional Standards Committee meeting on May 4th & 5th, 2004. After UNOS approval, the Hospital will begin performing liver transplants again.

Based on the fact that it was never the Hospital's intent to permanently terminate its Liver Transplant Program and the suspension of the program over a period of four years was due to the lack of program's key clinical persons during this timeframe, OHCA determines that the Liver Transplant Program was suspended by the Hospital out of necessity rather than terminated. During the entire time period since the program was suspended, the Hospital has been continuously active in seeking a viable candidate to reinvigorate this program. Since a candidate has been recruited and is now practicing at the Hospital and the Hospital is awaiting UNOS approval, it is clear to OHCA that the program should begin performing liver transplants in the near future.

Therefore, OHCA reconsiders its Certificate of Need Determination issued under Report Number 02-03 and herein reverses such Determination. As such, it is not necessary for the Hospital to file a Certificate of Need for the termination of the Liver Transplant Program. If, however, the Hospital fails to complete the process currently being undertaken in reinstating an active program, the Hospital will need to contact OHCA immediately in order for OHCA to determine whether to require a Certificate of Need at that time.

If you have any questions regarding the above, please contact Karen Roberts, OHCA Compliance Officer, at (860) 418-7001.

Sincerely,

Cristine A. Vogel
Commissioner

CAV: kr

Copy: Rose McLellan, Licensing Examination Assistant, DHSR, DPH