STATE OF CONNECTICUT

OFFICE OF HEALTH CARE ACCESS

M. JODI RELL GOVERNOR CRISTINE A. VOGEL COMMISSIONER

February 2, 2006

Andrea J. Ryann Community and Government Relations Manager The Danbury Hospital 24 Hospital Avenue Danbury, CT 06810

Re: Certificate of Need Determination, Report Number 05-30660-DTR
The Danbury Hospital
Expansion of Cardiac Device Implantation Involving Cardiac Defibrillators Implantation

Dear Ms. Ryann:

On December 21, 2005, the Office of Health Care Access ("OHCA") received a Certificate of Need ("CON") Determination request from The Danbury Hospital ("Hospital") for the expansion of cardiac device implantation at no additional cost. Please be advised that OHCA has reviewed your request and makes the following findings:

- 1. The Hospital is an acute care hospital located at 24 Hospital Avenue in Danbury, Connecticut. The Hospital currently offers a full-service cardiac program including angioplasty and open-heart service.
- 2. The Hospital's Cardiovascular Service Line ("Program") has existed for over twenty five years. The Hospital currently provides device implantation for cardiac pacemaker devices including single lead pacemakers, dual lead pacemakers and arrhythmia diagnostic devices.
- 3. The Hospital stated the following:
 - The Program implanted over a hundred (100) devices last fiscal year;
 - For over five years the Hospital has provided post procedure follow-up for all patients with Implantable Cardioverter Defibrillators (ICD) when these devices have been implanted at remote institutions;
 - The Hospital staff is thoroughly educated in the care and monitoring of patients with standard pacemakers defibrillators alike; and
 - The Hospital has an active patient encounter group for those patients that have received ICDs in the past.

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4. The Hospital states that, currently, patients requiring ICDs require overnight hospital admission and some patients require Defibrillators insertion immediately following successful coronary angioplasty or cardiac surgery and would require intra-hospital transfer.

- 5. The Hospital proposes to offer Device Implantation with ICD service at the Hospital.
- 6. The Hospital states that the proposed service is virtually similar to the implantation of pacemakers. There is a sterile atmosphere maintained, the laboratory is staffed with trained support personnel, a trained cardiologist or surgeon is present during the implantation, imaging is performed with existing fixed imaging, and patient preparation is identical.
- 7. The Hospital states that the differences between the existing device implantation services and the proposed ICD include lead selection for implantation and programming and testing of the device while the patient is in the laboratory.
- 8. The proposed service will require only existing staff training and no capital expenditure.

Based on the above findings, OHCA has determined that the proposed ICD service is not considered a new service for the Hospital, as the Hospital currently operates a full-service cardiac program including angioplasty and open-heart service. Therefore, a Certificate of Need is not required pursuant to Section 19a-638 of the Connecticut General Statute.

Thank you for informing OHCA of the Hospital's plans to offer the proposed service, however, no Certificate of Need is required. If you have any questions concerning this letter, please contact Steven W. Lazarus, Associate Health Care Analyst, at (860) 418-7001.

Sincerely,

Signed by Cristine A. Vogel Commissioner

CAV:swl

Copy: Rose McLellan License and Applications Supervisor, DPH, DHSR