

## **Office of Health Care Access**

# Request for Modification of a Previously Authorized Certificate of Need

Applicant:	Neurology Associates, LLC
Modification Docket Number:	07-30674-MDF
Description of Proposed Modification Request:	A request to modify a previous Certificate of Need authorization in order to vacate or revise CON Condition #4 which requires Neurology Associates, LLC to only use the authorized MRI unit "for its Practice and Practice patients, specifically for the use of neurological conditions."
Original Project Docket Numbers and Title	Docket Number 06-30674-CON: The acquisition of a 1.5 Tesla MRI Unit at a total capital expenditure of \$1,457,678
Intervenor	The William W. Backus Hospital
Statutory Reference:	Sections 4-181a(b), Connecticut General Statutes
Filing Date:	October 29, 2007
Hearing Date:	January 24, 2008
Decision Date:	April 29, 2008
Staff	Karen Roberts

**Project Description:** Neurology Associates, LLC requests a modification of the Certificate of Need authorization issued under Docket Number 06-30674-CON in order to vacate or revise CON Condition #4 which requires Neurology Associates, LLC to only use the authorized MRI unit "*for its Practice and Practice patients, specifically for the use of neurological conditions.*"

Neurology Associates, LLC Docket Number 07-30674-MDF

**Nature of Proceedings:** On August 31, 2007, the Office of Health Care Access ("OHCA") received a request for modification of the previous CON decision from Neurology Associates, LLC ("Applicant"). The Applicant requests that Condition #4 be revised or vacated and allow the Practice to utilize the scanner on all patients, whether or not such patients present with neurological conditions. Additional information was filed on October 29, 2007, and the modification request was deemed complete under Docket Number 07-30674-MDF.

OHCA is allowed to consider a modification to a previous agency final decision upon a showing of changed conditions pursuant to Section 4-181a(b) of the Connecticut General Statutes. A public hearing regarding this matter was held on January 24, 2008. On January 4, 2008, the Applicant was notified of the date, time, and place of the hearing. A notice was published in the Norwich Bulletin on January 8, 2008. Commissioner Cristine A. Vogel served as Presiding Officer in this matter.

The William W. Backus Hospital petitioned for intervenor status with full procedural rights in the proceeding, including the right to present evidence and argument as well as the right to cross-examine witnesses. The Presiding Officer granted this petition for status.

The Presiding Officer heard testimony from witnesses representing the Applicant and the Intervenor. In rendering this decision, the Presiding Officer considered the entire record of the proceeding. OHCA's authority to review and determine whether any change of conditions has occurred is established by Section 4-181a (b), C.G.S.

# **Findings of Fact**

 On August 28, 2006, the Office of Health Care Access ("OHCA") granted a Certificate of Need ("CON") under Docket Number 06-30674-CON, to Neurology Associates, LLC (the "Applicant" or the "Practice") to acquire a 1.5 Tesla Magnetic Resonance Imaging Unit at a total capital expenditure of \$1,457,678 for its office at One Towne Park Plaza in Norwich<sup>1</sup>. This acquisition was a replacement unit for an existing 1.0 Tesla MRI unit already being used by the Practice. Condition #4 of the CON authorization states the following:

"4. As stated in the proposal, the Applicant shall use the proposed MRI scanner for its Practice and its Practice patients, specifically for the use of neurological conditions."

2. Within the materials filed by the Applicant with OHCA under Docket Number 06-30674-CON and taken into account by OHCA in its CON decision under that docket number, the Applicant made the following statements:

<sup>&</sup>lt;sup>1</sup> William W. Backus Hospital was designated as an Intervenor in the matter under Docket Number 06-30674-CON.

- From the January 24, 2006 Letter of Intent filed by the Applicant with OHCA:
  - "Neurology Associates ... is proposing to upgrade that scanner to a 1.5 Tesla for the primary purpose of diagnosing and treating neurological disorders." "For instance, the current scanner is insufficient for diagnosing acute neurovascular disease."
- From the May 4, 2006 CON application submission and May 31, 2006 responses to completeness questions filed by the Applicant with OHCA:
  - "Neurology Associates, LLC also doing business as Multiple Sclerosis Care of Connecticut ("the Practice"), is a professional services limited liability company comprised of six (6) neurologists, all in a full-time clinical practice of neurology in eastern Connecticut."
  - *"The Practice must upgrade ... to assist the physicians in diagnosing neurological disorders at currently accepted medical standards"*
  - "The use of a Siemens 1.0T currently in operation is considered suboptimal by acceptable practice standards for certain types of scans regularly required in the field of neurology."
  - "It is clear that the Practice's current scanner is insufficient for diagnosing acute neurovascular disease. The proposed higher-field unit will allow the Practice to accept patients in need of vascular studies for imaging services."
  - "There will be no, to minimal, impact on the other providers because the Practice has proposed to upgrade its imaging services to better serve its existing and growing patient base"
  - The "proposed MRI unit will not be used for MRI scans for patients from outside the Practice."
- From July 14, 2006 and July 18, 2006 submissions by the Applicant to OHCA:
  - *"the request is related to the Applicant's need to provide state-of-the-art neurology services to its own patient base."*
  - "MRI imaging is an ancillary service provided to its neurology patients."
  - "The Practice is the most qualified to provide the specialized integrated neurology services with MRI and the provision of these services will have no adverse impact on any of the existing providers in the Service Area."
  - "The CON application submitted and completeness questions make it extremely clear to OHCA and the Hospital that the Practice is not looking to allow physicians who are not with Neurology Associates to utilize the MRI, nor is it looking to permit patients who are not patients with the Practice to utilize the scanner."
- 3. Subsequent to the August 28, 2006 CON decision containing Condition #4, the Applicant did not request reconsideration pursuant to Section 4-181a(a) of the Connecticut General Statutes nor did the Applicant appeal the CON decision as allowed by Section 4-183 of the Connecticut General Statutes.

- 4. On April 4, 2007, the Applicant informed OHCA that the Applicant "*is in compliance with the Office of Health Care Access's Final Order*" in that the new MRI unit was acquired and fully operational.
- 5. Approximately four months subsequent to project implementation, on August 31, 2007, OHCA received the Applicant's request for modification of the previous CON Order. The Applicant requests that Condition #4 be revised or vacated and "allow the Practice to utilize the Scanner on all patients of the Practice, whether or not such patients present with neurological conditions." Additional information was filed on October 29, 2007, and the modification request was deemed complete under Docket Number 07-30674-MDF.
- 6. The Applicant lists the following reasons why it believes there has been a change in conditions which has occurred as justification for the modification request:
  - a) "First, the Practice possesses the most advanced MRI capabilities in the community."
  - b) "Second, The William W. Backus Hospital (the "Hospital") did not proceed with a CON authorization to establish a satellite MRI facility within its primary service area, despite its Determination Request, which OHCA classified as the Hospital's Letter of Intent in Docket Number 05-30635-DTR."
  - c) "Third, upon information and belief, the Hospital has failed to upgrade and implement its MRI to expand its capabilities and functionality to be on par with the 1.5 Tesla Avanto MRI maintained by the Practice, as previously proposed."
  - d) "Fourth, according to OHCA's Findings of Fact in Docket Number 06-30766-CON, Norwich Radiology Group, PC ("NRG") performed eight hundred forty-six (846) MRI scans using a low-field MRI scanner in 2006. Since that low field MRI scanner has been taken out of service, there is a need to fulfill at least 846 scans in the community."
  - e) "Fifth, MRI scans of the breast have become the standard of care. As such, the number of referral for MRIs is consistently increasing and is projected to continue to increase. The MRI scans recommended for the diagnosis of breast cancer require special imaging equipment. At present, the Practice's Scanner is not capable of performing the breast MRIs." "Most importantly, the Practice has no intention of providing breast MRI. The Hospital's MRI, however, is capable of performing the breast MRI. Accordingly, the increased need for MRIs, due to the increased need for breast MRIs, will have to be absorbed by the Hospital. This increase, coupled with the eight hundred forty-six (846) MRI scan absorption, will certainly yield a significant increase in referrals to imaging providers in the community, including the Practice."
  - f) The Applicant also states that it is "receives a substantial volume of direct referrals of patients with conditions apart from or in addition to neurological conditions."

- On January 4, 2008, under Docket Number 07-31070-WVR, OHCA granted a Certificate of Need to the William W. Backus Hospital ("Backus Hospital") to acquire a Siemens 1.5 Tesla MAGNETOM Avanto MRI unit to replace its existing MRI unit.
- 8. On December 14, 2006, OHCA granted a CON to William W. Backus Hospital ("Backus Hospital") and Norwich Radiology Group, Inc under Docket Number 06-30766-CON. In that CON authorization, OHCA approved Backus Hospital to acquire the assets of Norwich Radiology Group, Inc. at its Norwich office location, including the CT scanner. OHCA specifically denied the acquisition of Norwich Radiology Group, Inc.'s MRI unit. OHCA's decision in this matter, including the denial of the acquisition of the MRI unit, was made subsequent to OHCA's CON authorization for Neurology Associates, LLC. In the Rationale section of OHCA's final decision in that matter, OHCA concluded that "there is sufficient MRI scanning capacity at the Hospital and the Hospital can add additional days to its existing mobile MRI scanner if it approaches capacity at the Hospital."
- 9. In its January 18, 2008 petition for Intervenor status in the matter under Docket Number 07-30674-MDF, Backus Hospital states that it has "absorbed the scan volume previously attributable to Norwich Radiology Group"<sup>2</sup> and that "it has the ability to expand hours and add days to its current MRI service in order to meet any demand in the community."
- 10. Backus Hospital filed a Letter of Intent under Docket Number 05-30635-LOI on November 15, 2005 for the establishment of satellite MRI services at 82 New Park Avenue in Franklin, Connecticut. According to page 5 of the Letter of Intent in that matter, the "satellite MRI once operational will allow the Hospital to discontinue the use of the second mobile MRI unit" at the Hospital's main campus. This Letter of Intent expired without a Certificate of Need application being filed with OHCA and OHCA acknowledged such expiration in an April 18, 2006 OHCA letter to Backus Hospital.
- 11. The Applicant has provided no evidence to demonstrate that Backus Hospital will be unable to accommodate any increase in volume specific to any possible increase in the number of breast MRI scans performed.
- 12. OHCA's decision in August 2006 to limit Neurology Associates, LLC's MRI unit to neurology related conditions was not dependent on fluctuations in the volume levels of other providers in the region.

<sup>&</sup>lt;sup>2</sup> Backus Hospital states that the capacity for its two existing MRI unit combined is 14,196 scans per year. In FY 2007, the units together provided 9,045 scans, a 14% increase over FY 2006. Backus Hospital's two units are therefore operating at approximately 64% of total available capacity. The Hospital indicates that this demonstrates the Hospital's ability to meet the demand created after the decommissioning of the Norwich Radiology Group's MRI unit in February 2007 as the result of OHCA's CON decision under Docket Number 06-30766-CON.

#### Discussion

Section 4-181a (b) of the Connecticut General Statutes allows for consideration of a modification to a previous final decision of the Agency upon a showing of changed conditions. The Applicant has not demonstrated nor has it provided any convincing evidence to show a change in the specific conditions, since OHCA reviewed the CON and issued its CON decision in 2006, which would warrant a modification of the previously authorized CON decision. The Applicant did not ask for reconsideration of the CON at that time and had fully implemented the previously authorized project in April 2007. Regarding each of the Applicant's points for which it states there has been a change in conditions, OHCA finds the following:

Regarding the Applicant's assertion that a change of conditions has taken place because the Practice possesses the most advanced MRI capabilities in the community, OHCA notes that it specifically approved this MRI unit under DN 06-30674-MDF with full knowledge of its capabilities. No evidence has been filed to demonstrate that a change in conditions has occurred related to this.

Regarding the Applicant's assertion that a change of conditions has taken place because Backus Hospital did not proceed with a CON authorization to establish a satellite MRI facility within its primary service area, OHCA notes that Backus Hospital's Letter of Intent for that matter expired prior to OHCA considering and acting upon the Neurology Associates, LLC CON matter under Docket Number 06-30674-CON. Therefore, OHCA acted upon the CON under Docket Number 06-30674-CON with full knowledge that Backus Hospital let its Letter of Intent under Docket Number 05-30635-LOI expire.

Regarding the Applicant's assertion that a change of conditions has taken place because the Hospital has failed to upgrade and implement its MRI to expand its capabilities and functionality to be on par with the 1.5 Tesla Avanto MRI maintained by the Practice, as previously proposed, OHCA notes that the OHCA decision under Docket Number 06-30674-CON for Neurology Associates, LLC to limit its use of the authorized MRI scanner for neurological conditions was made with full knowledge of Backus Hospital's MRI capabilities at that time and without any requirements specific to Backus Hospital changing, upgrading or increasing its MRI capability. OHCA further notes that Backus Hospital has since obtained approval to upgrade its fixed base unit to the same unit being used by the Applicant.

Regarding the Applicant's assertion that a change of conditions has taken place because the Norwich Radiology Group, P.C. MRI scanner was taken out of service pursuant to Docket Number 06-30766-CON, and therefore, there is a need to fulfill at least 846 scans in the community, OHCA notes that in its December 14, 2006 CON decision in the matter under Docket Number 06-30766-CON, the acquisition of Norwich Radiology Group, Inc's assets by Backus Hospital, OHCA specifically denied the acquisition of the MRI scanner and OHCA indicated that "there is sufficient MRI scanning capacity at the Hospital and the Hospital can add additional days to its existing mobile MRI scanner if it approaches capacity at the Hospital". Further, Backus Hospital now states that it has "absorbed the scan volume previously attributable to Norwich Radiology Group" and that "it has the ability to expand hours and add days to its current MRI service in order to meet any demand in the community." Neurology

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Associates, LLC has not demonstrated that there has been a change in conditions that has occurred specific to decommissioning of the Norwich Radiology Group, P.C.'s MRI scanner, which would warrant a modification of the decision in Docket Number 06-30674-CON.

Regarding the Applicant's assertion that a change of conditions has taken place because the Hospital will now have to absorb additional MRI scan volume due a potential increase in breast MRI scans, OHCA notes that the Applicant has provided no evidence to demonstrate that Backus Hospital will be unable to accommodate any increase in volume specific to any possible increase in the number of breast MRI scans performed. In addition, OHCA's decision in August 2006 to limit Neurology Associates, LLC's MRI unit to neurology related conditions was not dependent on fluctuations in the volume levels of other providers in the region. Therefore, Neurology Associates, LLC has not demonstrated that there has been a change in conditions that has occurred specific to Backus Hospital potentially experiencing an increase in breast MRI scans, which would warrant a modification of the decision in Docket Number 06-30674-CON, as any such fluctuation does not impact Neurology Associates, LLC's operation of its MRI scanner.

Finally, regarding the Applicant's assertion that a change of conditions has taken place because the Applicant has received *a substantial volume of direct referrals of patients with conditions apart from or in addition to neurological conditions*", OHCA finds no relevance or significance regarding this stated factor. The scope of the authorized MRI acquisition was specific to the use of the MRI for neurological related conditions and any referrals for non-neurological conditions which occur or occurred subsequent to OHCA's CON authorization has no bearing on this matter. Neurology Associates, LLC has not demonstrated that there has been a change in conditions that has occurred specific to this claim, which would warrant a modification of the decision in Docket Number 06-30674-CON.

Based on the foregoing, OHCA finds that the Applicant has failed to provide sufficient evidence of a change in conditions, pursuant to Section 4-181a (b), C.G.S. that would warrant a modification of the previously authorized Certificate of Need.

### Order

Based on the fact that there has been no demonstration of changed conditions as required by Section 4-181a (b) of the Connecticut General Statutes, the request for modification of Docket Number 06-30674-CON is hereby Denied. The Final Decision and Conditions set forth in the CON issued under Docket Number 06-30674-CON stand as previously ordered by OHCA.

Sincerely,

Signed by Commissioner Vogel on April 29, 2008

Cristine A. Vogel Commissioner

CAV/kr