STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

April 9, 2015

IN THE MATTER OF:

An Application for a Certificate of Need filed Pursuant to Section 19a-638, C.G.S. by:	Notice of Final Decision Office of Health Care Access Docket Number: 14-31965-CON
Molecular Neuroimaging, LLC	**Acquisition of a PET/CT Scanner**

To:

Kimberly Fabrizio
Sr. Director of Regulatory Affairs
Molecular Neuroimaging, LLC
60 Temple Street
New Haven, CT 06510

Dear Ms. Fabrizio:

This letter will serve as notice of the approved Certificate of Need Application in the above-referenced matter. On April 9, 2015, the Final Decision, attached hereto, was adopted and issued as an Order by the Department of Public Health, Office of Health Care Access.

Kimberly Martone (ICR)

Kimberly R. Martone
Director of Operations

Enclosure
KRM: amv

Department of Public Health
Office of Health Care Access
Certificate of Need Application

Final Decision

Applicant: **Molecular Neuroimaging, LLC.**
60 Temple Street, New Haven, CT 06510

Docket Number: **14-31965-CON**

Project Title: **Acquisition of a Positron Emission Tomography/Computed Tomography Scanner**

Project Description: Molecular Neuroimaging, LLC ("Applicant") seeks authorization to purchase a Positron Emission Tomography/Computed Tomography Scan camera ("PET/CT") and upgrade its facility to accommodate the proposed PET/CT with a total capital expenditure of $589,149.

Procedural History: The Applicant published notice of its intent to file a Certificate of Need ("CON") application in *The New Haven Register* on August 28, 29 and 30, 2014. On November 18, 2014, the Office of Health Care Access ("OHCA") received the initial CON application from the Applicant for the above-referenced project and deemed the application complete on January 20, 2015. OHCA received no responses from the public concerning the Applicant's proposal and no hearing requests were received from the public per Connecticut General Statutes ("Conn. Gen. Stat.") § 19a-639a(e). Deputy Commissioner Brancifort considered the entire record in this matter.

Findings of Fact and Conclusions of Law

To the extent the findings of fact actually represent conclusions of law, they should be so considered, and vice versa. *SAS Inst., Inc., v. S & H Computer Systems, Inc.*, 605 F.Supp. 816 (Md. Tenn. 1985).

1. Molecular Neuroimaging, LLC ("MNI" or "Applicant") is a for-profit research company located at 60 Temple Street in New Haven, Connecticut specializing in the application of biomarkers in drug development for neurodegenerative and neuropsychiatric disorders. Exhibit A, p. 2

2. MNI currently develops and conducts PET and SPECT imaging studies to support early drug development and investigational trials, emphasizing imaging outcome measures for evaluating disease progression. Exhibit A, p. 2

3. MNI provides services across the pre-clinical and clinical spectrum including radioligand[1] development and manufacturing; design and implementation of clinical trials and customized clinical imaging site coordination and management. These research activities are conducted both independently and in collaboration with 30 global pharmaceutical and biotech companies as well as research organizations such as the Michael J. Fox Foundation, the National Institutes of Health ("NIH") and the Department of Defense. Exhibit A, pp. 2-4, 11

4. The Applicant currently operates a Siemens HR Positron Emission Tomography ("PET") scanner and a Pickler International 3000XP Single Photon Emission Computed Tomography ("SPECT") camera. Exhibit A, p. 3

5. PET imaging is an essential component of the Applicant's research, which is focused on developing new therapies for unmet medical needs in neurodegenerative conditions such as Alzheimer's ("AD"), Parkinson's and Huntington's disease. Exhibit A, p. 2

6. AD and Parkinson's disease are the two most common and rapidly expanding neurodegenerative disorders, with 4 million people in the United States being affected by AD and 1 million people affected by Parkinson's disease. It is estimated that over 50 million people worldwide will have some form of dementing illness by 2020. Exhibit A, p. 6

7. The Applicant's existing PET scanner is 13 years old, has limited efficiencies and requires a significant amount of continued maintenance. While afforded the opportunity to perform multiple PET studies, due to the logistics of the use of radiopharmaceuticals and the limitations of its existing equipment, MNI must often delay the initiation of new studies until existing studies are completed. Exhibit A, pp. 3, 7

[1] A radioligand is a radioactive biochemical substance that is used for diagnosis or for research-oriented study of the receptor systems of the body. In a neuroimaging application the radioligand is injected into the pertinent tissue or infused into the bloodstream.

8. The Applicant is seeking to acquire a reconditioned Siemens Biograph 64 slice PET/6 slice CT Positron Emission Tomography/Computed Tomography scanner ("PET/CT").[2] Exhibit A, pp. 4, 195

9. The proposed scanner will be used in research focusing on developing new therapies for neurodegenerative conditions such as AD, Parkinson's and Huntington's diseases, as well as other neurologic and psychiatric disorders including Schizophrenia, Depression, Multiple Sclerosis, and Fragile X Syndrome. Exhibit A, p. 2, 11

10. NIH and pharmaceutical research sponsors require state-of-the art brain pet imaging for their planned clinical studies and researchers must demonstrate the availability of PET imaging to be considered as clinical sites for these studies. Exhibit A, p. 5

11. The development of therapeutics for such diseases relies on large multi-center studies aimed at evaluating the efficacy of drugs. The availability of PET imaging biomarkers is critical in these large clinical studies to ensure an accurate diagnosis and disease progression monitoring. Exhibit A, p. 5

12. The addition of a second, technologically more sophisticated and efficient camera will expand the number of PET slots available to conduct research and increase the number of research scans that can be conducted. Exhibit A, pp. 2-3

13. The proposed scanner will make the scan acquisition process much more efficient. The scan will be obtained in seconds instead of minutes, resulting in minimal scan time and greater comfort for the research subject. Imaging time for whole body studies, where 8-10 bed positions are required, can be reduced by 45-60 minutes. Exhibit A, p. 3

14. The proposed camera's CT component will provide attenuation correction, resulting in additional clarity and offers an improved image of the human anatomy, which is crucial in analyzing PET images. Exhibit A, p. 3

15. The CT component will also allow for several advanced imaging processing methods to be applied to the PET images, most notably, the ability to use the CT image for a highly accurate registration to the research subject's available MRI scan. Exhibit A, p. 3

16. The PET/CT will support the Applicant's translational research,[3] identifying radioligands for use in clinical studies. Exhibit A, p. 4

---

[2] PET/CT scans provide images that pinpoint the anatomic location of abnormal metabolic activity within the body. http://www.radiologyinfo.org/en/pdf/pet.pdf

[3] Translational research is engineering research that aims to make findings from basic science useful for practical applications that enhance human health and well-being. This has been attempted particularly in medicine with translational medicine, research that aims to move "from bench to bedside" or from laboratory experiments through clinical trials to point-of-care patient applications. http://en.wikipedia.org/wiki/Translational_research

17. The Applicant submitted several scholarly articles supporting the increasing role biomarker research/imaging will have in clinical trials. For example, an article "Perspective on the future role of biological markers in clinical therapy trials of Alzheimer's disease: a long range point of view beyond 2020," published in in *Biochemical Pharmacology*, notes that biomarkers appear to be the most promising avenue to scientific advances and may contribute to the progress in development of novel drugs for the treatment of AD and may help demonstrate targeted therapies. Exhibit B, p. 206 and completeness responses dated December 22, 2014.

18. The following table lists existing providers in the area:

TABLE 1
RESEARCH PET/CTS IN AREA

Facility Name	Facility Address	Services	Days/Hours of Operation
Yale University	New Haven, CT	PET/PET CT	*
GE Discovery PET/CT Scanner	New Haven, CT	PET/PET CT	*

Source: CMS.gov; equipment listed as a research site on a PET imaging clinical study on clinicaltrials.gov
*unknown
Exhibit A, p. 8

19. The Applicant's historical and projected utilization is as follows:

TABLE 2
APPLICANT'S HISTORICAL AND PROJECTED UTILIZATION
FISCAL YEARS 2011-2018

			Projected Utilization				
Equipment	FY2012	FY2013	FY 2014*	FY 2015**	FY 2016	FY 2017	FY2018
SPECT	166	187	165	170	170	170	170
PET	148	210	270	280	285	290	290
PET/CT***			0	80	192	225	250
Total	**316**	**397**	**435**	**530**	**647**	**685**	**710**

*Annualized for 2014 based on actual scans January through August 2014
** First year is a partial year for May-December.
***Proposed camera
Note: Base year 2015 estimate of scans developed from current prospect list of new studies (10 scans per month for a total of 80 in 2015). Full year utilization projections based on growth experienced with existing PET scanner, recent experience and market knowledge.
Exhibit A, p. 9; Exhibit B, pp. 209-10

20. The proposal's total capital expenditure is itemized below:

TABLE 3
PROPOSAL CAPITAL EXPENDITURE

Purchase/Lease	Cost
Equipment (Medical, Non-medical Imaging)	$465,000
Construction/Renovation**	$124,149
Total Project Cost	**$589,149**

Exhibit A. p 13

21. Funding will be provided by a line of credit in the amount of $750,000. Exhibit A, p. 14

22. The Applicant will be able to reduce the cost per scan based on the efficiencies yielded from having a second camera with only a modest increase in non-camera costs, such as staffing. A reduced cost per scan will allow MNI to pass savings on to research sponsors. Exhibit A, pp. 14, 16

23. The population to be served by the applicant is study participants involved in research trials for new therapies for neurodegenerative disorders. Exhibit A, p. 6

24. Study participants will primarily include volunteers with neurodegenerative disorders such as AD, Parkinson and Huntington disease and healthy control subjects. All research participants will provide written informed consent in accordance with the Department of Health and Human Services' ("HHS") guidelines and will be compensated for their time as volunteers of the research. Exhibit A, p. 6, 7

25. While the proposal will not have any immediate impact on the quality of health care delivery in the region, the research conducted at MNI will continue to contribute to the development of new diagnostic tools and therapies for patients with neurologic and psychiatric illnesses. Exhibit A, p. 12

26. MNI is exclusively a research company and does not participate in any health care reimbursement programs. Exhibit A. p. 2

27. MNI does not offer any medical services to patients. Exhibit A, p.4

28. The Applicant does not provide direct care to patients and, as such, there will be no change in the patient payer mix. Exhibit A. p. 15

29. The proposed technologically advanced PET imaging camera will further meet the increasing demand for investigational PET imaging studies and will be a critical part of the evaluation

of new therapies for neurodegenerative disorders. It will allow the MNI to meet the demand for PET imaging services for local research investigators and advance PET analysis techniques for worldwide studies. Exhibit A, p. 5

30. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations not yet adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1))

31. This CON application is consistent with the overall goals of the Statewide Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2))

32. The Applicant has established that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3)).

33. The Applicant has demonstrated that its proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4)).

34. The Applicant has satisfactorily demonstrated that its proposal is strictly for research purposes. Therefore, it has no impact on the accessibility and cost effectiveness of health care delivery in the region. However, the proposal has the potential to improve the quality of health care delivery in the region. (Conn. Gen. Stat. § 19a-639(a)(5))

35. The Applicant has shown that there will be no change in access to the provision of health care services to the relevant populations and payer mix since the proposed equipment is strictly for research purposes. (Conn. Gen. Stat. § 19a-639(a)(6))

36. The Applicant has satisfactorily identified the population to be served and has satisfactorily demonstrated that this population has a need. (Conn. Gen. Stat. § 19a-639(a)(7))

37. The utilization of existing health care facilities and health care services in the Applicant's service area is not applicable given that this application pertains to research. (Conn. Gen. Stat. § 19a-639(a)(8))

38. The Applicant has satisfactorily demonstrated that this proposal would not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9)).

39. The Applicant has satisfactorily demonstrated that the proposal will not result in a reduction or change in access to services for Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10))

40. The Applicant has satisfactorily demonstrated that the proposal will have no impact on the diversity of health care providers and patient choices in the geographical region. (Conn. Gen. Stat. § 19a-639(a)(11))

41. The Applicant has satisfactorily demonstrated that the proposal will not result in any consolidation or adversely affect health care cost or accessibility to care. (Conn. Gen. Stat. § 19a-639(a)(12))

Discussion

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in Conn. Gen. Stat. § 19a-639(a). The Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Jones v. Connecticut Medical Examining Board, 309 Conn. 727 (2013).*

Molecular Neuroimaging, LLC ("MNI") is a for-profit research company located at 60 Temple Street in New Haven, Connecticut. MNI specializes in the application of biomarkers in drug development for neurodegenerative and neuropsychiatric disorders. *FF1* More specifically, MNI provides services across the pre-clinical and clinical spectrum, including radioligand development and manufacturing; clinical trial design and implementation as well as clinical imaging site coordination and management. MNI conducts research both independently and in collaboration with 30 global pharmaceutical and biotech companies as well as research organizations such as the Michael J. Fox Foundation, National Institute of Health and the Department of Defense. *FF3*

MNI's imaging studies support early drug development and investigational trials. *FF2* MNI currently operates one PET scanner and one SPECT camera to support its drug development and investigational trials. *FF4* The existing PET scanner is 13 years old and requires a significant amount of continued maintenance. Although MNI has been afforded the opportunity to perform multiple PET studies, due to the logistics involved with the use of radiopharmaceuticals and the limitations of its existing equipment, MNI cannot start the new studies until existing studies are completed. *FF7* Additionally, research sponsors require state-of-the art brain imaging for their clinical studies and researchers must demonstrate the availability of such imaging to be considered as clinical trial sites. *FF10* Moreover, development of pharmaceutical therapies rely on large multi-center studies aimed at evaluating the efficacy of drugs and the availability of imaging biomarkers is critical to ensure an accurate diagnosis and disease progression monitoring. *FF11*

The Applicant is seeking to acquire a 64 slice PET/6 slice CT Positron Emission Tomography-Computed Tomography scanner ("PET/CT"). *FF8* The proposed scanner's CT component will provide attenuation correction, resulting in additional clarity and an improved image of the human anatomy. *FF14* The scanner's CT component will also allow for several advanced imaging processing methods to be applied to the PET images, most notably, the ability to use the CT image for a highly accurate registration to the research subject's available MRI scan. *FF15* In addition, the PET/CT will allow for a more rapid image acquisition process that will result in shorter scan time and greater comfort for research subjects. *FF13* With the addition of the PET/CT scanner, the Applicant will have the ability to increase the number and quality of the scans acquired while performing more studies simultaneously. *FF12*

Because the PET/CT will be used for research purposes only and not for the delivery of health care services, the proposal has no impact on existing service providers in the area. *FF18, 27*

Likewise, it will not have an impact on the services provided to the Medicaid population. *FF 28* It will, however, indirectly benefit the state's population by helping to meet the demand for investigational PET imaging studies and the evaluation of new diagnostic tools and therapies for patients with neurodegenerative disorders. *FF7,16,17,23,25*

Acquisition of the PET/CT scanner will allow MNI to increase the number of its research scans, thus reducing the research cost of a scan. MNI will pass those savings along to its sponsors. *FF22* This has the potential to encourage an increased number of sponsored research studies thereby leading to new scientific knowledge and the hastening of improved treatments for diseases.

Both Alzheimer's and Parkinson's disease are two of the most common and rapidly increasing neurodegenerative disorders in the United States. *FF6* Research imaging is a critical tool in the development of new therapies for these and other neurologic and psychiatric disorders, including Huntington's disease, Schizophrenia, Depression, Multiple Sclerosis and Fragile X Syndrome. *FF5,9* MNI's research efforts will enhance knowledge about such disorders and have the potential to improve future treatment and quality of life outcomes for individuals suffering from these disorders. Therefore, OHCA concludes the Applicant has demonstrated a clear public need for the proposal.

Order

Based upon the foregoing Findings of Fact and Discussion, the Certificate of Need application of Molecular Neuroimaging, LLC for the acquisition of a PET/CT scanner is hereby **approved**.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the
Department of Public Health
Office of Health Care Access

April 9, 2015
Date

Janet M. Brancifort
Janet M. Brancifort, MPH
Deputy Commissioner

* * * Communication Result Report (Apr. 9. 2015 5:36PM) * * *

1) OHCA-98604187054
2)

Date/Time: Apr. 9. 2015 5:34PM

File No.	Mode	Destination	Pg(s)	Result	Page Not Sent
0132	Memory TX OHCA	912034014304	P. 12	OK	

Reason for error
E. 1) Hang up or line fail
E. 2) Busy
E. 3) No answer
E. 4) No facsimile connection
E. 5) Exceeded max. E-mail size
E. 6) Destination does not support IP-Fax

STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: KIMBERLY FABRIZIO

FAX: 203.508.1503 203.401.4304

AGENCY: MNI

FROM: OHCA

DATE: 4/09/15 **Time:**

NUMBER OF PAGES: 2
(including transmittal sheet

Comments:
Docket Number: 14-31965

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS

Phone: (860) 418-7001 *Fax: (860) 418-7053*

410 Capitol Ave., MS#13HCA
P.O.Box 340308
Hartford, CT 06134