



## Office of Health Care Access

### Report of Investigative Proceeding and Certificate of Need Determination

**Subject Title:** An Investigation into the acquisition of a PET scanner and/or PET-CT scanner and related costs, and the acquisition of a CT scanner for 2660 Main Street, Bridgeport practice location of Robert D. Russo, M.D. & Associates Radiology, P.C.

**Docket Numbers:** 06-30865-VST for the Investigative Proceeding and 06-30781-DTR for the Certificate of Need Determination

**Statutory Reference:** Section 19a-633 of the Connecticut General Statutes

**Proceeding Date:** December 12, 2006

**Presiding Officer:** Cristine A. Vogel

**Date of OHCA Report:** April 4, 2007

**Project Description:** An investigation into the acquisition of a PET scanner and/or PET-CT scanner and related costs and the acquisition of a CT scanner for 2660 Main Street, Bridgeport practice location of Robert D. Russo, M.D. & Associates Radiology, P.C.

**Nature of Proceedings:** On June 6, 2006, OHCA commenced a Certificate of Need ("CON") determination process as it had come to OHCA's attention that Robert D. Russo, M.D. & Associates Radiology, P.C was providing PET/CT services at its 2660 Main Street Bridgeport location. On November 9, 2006, pursuant to Section 19a-633 of the Connecticut General Statutes ("C.G.S."), the Office of Health Care Access ("OHCA") initiated an investigation into the acquisition of a PET scanner and/or PET-CT scanner and related costs and the acquisition of a CT scanner for 2660 Main Street, Bridgeport practice location of Robert D. Russo, M.D. & Associates Radiology, P.C. ("Russo MD PC"). Pursuant to Section 19a-633, C.G.S., OHCA may conduct any inquiry, investigation or hearing under the provisions of Chapter 368z, C.G.S.

On December 12, 2006, OHCA conducted an investigative proceeding regarding this subject matter. A notice of this investigative proceeding was provided to Russo, MD PC and to General Electric Company (“GE”). OHCA specifically requested the participation of GE in this investigative proceeding. The CON determination process remained pending under Report Number 06-30781-DTR throughout the Investigation held under Docket Number 06-30865-VST. Commissioner Cristine A. Vogel received testimony from Russo MD PC and GE as allowed by 19a-633, C.G.S.

## Findings of Fact

1. In a February 14, 2003 CON authorization, OHCA approved the proposal of Russo MD PC for the acquisition of three replacement CT<sup>1</sup> scanners under Docket Number (“DN”) 02-556. At the time of the CON review and authorization, Russo MD PC proposed to acquire three Phillips Medical Systems MX 8000 CT scanners at a per unit cost of \$703,995. The three replacement scanners were authorized to be located at 2660 Main Street in Bridgeport, 2909 Main Street in Stratford and 1261 Post Road in Fairfield. Condition #1 of the authorization required Russo MD PC to complete the project by February 28, 2005. (*September 12, 2002 Letter of Intent and CON decision under DN 02-556*)
2. Two of the authorized replacement CT scanners were placed in service prior to the CON expiration date; in August of 2003 in Fairfield and in January 2004 in Stratford. Russo MD PC acquired a Phillips MX 8000 unit for the Stratford location. Russo MD PC did not acquire a Phillips unit for the Fairfield location and instead acquired a General Electric (GE) LightSpeed 16 CT unit for Fairfield<sup>2</sup>. (*January 26, 2004 submission from Russo MD PC under DN 02-556 and the December 8, 2006 response to Interrogatories under Docket Number 06- 30865-VST*)

---

<sup>1</sup> Computed Tomography (CT) is a radiographic technique that produces an image of detailed cross section of tissue. Computed tomography uses a narrowly collimated beam of x-rays that rotates in a full arc around the patient to image the body in cross-sectional slices. The image is created by a computer that uses multiple attenuation readings taken around the periphery of the body part. The computer calculates tissue absorption and produces a representation of the tissues that demonstrates the densities of the various structures. Tumor masses, infarctions, bone displacement and accumulations of fluid may be detected.  
(Source: Mosby’s Medical Dictionary, seventh edition, 2006)

<sup>2</sup> The CON order was not specific regarding the particular CT scanners which must be acquired and OHCA authorized a cumulative project capital expenditure for all three CT scanners of \$2,211,985 (including renovation costs) rather than a cost per unit.  
(Source: CON decision for Docket Number 02-556)

3. On February 17, 2004, Russo MD PC filed a Letter of Intent to replace an “*approved CT Scanner with a Positron Emission Tomography*” unit at 2660 Main Street in Bridgeport. Russo MD PC indicated that it was proposing to acquire a GE Advance NXI PET<sup>3</sup> Scanner at a cost per unit of \$1,682,249. Russo MD PC filed an equipment quote dated December 18, 2003 for this new PET system. On July 16, 2004, the CON application was filed under DN 04-30252-CON. (*February 17, 2004 LOI and July 16, 2004 CON application under DN04-30252-CON*)
4. In the cover letter to the CON application under DN 04-30252-CON, Russo MD PC stated that “*our original intention was to acquire a PET Scanner, however, since we were approved for a replacement CT Scanner under Docket #02-556 for the replacement of three (3) CT Scanners and we have replaced only two (2) of those scanners, we feel the most efficient way to update our equipment to state of the art is to replace the third CT Scanner with a PET-CT<sup>4</sup> Scanner. Since we will use the PET-CT Scanner in its capacity as a separate PET and CT Scanners, we do not think this modification significantly alters our Letter of Intent*”. (*July 16, 2004 CON application under DN 04-30252-CON and CON decision under Docket Number 02-566*)
5. In the CON application under DN 04-30252-CON, Russo MD PC submitted a GE price quotation dated June 28, 2004 for a Discovery ST-8 Slice PET/CT Scanner, described as “*a State-of-the-art Computed Tomography and Positron Emission Tomography Scanner. The System Combines High Performance 8-slice CT with High Performance PET ...*” It further stated that it “*can be used as an integrated PET/CT scanner or as a standalone high quality diagnostic CT scanner ...*” “*It supports multiple sequencing protocols including the PET/CT protocol where CT acquisition is immediately followed by PET acquisition.*” The quote for the GE Discovery ST-8 Scanner listed PET subsystem components and CT Subsystem components separately. (*Pages 149 – 162 of the CON application under 04-30252-CON*)

---

<sup>3</sup> Positron Emission Tomography (PET) is a computerized radiographic technique that uses radioactive substances to examine the metabolic activity of various body structures. The patient either inhales or is injected with a metabolically important substance such as glucose, carrying a radioactive element that emits positively charged particles, or positrons. When the positrons combine with electrons normally found in the cells of the body, gamma rays are emitted. The electronic circuitry and computers of the PET device detect the gamma rays and construct color-coded images that indicate the intensity of the metabolic activity throughout the organ involved. (Source: Mosby’s Medical Dictionary, seventh edition, 2006)

<sup>4</sup> PET/CT is an imaging technology that combines PET and CT in a single device and provides simultaneous structural and metabolic (biochemical) information under almost identical conditions. The CT data are used (1) to calculate the attenuation correction for the PET scan and (2) to provide anatomic information for comparison with the PET scan. (Source: Schoder, H., PET/CT: A New Imaging Technology in Nuclear Medicine, Eur. J. Nucl. Med. Mol. Imaging, October 2003, Vol. 30, No. 10, 1419-1437 (as cited by Russo MD PC in 04-30252-CON).

6. On January 26, 2005, Russo MD PC filed with OHCA, a request to modify the CON under DN 02-556 and extend the CON expiration date from February 28, 2005 to June 28, 2005<sup>5</sup>. Russo MD PC indicated in its rationale that it *“would like to augment the third CT scanner with a PET and implementation is pending determination of DN 04-30252-CON”*. Russo MD PC noted that *“it is our intent to follow through with the upgrade of the new CT scanner in Bridgeport as authorized under DN 02-556 irrespective of whether or not the PET under DN 04-30252-CON is approved.”*<sup>6</sup> (January 26, 2005 modification request under DN 05-22929-MDF)
7. The following statements were made by Russo MD PC during the CON application and hearing process under DN 04-30252-CON:
  - *“The Applicant will use the requested equipment more for CTs and PETs separately than for combined PET/CTs.”*
  - *“The Applicant wishes to upgrade the existing CT scanner in Bridgeport with a PET/CT by ‘snapping-on’ the PET capability. This allows the scanner to be used as a CT scanner and a PET scanner separately, as well as a PET/CT. The advancements in technology would permit the Applicant to add PET capability to a CT scanner in a more cost effective manner rather than purchasing a separate piece of equipment.”*
  - *“It is important to reiterate here that the Applicant is seeking a PET, in an effort to ‘snap-on’ to the existing CT. This will enable the Applicant to do CTs and PETs separately and PET-CTs when appropriate ... “we do feel it is essential to be positioned for the future for PET-CT when this modality becomes the community standard.”*
  - Russo MD PC did *“not wish to project a PET CT scan volume ... ”* and that *“As the Applicant has previously stated, the Applicant’s request is to be able to perform PET.”*<sup>7</sup>
8. When asked at the public hearing for DN 04-30252-CON held on May 12, 2005, to explain the term “snapping on” as used throughout the CON application, Russo MD PC indicates that that term goes back to the original CT scanner replacement CON and he planned to snap on a PET to the CT to become a PET CT unit, but Dr. Russo indicated at the public hearing that *“As you can see by the documents, it is one unit, it’s a PET-CT scanner”*<sup>8</sup> (Testimony of Robert D. Russo, M.D. at the May 12, 2005 public hearing)

---

<sup>5</sup> A previous request of Russo MD PC for a modification of the CON under DN 02-556 had been denied by OHCA on January 4, 2005.

<sup>6</sup> On February 24, 2005, OHCA granted the modification of DN 02-556 and allowed Russo MD PC until June 28, 2005 to complete the acquisition of the previously authorized replacement CT scanner.

<sup>7</sup> On May 10, 2005, two days prior to the public hearing, Russo MD PC filed utilization projections for this CON which included for the first time, CT, PET and PET-CT projections. (May 10, 2005 Additional Prefile Testimony of DN 04-30252-CON)

<sup>8</sup> OHCA notes that at no time during the CON or hearing process for DN 04-30252-CON, did Russo MD PC indicate to OHCA that Russo MD PC was simultaneously pursuing and obtaining a preowned PET subsystem.

9. On June 10, 2005, OHCA denied Russo MD PC's CON application under DN 04-30252-CON to acquire a fixed PET/CT scanner for its Bridgeport office. (*CON DN 04-30252-CON*) Russo MD PC did not appeal from the denial of its CON application.
10. On June 29, 2005, Russo MD PC informed OHCA that the CT scanner authorized under DN 02-556 for the Bridgeport location "*became operational on June 27, 2005 when the first exam was performed.*" (June 29, 2005 letter from Russo MD PC under DN 02-556)
11. Under a Certificate of Need Determination process initiated by OHCA under Docket Number 06-30781-DTR on June 6, 2006 and an Investigative Proceeding initiated by OHCA under Docket Number 06-30865-VST, OHCA has gathered information regarding the fact that Russo MD PC had "*negotiated the separate purchase of a used PET to be delivered and installed at the 2660 Main Street site. This new CT and used PET is the combination in place at 2660 Main Street Bridgeport.*" (June 16, 2006 letter from Russo MD PC to OHCA)
12. Russo MD PC filed a Price Quotation for the preowned PET unit dated and accepted by Russo MD PC on May 5, 2005<sup>9</sup>. The unit is described as a preowned GE GoldSeal Advance NX/i PET Imaging System, which is a "*State of the Art Whole Body PET Camera System*". The Total Net Equipment Selling Price for this unit is listed as \$375,005 in the equipment quote. (June 16, 2006 letter from Russo MD PC to OHCA)
13. Russo MD PC also filed a GE price quotation for a CT scanner dated May 6, 2005 which describes that product as a "*CT Addition to Nxi PET Scanner System*" which is an "*Upgrade from Advance to the Discovery LS4*" and has a Total Net Equipment Selling Price of \$649,989. That quotation was accepted by Russo MD PC on May 6, 2005. It includes a LightSpeed Plus 4 Slice CT Subsystem. The quotation indicates that the "*Combined Scanner is Capable of Operating in PET/CT, PET and CT Operating Modes.*" (October 6, 2006 submission under Report Number 06-30781-DTR)
14. Russo MD PC indicates that the CT unit and the PET unit, both manufactured by GE, "*can be integrated in the field, without additional capital expenditure, by connecting the PET to the back of the CT gantry*". Russo MD PC further indicates that GE refers to the two integrated machines as the DISCOVERY LS system and that "*Notwithstanding this unified nomenclature, the CT and the PET scanners remain independently operable. The CT portion functions just as a LIGHTSPEED CT with the exception of  $\pm 30$  degree tilt. The ADVANCE NX/I PET operates independently of the CT and it can use 2 10mCi Ge (Germanium) lines for attenuation correction.*" (December 8, 2006 Response to Interrogatories)
15. GE had testified at the investigative proceeding that the Advance Nxi PET system is a standalone machine. GE further testified that once you have the tool (referring to PET/CT) it will be used as a PET/CT scanner; not individually as a PET scanner. (*Testimony of GE representative at Investigative Proceeding*)

---

<sup>9</sup> There is no indication in the filing what year this "preowned" PET was manufactured or whether it was used by another healthcare provider for PET only or was connected to a CT system to operate as a unified PET-CT unit.

16. GE testified that although the units can operate independently, they were designed always to be combined. *(Testimony of GE representative at Investigative Proceeding)*
17. At the investigative proceeding, the representative from GE was asked what is meant by the references to “snapping on” the pieces of equipment. GE explained that under the covers they are two separate units, the LightSpeed CT and Advance PET; the consoles are attached and can do CT, then PET. These units were developed as stand alone units. The only integration that was done is a new cover, longer table, and software. GE moves together the ring shaped objects and the units “talk to each other” and are “aligned on the same axis”. *(Testimony of GE representative at Investigative Proceeding)*
18. Dr. Russo stated at the proceeding that stand-alone PET, as a modality, has changed; where once PET was the choice for cardiac, neuro, and other indications, currently PET/CT is the modality of choice. This change was due to reimbursement. *(Testimony of Dr. Russo at Investigative Proceeding)*
19. The GE LightSpeed CT scanner, the Advance NXi PET scanner and the combined or integrated GE Discovery LS PET/CT system each have separate clearance approval from the US Food and Drug Administration. *(Testimony of GE representative at Investigative Proceeding)*
20. In a July 19, 2005 letter filed by Russo MD PC with OHCA, GE states that the “system was initially installed as an NXI CT scanner which was completed on June 19, 2005 and was then upgraded to the Discovery LS PET/CT system. The PET/CT system was installed ... and ready for first patient use on June 24, 2005.” *(File under 06-30781-DTR)*
21. The PET scanner was shipped to Russo MD PC on June 10, 2005 and arrived on June 14, 2005. *(December 15, 2006 submission of information from General Electric)*
22. In addition to the PET acquisition price of \$375,000 as noted in the GE price quotation, Russo MD PC also incurred \$1,600 in renovation costs related to the installation of the PET component. The lead shielding was already owned by Russo MD PC and previously used at another office location. Sales tax on these renovation costs was \$96.00. *(December 8, 2006 Response to Interrogatories)*

23. Russo MD PC provided to OHCA certain actual utilization statistics for the past year for the CT, PET and PET-CT services at the Bridgeport office location<sup>10</sup>. The utilization statistics are as follows:

	<b>June 2005 – June 2006 (full year)</b>	<b>June 2006 – November 2006 (five month period)</b>
<b>CT Scans</b>	1,242	806
<b>PET Scans</b>	0	0
<b>PET/CT Scans</b>	272	145

*(Unredacted Interrogatories filed December 8, 2006)*

24. GE confirmed at the Investigative Proceeding that only a GE LightSpeed CT unit and a GE Advance PET unit can be combined to become the integrated Discovery LS PET/CT unit and that no other manufacturer's products (such as a Phillips MX 8000) would be compatible or could be used in this integration. *(GE Representative testimony at the Investigational Proceeding)*

---

<sup>10</sup> Russo MD PC states in its December 8, 2006 response to interrogatories that "All figures associated with volume and frequency of service are proprietary and confidential trade secrets which cannot be disclosed nor subjected to Freedom on Information Act requests." Actual volume statistics are typically and frequently filed with OHCA by Applicants (including Russo MD PC) as part of the CON process and other processes before OHCA and are not considered by OHCA to be either proprietary or confidential trade secrets. All information filed by Russo MD PC on December 8, 2006 is part of this record and is available under the Freedom of Information Act.

## Discussion and Conclusions

The main purpose and intent of the processes undertaken by OHCA under CON Determination Report Number 30781-DTR and Investigative Proceeding under Docket Number 06-30865-VST was to gather and assess pertinent facts regarding the acquisition of the imaging equipment in question and to ascertain whether such acquisition was within or was in violation of the State Statutes which OHCA is mandated to oversee and enforce. The following is a discussion of these processes and OHCA's conclusion.

Dr. Russo demonstrated his intention to be a provider of PET/CT in 2004. This is clear from the CON application and hearing process undertaken under Docket Number 04-30252-CON. OHCA believes that it has been Russo MD PC's intent since 2004 to acquire and operate a PET/CT system, whether purchased as one unit (with one price quotation such as filed under DN 04-30252-CON) or purchased separately (with two separate price quotation and purchase orders, which is the approach used by Russo MD PC) and operated as one integrated PET/CT unit.

The original CT scanner which Russo MD PC sought under DN02-556 was a Phillips MX8000. Subsequent to that CON authorization, which was based on a proposal to acquire that Phillips unit, Russo MD PC sought a GE CT scanner which is the specific scanning equipment that is the CT component of the GE Discovery LS PET/CT unit. GE has indicated that equipment produced by another equipment vendor cannot be integrated with the GE Advance Nxi PET system to become the integrated Discovery LS PET/CT unit. GE testified that GE developed the technology to be able to combine an existing CT and an existing PET by removing the "covers" and combining the technology so the two units are aligned in the same axis and the patient remains on the same table. GE testified that although the units can operate independently, they were designed "always" to be combined.

GE did testify that the Advance Nxi PET system is a standalone machine. Dr. Russo stated at the proceeding that stand-alone PET, as a modality, has changed; where once PET was the choice for cardiac, neuro, etc., currently PET/CT is the modality of choice. This change is due to reimbursement. GE testified at the proceeding that once you have the tool (referring to PET/CT) it will be used as a PET/CT scanner; not individually as a PET scanner and a CT scanner. Despite this, Russo MD PC is asking OHCA to consider only the cost of the PET unit (PET subsystem of the Discovery LS PET/CT) merely by virtue of the fact that he had negotiated and entered into agreement with GE to purchase the two subcomponents separately, rather than as a single unit. Yet, it is clear that this is an integrated system and that Russo MD PC is using it as an integrated system. Russo MD PC has provided utilization volumes by modality which demonstrates the actual utilization of the CT function and of the combined PET/CT function; however, there have been no PET scans performed in the 17 months of data submitted.

OHCA acknowledges that GE allows the Lightspeed CT and the Advance Nxi PET to be purchased separately and that each unit can be operated independently of each other, yet the record demonstrates that the technology has been combined in a way to produce an integrated function, namely PET/CT and that this is the function that is being used. The equipment has never been used solely for PET studies. Therefore, it is apparent that Dr. Russo is operating a PET/CT system, not a PET scanner. PET/CT technology is a separate and distinct technology from PET technology alone or CT technology alone. This clear distinction has been recognized at both the federal<sup>11</sup> and state<sup>12</sup> level of government. Despite Russo MD PC's attempt to enter into contracts with his equipment vendor to allow for these two pieces of equipment to be obtained separately (noting that this occurred within one day of the other) Russo MD PC is clearly in possession of and is operating a PET/CT unit and recording PET/CT utilization statistics.

Based on the above, OHCA concludes that Russo MD PC has acquired this PET/CT unit in violation of the Certificate of Need laws in this State, since Russo MD PC has not received OHCA approval to acquire a PET/CT scanner, and, in fact was denied approval to acquire a PET/CT scanner on June 10, 2005 under Docket Number 04-30252-CON. Russo MD PC may continue to operate the CT scanner authorized under Docket Number 02-556, as modified by Docket Number 04-30252-CON as a stand alone CT scanner. Russo MD PC may continue to operate the GoldSeal Advance NX/I PET Imaging System that was acquired for \$375,004.60 pursuant to the GE Medical Systems quotation Number LTQCBJA dated May 5, 2005 as a stand alone PET scanner. The two pieces of equipment **may not be combined and/or integrated** as a PET/CT unit without first obtaining CON authorization from OHCA.

---

<sup>11</sup> According to the U.S. Federal Register, PET-CT is reimbursed (for CY 2007) differently from PET. The U.S. Department of Health and Human Services assigns PET/CT scans a different APC with a higher payment than PET to maintain the approximately \$100 difference between payments for these services and non-myocardial PET scans. "In this way, the differential payment between conventional PET and PET/CT scans will be preserved at an appropriate level." (Source: Federal Register/Vol. 71. No. 226/ Friday, November 24, 2006.)

<sup>12</sup> Conn. Gen. Stat. § 19a-639 (c) expressly requires CON authorization separately for CT scanners, PET scanners and PET/CT scanners.

Russo MD PC must provide evidence that the required separation of the CT scanner from the PET scanner has occurred by no later than Friday, April 20, 2007. Should this evidence not be provided by that date, OHCA fully reserves the right to take any and all further enforcement actions regarding this matter.

*Signed by Commissioner Vogel on April 4, 2007*

---

Date

---

Cristine A. Vogel  
Commissioner