

## Office of Health Care Access Certificate of Need Application

### **Final Decision**

**Applicant:** University of Connecticut Health Center,

**School of Dental Medicine** 

Docket Number: 06-30866-CON

**Project Title:** Acquisition and Operation of a Hitachi CB

MercuRay Maxillofacial Digital Imaging

System

**Statutory Reference:** Section 19a-639, Connecticut General Statutes

Filing Date: March 14, 2007

Decision Date: May 31, 2007

Default Date: June 12, 2007

Staff: Laurie K. Greci

**Project Description:** The University of Connecticut Health Center, School of Dental Medicine ("Applicant" or "SoDM") proposes to acquire and operate a Hitachi CB MercuRay Maxillofacial Digital Imaging System at a total capital expenditure of \$326,500.

**Nature of Proceedings:** On March 14, 2007, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application of The University of Connecticut Health Center, School of Dental Medicine ("Applicant" or "SoDM") seeking authorization to acquire and operate a Hitachi CB MercuRay Maxillofacial Digital Imaging System at a total capital expenditure of \$326,500. The Applicant is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

A notice to the public regarding OHCA's receipt of the Applicant's Letter of Intent to file its CON Application was published on December 16, 2007, in the *Hartford Courant*. OHCA received no responses from the public concerning the Applicant's proposal. Pursuant to 19a-639, three individuals or an individual representing an entity with five or more people had

until April 4, 2007, the twenty-first calendar day following the filing of the Applicant's CON Application, to request that OHCA hold a public hearing on the Applicant's proposal. OHCA received no hearing requests from the public by April 4, 2007.

OHCA's authority to review and approve, modify or deny this proposal is established by Section 19a-639, C.G.S. The provisions of this section as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

### **Findings of Fact**

Clear Public Need
Impact on the Applicant's Current Utilization Statistics
Contribution of the Proposal to the Accessibility and Quality of
Health Care Delivery in the Region

- 1. The School of Dental Medicine ("Applicant" or "SoDM") is the dental school of the University of Connecticut. It is located on the campus of the University of Connecticut Health Center ("UCHC") at 263 Farmington Avenue, Farmington, Connecticut. It is licensed by the State of Connecticut Department of Public Health as an outpatient clinic for the provision of dental services. (February 28, 2007, Initial CON Submission, page 162)
- 2. The SoDM is the largest single provider of dental services in the State of Connecticut. It provided more than 112,000 patients visits in Calendar Year 2006, with 60,000 visits by Medicaid enrolled dental patients. It provides oral health care services to underserved communities in the State. It is the only teaching and research institution in the state for dental medicine. (February 28, 2007, Initial CON Submission, pages 10 and 16)
- 3. The SoDM plans to establish a Center for Implant and Reconstructive Dentistry that will allow for all dental implant services to come together in one location. It will integrate clinical research and patient care. (February 28, 2007, Initial CON Submission, page 2)
- 4. The UCHC's primary service area includes the following towns: Avon, Bloomfield, Burlington, Canton, East Hartford, Farmington, Granby, Hartford, New Britain, Newington, Simsbury, and West Hartford. (February 28, 2007, Initial CON Submission, page 4)
- 5. The UCHC's secondary service area includes the following towns: Barkhamsted, Berlin, Bozrah, Bristol, Cromwell, East Granby, East Windsor, Glastonbury, Hartland, Harwinton, Litchfield, Manchester, New Hartford, Plainville, Plymouth, Rocky Hill, South Windsor, Southington, Torrington, Vernon, Wethersfield, Winchester, and Windsor. (February 28, 2007, Initial CON Submission, page 4)

<sup>1</sup> A dental implant is an artificial root that is placed into the jaw to hold a replacement tooth. The conventional treatment is often crowns and bridges.

- 6. The Applicant proposes to acquire and operate a Hitachi CB MercuRay Digital Imaging System ("CB MercuRay") to provide panoramic radiograph images. The CB MercuRay is a cone-beam volumetric tomography unit designed for dento-maxillofacial applications. It provides high resolution images of the jaws with high geometric accuracy with a short imaging time of approximately 10 to 20 seconds. The three-dimensional volumetric data can be used to generate computed tomographic images in any plane. (February 28, 2007, Initial CON Submission, page 3)
- 7. The Applicant stated that the proposal will:
  - provide high-resolution images of the jaws with high geometric accuracy in a short imaging time;
  - alleviate the need to use a multi-slice CT thus reducing the amount of radiation a patient is exposed to during the scan;
  - provide the superior spatial resolutions needed to make measurements; and
  - provide high-quality and high resolution images for research and clinical studies. (February 28, 2007, Initial CON Submission, pages 3 and 4)
- 8. The Applicant proposes to use the CB MercuRay in more complex implant restoration cases where determining the implant receptor sites and making measurement to choose an appropriate implant size are critical to a successful restoration outcome. Implant receptor sites rely on the available bone, the density of the bone, and the avoidance of important anatomical structures. The CB MercuRay will also be used for the treatment planning for pre- and post-operative assessment of jaw fractures, maxillofacial development defects, and intrabony pathology. (February 28, 2007, Initial CON Submission, pages 2 to 4)
- 9. The CB MercuRay will enable the School of Dental Medicine's dental students and postgraduate residents to be trained in the latest dental technology. They will receive training in the operation of the scanner, the manipulation of the digital data, and in the interpretation of the images acquired. (February 28, 2007, Initial CON Submission, page 15)
- 10. The CB MercuRay is an essential tool for the SoDM's research programs. The CB MercuRay will provide baseline, pre-surgical imaging for a large NIH-funded clinical study to evaluate the influence of osteoporosis on the success of alveolar bone augmentation and dental implant placement. The study received funding in September 2006 and requires the recruitment of post-menopausal women. (February 28, 2007, Initial CON Submission, pages 4 and 16)
- 11. The SoDM's Department of Oral Rehabilitation, Biomaterials, and Skeletal Development has an approved grant-funded research project sponsored by the National Institute of Dental and Craniofacial Research to study the clinical methods for regenerating bone associated with dental implants. It is a five-year study where the research subjects will receive four CB MercuRay scans in each of the first three years and one scan in each of the last two years. (February 28, 2007, Initial CON Submission, page 9)

12. The University Dentists Implant Patients, Procedures, and Radiographic Dental Exams by Fiscal Year are reported in the following table:

Table 1: Actual Utilization for Implant Patients by Fiscal Year

	Procedures (Patients)			
Type of Case or Scan	FY 2004	FY 2005	FY 2006	FY 2007*
Surgical Cases	69 (34)	90 (44)	144 (68)	216 (104)
Reconstructive Cases	62 (43)	84 (72)	142 (100)	252 (162)
Total Cases	131 (77)	174 (116)	286 (168)	468 (266)
Radiographic Scans**:				
Panoramic	16	21	19	28
Tomographic	9	10	14	31
Periapical	61	97	142	286
Total Scans	86	128	175	345

<sup>\*</sup> Annualized.

- 13. The SoDM estimates that by the fourth year of operations, 75% of patients requiring oral and maxillofacial surgery will be candidates to receive a cone beam scan. (February 28, 2007, Initial CON Submission, pages 8 and 9)
- 14. The number of scans that the Applicant projects to be performed during the first three years of operation is summarized in the following table:

Table 2: Number of CB-DIS Scans by Fiscal Year and Referral Source

Referral Source:	FY 2008*	FY 2009	FY 2010	FY 2011
New University Dentists Implant Cases	992	1,309	1,440	1,584
Oral/Maxillofacial Surgery Cases	37	63	89	133
Osteoporosis/Implant Study	160	160	160	40
Referrals from School of Dental Medicine	125	165	182	200
Referrals from community dentists	83	110	121	133
Total	1,397	1,807	1,991	2,090

<sup>\*</sup> Fiscal year is July 1 to June 30. Expected start of proposal is September 1, 2007. SoDM estimates the CB MercuRay will replace 50% to 75% of CT scans, 100% of tomographs, and 70% of the panoramic radiographs. It will not replace periapical radiographs, though a follow-up CB MercuRay scan may be performed.

(February 28, 2007, Initial CON Submission, page 8 and March 22, 2007, E-mail Response, Attachment 1)

<sup>\*\*</sup> Panoramic radiographs provide a broad coverage of upper and lower jaws on a single film. Tomographic scans, also referred to as cross-sectional radiographs are slices of 3 to 5 mm thick of the maxilla or mandible taken by a special complex motion tomographic unit. Periapical scans show several entire teeth, including crowns and all of the roots and some of the surrounding tissues on one small film taken with a dental x-ray unit.

(March 4, 2007, Supplemental Submission, page 5)

15. The Applicant maintains and adheres to the practice guidelines outlined by the American Academy of Oral and Maxillofacial Radiology. (February 28, 2007, Initial CON Submission, page 11)

# Financial Feasibility of the Proposal and its Impact on the Applicant's Rates and Financial Condition Impact of the Proposal on the Interests of Consumers of Health Care Services and Payers for Such Services Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines

16. The total capital expenditure of \$326,500 for the proposal consists of the following components:

**Table 3: Total Proposed Capital Expenditure** 

Component	Cost
Medical Equipment (Purchase)	\$265,000
Construction/Renovation	61,500
Total Capital Expenditure	\$326,500

(February 28, 2007, Initial CON Submission, page 18)

- 17. The proposal involves the renovation and expansion of an existing dental suite. (*November 15, 2006, CON Determination Form, page 6*)
- 18. The proposal will be financed with operating funds of \$326,500. (February 28, 2007, Initial CON Submission, page 19)
- 19. The Applicant projects the following incremental revenues and expenses from operations with the proposal:

Table 4: Proposed Incremental Revenues and Expenses with the Proposal by Fiscal Year

Incremental	FY 2008	FY 2009	FY 2010
Net Patient Revenue	\$261,709	\$338,614	\$373,181
Operate Expenses	233,888	37,500	341,195
Gain from Operations	\$ 27,821	\$ 21,114	\$ 31,986

(February 28, 2007, Initial CON Submission, page 312)

- 20. The CB-DIS is expected to become operational in August 2007. (February 28, 2007, Initial CON Submission, page 313)
- 21. A new cost center will be established and the University Dentists will bill for the service. (February 28, 2007, Initial CON Submission, page 192)

22. The following table reports the projected payer mix for the proposal:

**Table 6: The Payer Mix for the Proposal** 

Payer	Current	FY 2008	FY 2009	FY 2010
Medicare	3.9	3.8	3.8	3.8
Medicaid	14.9	14.5	14.4	14.4
<b>Total Government</b>	18.8	13.3	18.2	18.3
Commercial	50.5	48.2	47.8	47.6
Self Pay and Uninsured	30.7	33.6	34.0	34.2
<b>Total Non-Government</b>	81.2	81.7	81.8	81.9
Total	100	100	100	100

(February 28, 2007, Initial CON Submission, page 312)

- 23. Most insurers do not cover dental implant treatment, tomograms, or other procedures examinations performed during implant treatment planning. Currently, Medicare does not reimburse for dental services. It is not expected that the cone beam scan will be covered. Cone beam scans performed for medically necessary evaluations of facial trauma and pathology will be covered by medical insurance. (*March 14*, 2007, *Supplemental Submission*, page 1)
- 24. Patients participating in research studies will not be charged for any diagnostic or examination procedures including biochemical markers, imaging procedures, or clinical examinations. (March 14, 2007, Supplemental Submission, page 1)
- 25. The UCHC provides a reduce cost rate for medically necessary services incurred by State of Connecticut legal residents whose household income does not exceed 250% of the Federal Income Poverty Guidelines for a family unit. (March 14, 2007, Supplemental Submission, page 4)
- 26. There is no State Health Plan in existence at this time. (February 28, 2007, Initial CON Submission, page 2)
- 27. The Applicant has adduced evidence that this proposal is consistent with its long-range plan. (February 28, 2007, Initial CON Submission, page 3)
- 28. The Applicant participates in energy conservation and group purchasing to improve productivity and contain costs. (February 28, 2007, Initial CON Submission, page 15)
- 29. The Applicant has a major commitment to the teaching of dental students, residents, and post-graduates. (February 28, 2007, Initial CON Submission, page 15)
- 30. Because of the Applicant's association with the UCHC, the patient population is geographically diverse. Because of the subspecialty mixes of the faculty of the SoDM, the patient population is also clinically diverse. (February 28, 2007, Initial CON Submission, page 27)

- 31. The Applicant has sufficient technical and managerial competence to provide efficient and adequate services to the public. (*February 28, 2007, Initial CON Submission, Exhibit 5*)
- 32. The Applicant's rates are sufficient to cover the proposed capital expenditure and operating costs. (February 28, 2007, Initial CON Submission, pages 188 and 190)

### Rationale

The Office of Health Care Access ("OHCA") approaches community and regional need for Certificate of Need ("CON") proposals on a case by case basis. CON applications do not lend themselves to general applicability due to a variety of factors, which may affect any given proposal; e.g. the characteristics of the population to be served, the nature of the existing services, the specific types of services proposed to be offered, the current utilization of services and the financial feasibility of the proposal.

The School of Dental Medicine ("Applicant" or "SoDM") is the dental school of the University of Connecticut. It is located on the campus of the University of Connecticut Health Center ("UCHC") at 263 Farmington Avenue, Farmington, Connecticut. It is licensed by the State of Connecticut Department of Public Health as an outpatient clinic for the provision of dental services. The SoDM is the largest single provider of dental services in the State of Connecticut. It provided more than 112,000 patients visits in Calendar Year 2006, with 60,000 visits by Medicaid enrolled dental patients. It provides oral health care services to underserved communities in the State. It is the only teaching and research institution in the state for dental medicine.

The Applicant proposes to acquire and operate a Hitachi CB MercuRay Digital Imaging System ("CB MercuRay") to provide panoramic radiograph images. The CB MercuRay is a cone-beam volumetric tomography unit designed for dento-maxillofacial applications. The Applicant stated that the proposal will provide high-resolution images of the jaws with high geometric accuracy in a short imaging time; alleviate the need to use a multi-slice CT thus reducing the amount of radiation a patient is exposed to during the scan; and provide the superior spatial resolutions needed to make measurements. The proposal will also provide high-quality and high resolution images for research and clinical studies.

The SoDM plans to use the CB MercuRay for clinical research projects and educational opportunities for dental school students, residents, and post-graduates. The Applicant proposes to begin using the CB MercuRay in two research studies that the SoDM has been granted. The CB MercuRay will provide baseline, pre-surgical imaging for a large NIH-funded clinical study to evaluate the influence of osteoporosis on the success of alveolar bone augmentation and dental implant placement. The study received funding in September 2006 and requires the recruitment of post-menopausal women. The SoDM's Department of Oral Rehabilitation, Biomaterials, and Skeletal Development has an approved grant-funded research project sponsored by the National Institute of Dental and Craniofacial Research to study the clinical methods for regenerating bone associated with dental implants. It is a five-year study where the research subjects will receive four CB MercuRay scans for the first three years and one scan in the remaining years.

As the dental school of the University of Connecticut, the Applicant will use the CB MercuRay to train its students in the latest dental technology. The students will receive training in the operation of the scanner, the manipulation of the digital data, and in the interpretation of the images acquired. In addition, the CB MercuRay will be a valuable tool

for the treatment of patients of the University Dentists, the faculty practice plan of the SoDM, that require dental implants, and patients that are referred to the Applicant by community dentists.

Based on the foregoing reasons, OHCA finds that the CON proposal will improve the quality of the Applicant's research and teaching responsibilities. It will also contribute to the overall quality of care to dental patients in the region.

The proposal is financially feasible. The total capital expenditure associated with the Applicant's proposal is \$326,500, consisting of \$265,000 for the CB MercuRay and \$61,500 to renovate and expand an existing dental suite. The proposal will be financed with operating funds. The Applicant projects incremental gains of \$27,821, \$21,114, and \$31,986 for FYs 2008, 2009 and 2010, respectively. Patients participating in research studies will not be charged for any diagnostic or examination procedures. The Application also provides medically necessary services at reduced rates for residents that meet certain income guidelines. Although OHCA cannot draw any conclusions, the Applicant's volume and financial projections upon which they are based appear to be reasonable and achievable.

Based on the foregoing Findings and Rationale, the Certificate of Need application of the School of Dental Medicine at the University of Connecticut Health Center to acquire and operate a Hitachi CB MercuRay Digital Imaging System, at a total capital expenditure of \$326,500, is hereby GRANTED, subject to conditions.

### ORDER

The University of Connecticut Health Center's School of Dental Medicine is hereby authorized to acquire and operate a Hitachi CB MercuRay Maxillofacial Digital Imaging System, at a total capital expenditure of \$326,500, subject to the following conditions:

- 1. This authorization shall expire May 31, 2008. Should the Applicant's project not be completed by that date, the Applicant must seek further approval from OHCA to complete the project beyond that date.
- 2. The Applicant shall not exceed the approved capital expenditure of \$326,500. In the event that the Applicant learns of potential cost increases or expects that the final project costs will exceed those approved, the Applicant shall notify OHCA immediately.
- 3. With respect to the acquisition of the new digital imaging system, the Applicant shall notify OHCA regarding the following information in writing by no later than one month after the equipment becomes operational:
  - i) The name of the digital imaging system's manufacturer;
  - ii) The model name and description of the digital imaging system; and
  - iii) The initial date of the operation of the digital imaging system.
- 4. Should the Applicant propose any change in its dental imaging services, the Applicant shall file with OHCA a Certificate of Need Determination Request regarding the proposed service change.

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

By Order of the Office of Health Care Access

May 31, 2007

Signed by Cristine Vogel Commissioner

CAV:lkg