

**MINUTES
STATE HEALTH FACILITIES COUNCIL
AUGUST 19, 2009
LUCAS STATE OFFICE BUILDING
321 EAST 12TH STREET
FIFTH FLOOR, ROOM 517-518
DES MOINES, IA**

I. 10:00 ROLL CALL

MEMBERS PRESENT: Karen Hope, Chairperson, Chuck Follett, Suki Cell, Marc Elcock and Cynthia Beauman

STAFF PRESENT: Barb Nervig; Heather Adams, Counsel for the State

II. PROJECT REVIEW

1. McFarland Clinic, P.C., Ames, Story County: Replace 4-slice computed tomography (CT) scanner and a positron emission tomography (PET) scanner with a 64-slice PET/CT scanner - \$2,585,500.

Staff report by Barb Nervig. The applicant was represented by Jeb Lee, Debra Thompson, Russ Wilson and Debra Prow. The applicant made a presentation and answered questions posed by the Council.

No affected parties appeared at the hearing.

A motion by Follett, seconded by Cell, to Grant a Certificate of Need carried 5-0.

2. St. Luke's Hospital, Cedar Rapids, Linn County: Establish radiation therapy services with purchase of PET/CT scanner and linear accelerator – \$5,500,000.

Council member Cell stated she is a cancer patient who has received services from Hall Radiation in Cedar Rapids. No one in the room objected to Council member Cell voting on this proposal.

Staff report by Barb Nervig. The applicant was represented by Doug Gross of Brown Winick Law, Ted Townsend, Mike Sundall, Robert Brimmer, Terri Christoffersen, Kimberly Ibester, Michelle Niermann and Mike Kelly. The applicant made a presentation and answered questions posed by the Council. A motion by Beauman, seconded by Follett to accept the presentation slides used by the applicant into the record carried 5-0.

Affected parties appearing at the hearing were Ed McIntosh of Dorsey & Whitney representing Mercy Medical Center, Timothy Charles and Kris Sargent of Mercy Medical Center, Kevin Murray of Radiation Oncology of Cedar Rapids, Kim Salzbrenner of Hall Radiation Center, Mary Quash, Randy Easton and Marcia Stark of Wellmark Blue Cross. A motion by Cell, seconded by Beauman to accept the presentation slides used by Mercy Medical Center into the record carried 5-0.

A motion by Follett, seconded by Elcock, to Grant a Certificate of Need failed 1-4. Beauman, Elcock, Cell and Hope voted no.

A motion by Beauman, seconded by Elcock to DENY a Certificate of Need carried 4-1. Follett voted no.

III. REQUESTS FOR DETERMINATION OF NON-REVIEWABILITY AND THE DEPARTMENT'S RESPONSES

1. The Kahl Home, Davenport, Scott County: Construct replacement facility with the same number of beds (135) and in the same county as current facility.

Staff report by Barb Nervig. A motion by Beauman, seconded by Elcock to support the Department's determination carried 5-0.

2. Wesley Retirement Services, Inc./Pella Regional Health Center, Marion County: Change in licensure and designation of 36 existing long term care beds.

Staff report by Barb Nervig. A motion by Beauman, seconded by Cell to support the Department's determination carried 5-0.

The next two meetings of the Council will be December 2, 2009 and April 7, 2010.

4. PET scans are increasingly used in the diagnosis and treatment of oncology patients and Medicare recently decided to expand coverage for initial testing with PET for beneficiaries with solid tumor cancers.
5. While the demand for PET scans is growing, the current PET scanner is becoming increasingly unreliable and more obsolete. The applicant states that in the last year, the PET scanner has been inoperable approximately 13 days.
6. The technology in the current scanner causes some of the providers to send patients to sites that offer PET/CT because they need the more exact information gained when the PET and CT are completed at the same time.
7. The applicant states that according to PET/CT vendors, stand-alone PET scanners are no longer marketed in the U.S.; all current sales of PET scanners are PET/CT scanners.
8. Within the primary service area of Boone and Story Counties, there are no other providers of PET scan or PET/CT scan services and outside the primary service area, no individual county accounts for greater than 10 percent of the total number of scans.
9. The availability of PET/CT services in Ames increases accessibility to patients that are unable or unwilling to travel longer distances for care. Most patients utilizing these services are being monitored by several different medical specialists. Offering this service in Ames enables patients to coordinate appointments allowing them to make fewer and shorter trips resulting in less cost to the patient, both in mileage and time off from work.
10. The applicant explored several possible solutions before concluding that the proposed equipment is the most effective both financially and technologically to fulfill current and future needs. The financial evaluation determined that neither the PET nor CT volumes alone would support the purchase of separate scanners but the combined volume would. The purchase of a less costly 16-slice PET/CT scanner would alleviate problems in the PET department but would not fulfill technological needs in the CT department. The purchase of two separate scanners (16-slice PET/CT and 64-slice CT) would have allowed all clinical needs to be fulfilled but at a higher acquisition cost and higher operating cost.
11. Originally, the PET scanner was a coordinated program between McFarland Clinic and Mary Greeley Medical Center; the scanner was owned by Health Ventures of Central Iowa, a joint venture between the two entities. Due to changes in the federal Stark regulations, it was mutually agreed by both parties that McFarland would assume full ownership of the service. This change of ownership occurred January 1, 2007.
12. A letter of support from the CEO of Mary Greeley Medical Center stated that the hospital does not have a PET scanner and their patients utilize McFarland Clinic's PET scanner on a regular basis. No letters of opposition were received.
13. The PET/CT scanner will be purchased directly from the vendor and has an estimated useful life of 5 years. The applicant states there will be no operating deficit as a result of this

project. The applicant also states that patient charges will not be increased due to the acquisition of the replacement PET/CT scanner. Financial projections for PET and CT services show revenues exceeding expenses, using estimated volumes for the new scanner.

14. The applicant states that \$485,500 is available from cash on hand. The remaining \$2.1 million will be borrowed. First American Bank has offered the applicant a five year loan at 6.35% five year fixed rate or a three year fixed rate of 6.00%.
15. Two full time employees are needed for the existing scanners. Although the number of employees needed for this project will not change, there will be a change in the distribution of personnel. Currently a full time nuclear medicine tech completes all PET scans and a full time CT tech completes the CT scans. After the installation of the proposed scanner, a half time nuclear medicine tech will be needed to complete the PET scans and 1.5 full time CT techs will assist with PET scans in the morning and complete CT scans in the afternoon.
16. The applicant states that although PET/CT scans can be utilized by many different types of providers, the primary referring providers are oncologists and the providers interpreting the scans are radiologists. There are currently seven board certified radiologists working at McFarland Clinic who will be directly involved in the use of the proposed scanner.
17. The proposed PET/CT scanner will be installed in the current location of the 4-slice CT scanner in the McFarland Clinic Radiology Department which will require remodeling the area to accommodate the scanner, holding rooms, and a hot lab needed for completion of PET scans. The current PET scanner is located in a building adjacent to the clinic in space leased from Mary Greeley Medical Center. The lease will be discontinued once the new PET/CT scanner is installed. The applicant estimates the remodeling costs to be \$285,000.

CONCLUSIONS OF LAW

In determining whether to issue a certificate of need, the Council considers the eighteen criteria listed in Iowa Code § 135.64(1)(a)-(r). In addition, the legislature has provided that the Council may grant a certificate of need only if it finds the following four factors exist:

- a. Less costly, more efficient or more appropriate alternatives to the proposed institutional health service are not available and the development of such alternatives is not practicable;
- b. Any existing facilities providing institutional health services similar to those proposed are being used in an appropriate and efficient manner;
- c. In the case of new construction, alternatives including but not limited to modernization or sharing arrangements have been considered and have been implemented to the maximum extent practicable;

- d. Patients will experience serious problems in obtaining care of the type which will be furnished by the proposed new institutional health service or changed institutional health service, in the absence of that proposed new service.

1. The Council concludes that less costly, more efficient or more appropriate alternatives to the proposed health service are not available and the development of such alternatives is not practicable. The Council concludes that the proposal is essentially the replacement of existing equipment; a separate PET scanner and CT scanner to be replaced with a single PET/CT scanner. The Council takes note that stand alone PET scanners are no longer marketed in the U.S. and that purchase of two separate scanners would have resulted in higher acquisition and operating costs. Iowa Code Sections 135.64(1) and 135.64(2)a.

2. The Council concludes that existing facilities providing health services similar to those proposed will continue to be used in an appropriate and efficient manner and will not be impacted by this project. The Council concludes that the applicant is the sole provider of this service in the Story and Boone Counties, the primary service area. Iowa Code Sections 135.64(1) and 135.64(2)b.

3. The Council concludes that the proposed project does not involve new construction but will require remodeling the area to accommodate the scanner, holding rooms, and a hot lab needed for completion of PET scans. The Council concludes that the remodeling costs are estimated to be \$285,000. Iowa Code Sections 135.64(1) and 135.4(2)c.

4. The Council concludes that patients will experience problems in obtaining care of the type which will be furnished by the proposed changed health service, in the absence of that proposed service. The Council concludes that patients in Story and Boone County have experienced problems in obtaining PET/CT scans due to the downtime of the current equipment. The Council also takes note that the combined scanner provides more exact information to the provider. Iowa Code Sections 135.64(1) and 135.64(2)d.

The facts, considered in light of the criteria contained in Iowa Code Section 135.64 (1 and 2) (2009), led the Council to find that a Certificate of Need should be awarded.

The decision of the Council may be appealed pursuant to Iowa Code Section 135.70 (2009).

It is required in accordance with Iowa Administrative Code 641- 202.12 that a progress report shall be submitted to the Iowa Department of Public Health six (6) months after approval. This report shall fully identify the project in descriptive terms. The report shall also reflect an amended project schedule if necessary.

The Certificate of Need is valid for a twelve (12) month period from the date of these findings. This is subject to the meeting of all requirements of the Iowa Department of Public Health. Requests for extension of a Certificate of Need must be filed in writing to the Iowa Department of Public Health from the applicant no later than forty-five (45) days prior to the expiration of the Certificate. These requests shall fully identify the project and indicate the current status of the project in descriptive terms.

No changes that vary from or alter the terms of the approved application including a change in the approved dollar cost shall be made unless requested in writing to the department and approved. Failure to notify and receive permission of the department to change the project as originally approved may result in the imposition of sanctions provided in Iowa Code section 135.73 (Iowa Administrative Code [641]202.14).

Dated this _____ day of March 2010

Karen Hope, Chairperson
State Health Facilities Council
Iowa Department of Public Health

cc: State Health Facilities Council
Iowa Department of Inspections and Appeals:
Health Facilities Division

in out-migration of cancer patients from their service area and their desire to provide a seamless continuum of care for cancer patients as rationale for their proposal.

3. The applicant has seen a steady increase in the number of cancer patients receiving care at St. Luke's in recent years. In 2008, St. Luke's diagnosed 712 new cancer cases, which represents an increase of 22.5 percent over the past six years according to the applicant.
4. The applicant cites the National Cancer Institute's projection that cancer rates across the nation will more than double between 2000 and 2050.
5. The applicant also states that St. Luke's is the largest hospital in Iowa that does not offer radiation therapy services.
6. The following table displays the estimated new cancer cases for the three-county primary service area and the four-county secondary service area. This table shows fairly steady numbers of new cases.

Estimated Number of New Cancers in Iowa
Source: State Health Registry of Iowa

County	2009	2008	2007	2006	2005
Linn	985	985	985	970	950
Benton	140	150	140	145	145
Jones	115	115	115	125	115
Total	1240	1250	1240	1240	1210
Buchanan	115	125	125	125	125
Cedar	110	120	115	120	130
Delaware	105	100	85	95	95
Iowa	100	105	95	95	100
Total	430	450	420	435	450
Grand Total	1670	1700	1660	1675	1660

7. Attached to this decision and incorporated herein are two line graphs of invasive cancer incidence rates for both Linn County and the state as a whole. This data, the most current available, is for 2002-2006. Although the incident rate for Linn County is slightly higher than the state as a whole, both graphs again display a fairly steady trend.
8. St. Luke's, Mercy and the physician community have been having discussions to establish a joint community cancer center. Both the applicant and Mercy state in separate letters submitted to the Department that they are hopeful that a joint cancer center can be developed in Cedar Rapids.
9. The applicant states that their proposal to purchase a linear accelerator would allow the development of a community cancer center to move forward. The applicant states that the cancer center in which they propose to establish radiation therapy services is being designed to accommodate a second linear accelerator.
10. In June 2005, Hall Radiation Center received a CON to add a tomotherapy linear accelerator bringing the total number of accelerators to three. At that time St. Luke's submitted a letter

of support for the purchase, however stated that based on need requirements they felt the equipment should be purchased as a replacement rather than an addition. The tomotherapy accelerator was put into service in 2006.

11. Hall Radiation Center very recently replaced their oldest accelerator (11 years old) with a Varian Trilogy, the same accelerator proposed by this application.
12. Radiation therapy services draws patients from a wider geographical area than other services. There are currently 12 linear accelerators in the service area. Radiation therapy services are currently available at Mercy Medical Center in Cedar Rapids (three linear accelerators), as well as in Iowa City (four accelerators at UIHC and one at Mercy), Waterloo (one radiation center operating two accelerators) and Dubuque (one radiation center operating two accelerators), all within similar travel times from the rural counties in the secondary service area of the applicant.
13. Five letters of support for the proposal of St. Luke's to offer radiation therapy services were submitted. Letters were received from Physician's Clinic of Iowa, OB Gyn Associates, Radiology Consultants of Iowa, Jones Regional Medical Center and Doug Neighbor. Mr. Neighbor's letter supports a jointly governed community cancer center.
14. Eight letters of opposition were submitted. Letters in opposition were received from Mercy Medical Center, Wellmark, Rockwell-Collins, Breast Care Center in Waterloo, Leslee Sandberg, PhD., Kyle Slogman of Skogman Homes, David Neuhaus of Fairfax Bank and Tony Golobic of Great America Leasing Corporation. Both Mr. Neuhaus and Mr. Golobic are members of the Board of Trustees of Mercy Medical Center.
15. Those in opposition primarily feel that the proposal would result in a costly duplication of services; some also encourage continued talks regarding a community cancer center.
16. Mercy states that the patients to be served by St. Luke's will otherwise be appropriately served at the Hall Radiation Center. Mercy testified that their proposal would result in a reduction in the number of patients treated at Hall, which would increase the cost of providing treatment per patient as the costs must be spread over a significantly smaller patient base. Wellmark also states that the duplication of services would result in adding costs to the health care system.
17. The applicant states that funds for the proposal are available from cash on hand and that their proposed charges are consistent with other similar hospitals in Iowa.
18. The utilization of the three linear accelerators at the Hall Radiation Center follows:

Calendar Year	Linear Accelerator Treatments	Average Treatments Per Day	Average Treatments Per Accelerator per Day
2006	12,866	51.5	17.2
2007	13,469	53.9	18.0
2008	14,154	56.6	18.9

2009	14,465	57.9	19.3
2010	14,783	59.1	19.7
2011	15,108	60.4	20.1

Data provided by Mercy Medical Center (shaded rows are projections)

19. The Council heard testimony that Hall Radiation Center is operating at less than 60%. For comparative purposes; each of the 3 accelerators at Mercy—Des Moines operate at 36 treatments per day compared to 19 per day at Hall. Mercy stated that the Hall Radiation Center will have excess capacity to treat patients for the next 20 years.
20. The applicant indicates the need for 8 full-time equivalent positions to support its radiation therapy program: medical physicist (1 FTE), dosimetrist (1 FTE) general radiology technician/support (1 FTE), registered nurses (2 FTEs) and radiation therapy technologists (3 FTEs). Many of these positions require specialized training.
21. The applicant states that the linear accelerator will be purchased at an approximate cost of \$3 million with an estimated useful life of 10 years. The PET/CT will be purchased at a cost of \$1.5 million with a useful life of 5 years. Finally, the facility build out is \$1 million. The application states that the \$5.5 million dollars is available from cash on hand.

CONCLUSIONS OF LAW

In determining whether to issue a certificate of need, the Council considers the eighteen criteria listed in Iowa Code § 135.64(1)(a)-(r). In addition, the legislature has provided that the Council may grant a certificate of need only if it finds the following four factors exist:

- a. Less costly, more efficient or more appropriate alternatives to the proposed institutional health service are not available and the development of such alternatives is not practicable;
- b. Any existing facilities providing institutional health services similar to those proposed are being used in an appropriate and efficient manner;
- c. In the case of new construction, alternatives including but not limited to modernization or sharing arrangements have been considered and have been implemented to the maximum extent practicable;
- d. Patients will experience serious problems in obtaining care of the type which will be furnished by the proposed new institutional health service or changed institutional health service, in the absence of that proposed new service.

1. The Council concludes that less costly, more efficient or more appropriate alternatives to the proposed health service are available and the development of such alternatives is practicable. The Council concludes that radiation therapy services currently offered at the Hall Radiation Center are an appropriate alternative to the proposed project. The Council concludes that existing services in the area at the Hall Radiation Center are underutilized and have the existing

capacity to meet the current and future needs of the patients. The Council concludes that the proposal represents an unnecessary and costly duplication of radiation therapy services in Cedar Rapids due to the current availability of appropriate alternatives. Iowa Code Sections 135.64(1) and 135.64(2)a.

2. The Council concludes that existing facilities providing health services similar to those proposed are not currently being used in an appropriate and efficient manner and will be impacted by this project. The Council concludes the Hall Radiation Center is operating at less than 60% capacity. The Council concludes that patients to be served by the applicant will be patients otherwise served at the Hall Radiation Center and that the reduction in the number of patients treated at Hall will mean the cost of providing treatment per patient will increase as the costs must be spread over a significantly smaller patient base. The Council also concludes that staffing could also be adversely affected at the existing facility. Iowa Code Sections 135.64(1) and 135.64(2)b.

3. The Council concludes that the proposed project involves facility build out costs of one million dollars. Iowa Code Sections 135.64(1) and 135.4(2)c.

4. The Council concludes that patients will not experience serious problems in obtaining care of the type which will be furnished by the proposed changed health service, in the absence of that proposed service. The Council concludes that patients in Cedar Rapids have not and will not experience serious problems in obtaining radiation therapy services at Hall Radiation Center. The Council further concludes that the 12 accelerators currently operating in the extended service area have capacity to serve the projected number of cancer patients in Linn and surrounding counties. Iowa Code Sections 135.64(1) and 135.64(2)d.

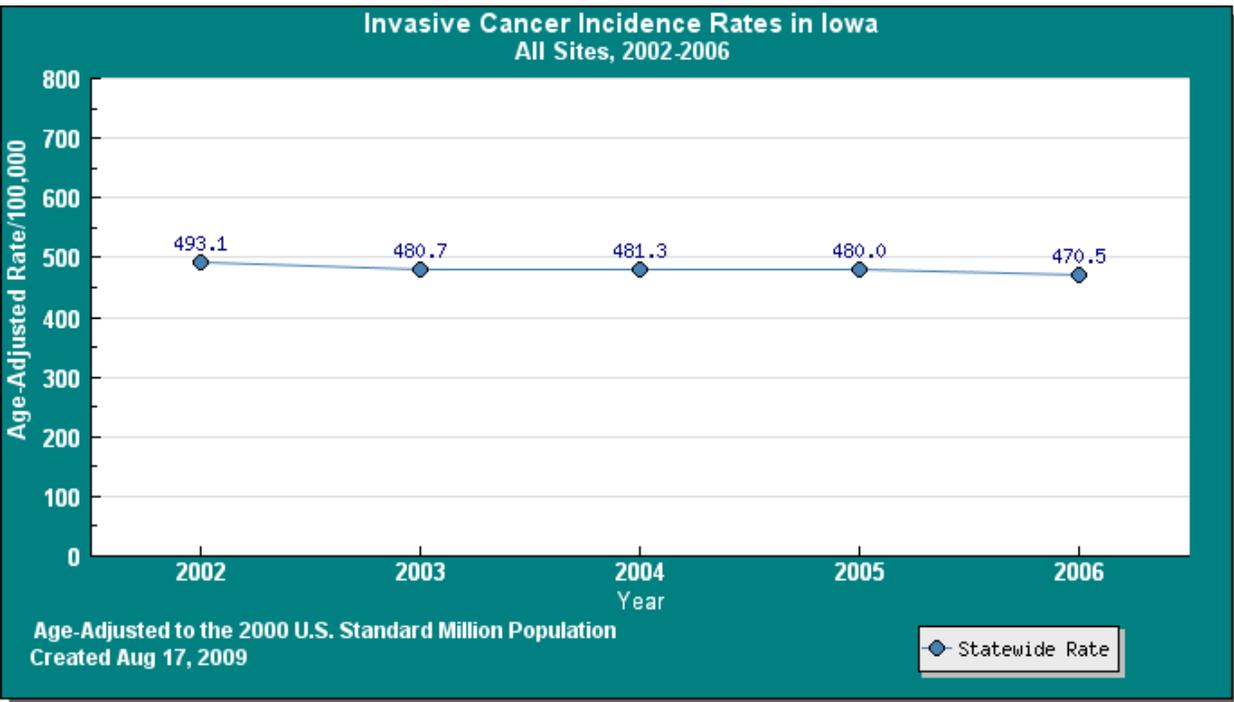
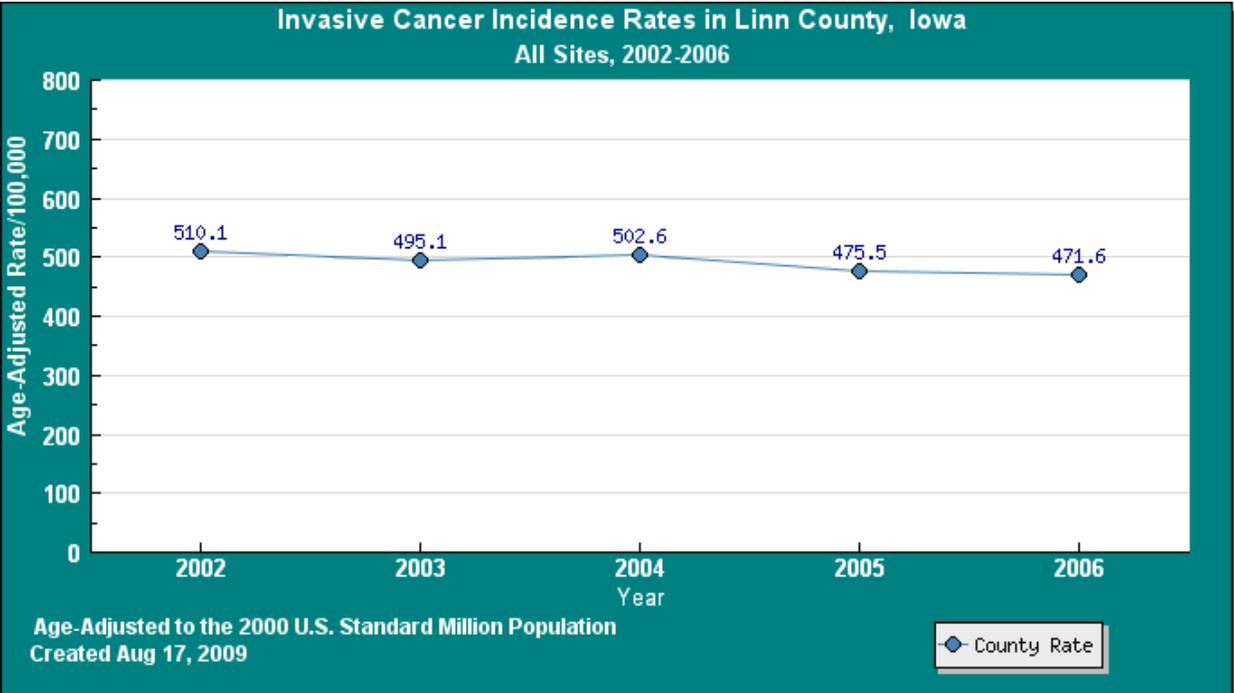
The facts, considered in light of the criteria contained in Iowa Code Section 135.64 (1 and 2) (2007), led the Council to find that a Certificate of Need should be denied.

The decision of the Council may be appealed pursuant to Iowa Code Section 135.70 (2007).

Dated this _____ day of March 2010

Karen Hope, Chairperson
State Health Facilities Council
Iowa Department of Public Health

cc: State Health Facilities Council
Iowa Department of Inspections and Appeals:
Health Facilities Division



Source: State Health Registry of Iowa