

MINUTES
STATE HEALTH FACILITIES COUNCIL
NOVEMBER 3, 2014
BUILDING 7, OAK AND MAPLE ROOMS
DMACC CAMPUS, ANKENY

8:30 AM: ROLL CALL

MEMBERS PRESENT: Bill Thatcher, Chairperson, Bob Lundin, Roberta Chambers and Connie Schmett.

STAFF PRESENT: Barb Nervig, Kala Shipley and Heather Adams, Counsel for State

I. APPROVAL OF PROPOSED CHANGES TO IAC 641—CHAPTER 202 FOR ADOPTION

A motion by Lundin, seconded by Chambers, to approve, carried 4-0.

II. REQUEST FOR DETERMINATION OF NON-REVIEWABILITY AND THE DEPARTMENT'S RESPONSE

1. Iowa Lutheran Hospital, Des Moines, Polk County: Extend outpatient surgery services to a freestanding location in Ankeny, Polk County--\$1,299,000.

Staff report by Barb Nervig. A motion by Chambers, seconded by Schmett, to affirm the Department's determination, carried 3-0. Lundin abstained.

III. PROJECT REVIEW

1. University of Iowa Hospitals & Clinics, Iowa City, Johnson County: Add a second pediatric cardiac catheterization lab -- \$6,200,000

Staff report by Barb Nervig. The applicant was represented by Colleen Flory, George Mesias, Abhay Divekar, Bob Miller, and John Staley. The applicant made a presentation and answered questions posed by the Council.

No affected parties appeared at the hearing.

A motion by Lundin, seconded by Schmett, to grant a Certificate of Need carried 4-0.

2. St Luke's Regional Medical Center-Sioux City, Sioux City, Woodbury County: Convert peripheral vascular lab to a second cardiac catheterization lab -- \$300,000.

Staff report by Kala Shipley. The applicant was represented by Doug Gross of Brown, Winick, Graves, Gross, Baskerville, & Schoenebaum P.L.C.; Lynn Wold, Chief Operating Officer; and Jon Peacock. The applicant made a presentation and answered questions posed by the Council.

No affected parties appeared at the hearing.

A motion by Chambers, seconded by Schmett, to grant a Certificate of Need, carried 4-0.

3. Wesley Retirement Services, Inc. (Halcyon House), Washington, Washington County: Replace 37-bed nursing facility with 54-bed nursing facility -- \$10,350,000.

Staff report by Kala Shipley. The applicant was represented by Ed McIntosh of Dorsey & Whitney; Chris Marshall, Executive Director; Cindy Epperly; and Tina Hoffman. The applicant made a presentation and answered questions posed by the Council.

No affected parties appeared at the hearing.

A motion by Lundin, seconded by Chambers, to grant a Certificate of Need, carried 4-0.

4. Stonehill Franciscan Services, Dubuque, Dubuque County: Re-review of project approved 10/08/2013 to convert 41 residential care beds to 21 nursing care facility beds at a cost of \$693,375. Cost Over-run of \$231,625 (33.4% of approved \$693,375).

Staff report by Barb Nervig. The applicant was represented by Ed McIntosh of Dorsey & Whitney and Eric Thomas. A motion by Schmett, seconded by Chambers, to approve the cost overrun and grant a two-month extension carried 4-0.

IV. EXTENSIONS OF PREVIOUSLY APPROVED PROJECT:

1. Stonehill Franciscan Services, Dubuque, Dubuque County: Convert 41 residential care beds to 21 nursing facility beds – \$693,375.

Staff reviewed the progress on this project. A motion by Schmett, seconded by Chambers, to approve the cost overrun and grant a two-month extension carried 4-0.

2. Whittier Living & Rehabilitation Center, Sioux City, Woodbury County: Build 78-bed nursing facility – \$8,960,415.

Staff reviewed the progress on this project. The applicant was represented by Ken Watkins of Davis Law and Stephanie Amick and Joseph P. DeWitt. A motion by Schmett, seconded by Chambers, to grant a four-month extension carried 4-0. The Council requested that a representative of the applicant be present at the next meeting to review the progress of the project and address the cost over-run.

LUNCH BREAK

3. Marshalltown Medical & Surgical Center, Marshalltown, Marshall County: Relocate outpatient services – \$34,900,000.

Staff reviewed the progress on this project. A motion by Lundin, seconded by Schmett, to grant a one year extension carried 4-0.

V. PROJECT REVIEW (CONTINUED)

5. Marshalltown Medical & Surgical Center, Marshalltown, Marshall County: Initiate radiation therapy services -- \$3,700,000.

Staff report by Kala Shipley. The applicant was represented by Doug Gross of Brown, Winick, Graves, Gross, Baskerville, & Schoenebaum P.L.C.; John Hughes, CEO of Marshalltown Medical and Surgical Center; Carol Hibbs; Shane Hopkins; Ariel Guerra; and Karen Frohwein.

Affected parties at the hearing speaking in support of the proposal were Lizeth Garcia-Jennings and Marti Jefferson.

Affected parties at the hearing in opposition to the proposal were William McGinnis; Brian Dieter, CEO of Mary Greeley Medical Center; and Melissa Kacmarsky, Mary Greeley Medical Center.

A motion by Lundin, seconded by Chambers, to Deny a Certificate of Need, carried 3-1. Schmett voted no.

VI. APPROVE MINUTES OF PREVIOUS MEETING (OCTOBER 2014)

A motion by Chambers, seconded by Schmett, to approve the minutes of the October 21, 2014 meeting, passed unanimously by voice vote.

The meeting was adjourned at 3:30 PM.

The date of the Council's next meeting is February 23, 2015.

**IOWA DEPARTMENT OF PUBLIC HEALTH
STATE HEALTH FACILITIES COUNCIL**

IN THE MATTER OF THE APPLICATION OF)
)
WESLEY RETIREMENT SERVICES, INC.) **DECISION**
(HALCYON HOUSE))
)
WASHINGTON, IOWA)

This matter came before the State Health Facilities Council for hearing on Monday, November 3, 2014.

The application proposes the replacement of a 37-bed nursing facility with a 54 bed nursing facility at an estimated cost of \$10,350,000.

Wesley Retirement Services (Halcyon House) applied through the Iowa Department of Public Health for a Certificate of Need.

The record includes the application prepared by the project sponsor and written analysis prepared by Iowa Department of Public Health staff and all the testimony and exhibits presented at the hearing. Kala Shipley of the Iowa Department of Public Health summarized the project in relation to review criteria. Ed McIntosh of Dorsey & Whitney; Chris Marshall, Executive Director, Cindy Epperly and Tina Hoffman were present representing the applicant. The applicant made a presentation and answered questions.

No affected parties appeared at the hearing.

The Council, after hearing the above-mentioned testimony and after reading the record, voted 4-0 to grant a Certificate of Need. As a basis for their decision the Council, considering all the criteria set forth pursuant to Iowa Code Section 135.64 (1 and 2) (2013) made the following findings of fact and conclusions of law:

FINDINGS OF FACT

1. Wesley Life Halcyon House is a Continuing Care Retirement Community (CCRC) located in Washington, Iowa.
2. The Halcyon House currently has 76 independent living beds, 9 assisted living beds, 16 assisted living memory care beds, 37 NF/SNF beds and 7 RCF beds. The Nursing Facility building at Halcyon House was built in 1959 and includes 37 NF/SNF beds. Five of the 37 NF/SNF beds are private and 32 are semi-private.
3. The applicant states a 16-bed assisted living memory care household was opened in 2007.

4. The applicant states that the average age of all residents on the Halcyon House campus is 86.4 years. The average age of Halcyon House Nursing Facility residents is 87 years.
5. The average length of stay in the nursing facility is 179 days, or approximately six months.
6. The applicant reports that over the past couple of years seven Halcyon House residents were placed in CCDI units providing the NF-level of care. Two CCDI units are located in Washington County but none are located in the town of Washington. Pleasantview Home is a 9-bed CCDI unit located 16 miles away and Parkview Manor is a 13-bed CCDI unit located nearly 30 miles from the Halcyon House.
7. Representatives from both current CCDI units within Washington County reported 100% occupancy on a staff telephone survey. The applicant states they contacted two other southeast Iowa CCDI units between 55 and 60 miles away over the past few years and both also reported 100% occupancy.
8. The applicant states that there is no longer a need for the RCF beds and proposes to eliminate the seven current RCF beds.
9. The applicant proposes to replace the existing 37-bed institutional nursing facility with two 18-bed NF households and one 18-bed Chronic Confusion or Dementing Illness (CCDI) unit in order to complete the continuum of care on the campus. The applicant plans to relocate current RCF residents to the proposed NF rooms.
10. The applicant states the proposed project is intended to fulfill the long-range plan to provide memory support care at both the assisted living and nursing facility levels of care and provide private rooms in a homelike setting for all Halcyon House residents.
11. The applicant indicates the 55 year old Health Center building will be in need of major infrastructure updates in the near future if it were to continue as a NF/SNF building.
12. Overall, the seven-county region, as calculated by the bed need formula, is underbuilt by 671 beds. Washington County is underbuilt by 3 beds. See the following table for additional bed information.

**Nursing Facility Beds by County
Number Needed by CON Formula/Number Licensed/Difference**

County	Projected 2019 Population Age 65+	# of NF Beds needed per bed need formula	# of licensed & approved NF Beds as of 10/06/14	Difference – Formula vs. Licensed & Approved*
Washington	4,614	324	321	-3
Henry	3799	268	245	-23
Iowa	3,229	227	237	+10
Jefferson	4309	298	135	-163
Johnson	19,014	1127	617 ¹	-510
Keokuk	2162	151	168	+17
Louisa	2,040	144	145	+1
Totals	39,167	2539	1868	-671

¹ October, 2014: 40 beds approved at Legacy Gardens and 10 beds approved at Oaknoll Retirement Residences
 *A positive (+) number means the county is overbuilt and a negative (-) indicates an underbuild

13. Over the span of the last three years the total number of beds in the seven-county area has increased by 37 beds. There has been no change in the number of NF beds in Washington County in the last three years. See the following table for additional detail.

Nursing Facility Beds by County
Difference in Number between October 2011 and October 2014

County	# of NF Beds (facilities) as of 10/11	# of NF Beds (facilities) as of 10/14	Difference in # of NF Beds
Washington	321(5)	321(5)	0
Henry	245(5)	245(5)	0
Iowa	229(4)	237(4)	+8
Jefferson	126(2)	135(2)	+9
Johnson	525(7)	547(7)	+22
Keokuk	170(3)	168(3)	-2
Louisa	145(3)	145(3)	0
Totals	1761 (29)	1798 (29)	+37

14. The applicant states their primary market area is Washington and surrounding communities located in Washington, Henry, and Keokuk counties and supports this by providing patient origin data for admissions from 2011 to 2013 as follows: 79% are from Washington County, 10% are from Keokuk County, 4% are from Jefferson County, 2% are from Henry County, and the remaining 5% are from five additional Iowa counties. The applicant anticipates the majority of the persons who will utilize the proposed nursing care beds will come from within the Halcyon House community.
15. There are currently 1,868 licensed and approved nursing facility beds in the seven counties, 107 licensed and approved beds (5.7% of all beds) in dedicated CCDI units.

Number of CCDI Beds by County

County	# of CCDI Beds (facilities)
Washington	22(2)
Henry	0
Iowa	15(1)
Jefferson	13(1)
Johnson	57(3) ¹
Keokuk	0
Louisa	0
Totals	107(7)

¹ October, 2014: 20 beds approved at Legacy Gardens

Data Sources: Department of Inspections & Appeals – Summary of Long Term Care Facilities

16. The results of a recent phone survey of facilities in the seven-county area conducted by department staff are provided in the table below.

**Phone Survey of Nursing Facilities Located in Washington County
& Counties Contiguous to Washington County
Conducted October 2014**

Facility by County	Licensed Beds	Empty Beds	Percent Occupied
WASHINGTON COUNTY			
All American Restorative Care	90	37	59%
Halcyon House	37	2	96%
Parkview Manor	62	13	79%
Pleasantview Home	80	2	98%
United Presbyterian Home	52	6	88%
Washington County Hospital	43	11	74%
TOTALS	364	71	81%
HENRY COUNTY			
Arbor Court	62	2	97%
Henry County Health Center	49	4	92%
New London Nursing & Rehab Center	49	10	80%
Parkview Home	34	9	74%
Pleasant Manor Care Center	50	3	94%
Sunrise Terrace Nursing & Rehabilitation Center	50	7	86%
TOTALS	294	35	88%
IOWA COUNTY			
Colonial Manor of Amana	60	6	90%
English Valley Care Center	60	13	78%
Highland Ridge Care Center	59	0	100%
Rose Haven Nursing Home	58	4	93%
TOTALS	237	23	90%
JEFFERSON COUNTY			
Parkview Care Center	70	13	81%
Sunny Brook Living Care Center	65	5	92%
TOTALS	135	18	87%
JOHNSON COUNTY			
Atrium Village	20	7	65%
Briarwood Healthcare Center	64	7	89%
Iowa City Rehab & Health Care Ctr.	89	27	70%
Lantern Park Nursing & Rehab Ctr	90	10	89%
Lone Tree Health Care Center	44	11	75%
Mercy Hospital	16	0	100%
Oaknoll Retirement Residence	48	3	94%
Solon Nursing Care Center	92	12	87%
Windmill Manor	120	35	71%
TOTALS	583	112	81%
KEOKUK COUNTY			
Manor House Care Center	72	20	72%
Maplewood Manor	46	23	50%
Sigourney Care Center	50	16	68%
TOTALS	168	59	65%
LOUISA COUNTY			
Colonial Manor of Columbus Jct	46	11	76%
Morning Sun Care Center	50	4	92%
Wapello Nursing & Rehab Center	49	13	73%
TOTALS	145	28	81%

17. All-American Care submitted a letter of opposition stating they have empty beds in Washington.
18. The United Presbyterian Home, another NF in Washington, submitted a letter of support. Additional letters of support were received from a Halcyon House Independent Living resident, a medical doctor and a nurse case manager from Washington County Hospital and Clinics, and the City Administrator of Washington. A letter of support was also received from the Director of Nursing at The Klein Center in West Burlington stating a need for CCDI services in southeast Iowa.
19. Morning Sun Care Center submitted occupancy data for their facility.
20. The applicant, Wesley Retirement Services, Inc. reports existing debt of \$2,944,527.34.
21. The applicant includes a conditional letter of interest from Central State Bank to finance the loan portion of the proposed project (\$8,350,000). The applicant indicates the \$2M for the balance of the project will be funded through gifts and contributions yet to be raised. The applicant reports utilizing the services of a fundraising company and having made application for grant funding. The applicant is projecting no operating deficit and will use existing cash reserves for start-up funds.
22. The applicant indicates that the proposal will result in the need for 10.5 additional FTEs; 7.5 of these in the nursing category of RNs and certified nursing aides (CNA). The remaining FTEs include 1.1 administrative, 1.7 dietary, .2 housekeeping, .3 laundry, and 0.2 maintenance, with a .5 FTE reduction in assisted living staff.
23. The proposal calls for the replacement of the existing Nursing Facility building with three 18-bed households resembling the design of a typical residential home totaling 28,621 square feet of new construction.
24. Site costs include \$138,495 for demolition. The total facility costs are \$9,397,370. Moveable equipment costs are listed at \$501,760 and financing costs total \$312,375. The total project cost is \$10,350,000. The turn-key cost per bed is \$191,667.

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 takes note that the Halcyon House NF level of care has a high occupancy. The average age of the residents is in the mid to upper 80s and the 55 year old Health Center building will be in need of major infrastructure updates in the near future if it were to continue as a NF/SNF building. The Council concludes that appropriate alternatives are not available for CCDI care. The Council notes that the applicant has memory care available only at the Assisted Living level, has placed seven residents over 30 miles away for memory care at the NF level in the past few years, and the two CCDI units in Washington County are up to 60 miles away and are at maximum occupancy. The Council concludes that the proposal is an appropriate option to accommodate admissions of Halcyon House residents and others within the community who need skilled nursing and memory care. 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 bed need formula indicates Washington County is underbuilt by three beds; while the seven-county region is underbuilt by 671 beds. The phone survey conducted by Department staff indicates a county wide occupancy of approximately 81% for the nursing facilities and 100% for the CCDI units in Washington County. The Council has previously concluded that occupancy rates of over 85% indicate appropriate and efficient utilization of existing nursing facilities. However, the Council finds that three of the six facilities in the county operate at or significantly above 85%. Additionally, the Council notes that Halcyon House is a continuing care community with high occupancy and 18 of the proposed beds will be designated for CCDI; therefore the Council concludes that the replacement and addition of 17 nursing facility beds at Halcyon House will have minimal impact on the appropriate and efficient use of other nursing facilities. Iowa Code Sections 135.64(1) and 135.64(2)b.

3. The Council concludes that the proposed project is the replacement of the existing Nursing Facility building with three 18-bed households resembling the design of a typical residential home totaling 28,621 square feet of new construction. The Council concludes that alternatives including modernization and sharing arrangements have been considered and implemented to the maximum extent practicable. 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 health service, in the absence of that proposed service. The Council takes note that the applicant has NF level of care with high occupancy and memory care at the assisted living level of care. The Council concludes that the high occupancy of the

applicant's NF beds and the high occupancies of the CCDI units in the service area demonstrate that patients will experience serious problems in obtaining care absent the proposed additional beds. 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) (2013), led the Council to find that a Certificate of Need should be awarded.

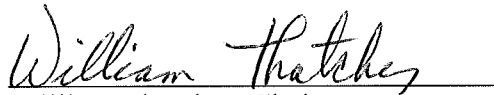
The decision of the Council may be appealed pursuant to Iowa Code Section 135.70 (2013).

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 9th day of February 2015


William Thatcher, Chairperson
State Health Facilities Council
Iowa Department of Public Health

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

IOWA DEPARTMENT OF PUBLIC HEALTH
STATE HEALTH FACILITIES COUNCIL

IN THE MATTER OF THE)
CERTIFICATE OF NEED EXTENSION FOR)
MARSHALLTOWN MEDICAL & SURGICAL)
CENTER)
MARSHALLTOWN, IOWA)

DECISION

This matter came before the State Health Facilities Council for review on Monday, November 3, 2014. The applicant was represented by Doug Gross of Brown, Winick, Graves, Gross, Baskerville, & Schoenebaum P.L.C. and John Hughes, CEO of Marshalltown Medical and Surgical Center.


The project, the construction of an Outpatient Service Center, was originally approved on November 4, 2013 at an estimated cost of \$34,900,000.

This request for extension states that the major structural components have been completed. Mechanical, electrical and plumbing systems are reportedly being installed. The expected completion date is unchanged and remains August 2015.

The Council, after reading the extension request and hearing comments by staff and the applicant, voted 4-0 to Grant an Extension of Certificate of Need per Iowa Administrative Code 641—202.13. The decision is based upon the finding that adequate progress is being made.

The extension is valid for one year.

Dated this 23rd day of February 2015



William Thatcher, Chairperson
State Health Facilities Council
Iowa Department of Public Health

cc: Health Facilities Council
Department of Inspections & Appeals, Health Facilities Division

**IOWA DEPARTMENT OF PUBLIC HEALTH
STATE HEALTH FACILITIES COUNCIL**

IN THE MATTER OF THE APPLICATION OF)
)
MARSHALLTOWN MEDICAL & SURGICAL CENTER)
)
MARSHALLTOWN, IOWA)

DECISION

This matter came before the State Health Facilities Council for hearing on Monday, November 3, 2014.

The application proposes the initiation of radiation therapy services at an estimated cost of \$3,700,000.

Marshalltown Medical & Surgical Center applied through the Iowa Department of Public Health for a Certificate of Need.

The record includes the application prepared by the project sponsor and written analysis prepared by Iowa Department of Public Health staff and all the testimony and exhibits presented at the hearing. Kala Shipley of the Iowa Department of Public Health summarized the project in relation to review criteria. The applicant was represented by Doug Gross of Brown, Winick, Graves, Gross, Baskerville, & Schoenebaum P.L.C.; John Hughes, CEO of Marshalltown Medical and Surgical Center; Carol Hibbs; Shane Hopkins; Ariel Guerra; and Karen Frohwein were present representing the applicant. The applicant made a presentation and answered questions.

Affected parties at the hearing speaking in support of the proposal were Lizeth Garcia-Jennings and Marti Jefferson.

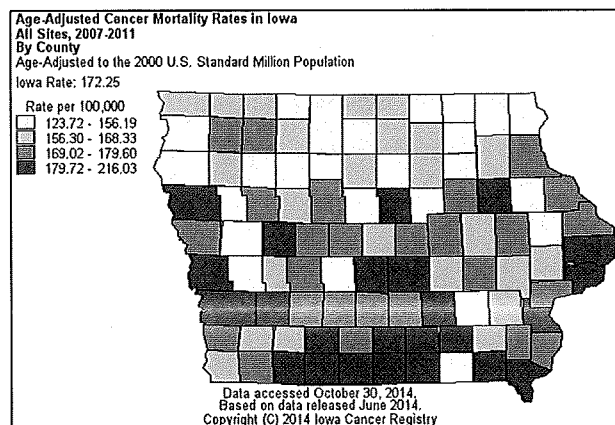
Affected parties at the hearing in opposition to the proposal were William McGinnis; Brian Dieter, CEO of Mary Greeley Medical Center; and Melissa Kacmarsky, Mary Greeley Medical Center.

The Council, after hearing the above-mentioned testimony and after reading the record, voted 3-1 to Deny a Certificate of Need. As a basis for their decision the Council, considering all the criteria set forth pursuant to Iowa Code Section 135.64 (1 and 2) (2013) made the following findings of fact and conclusions of law:

FINDINGS OF FACT

1. Marshalltown Medical & Surgical Center (MMSC) is 125-bed acute care medical facility located in a rural area, Marshall County.

2. The applicant's primary service area includes Marshall and Tama counties. Portions of the four rural counties of Grundy, Hardin, Jasper, and Poweshiek comprise the applicant's secondary service area.
3. The applicant reports over 19% of Marshall County residents are of Hispanic origin compared with 5% statewide and one of the largest Native American communities in the state is located in the MMSC service area. The applicant states that data indicate Native Americans in Iowa and three nearby states have a 28% higher cancer incidence rate than Caucasians.
4. MMSC is seeking to establish a cancer center with radiation therapy services. The applicant received CON approval in November 2013 to construct a new outpatient services center and the proposed linear accelerator would be located at the new site.
5. The applicant reports that patients in the MMSC service area needing radiation therapy services currently travel to Ames, Cedar Rapids, Waterloo, Fort Dodge, Des Moines or Iowa City. Evidence introduced at hearing indicates that the majority of patients from Marshalltown seeking radiation therapy services currently utilize Mary Greeley Medical Center in Ames. The applicant stated at hearing that the drive time for a Marshalltown resident to Ames for radiation therapy is 46 minutes. One affected party testified that the drive takes 37 minutes, and a former patient testified that her drive time from Marshalltown to Ames was 40 minutes. Many of the letters of support received from former cancer patients indicated the drive time from Marshalltown to Ames was between 40 – 45 minutes.
6. The poverty rate in Marshall County is 13.2%, exceeding the state average of 12.7%.
7. The map below shows age-adjusted cancer mortality rates over a five year period by county. Jasper and Hardin counties have the highest mortality rates in the MMSC service area with Marshall and Tama falling in the range of the state average, slightly exceeding the Iowa rate.

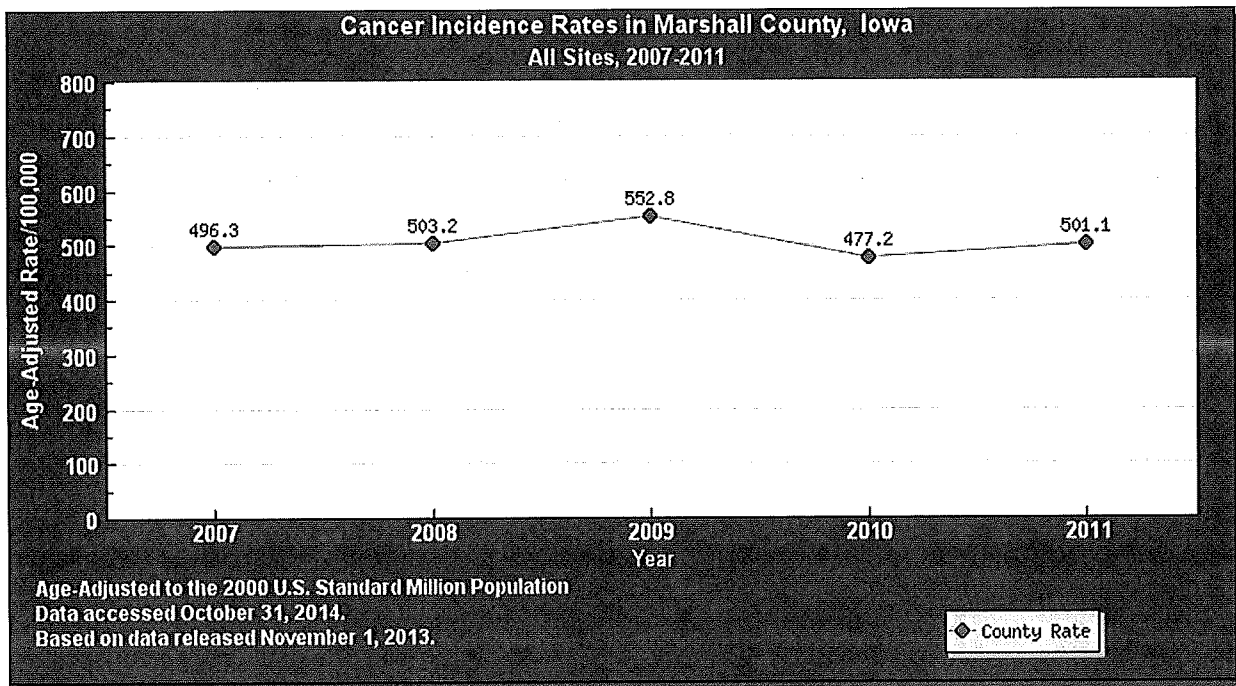


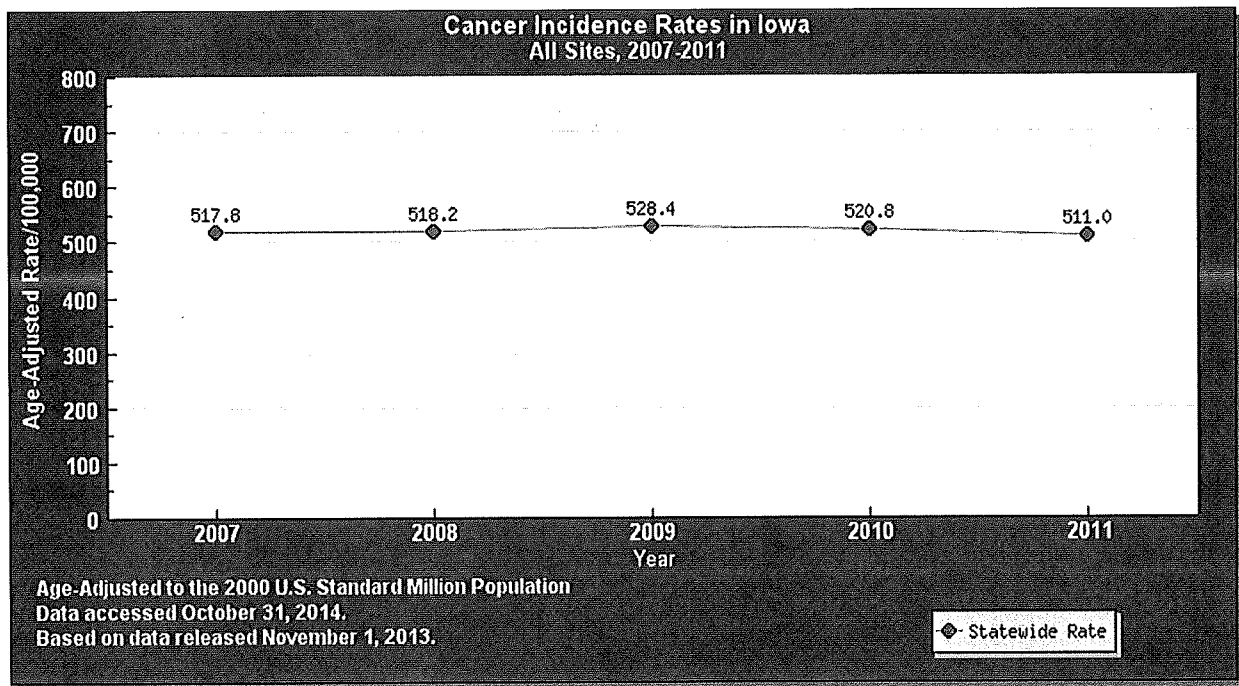
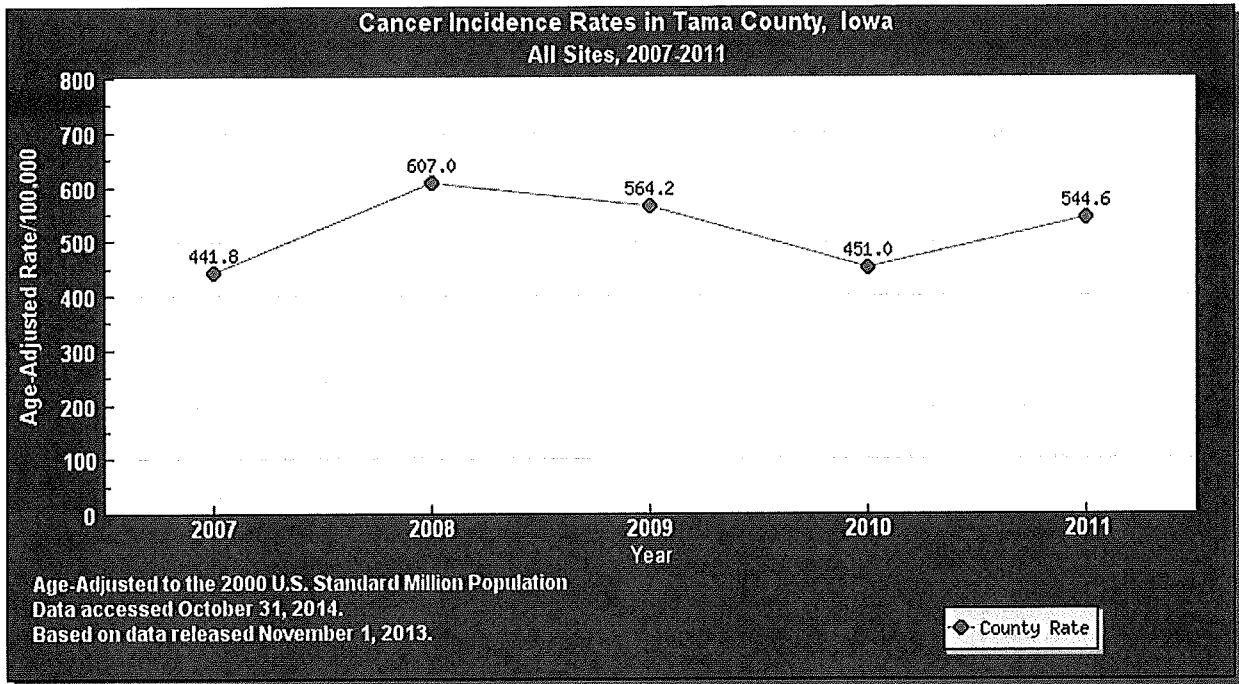
8. The following table displays the estimated new cancer cases for the two-county primary service area and the four-county secondary service area. This table shows fairly steady numbers averaging 910 new cases per year.

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

County	2014	2013	2012	2011	2010
Marshall	235	240	250	230	240
Tama	120	120	130	120	115
Total	355	360	380	350	355
Grundy	85	95	95	85	90
Hardin	125	130	130	120	120
Jasper	235	225	240	230	220
Poweshiek	105	105	110	100	105
Total	550	555	575	535	535
Grand Total	905	915	955	885	890

9. The Iowa Cancer Registry provides “all cancer incidence rates” for both Marshall County and Tama County and the state as a whole for the time period of 2007 to 2011. The incidence rate for Marshall County is slightly lower compared to the state as a whole in three out of the five years. The incidence rate for Tama County is slightly higher than the state incidence rate for three of the five years.





10. The applicant proposes to purchase a Varian TrueBeam Linear Accelerator at an approximate cost of \$2.7 million with an estimated useful life of 7 years. A vault will be constructed to house the linear accelerator costing an additional \$1M; for a project total of \$3.7M.

11. The applicant reports having one CT unit and received CON approval in 2013 for a second CT scanner. The applicant will not be purchasing an additional one for this project.
12. The applicant states that \$1,700,000 for the proposal is available from cash on hand and the remaining \$2,000,000 will come from gifts and contributions. The applicant reports \$1,225,000 pledged toward this project at the time of CON application.

Utilization Rates

13. The CON standards state that there should be no additional megavoltage radiation therapy units of comparable size within 90 minutes surface travel time of existing units which would reduce the projected volume of treatments per annum in existing units of comparable size to less than 6,000 treatments per annum and which would result in less than 300 projected new patients per annum for that existing unit. IAC 641—203.3(3)b(4).
14. Utilization data of existing radiation therapy services was not provided by any providers in the area. However, utilization data was provided to IDPH as part of previous CON applications and is displayed below.

In the following tables, the last row (shaded) displays the average number of treatments per accelerator.

**University of Iowa Hospitals and Clinics (four linear accelerators)
Historical and Estimated Radiation Therapy Treatments**

<i>FY 2011</i>	<i>FY 2012</i>	<i>FY 2013</i>	<i>FY 2016</i>	<i>FY 2017</i>	<i>FY 2018</i>
20,191	20,457	18,711	19,782	20,178	20,582
5,048	5,114	4,678	4,946	5,045	5,146

**Iowa City Cancer Treatment Center (one linear accelerator)
Number of Radiation Therapy Treatments**

<i>2009</i>	<i>2010</i>	<i>2011</i>	<i>2012</i>	<i>2013</i>
4,240	3,580	3,920	3,260	3,280
4,240	3,580	3,920	3,260	3,280

**Covenant Medical Center, Waterloo (two linear accelerators)
Number of Radiation Therapy Treatments**

<i>FY 12</i>	<i>FY 13</i>	<i>FY 14</i>
13,213	12,225	10,107
6,607	6,113	5,054

**Hall Radiation Center, Cedar Rapids (three linear accelerators)
Number of Radiation Therapy Treatments (Actual and Projected)**

<i>CY 2011</i>	<i>CY 2012</i>	<i>CY 2013</i>	<i>CY 2014</i>	<i>CY 2015</i>	<i>CY 2016</i>
14,488	13,543	14,591	14,600	14,600	14,600
4,829	4,514	4,864	4,867	4,867	4,867

15. Mercy Medical Center in Cedar Rapids wrote a letter of opposition and reports the Hall Radiation Center is operating at 60% of capacity for three linear accelerators.
16. Mary Greeley Medical Center stated at hearing that new radiation therapy patients remained steady with a slight decline from fiscal year 2012 to 2014.

Mary Greeley Medical Center
New Radiation Patients

<i>FY2012</i>	<i>FY2013</i>	<i>FY2014</i>
397	399	385

17. Mary Greeley Medical Center (MGMC) stated at hearing that 4460 treatments were completed per linear accelerator at their facility in fiscal year 2014. MGMC further reported that the American College of Radiation Oncology (ACRO) guidelines are 6783 treatments per linear accelerator. MGMC testified that approving MMSC's project would reduce the number of treatments provided at MGMC per year below CON and ACRO guidelines and would substantially drop Mary Greeley's efficiency.
18. Dr. William McGinnis, a radiation oncologist, stated at hearing that there is a reduction in the number of radiation therapy treatments as the standard of care for treatment of breast and prostate cancers is changing.

Staffing

19. The applicant states McFarland Clinic currently provides both radiation and medical oncology services on a full-time basis in Ames and Fort Dodge, but only part-time medical oncology services in Marshalltown. MMSC has an agreement with McFarland Clinic to expand services in Marshalltown for radiation oncology. In addition, the applicant plans to add five additional staff including two radiation therapists, one dosimetrist, and two clerical support personnel. MMSC intends to recruit for the five positions through Midwestern schools, recruiting websites, and recruiting firms.
20. The following letters of opposition were received for the MMSC project and mention staffing as a reason for objecting to new radiation therapy sites.
- A representative from Mercy Medical Center in Cedar Rapids reports spending \$2M supporting specialized staff, not including the cost of the radiation oncologists.
 - Radiation Oncology of Cedar Rapids states a radiation oncologist is required to be onsite for every treatment. They also report there is a need for at least five additional radiation

oncologists in Iowa with shortages being covered with temporary assignments and retired physicians.

- Dr. William McGinnis states there is difficulty in recruiting radiation oncologists to Iowa.
- The Iowa Society of Therapeutic Radiation Oncology reports adequate patient volumes are needed to maintain competence of personnel. Adding new radiation therapy sites may cause underutilization of existing locations.

Letters of Support and Opposition

21. A letter of support was submitted by McFarland Clinic, citing the travel concerns of their patients.
22. Nearly 1000 additional letters of support for MMSC's proposal to offer radiation therapy services were submitted by the posted deadline for submittal of letters from affected parties. Many of the individuals submitting letters describe their personal experiences with cancer treatment and the difficulties experienced traveling to radiation therapy treatments.
23. Five letters of opposition were submitted by the posted deadline for submittal of letters from affected parties. Mary Greeley Medical Center in Ames and Mercy Medical Center in Cedar Rapids submitted letters of opposition. The remaining three letters were from Iowa radiation oncologists. The Iowa Society of Therapeutic Radiation Oncology, an organization of radiation oncologists and radiation physicists, submitted a letter containing the signatures of 34 of its members which asserted the project should be denied as it would duplicate services already available in the service area. In addition, one letter was received from Dr. William McGinnis, radiation oncologist objecting to the proposal on the ground that the duplication of services would drive up cost and diminish quality of care; and one letter was received from Radiation Oncology of Cedar Rapids representing three radiation oncologists stating that an increase in the number of radiation treatment facilities will lead to increased costs and difficulties recruiting qualified staff.

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. The Council takes note that several alternatives to radiation therapy services are available within 90 minutes surface travel time, with Mary Greeley Medical Center in Ames a surface travel time of approximately 40 minutes. The Council concludes that the testimony uniformly indicated that the quality of care at existing providers is excellent and that existing alternatives are being utilized currently for quality radiation therapy services. Existing providers have invested substantial resources, including maintaining a high level of staffing and expensive equipment, to provide radiation therapy services. The Council concludes that duplicating these expenses at MMSC for a relatively low volume of patients would not be a less costly or more appropriate alternative to the continued use of existing providers. 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 being used in an appropriate and efficient manner and would be negatively impacted by this project. The Council notes that existing linear accelerator sites report being underutilized and indicate approval of the MMSC project would substantially drop efficiency of the existing sites. The Council further notes there has been a decline in the number of new radiation therapy patients at Mary Greeley Medical Center over the past three years and that this project would impact Mary Greeley most significantly to the detriment of the quality of care provided at that facility. The Council concludes adequate patient volumes are needed to maintain competence of personnel and quality service and that approval of this project may lead to a decrease in the quality of care in this service area. Iowa Code Sections 135.64(1) and 135.64(2)b.

3. The Council concludes that the proposed project involves construction of a vault to house the linear accelerator at an estimated cost of \$1M to be located at the new hospital facility campus. Iowa Code Sections 135.64(1) and 135.4(2)c. The Council concludes that alternatives including but not limited to sharing arrangements have not been considered or implemented to the maximum extent practicable. The Council expressed interest in the applicant and existing providers exploring alternative arrangements to transport radiation therapy patients to existing providers.

4. The Council concludes that patients will not experience serious problems in obtaining care of the type which will be furnished by the proposed health service in the absence of that proposed service. Radiation therapy services are currently available in the applicant's service area in Ames, Des Moines, Waterloo, and Cedar Rapids; all within 90 minutes surface travel time. The majority of cancer patients from Marshalltown currently receive radiation therapy services in Ames, a surface travel time of approximately 40 minutes. While the Council is sympathetic to the many patients who submitted letters of support and testified in support of this project, the Council is unable to conclude that a 40 minute travel time to receive radiation therapy services constitutes a serious problem in obtaining such services. 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) (2013), 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 (2013).

Dated this 9th day of February 2015



William Thatcher, Chairperson
State Health Facilities Council
Iowa Department of Public Health

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

conditions has also occurred. Finally, architect and engineering fees inadvertently omitted from the original CON application are estimated to total \$66,287.

4. The estimated total cost of the project is now \$925,000, a 33.4% increase in the original total project costs.

CONCLUSION

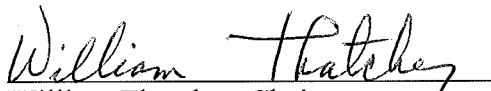
The Council concludes that the proposed change to the originally approved project represents an increase of approximately 33.4% in the cost of the project but does not substantially alter the nature and scope of the originally approved project.

Pursuant to 641 IAC 202.14, the Council therefore approves the request to modify the certificate of need originally granted October 8, 2013 to \$925,000 as the approved cost of the project.

The decision of the Council may be appealed pursuant to Iowa Code section 135.70(2013).

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 9th day of February 2015


William Thatcher, Chairperson
State Health Facilities Council
Iowa Department of Public Health

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

**IOWA DEPARTMENT OF PUBLIC HEALTH
STATE HEALTH FACILITIES COUNCIL**

IN THE MATTER OF THE)
CERTIFICATE OF NEED EXTENSION FOR)

STONEHILL FRANCISCAN SERVICES)

DUBUQUE, IOWA)

DECISION

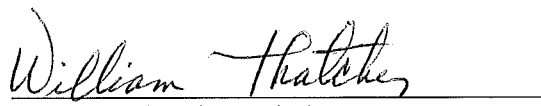
This matter came before the State Health Facilities Council for review on Monday, November 3, 2014. The applicant was represented by Ed McIntosh of Dorsey & Whitney and Eric Thomas.

The project, the conversion of 41 residential care beds to 21 nursing facility beds, was originally approved on October 8, 2013 at an estimated cost of \$693,375. An extension request received in October 2014 stated that the project should be complete no later than mid-December, 2014. That extension request also indicated there is a cost over-run of \$231,625 (33.4% of approved \$693,375) which requires further review and approval by the Council. Therefore, a one-month extension was granted on October 21, 2014.

The Council, after reading the extension request and hearing comments by staff and the applicant, voted 4-0 to Grant an Extension of Certificate of Need per Iowa Administrative Code 641—202.13. The decision is based upon the finding that adequate progress is being made.

The extension is valid for two months.

Dated this 9th day of February 2015



William Thatcher, Chairperson
State Health Facilities Council
Iowa Department of Public Health

cc: Health Facilities Council
Department of Inspections & Appeals, Health Facilities Division

IOWA DEPARTMENT OF PUBLIC HEALTH
STATE HEALTH FACILITIES COUNCIL

IN THE MATTER OF THE)
CERTIFICATE OF NEED EXTENSION FOR)

WHITTIER LIVING AND REHAB CENTER)

DUBUQUE, IOWA)

DECISION

This matter came before the State Health Facilities Council for review on Monday, November 3, 2014. The applicant was represented by Ken Watkins of Davis Law and Stephanie Amick and Joseph P. DeWitt.

The project, the construction of a 78-bed nursing facility, was originally approved on October 7, 2013 at an estimated cost of \$8,960,415. An extension request received in October 2014 stated that land has been purchased, design plans have been approved and groundbreaking work on the foundation was expected to begin on October 1, 2014. The extension request also indicated the location of the project has changed; the purchase price and site preparation costs were less than the proposed property. Also, the projected construction costs have changed as design changes were necessary to comply with the Department of Inspections & Appeals standards.

The Council granted a one month extension on October 21, 2014 and requested a representative of the applicant appear at their November 3, 2014 meeting to discuss changes to this project.

The applicant presented cost information indicating a cost over-run which requires further review and approval by the Council. Since the new cost information was not received in advance of the meeting, the Council deferred action on the cost over-run to their next meeting.

The Council, after reading the extension request and hearing comments by staff and the applicant, voted 4-0 to Grant an Extension of Certificate of Need per Iowa Administrative Code 641—202.13. The decision is based upon the finding that adequate progress is being made.

The extension is valid for four months.

Dated this 9th day of February 2015

William Thatcher

William Thatcher, Chairperson
State Health Facilities Council
Iowa Department of Public Health

cc: Health Facilities Council
Department of Inspections & Appeals, Health Facilities Division

**IOWA DEPARTMENT OF PUBLIC HEALTH
STATE HEALTH FACILITIES COUNCIL**

IN THE MATTER OF THE APPLICATION OF)
)
ST. LUKE’S REGIONAL MEDICAL CENTER)
(ST. LUKE’S HEALTH SYSTEM))
)
SIOUX CITY, IOWA)

DECISION

This matter came before the State Health Facilities Council for hearing on Monday, November 3, 2014.

The application proposes the expansion of cardiac catheterization services with the conversion of a peripheral vascular lab to a cardiac catheterization lab at an estimated cost of \$300,000.

St. Luke’s Regional Medical Center applied through the Iowa Department of Public Health for a Certificate of Need.

The record includes the application prepared by the project sponsor and written analysis prepared by Iowa Department of Public Health staff and all the testimony and exhibits presented at the hearing. Kala Shipley of the Iowa Department of Public Health summarized the project in relation to review criteria. The applicant was represented by Doug Gross of Brown, Winick, Graves, Gross, Baskerville, & Schoenebaum P.L.C.; Lynn Wold, Chief Operating Officer; and Jon Peacock. The applicant made a presentation and answered questions.

No affected parties appeared at the hearing.

The Council, after hearing the above-mentioned testimony and after reading the record, voted 4-0 to grant a Certificate of Need. As a basis for their decision the Council, considering all the criteria set forth pursuant to Iowa Code Section 135.64 (1 and 2) (2013) made the following findings of fact and conclusions of law:

FINDINGS OF FACT

1. St. Luke’s Regional Medical Center is a 346-bed hospital located in Sioux City. The not-for-profit hospital is an affiliate of UnityPoint Health.
2. The applicant’s primary service area includes Woodbury and Plymouth counties in Iowa, one county in Nebraska, and one county in South Dakota. The secondary service area includes five primarily rural, contiguous Iowa counties to Woodbury and Plymouth counties and three additional counties in Nebraska and South Dakota.
3. St. Luke’s Regional Medical Center currently operates one cardiac catheterization lab, one peripheral vascular lab, and one electrophysiology lab.

4. Mercy Medical Center-Sioux City is a 484-bed hospital and is the other hospital in the community. Mercy Medical Center-Sioux City operates two cardiac catheterization labs and one electrophysiology lab.
5. The applicant reports being the provider for over 50 percent of all emergency visits in the community, with cardiac-related symptoms being among the primary diagnoses in the emergency room.
6. Utilization data provided by the applicant show an increase in the total number of combined cardiac catheterization, vascular, and electrophysiology procedures from 2011 to 2013.

Cardiac Catheterization Procedures (Excludes Vascular and Electrophysiology Procedures)				
County	2011	2012	2013	2014*
Buena Vista	10	15	12	22
Cherokee	4	10	12	36
Ida	1	4	7	10
Monona	7	8	17	26
Plymouth	25	13	32	66
Sioux	6	12	15	34
Woodbury	104	102	202	340
Dakota (Neb)	9	9	24	56
Dixon (Neb)	2	6	5	20
Thurston (Neb)	3	2	1	2
Clay (SD)	0			2
Union (SD)	7	18	20	26
Other	7	19	28	64
Totals	185	218	375	704

*Annualized based on procedures performed during six months ending June 30, 2014

7. The applicant reports downtime of the lab occurred four times in the past twelve months due to maintenance issues such as a water line break rendering the lab unusable for seven days.
8. The applicant states St. Luke's Regional Medical Center has been forced to remove a patient from the procedure table to accommodate an emergent patient on at least ten occasions after treating cardiologists carefully considered the risks to both patients.
9. St. Luke's Regional Medical Center has a professional services agreement with Cardiovascular Associates, P.C. ("CVA"). The applicant states CVA performed over 73 percent of its procedures at St. Luke's in 2013.
10. The applicant proposes to convert the existing peripheral vascular lab to serve as both a peripheral vascular lab and a backup cardiac catheterization lab to then operate a total of two cardiac catheterization labs and one electrophysiology lab.
11. The applicant reports the majority of equipment that will be required is already in use in St. Luke's peripheral vascular lab; the alternative would be to either establish a separate and more costly dedicated cardiac catheterization lab or send emergent patients to another facility potentially delaying treatment.

12. The applicant provided the following projections of volume after the installation of the proposed second lab for cardiac catheterization, vascular and electrophysiology procedures combined.

Cardiac Catheterization, Vascular, and EP Procedures			
County	2015	2016	2017
Buena Vista	62	63	64
Cherokee	60	60	60
Ida	44	45	46
Monona	41	42	43
Plymouth	175	179	181
Sioux	91	92	93
Woodbury	1,047	1,065	1,075
Dakota (Neb.)	123	125	127
Dixon (Neb.)	29	29	29
Thurston (Neb.)	19	20	20
Clay (S.Dak.)	4	4	5
Union (S.Dak.)	99	100	105
Other	118	125	133
Totals	1,912	1,949	1,981

13. Mercy Medical Center in Sioux City provided the following procedure numbers for their two cardiac catheterization labs and one electrophysiology lab.

Inpatients' Primary Procedures	Actual Utilization						Projected Utilization		
	CY2011		CY2012		CY2013		CY2014	CY2015	CY2016
	MMC	UPSL	MMC	UPSL	MMC	UPSL	MMC	MMC	MMC
5: Vascular Surgery	662	154	639	184	425	242	425	425	425
52: Electrophysiology/Devices	234	96	255	73	181	79	180	180	180
53: Invasive Cardiology	2,296	754	2,364	813	1,786	456	1,780	1,780	1,780
54: General Cardiology	1,060	580	972	516	953	425	950	950	950
56: Vascular Diseases	88	58	84	52	72	42	70	70	70
Total	4,340	1,642	4,314	1,638	3,417	1,244	3,405	3,405	3,405
Community Total	5,982		5,952		4,661				

Selected Inpatients' Procedures Performed in Cath Lab

Patients' Primary Procedures	2,849	997	2,986	1,035	2,271	766	2,275	2,275	2,275
Patients' Additional Procedures	2,990	1,086	3,129	1,055	2,470	817	2,470	2,470	2,470
Total	5,839	2,083	6,115	2,090	4,741	1,583	4,745	4,745	4,745
Community Total	7,922		8,205		6,324				

Selected Outpatients' Primary Procedures Performed in Cath Lab

45. Percutaneous transluminal coronary angioplasty (PTCA)*	39	65	50	81	7	11	10	10	10
47. Diagnostic catheterization, coronary arteriography	265	288	309	342	379	200	380	380	380
48. Insertion, revision, replacement, removal of cardiac pacemaker or cardioverter/defibrillator	170	134	99	109	62	109	60	60	60
Total	474	487	458	532	448	320	450	450	450
Community Total	961		990		768				

Source: Iowa Hospital Association, Dimensions Database Sept 2014

MMC-SC Mercy Medical Center

UPSL = Unitypoint St. Luke's

*In CY13, PTCA codes changed & working with IHA to identify volumes

14. A Mercy Medical Center Sioux City spokesperson reported they are expecting volumes for procedures completed in the local catheterization labs to reflect no significant increase and there will be a continued shift from inpatient procedures to the outpatient setting.

Additionally, the Mercy spokesperson reported projections for Mercy procedures over the next three years will be held constant.

15. Letters of support were received from Cardiovascular Associates, P.C. and the CEO/administrators from the following three area hospitals: Orange City Area Health System, Cherokee Regional Medical Center, and Floyd Valley Hospital.
16. No letters were received in opposition to St. Luke's application to convert a peripheral vascular lab to a cardiac catheterization lab.
17. The applicant states no additional staff will be needed for the conversion of the peripheral vascular lab to a backup cardiac catheterization lab. St. Luke's currently has one cardiology program manager, six registered nurses, and six cardiac catheterization lab technologists.
18. The applicant states there will be no construction for the conversion of the peripheral vascular lab to a backup cardiac catheterization lab.
19. The applicant states the majority of the required equipment is currently being used in St. Luke's peripheral vascular lab and proposes the purchase of hemodynamics monitoring equipment, specifically a Merge (Model V2) Version 10.0.
20. The estimated purchase price of the equipment is \$300,000. The applicant states cash on hand will be used for the purchase of the proposed equipment.

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 takes note that there has been downtime of the current cardiac catheterization lab four times in the past twelve months and removal of a patient from the procedure table to accommodate an emergent patient on at least ten occasions. The Council further notes the alternative would be to either establish a separate and more costly dedicated cardiac catheterization lab or send emergent patients to another facility potentially delaying treatment. The Council concludes that the need for a back-up cardiac catheterization lab supports the need for conversion of the peripheral vascular lab to a cardiac catheterization lab. 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 takes note that the other provider of cardiac catheterization services in Sioux City (Mercy Medical Center) indicates projections for Mercy procedures over the next three years will be held constant. The Council further notes that there are no objectors to the proposal. The Council concludes that a second cardiac catheterization lab at St. Luke's Medical Center will enable the applicant to continue to offer the services in an appropriate and efficient manner and the other existing provider of the service will not be impacted. Iowa Code Sections 135.64(1) and 135.64(2)b.

3. The Council concludes that the proposed project does not involve new construction as the applicant has existing space and the majority of the required equipment to accommodate the new cardiac catheterization lab. 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 health service, in the absence of that proposed service. The Council concludes that a second cardiac catheterization lab at St. Luke's Medical Center will decrease the number of delays due to downtime and emergent cases. The Council concludes that the addition of a second lab will make it more likely that patients in the area will receive the services they need in a timely and efficient fashion. 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) (2013), 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 (2013).

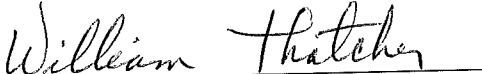
It is required in accordance with Iowa Administrative Code 641-202.12 that a progress report shall be submitted to the Iowa Department of Public Health six (6) months after approval. This report shall fully identify the project in descriptive terms. The report shall also reflect an amended project schedule 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 9th day of February 2015


William Thatcher, Chairperson
State Health Facilities Council
Iowa Department of Public Health

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

**IOWA DEPARTMENT OF PUBLIC HEALTH
STATE HEALTH FACILITIES COUNCIL**

IN THE MATTER OF THE APPLICATION OF)
)
UNIVERSITY OF IOWA HOSPITALS & CLINICS)
)
IOWA CITY, IOWA)

DECISION

This matter came before the State Health Facilities Council for hearing on Monday, November 3, 2014.

The application proposes the expansion of cardiac catheterization services with the addition of a second pediatric lab at an estimated cost of \$6,200,000.

University of Iowa Hospitals and Clinics applied through the Iowa Department of Public Health for a Certificate of Need.

The record includes the application prepared by the project sponsor and written analysis prepared by Iowa Department of Public Health staff and all the testimony and exhibits presented at the hearing. Barb Nervig of the Iowa Department of Public Health summarized the project in relation to review criteria. Colleen Flory, George Mesias, Abhay Divekar, Bob Miller, and John Staley were present representing the applicant. The applicant made a presentation and answered questions.

No affected parties appeared at the hearing.

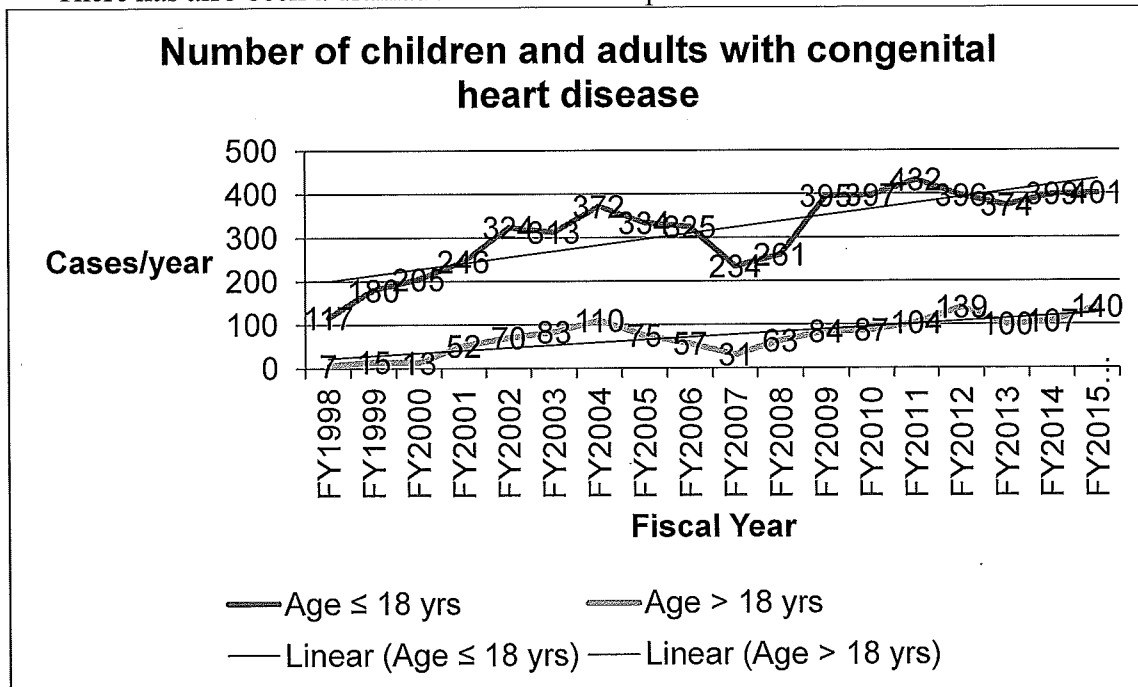
The Council, after hearing the above-mentioned testimony and after reading the record, voted 4-0 to grant a Certificate of Need. As a basis for their decision the Council, considering all the criteria set forth pursuant to Iowa Code Section 135.64 (1 and 2) (2013) made the following findings of fact and conclusions of law:

FINDINGS OF FACT

1. The University of Iowa Hospitals and Clinics (UIHC) is proposing the addition of a second pediatric cardiac catheterization lab on the west side of the fifth floor of the John Pappajohn Pavilion. The applicant states this location will make it possible for the cardiac catheterization service to utilize the pre- and post-procedure facilities of the pediatric operating suite that will be developed in the new Children's Hospital.
2. Historically, the applicant states the pediatric cardiac catheterization laboratory, (PCCL), was a diagnostic procedural suite. Over the last several decades the capabilities of the PCCL have broadened and it has become a high complexity, state of the art diagnostic and therapeutic laboratory. During this natural progression, two distinct service lines have emerged, namely, diagnostic/therapeutic catheterization and non-invasive/invasive

electrophysiology. In contrast to most adult service lines, in pediatrics, these service lines developed utilizing the same PCCL.

3. The average patient for both service lines has increased in complexity, becoming smaller, more critically ill, or possessing a more complex anatomy. As a result, these procedures are frequently performed during an immediate postoperative high risk period. The resulting effect is that procedure length has increased while the overall demand for procedures continues to grow.
4. Additionally, the applicant states that adults with congenital heart disease who were previously treated during childhood are now requiring general anesthesia for safe conduct of these complicated procedures. These procedures are performed by pediatric catheterization and pediatric electrophysiology physicians in the PCCL because of their familiarity with the anatomy associated with congenital heart disease (CHD).
5. As a natural progression to improve transcatheter technologies, a number of procedures previously within the surgeon's domain are now regularly performed in the PCCL, either as a stand-alone procedure or as a hybrid procedure. Neither the operating room, nor the current PCCL provide optimal infrastructure for this rapidly growing field. By combining these procedures in a hybrid lab, children with congenital heart disease will experience fewer interventions and less anesthesia.
6. The applicant provides data from 1998 to the present, showing a nearly threefold increase in the total PCCL procedural volume. This encompasses pediatric and adult congenital patients. There has also been a dramatic increase in the procedural volume for the EP service line.



7. The applicant states that most patients in the PCCL require general anesthesia or deep procedural sedation. In general, the requirement of general anesthesia or deep procedural sedation adds at least one hour when compared to a typical adult procedure time (non-CHD) in the adult laboratory.
8. Based on time data from April 2010 to date, an average procedure requires 4 hours. Using 250 working days a year and an average of 500 cases per year, the University of Iowa Children's Hospital performs an average of two cases per day, with an average duration of four hours per patient. With this volume and procedure length, the PCCL has been operating at or near 100% capacity for the last five years.
9. In general, electrophysiology procedures take longer and therefore the two service lines compete for available time. Providing the two service lines in one lab has only been possible to achieve through reliance on overtime and performing procedures well beyond 8:00 pm. The applicant feels this is no longer a suitable operational strategy.
10. The CON standards for pediatric cardiac catheterization labs indicate each lab should project a minimum of 150 catheterizations annually. 641—IAC 203.2(3)“c”(2). The standards further state that there should be no additional cardiac catheterization units initiated which would reduce the volume of the existing units below 150 pediatric catheterizations; existing providers of consequence are those within three hours surface travel time. 641—IAC 203.2(3)“d”(2).
11. The applicant states that Mercy Des Moines also has a PCCL; however Mercy does not have access to a pediatric electrophysiologist and Mercy's referrals for these procedures are directed to UIHC. The UI children's Hospital pediatric cardiology group has informed Mercy Des Moines of this proposal for a second pediatric lab at UIHC and Mercy expressed no opposition.
12. The geographical service area for this project will include the general service area of the UIHC, which encompasses the state of Iowa, west central Illinois, and parts of other contiguous states. Patients with certain diagnoses from other states and several foreign countries may also have cardiac catheterization procedures that require the use of the proposed system. The application includes several maps illustrating patient origins, both historical and projected. The applicant does not expect this project will significantly alter the geographic distribution or the patient population of University Hospitals.
13. The applicant states the option of partnering with another institution has been considered, but is not feasible given that the University of Iowa Children's Hospital is the only provider of many of the services needed to safely operate a comprehensive pediatric cardiac catheterization laboratory. These requirements include the need for 24/7 cardiac surgical expertise, extracorporeal support, a pediatric cardiac transplantation program, a pediatric nephrology division with ability to perform all modalities of dialysis availability of pediatric cath lab personnel certified in PALS and ACLS, availability of blood bank services, access to pediatric general surgery, and the presence of an invasive pediatric electrophysiologist.
14. The applicant has cash on hand to fund the proposal. The hospital standard rate schedule will be used to determine patient charges. The applicant states these rates are based on a fully-

allocated/average cost accounting methodology, and thus the costs relevant to these clinical procedures are covered in the charges. When utilized for clinical research procedures, the hospital will receive reimbursement through the research grants that fund these studies.

15. A strong historical linkage of referrals from community physicians, hospitals and health professionals throughout the state has grown to provide Iowans with a stratified system of care with University Hospitals serving at the apex of this system as the tertiary care center in Iowa's health care delivery system.
16. University Hospitals has transfer agreements with virtually every hospital in the state, which outlines the responsibilities of the parties in referring patients to and from the tertiary care center. Also, the UIHC has entered into agreements with most managed care programs to assure that Iowans affiliated with these programs may be referred to the UIHC whenever necessary.
17. The Division of Cardiology in the Stead Family Department of Pediatrics at the University of Iowa Hospitals and Clinics serves as the only site in Iowa for training future pediatric cardiologists who will care for children in Iowa and beyond. The division also provides mandatory pediatric cardiology rotations for the adult cardiology fellowship program. The availability of sufficient up-to-date equipment and technologies is essential to ensure that the cardiology fellows are knowledgeable and well trained.
18. The cardiac catheterization and electrophysiology programs participate in numerous multi-institutional (funded) and institutional clinical research studies. In order to maintain excellence in clinical research, it is crucial to have a state of the art cardiac catheterization laboratory capable of performing the highest quality investigational studies and clinical procedures. The pediatric cardiologists have published results of their studies in several well-known journals and are in the process of developing additional simulation based projects.
19. According to the applicant, at the present time, the University of Iowa Department of Pediatrics, Division of Pediatric Cardiology is the only entity in the state that can provide comprehensive medical, transcatheter and surgical treatment options for children and adults with congenital heart disease.
20. Based on national projections, the applicant anticipates continued growth for advanced interventional catheterization and electrophysiology subspecialty services, both of which are performed in the same interventional laboratory. With a second pediatric cardiac catheterization laboratory, the University of Iowa Hospitals & Clinics will be able to serve patients in more rapid sequence, and facilitate better access for patients and families, especially those traveling from distant points across Iowa and surrounding states.
21. The applicant states that Mercy Des Moines also has a PCCL; however Mercy does not have access to a pediatric electrophysiologist and Mercy's referrals for these procedures are directed to UIHC.
22. The UI children's Hospital pediatric cardiology group has informed Mercy Des Moines of this proposal for a second pediatric lab at UIHC and Mercy expressed no opposition.

23. The applicant states that the lab will need an additional 0.5 FTE radiologic technologist and an additional 1.0 FTE Registered Nurse. Existing staff will provide the necessary training to operate the new equipment systems and will be supported, as necessary, by technical and engineering staff from the Department of Radiology. To meet these needs, an existing Radiologic Technologist position will be increased from 50% to 100% time.
24. The University of Iowa pediatric cardiology program is the only program in the state of Iowa that is involved in training the future generation of pediatric cardiologists. At the present time they have a long running (32 years) T32 (funded by NIH) fellowship training grant with either 4 or 5 fellows at any given time. These trainees are required to be present in the pediatric cardiac catheterization laboratory for pediatric catheterization and electrophysiology as a condition of their board certification.
25. A common conundrum for academic physicians is how to train fellows in procedures while maintaining high standards of patient care and safety. By having two cardiac catheterization laboratories, the fellows can rotate between the two laboratories, even on the same day, and perform portions of the procedure most suitable to their level of training. In the last 2-3 years, there has been increasing request for adult cardiology fellow trainees to seek elective rotations in the pediatric cardiac catheterization laboratory.
26. The applicant plans to purchase the Siemens Artis Q zen system. The requested cardiac angiographic system would be purchased under the UIHC's Master Strategic Alliance Agreement with Siemens. This agreement was established following a competitive bidding process that involved all major radiologic equipment vendors and provides an average minimum discount of 37%.
27. The estimated project cost to purchase and install this new system is approximately \$6.2 million, comprised of \$2.58 million in construction/renovation costs, \$250,000 in fees and furnishing costs, approximately a million dollars in related facility equipment, and \$2.4 million in angiography equipment. The applicant states funds on hand will be used.

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 takes note that the option of partnering with another institution has been considered, but is not feasible given that the University of Iowa Children's Hospital is the only provider of many of the services needed to safely operate a comprehensive pediatric cardiac catheterization laboratory. The Council further notes that data shows a nearly threefold increase in the total PCCL procedural volume since 1988; procedure length has increased while the overall demand for procedures continues to grow; the PCCL has been operating at or near 100% capacity for the last five years, which has only been possible to achieve through reliance on overtime and performing procedures well beyond 8 pm. The Council concludes that this is no longer a suitable operational strategy and a second lab is the most efficient and appropriate option. 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 takes note that that Mercy Des Moines also has a PCCL; however Mercy does not have access to a pediatric electrophysiologist and Mercy's referrals for these procedures are directed to UIHC. The Council further notes that UI children's Hospital pediatric cardiology group informed Mercy Des Moines of this proposal for a second pediatric lab at UIHC and Mercy expressed no opposition. The Council concludes that existing facilities providing pediatric cardiac catheterization laboratory services will continue to be used in an appropriate and efficient manner. Iowa Code Sections 135.64(1) and 135.64(2)b.

3. The Council finds that the applicant considered other arrangements to provide the two lines of services. The Council concludes that space for the proposed project has been identified and is immediately adjacent to the new children's hospital (still under construction) operating rooms. 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 takes note that at the present time, the University of Iowa Department of Pediatrics, Division of Pediatric Cardiology is the only entity in the state that can provide comprehensive medical, transcatheter and surgical treatment options for children and adults with congenital heart disease. The Council further notes that based on national projections, the applicant anticipates continued growth for advanced interventional catheterization and electrophysiology subspecialty services, both of which are performed in the same interventional laboratory. The Council concludes that with a second pediatric cardiac catheterization laboratory, the University of Iowa Hospitals & Clinics will be able to serve patients in more rapid sequence, and facilitate better access for patients and families. Iowa Code Sections 135.64(1) and 135.64(2)d.

5. In the evaluation of applications for certificates of need submitted by university hospital at Iowa City, the unique features of that institution relating to statewide tertiary health care, health

science education, and clinical research shall be given due consideration. Iowa Code Section 135.64(3). The Council notes that the UIHC pediatric cardiology program is the only program in the state of Iowa that is involved in training the future generation of pediatric cardiologists and at the present time they have a long running (32 years) T32 (funded by NIH) fellowship training grant with either 4 or 5 fellows at any given time. The Council concludes that the availability of sufficient up-to-date equipment and technologies is essential to ensure that the cardiology fellows are knowledgeable and well trained. The Council also takes note that the cardiac catheterization and electrophysiology programs participate in numerous multi-institutional (funded) and institutional clinical research studies and the pediatric cardiologists have published results of their studies in several well-known journals and are in the process of developing additional simulation based projects. The Council concludes that in order to maintain excellence in clinical research, it is crucial to have a state of the art cardiac catheterization laboratory capable of performing the highest quality investigational studies and clinical procedures.

The facts, considered in light of the criteria contained in Iowa Code Section 135.64 (1 and 2) (2013), led the Council to find that a Certificate of Need should be awarded.

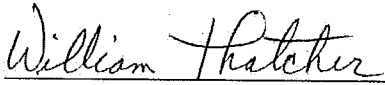
The decision of the Council may be appealed pursuant to Iowa Code Section 135.70 (2013).

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 18th day of February 2015


William Thatcher, Chairperson
State Health Facilities Council
Iowa Department of Public Health

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