REVIEW OF PROVIDENCE ALASKA MEDICAL CENTER CERTIFICATE OF NEED APPLICATION FOR CONSTRUCTION OF AN ELECTROPHYSIOLOGY LABORATORY

September 14, 2009

Sean Parnell
Governor

William H. Hogan
Commissioner

State of Alaska/DHSS
Division of Health Care Services
Section of Health Planning and Systems Development
Certificate of Need Program

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BACKGROUND

Providence Alaska Medical Center (PAMC) is owned and operated by Providence Health and Services as a not-for-profit Catholic healthcare organization with sister organizations and facilities in four western states. Through the Sisters of Providence this organization has had a presence in Alaska, beginning in Nome, since 1902. Currently Providence Health and Services Alaska operates four hospitals in communities in Alaska: Anchorage, Kodiak, Seward, and Valdez.

PAMC is currently licensed by the State of Alaska as an acute care hospital with 326 beds including 27 psychiatric beds and 10 rehabilitation beds.

PAMC is also accredited by the Joint Commission on Healthcare Organizations (JCAHO). The facility was surveyed in July 2008 and is accredited through October 2011.

In the last five years, through the Certificate of Need process, PAMC has been reviewed and approved for the following projects:

2004: Magnetic Resonance Imaging System
2005: Construction of a 60 bed Long Term Acute Care Hospital as a joint venture
2006: Expansion of the Post Anesthesia Care Unit
Relocation and Expansion of the Cancer Center
2007: Expansion of the Cardiovascular Observation Unit
Relocation and Expansion of Sports Medicine/Rehabilitation Therapy
Expansion of the Neonatal Intensive Care Unit
Addition of a Cardiac Catheterization Laboratory
2009: Construction of an Ambulatory Surgical Center as a joint venture
2009: Expansion and Relocation of the Sleep Disorders Center

PAMC maintains an open door philosophy consistent with values of the Sisters of Providence. They provide health care to all individuals regardless of race, creed, or ability to pay.

PROJECT DESCRIPTION:

PAMC is requesting a Certificate of Need be granted for construction of a single Cardiac Electrophysiology (EP) Laboratory on the hospital campus. Ultrasound will be relocated into existing Clinical Laboratory office space and the Clinical Laboratory office will be relocated into vacant space formerly used for cancer therapy. There will be no disruption in service to the Heart and Vascular Center and its labs during construction. Other relocations will be staged to address each move with as little disruption as possible. No disruption to patient services is anticipated.[1]

[1]Providence Alaska Medical Center Certificate of Need Application June 2009 pg.41

A total of 6,458 square feet will be renovated as a part of this project.

No additional patient beds or operating suites will be added as a part of this project nor will there be additional square footage added to the facility. Because of this fact, acute care hospital services review standards and methodologies were not used in the review of this application. Cardiac catheterization service review standards were also not used in the review of this application as there will be no change in catheterization services provided with the addition of an EP lab. There are no specific review standards for electrophysiology services.

Estimated cost of this project is $7,030,727 including construction, architecture, engineering fees, relocation expenses and capital equipment. It will be financed by PAMC through accumulated revenue.

The EP laboratory is expected to be operational in July 2010.

DESCRIPTION OF CARDIAC ELECTROPHYSIOLOGY:

Electrophysiology (EP) procedures diagnose, manage, and treat abnormal heart rhythms. This is done with defibrillator implants, internal cardiac defibrillators, and ablations.

Atrial Fibrillation (AF) is the leading cause of cardiac arrhythmia. AF may be associated with structural heart disease, although a substantial proportion of patients with AF have no detectable heart disease. The incidence of AF increases with age. Patients aged 60-64 currently have a rate of 100 patients per 1000 population. By the age of 80-84, the rate increases to 450 patients per 1000 population. The median age of AF patients is about 75 years old and approximately 70% of all AF patients are between 65 and 85 years old.[2]

AF patients are at higher risk of stroke, sudden cardiac arrest, and congestive heart failure. AF is the second leading cause of stroke in the United States.[3]

AF has traditionally been treated with drug therapy: blood thinners to prevent blood clots and antiarrhythmic drugs (AAD) which become less effective over time and approximately half of these patients eventually develop resistance to them.[4]

The American College of Cardiology, American Heart Association, and European Society of Cardiology have outlined guidelines for treatment of AF. Ablation has become a preferred treatment for atrial fibrillation (AF) that is not responsive to control with medication or electrical cardioversion.[5]

[2] American College of Cardiology website www.acc.org
[3] American Heart Association website www.americanheart.org
[4] American College of Cardiology website www.acc.org
[5] ACC/AHA/ESC 2006 Guidelines for the Management of Patients With Atrial Fibrillation J Am Coll Cardiol, 2006; 48:149-246

Ablations are performed by inserting a catheter into the patient's atria with a tip that emits radiofrequency energy to destroy (scar) the abnormal electrical pathways responsible for the arrthymia. This procedure is usually performed as an outpatient procedure.

Studies of the efficacy of catheter ablation for AF have shown that 52% of patients are able to stop with AAD therapy and another 23.9% are able maintain control with AAD which was ineffective prior to the ablation.[6]

REVIEW STANDARDS

General Review Standards Applicable to All CON Applications

General Review Standard #1- Documented Need: The applicant documents need based on current use within the state, need for service, and national care standards.

The application outlined the needs that would be met as a result of this project:

1. Current Use: Currently two facilities offer EP services in the state and they are both located in Anchorage: PMAC and Alaska Regional Hospital. PAMC currently uses cardiac catheterization lab space for procedures which places a burden on both services since EP procedures can take up to 5 hours for one patient.[7] Alaska Regional Hospital has a dedicated EP Laboratory. The applicant demonstrated EP lab volumes have increased from 2006 (1,726 procedures) through 2008 (1,793 procedures). Volumes were combined for both facilities as the EP cardiologists have medical staff privileges at both facilities and schedule based on availability and urgency for care. Currently, there is a three month waiting list at PAMC for EP lab procedures. This waiting time has been constant 2006-2008.

2. Need for Service: The applicant demonstrated the need for service based on the increase in the aging population of the state and the anticipated increase of AF patients, especially those over age 60. The applicant used statewide population figures and projections to determine need as the only EP services for the entire state are located in Anchorage. [8] The application also discussed the need for more prompt patient access to services due to the fact that, while few patients require emergency EP services, it is necessary to treat these patients as soon as possible since treatment with AAD has proven to be inadequate or not effective. This places the patient at risk of debilitating disease such as stroke or sudden cardiac arrest.[9]

[6] Worldwide Survey on the Methods, Efficacy, and Safety of Catheter Ablation for Human Atrial Fibrillation J Am Heart Assoc 2005;111;1100-1105
[7] Providence Certificate of Need Application June 2009 pg.19
[8] Providence Alaska Medical Center Certificate of Need Application June 2009 pg.19
[9] Providence Alaska Medical Center Certificate of Need Application June 2009 pg.22

3. National Trends: As mentioned in the previous section of this review, the American College of Cardiology, American Heart Association, and European Society of Cardiology have outlined guidelines for treatment of AF and ablation has become a preferred treatment for atrial fibrillation (AF) that is not responsive to control with medication or electrical cardioversion.[10] This has been developed as a standard of care. The applicant discussed the need to increase service capacity in order to meet this standard of care and the challenges with an increased wait list for service.

This standard is met. The applicant documented need for services.

General Review Standard #2 – Relationship to Applicable Plans:

There are no local, state or federal health plans that specifically address the community need for an Electrophysiology Laboratory.

The applicant does demonstrate that the proposed project is consistent with the goals and long-term strategic plan set out by PAMC through their cardiovascular service. Excerpts of the plan were referenced in the application.

This standard is not applicable as there are no appropriate plans pertaining to this project.

The applicant does however address the fact that this project is addressed in the facility and their cardiovascular service strategic planning.

General Review Standard #3 – Stakeholder Participation:

The applicant consulted with physicians, nurses, and technicians regarding the location, design and equipment for the lab.

As stated by the application, "Patients were not involved in the room design as this is highly technical equipment and expert knowledge is required".[11]

This review standard is only partially met due to the fact that service providers were included in the needs assessment but there was no patient participation in process.

General Review Standard #4 – Alternatives Considered:

The applicant demonstrates that they have assessed alternative methods of providing the proposed services and demonstrates that the proposed services are the most suitable approach.

[10] ACC/AHA/ESC 2006 Guidelines for the Management of Patients With Atrial Fibrillation J Am Coll Cardiol, 2006; 48:149-246

[11] Providence Alaska Medical Center Certificate of Need Application June 2009 pg 36.

The applicant explored four alternatives for the current project:

1. Do nothing: It was determined that this was not an acceptable alternative for two reasons: The current two facilities are not adequate to accommodate the increase in need for EP services statewide and, there is currently a 3 month waiting list for procedures. While not emergent, the ability to meet patient needs without placing them at additional risk of stroke or sudden cardiac arrest was deemed not an acceptable by the applicant.

2. Change use of existing catheterization labs: This option was not considered acceptable as all four labs are fully functioning near capacity. There are no catheter labs that can accommodate the increased need for EP services.

3. Utilize another laboratory in the community: Currently Alaska Regional Hospital provides EP services and is operating at capacity. This alternative was reviewed as an option, as the EP cardiologists have privileges in both facilities but it was felt that it would not address the growing need for services statewide.

4. Add a new lab: This was felt to be most appropriate to provide additional capacity and to reduce the time patients must wait for services.

This review standard is met as alternatives were discussed and documented by the applicant.

General Review Standard #5 – Impact on the Existing System:

The applicant describes the anticipated impact on the statewide health care system.

Currently, there is only one other facility that provides EP services for patients throughout the state.[12] Utilization of both facilities was documented and both labs are at capacity. The EP cardiologists have medical staff privileges at both facilities and schedule accordingly based on availability and urgency for care.

The application outlines the anticipated impact on the state's current health delivery system and documents how the addition of an EP lab to PAMC will allow for a reduction in the amount of time a patient must wait for service.

This review standard is met.

[12] Alaska Regional Hospital, Anchorage Alaska.

General Review Standard #6 – Access:

The applicant demonstrates that the project's location is accessible to patients and to ancillary services. The construction of the EP lab will not displace or disrupt current cardiac catheterization services.

The proposed project would be located in the hospital with full access to all the services offered to inpatients as well as outpatients. EP laboratory services are scheduled 5 days per week from 8am-5pm, however, labs are available for urgent or emergency patients via treatment teams on call 24 hours a day/seven days a week.

Travel time for most of PAMC's area patients is approximately 30 minutes by private vehicle as well as regular service by the city transit system. Anchorage International Airport is also accessed by regular city transit service, private vehicles, or taxicabs.

This review standard is met.

SERVICE SPECIFIC STANDARDS AND METHODOLOGY

This application for construction of an EP lab does not increase inpatient bed capacity or add any new services to the facility. Because of this fact, service specific standards and methodologies were not used in the review of this application.

FINANCIAL FEASIBILITY AND COST TO MEDICAID

Review of the application by the Department's Office of Rate Review indicates there will be no increase in the Medicaid reimbursement rate for 2010-2011rate years. In FY2011 costs will rise by approximately $1.11 million due to the increased number of procedures related to the new capacity and not an increase in the percentage of patients who are Medicaid recipients.

Between FY2011 and FY2015 the cost to Medicaid is expected to level not experience such an increase. That increase will be less than $270,000 for the five fiscal years combined.

The project appears to be financially feasible.

A complete analysis from the Office of Rate Review is in Appendix A of this report.

PUBLIC COMMENT SUMMARY

A written public comment period was held from July 16, 2009 to August 17, 2009. One comment was received by a patient in favor of the application who had an EP ablation performed in 2008. This patient is also a physician in Anchorage. A public meeting was held in Anchorage on August 4, 2009. Five employees from PAMC attended as well as a physician from the Alaska Heart Institute who utilizes PAMC for EP procedures. The physician who provided written comments was also in attendance providing his testimony in support of the project. No one spoke in opposition to the project.

RECOMMENDATION

It is recommended that Providence Alaska Medical Center be granted a Certificate of Need for construction of one 1,958 square foot Electrophysiology Laboratory, renovation of 3,080 square feet for relocation of Ultrasound and associated services, and renovation of 1,430 square feet for relocation of a portion of Clinical Laboratory services. All are located in PAMC. The total cost of the project is $7,030,727. The anticipated completion date is July 31, 2010.

APPENDIX A
ESTIMATED COST TO MEDICAID – OFFICE OF RATE REVIEW

STATE OF ALASKA

DEPT. OF HEALTH AND SOCIAL SERVICES

OFFICE OF RATE REVIEW

SEAN PARNELL, GOVERNOR

3601 C Street, Suite 978
Anchorage, AK 99503
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MEMORANDUM

Date: September 9, 2009

To: Ms. Karen S. Lawfer
CON Coordinator

From: Jack Nielson
Executive Director

Subject: Certificate of Need (CON) Review for Providence Alaska Medical Center's Electrophysiology Laboratory

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Providence Alaska Medical Center proposes to build an electrophysiology laboratory which will utilize existing space and be dedicated to providing cardiac catheter ablations for Outpatients.

Currently, the facility estimates that they have a 3 month waiting list for this service and projects that as the population ages the demand for this type of service will continue to increase. The proposed project would enable the facility to provide an additional 562 outpatient cardiac ablations per year and decrease the average patient's waiting time.

The facility plans to relocate the clinical laboratory's administrative offices to space which is currently vacant. Next the facility will move the ultrasound department into the space vacated by the administrative offices and finally, use the space vacated by the ultrasound department for the electrophysiology laboratory. Total capital cost for the CON project is estimated at $7,030,727.

Per 7 AAC 43.685(f)(3), granting of immediate additional capital payment add-on amounts to a per-day rate through a Certificate of Need requires that approved capital expenditures for the project be at least $5,000,000. This project meets that requirement; however, a CON add-on to the hospital inpatient per-diem rate would not be applicable since the new services are planned to be provided to outpatients. The submitted CON application for this project states that the procedures are minimally invasive and require very short hospital stays. Additionally, the facility provided a projected income statement which has all of the revenue earned for these procedures under the outpatient hospital procedures category.

There will be increased charges to the Medicaid program for the additional outpatient hospital services as well as additional physician professional fees related to providing these services. Since these procedures will be provided as outpatient services, there will not be a change to the overall Medicaid outpatient reimbursement rate for the 2010-2011 rate years.

(Continued on Page 2)

Estimated annual cost of the project to the program includes outpatient hospital revenue, as well as, hospital and private physicians' professional fees:

	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015
Estimated per procedure outpatient charges	87,387	90,009	92,709	95,490	98,355	101,306
Inflation factor	1.03	1.03	1.03	1.03	1.03	1.03
Total per procedure	90,009	92,709	95,490	98,355	101,306	104,345
# of procedures	281	562	562	562	562	562
Estimated gross charges	25,292,451	52,102,449	53,665,522	55,275,488	56,933,753	58,641,765
Medicaid utilization %	11.35%	11.35%	11.35%	11.35%	11.35%	11.35%
Medicaid gross charges	2,870,379	5,912,980	6,090,369	6,273,081	6,461,273	6,655,111
Medicaid Outpatient rate*	36.32%	36.32%	36.32%	36.32%	36.32%	36.32%
Estimated cost to the Medicaid program	1,042,522	2,147,594	2,212,022	2,278,383	2,346,734	2,417,136

*Current Outpatient rate

Should you have any questions please contact Sheila Heiker at (907) 334-2468 or me at 334-2447.