

**REVIEW OF THE PROVIDENCE ALASKA MEDICAL CENTER
CERTIFICATE OF NEED APPLICATION FOR
TWO CARDIAC CATHETERIZATION LABORATORIES**

May 3, 2007



**Sarah Palin
Governor**

**Karleen K. Jackson, Ph.D.
Commissioner**

**Anthony Lombardo
Deputy Commissioner**

**State of Alaska/DHSS
Office of the Commissioner
Health Planning & Systems Development Unit
Certificate of Need Program**

TABLE OF CONTENTS

EXECUTIVE SUMMARY 2

GENERAL REVIEW STANDARDS MATRIX A 3

CARDIAC CATH LAB SPECIFIC REVIEW STANDARDS MATRIX B..... 4

PROJECT DESCRIPTION 6

REVIEW STANDARDS

 General Review Standards Applicable to All CON Applications

 #1 Documented Need 6

 #2 Relationship to Plans 8

 #3 Stakeholder Participation 8

 #4 Alternatives Considered 8

 #5 Impact on Existing System 9

 #6 Accessibility 9

 Review Standards Specific to Cardiac Catheterization Services

 #1 Standard for Community with Existing Cardiac Cath Labs 9

 #2 Standard for Pediatric Cardiac Cath Labs 9

 #3 Rapid Access for Facilities without Onsite Cardiac Surgery 9

 #4 Standards for facilities Without Onsite Cardiac Surgery 10

 #5 Minimum number of Catheterizations..... 10

 #6 Pacemaker Standard 10

DETERMINATION OF NEED SUMMARY 10

PUBLIC COMMENT SUMMARY...11

FINANCIAL FEASIBILITY AND COST TO MEDICAID..... 12

APPENDICES

APPENDIX A – Alaska Cardiac Cath Laboratory Review Methodology.....13

APPENDIX B - Detailed Determination of Need Calculations..... 16

APPENDIX C – Projection of Need Tables..... 18

APPENDIX D – Estimated Cost of Projects to Medicaid..... 21

EXECUTIVE SUMMARY

Providence Alaska Medical Center (“PAMC”) submitted a Certificate of Need (“CON”) application to build two cardiac catheterization labs to perform interventional radiology and cardiac catheterization procedures. The projected cost to remodel 1,500 square feet of space and purchase equipment is \$5.0 million. The applicant plans to have the first lab operational by May 2007 and the second lab by January 2008 if approved.¹

The PAMC CON application was originally submitted to compete with a CON application from Alaska Regional Hospital (“ARH”). However, after review of the applications, the Department determined that the proposed projects were for different services and thus concurrent review was not appropriate. This review addresses the PAMC application only.

Application of the *Alaska Certificate of Need Review Standards and Methodologies* applicable to cardiac catheterization laboratories results in a determination of need for eight such laboratories in Anchorage by 2010. Currently, there exist seven cardiac catheterization laboratories within the Municipality of Anchorage. Additionally, a cardiac catheterization laboratory exists at Mat-Su Regional Medical Center, and another has been approved for Fairbanks Memorial Hospital that that is scheduled to be operational in 2008. These two facilities will serve the Mat-Su Borough and the Interior Region of the state.

Recommendation: The staff recommends that one cardiac catheterization laboratory be approved for PAMC with a completion date of December 31, 2007. The staff further recommends that the CON be conditioned on the applicant submitting a revised budget reflecting a decrease from requested two cardiac catheterization laboratories to the recommended one lab within 30 days after receiving notice of this decision.

¹ Note: As far as is known, the applicant has not started construction on the project yet. The projected date that the first lab would be operational was an estimate that is not likely to be met because approval of the project was delayed an additional 30 days in order to gather additional information that was needed. It is likely that the opening of the first lab would be delayed up to three months after the approval date.

CERTIFICATE OF NEED GENERAL REVIEW STANDARDS MATRIX A

PROVIDENCE ALASKA MEDICAL CENTER CARDIAC CATHETERIZATION LAB EXPANSION CERTIFICATE OF NEED REVIEW - May 3, 2007	
GENERAL CERTIFICATE OF NEED REVIEW STANDARDS	Standard Met?
General Review Standard #1 -- Documented Need: The applicant documents need for the project by the population served, or to be served, including, but not limited to, the needs of rural populations in areas having distinct or unique geographic, socioeconomic, cultural, transportation, and other barriers to care. In applying this standard, the department will also consider, when appropriate, whether the service is in an area of the state that is unserved or under-served in the type of proposed service.	Met
General Review Standard #2 Relationship to Applicable Plans: The applicant demonstrates that the project, including the applicant’s long-range development plans, augments and integrates with relevant community, regional, state, and federal health planning, and incorporates or reflects evidence-based planning and service delivery.	Met
General Review Standard #3 – Stakeholder Participation: The applicant demonstrates effective formal mechanisms for stakeholder participation in planning for the project and in the design and execution of service.	Met
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.	Met
General Review Standard #5 – Impact on the Existing System: The applicant demonstrates the impact on existing health care systems within the project’s service area that serve the target population in the service area, and health care systems that serve the target population in other regions of the state.	Met
General Review Standard #6 – Access: The applicant demonstrates that the project’s location is accessible to patients and clients, their immediate and extended families and community members, and to ancillary services. This includes the relocation of existing services or facilities.	Met

CERTIFICATE OF NEED SPECIFIC REVIEW STANDARDS MATRIX B

CARDIAC CATHETERIZATION LAB SPECIFIC REVIEW STANDARDS	Standard Met?
Cardiac Cath Lab Specific Review Standard #1: No new cardiac catheterization laboratories will be approved in a community with existing cardiac catheterization services unless all existing adult laboratories are operating at an average of at least 75% of capacity or an average of at least 750 procedures per year.	Met
Cardiac Cath Lab Specific Review Standard #2: The applicant for a facility that will offer pediatric cardiac catheterization demonstrates that at least 250 procedures per year will be performed	N/A
Cardiac Cath Lab Specific Review Standard #3: The applicant for a facility that will offer primary angioplasty without onsite cardiac surgery capability must have a proven and tested plan for rapid access (within 90 minutes from declaration of emergency to the patient being in a cardiac surgical operating room). Appropriate hemodynamic support capability for such a transfer must exist as well as a team of appropriately trained individuals. The ability to place an intraaortic balloon pump (IABP) and temporary transvenous pace- maker for stabilization before transport must also exist.	N/A
Cardiac Cath Lab Specific Review Standard #4a: Patients with acute coronary syndromes, severe congestive heart failure, pulmonary edema due to acute ischemia, severe multi-vessel or left main disease, and severe left ventricular dysfunction associated with valvular disease are excluded.	N/A
Cardiac Cath Lab Specific Review Standard #4b: Patients with complex (Type IIb and III) coronary lesions and other high-risk anatomic situations (only remaining coronary artery, vessel to be treated supplies more than 40% of remaining viable myocardium, etc.) are excluded. Facilities requesting approval for percutaneous coronary intervention (PCI) services in the absence of onsite cardiac surgery must develop criteria to screen for the types of clinical and anatomic situations appropriate and inappropriate for their facility based on published criteria in the literature.	N/A
Cardiac Cath Lab Specific Review Standard #4c: A plan for proper oversight must be approved by the department before approval of a Certificate of Need. The plan must include: accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO); membership in the American College of Cardiology – National Cardiovascular Data Registry (for benchmarking outcomes); an independent peer review of the program by the Society for Cardiovascular Angiography and Interventions or the American Medical Foundation for Peer Review, to be conducted once in the first six months and then annually thereafter for the first three years, to ensure that all issues related to quality assurance are monitored and addressed; and supplying the department with all reports and data developed within 10 working days after each is developed.	N/A
Cardiac Cath Lab Specific Review Standard #4d: The laboratory director must have extensive experience performing coronary interventions (more than 500 procedures performed during their career and more than 75 procedures annually during the past two years), and must have and maintain a certificate of "Added Qualifications" in Interventional Cardiology from the American Board of Internal Medicine.	N/A

Review of the Providence Alaska Medical Center
Certificate of a Need Application for Two
Cardiac Catheterization Laboratories

May 3, 2007

<u>Cardiac Cath Lab Specific Review Standard #4e:</u> The laboratory must maintain a quality standard for diagnostic catheterization mortality of less than 3 per 1000 procedures and for PCI of less than 1 per 100 procedures.	N/A
<u>Cardiac Cath Lab Specific Review Standard #5:</u> An applicant who seeks to establish new cardiac catheterization services in a community without existing services demonstrates that the facility is likely to perform a minimum of 500 cardiac catheterizations per year by the third year after program implementation.	N/A
<u>Cardiac Cath Lab Specific Review Standard #6:</u> The applicant demonstrates that the facility has the capability of providing immediate transvenous pacemakers in case of cardiac arrest.	Met

REVIEW OF THE PROVIDENCE ALASKA MEDICAL CENTER CERTIFICATE OF NEED APPLICATION FOR TWO CARDIAC CATHETERIZATION LABORATORIES

PROJECT DESCRIPTION

PAMC proposes to remodel 1,500 square feet of space and purchase a Phillips Allura Xper FD20 monoplane with rotatable flat detectors designed for cardiac and interventional radiology catheterization procedures. The projected cost of the PAMC project is \$5.0 million. If approved, the applicant proposes to open one cardiac catheterization laboratory in May 2007 and the second in January 2008.

Cardiac catheterization is a procedure used to study the condition and functioning of the heart by inserting a long, thin tube called a catheter into an artery or vein and running it to the heart. When the catheter reaches the heart, the coronary arteries are filled with contrast dye and X-ray pictures are then taken. The pictures are then evaluated for blockages, assessment of the pumping function of the heart, operation of the heart valves, and other problems. Coronary angiography and angiogram are other terms used to describe cardiac catheterization.

Cardiac catheterization services were first implemented in Alaska at PAMC in 1975. ARH began providing cardiac catheterization services in 1993; the Alaska Heart Institute (“AHI”) opened a freestanding diagnostic cardiac catheterization lab in Anchorage in 2003; the Mat-Su Regional Medical Center (“Mat-Su”) opened a cardiac catheterization lab in Wasilla in 2006; and Fairbanks Memorial Hospital (“FMH”) was approved to build a cardiac catheterization lab that is scheduled to be operational in 2008. The AHI lab is exclusively diagnostic, the Mat-Su facility provides diagnostic and some emergency procedures; and the FMH facility will be primarily diagnostic but will perform some elective interventional cardiac catheterizations.

There currently are eight existing cardiac catheterization laboratories in Alaska, with seven in the Municipality of Anchorage. PAMC has four cardiac catheterization laboratories, ARH has two labs, and AHI and Mat-Su each have one lab. One additional cardiac catheterization laboratory has been approved for FMH and is expected to be operational in 2008. The seven labs in the Municipality of Anchorage are the labs that are relevant to this CON application review.

REVIEW STANDARDS

General Review Standards Applicable to All CON Applications

General Review Standard #1- Documented Need *The applicant documents need for the project by the population served, or to be served, including, but not limited to, the needs of rural populations in areas having distinct or unique geographic, socioeconomic, cultural, transportation, and other barriers to care.*

The applicant documented its reasons for requesting additional cardiac catheterization capacity. Specifically, PAMC described the use of its four existing catheterization laboratories and projected a need for two more such laboratories. PAMC supported its need for the proposed project based on utilization data, waiting lists, the number of cardiologists sharing the facilities, and patient flow issues. Utilizing this data, PAMC stated in its application that utilization of the existing services at PAMC increased 24% between 2004 and 2005. PAMC also projected that its number of patients will increase an additional 5% in 2007 and will continue to increase at a rate of 6% annually from 2008-2009. Factors referenced by PAMC as affecting utilization of its cardiac catheterization services include population growth and population aging. Additionally, PAMC noted that as more complex procedures are performed in this venue, there is an increase in the average time needed to perform such procedures. For example, some procedures now take up to eight hours, significantly affecting the throughput and availability of the catheterization labs. The need to provide emergency services, availability of observation beds, and the number of cardiologists using the facilities affect scheduling and the ability to use cath labs efficiently.

Some service delays occur because there has been a lack of cardiac observation beds for patient prep and post catheterization recovery. A previous CON application from PAMC for more cardiac observation beds stated that the lack of these beds had at times delayed the start of cardiac catheterization procedures.² The cardiac observation bed CON application was approved, which should alleviate some of the problems with throughput and scheduling.

The number of physicians using PAMC cath labs has nearly doubled in the last six years. In 2001, there were 11 cardiologists using the cardiac catheterization labs and at the time this application was submitted, there were 16 cardiologists and three interventional radiologists credentialed to use the PAMC cardiac catheterization laboratories.³ The applicant also states that PAMC has a three month waiting list for cardiac ablations.⁴ An ablation is a procedure performed to identify and destroy a small amount of heart tissue that is causing irregular heart rhythm. Additional information provided by the applicant indicates that ablations are the only cardiac catheterization lab procedure that has a waiting list. It is an elective procedure that is only performed by three cardiologists who are specialists in electrophysiology. Each procedure takes four to six hours, which makes scheduling and coordinating available time difficult. Most other procedures are more urgent and need to be done in a timely manner.⁵ Since ablations are elective and less urgent, and there is a lack of cardiac catheterization laboratories, all other procedures have priority. PAMC performed 277 ablations in 2006 and is scheduling 6-8 per week.⁶

² PAMC CON application "Expansion of Cardiovascular Observation". January 2007. Page 11.

³ PAMC CON application "Expansion of Cardiovascular Observation". January 2007. Page 10.

⁴ A technique used to destroy abnormal heart tissue that is causing an arrhythmia.

⁵ Email. Lisa Wolf. April 23, 2007.

⁶ Email. Lisa Wolf. May 1, 2007.

General Review Standard #2 – Relationship to Applicable Plans: The applicant demonstrates that the project, including the applicant’s long-range development plans, augments and integrates with relevant community, regional, state, and federal health planning, and incorporates or reflects evidence-based planning and service delivery. A demonstration under this standard should show that the applicant has checked with the department regarding any relevant state plan, with appropriate federal agencies for relevant federal plans, and with appropriate communities regarding community or regional plans.

The State of Alaska CON methodology for cardiac catheterization is the only relevant state or federal planning document for this service.

PAMC states that the new catheterization labs are a part of its 2007—2009 strategic plan and has therefore met this standard.

General Review Standard #3 – Stakeholder Participation: The applicant demonstrates evidence of stakeholder participation in planning for the project and in the design and execution of services.

PAMC stated that nurses, technologists and physicians were involved in the selection of laboratory equipment and the location and design of the cardiac catheterization laboratory.⁷ Therefore, this standard has been met.

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.

PAMC meets this standard by demonstrating that they have considered different alternatives for providing the services. PAMC considered four options: doing nothing; changing the function and scheduling of the labs; using another lab in the community; adding one new lab; and adding two new labs. Doing nothing was not considered suitable because of current long waiting periods (up to 3 months for ablations), and the increase in demand. The applicant states that using another lab in the community was not feasible because the four radiologists at PAMC do not have privileges at ARH and those labs do not have enough excess capacity to meet the growing need. Scheduling changes were not chosen because the four labs are reaching capacity and do not have the time available for additional procedures. Although one lab would reduce overtime and better handle the growth, this option was not proposed because PAMC believed that two labs would allow PAMC to meet current demands and grow with the population and physicians’ needs.

⁷ Supplemental information provided in response to the completeness check, received via letter from Lisa Wolf, February 15, 2007.

General Review Standard #5 – Impact on the Existing System *The applicant briefly describes the anticipated impact on existing health care systems within the project’s service area that serve the target population in the service area, and the anticipated impact on the statewide health care system.*

PAMC meets this standard through their discussion on the regional health care system. PAMC states that its two new labs will increase the availability of services and reduce overtime and waiting periods. Most cardiologists have privileges at both ARH and PAMC and therefore can choose where they want to perform a procedure. Interventional radiologists are under contract to the individual hospitals and therefore would not use another hospital.

General Review Standard #6 – Access: *The applicant demonstrates that the project’s location is accessible to patients and clients, their immediate and extended families and community members, and to ancillary services. This includes the relocation of existing services or facilities.*

PAMC meets this standard. Their project is accessible to patients, families and ancillary services since it is located in the center of Anchorage and is within a half hour’s drive for most residents and patients arriving from the airport. PAMC’s location in Anchorage makes it accessible to approximately 42% of the total state population.

Review Standards Specific to Cardiac Catheterization Services

CC Lab Specific Review Standard #1 - *No new cardiac catheterization laboratories will be approved in a community with existing cardiac catheterization services unless all existing adult laboratories are operating at an average of at least 75% of capacity or an average of at least 750 procedures per year.*

The applicant demonstrated that the requirement of this standard is met. There are seven existing cardiac catheterization labs in Anchorage including four at PAMC, two at ARH, and one at AHI (which did not respond to the Department’s request for data). In 2006, these labs treated 5839 patients, resulting in an average of 834 patients per lab per year, and operated at an average of 83% of capacity.

CC Lab Specific Review Standard #2: *The applicant for a facility that will offer pediatric cardiac catheterization demonstrates that at least 250 procedures per year will be performed.*

This standard does not apply to PAMC because this project does not propose to develop a dedicated pediatric cardiac catheterization laboratory.

CC Lab Specific Review Standard #3 - *The applicant for a facility that will offer primary angioplasty without on-site cardiac surgery capability must have a proven and tested plan for rapid access (within 90 minutes from declaration of emergency to the patient being in a cardiac surgical operating room). Appropriate hemodynamic support capability for such a*

transfer must exist as well as a team of appropriately trained individuals. The ability to place an intraaortic balloon pump (IABP) and temporary transvenous pacemaker for stabilization before transport must also exist.

This standard is not applicable because PAMC has existing on-site cardiac surgery capabilities.

CC Lab Specific Review Standard #4 - A facility requesting authorization to perform elective coronary interventions must be located within a hospital or in a laboratory attached to a hospital with onsite cardiac surgery capability. The department may approve a laboratory that is not located within a hospital or not attached to a hospital with onsite cardiac surgery capability, if the following conditions are met:

None of the cardiac catheterization standards in #4 (including standards 4a through 4e) apply to PAMC because they have on-site cardiac surgery capabilities. PAMC is accredited by the Joint Commission on Accreditation of Healthcare Organizations, which is one of the components of standard #4e. PAMC was surveyed in October 2005 and received accreditation for 2005 – 2008.

Cardiac Cath Lab Specific Review Standard #5: An applicant who seeks to establish new cardiac catheterization services in a community without existing services demonstrates that the facility is likely to perform a minimum of 500 cardiac catheterizations per year by the third year after program implementation.

This standard does not apply because Anchorage has existing cardiac catheterization laboratories.

Cardiac Cath Lab Specific Review Standard #6 The applicant demonstrates that the facility has the capability of providing immediate transvenous pacemakers in case of cardiac arrest.

PAMC states that it can provide immediate transvenous pacemakers in case of cardiac arrest.

DETERMINATION OF NEED SUMMARY

The State of Alaska cardiac catheterization methodology to determine need for additional cardiac catheterization laboratories shows that there will be a need for 7.9 cardiac cath labs in the community of Anchorage in 2010. Currently there are seven existing labs. As a result, the State of Alaska methodology shows that there is a need for one additional cardiac catheterization laboratory in the community of Anchorage within the next three years.

As of April 2007 (date of this CON review) the Department has been provided with patient use data for the years 2004, 2005 and 2006 respectively for the following facilities: PAMC (four labs), and ARH (2 labs). AHI has not responded to written requests for data. For purposes of estimation of use, the AHI CEO's statement that AHI treats "8-10 patients a week" permits use

of 520 patients per year to be used for calculating use rates.⁸ Staff acknowledge that patients from across the state have used the Anchorage services during the period for calculation of the use rate. Neither military nor tribal hospitals have these services, so no adjustment is required to either population or use data for calculating use rates. Patients from Southeast Alaska may use out of state services at a higher rate than other residents of the state but no changes in those use patterns are anticipated that would impact the need calculations.

It is expected however that the new cardiac catheterization services implemented in Wasilla in 2006 and the cardiac catheterization laboratory approved for Fairbanks may accommodate some of the demand that was met previously in Anchorage. However, the extent of that change is unknown. Services in those areas may meet a previously unmet need for diagnostic procedures, with similar levels of use in the Anchorage facilities remaining constant. The tertiary care facilities (those with open heart surgery, PAMC and ARH) will continue to serve a portion of the need from the outlying areas. Thus no adjustment is made for market share impact of the new facilities. The use rates effective for the Municipality of Anchorage are based on the population of the state excluding the Mat-Su and Interior populations. The same result of a need estimate of 7.9 cath labs in 2010 occurs if the population of the Municipality of Anchorage is used rather than “balance of state.” The strictly community-based use rate calculation is shown in Table 1 on page 19.

In their application, PAMC noted their disagreement with the state’s standards and methodologies and provided an alternative methodology for consideration. Specifically, the applicant stated: “The [CON] methodology is flawed as it does not take into account volume growth as a result of: new physicians, new types of procedures, and increasing use rates driven by population increases in people over age 45. Both internal and external data sources provide evidence of significant growth in catheterization lab volumes proving the State’s methodology is inconsistent with what is happening in the marketplace.”⁹

Although medical practice in this area is changing rapidly, it is uncertain at the current time exactly what those effects may be. The applicable standards do not provide for demand created by additional providers, until that demand is reflected in actual utilization changes. Use of the applicable standards and methodologies contained in the *Alaska Certificate of Need Review Standards and Methodologies* document is required by 7 AAC 07.025.

PUBLIC COMMENT SUMMARY

A written public comment period was held from February 2, 2007 to March 5, 2007. A public meeting was held on February 22, 2007, and included presentations and comments for the ARH neuroradiology project and the PAMC project to build two cardiac catheterization laboratories. At the time of the public hearing, a determination had not been made to consider the two projects

⁸ Baxter Burton. Telephone conversation. March 22, 2007.

⁹ PAMC CON application for “Two Catheterization Laboratories”. January 2007. Page 12

separately. The Department received a total of two letters of support for the ARH project. No other written comments were received via email, US postal service, or fax. Eleven individuals attended the public meeting and four people provided comments (two were presenters). All those who commented on the ARH project supported it. During the meeting, the presenter for ARH stated that he believed that the two applications were different and that the ARH application should not be reviewed concurrently with the PAMC project because the ARH project was seeking to offer a different service (stroke) from the cardiac catheterization service contained in the PAMC application.

FINANCIAL FEASIBILITY AND COST TO MEDICAID

PAMC is a facility that is financially strong and should have no problem financing the project since they had a total net operating income of \$108.3 million for the entire facility during the five-year period of 2001 to 2005. The project is financially feasible.

If approved, the project would significantly increase Medicaid expenditures. The proposed project for two additional cardiac catheterization laboratories would increase the annual capital cost to Medicaid by \$318,457 in 2008 to \$1,105,320 in 2012. Specific annual Medicaid increases are detailed below.

	2008	2009	2010	2011	2012
Inpatient Capital	\$79,144	\$79,144	\$79,144	\$79,144	\$79,144
Inpatient Operating					\$694,351
OP Charge Increase	\$239,313	\$331,575	\$331,575	\$331,575	
Outpatient Capital					\$33,919
Outpatient Operating					\$297,656
Total Cost to Medicaid	\$318,457	\$410,719	\$410,719	\$410,719	\$1,105,320

If only one cardiac catheterization laboratory is approved, it is expected that the cost to Medicaid would be halved. The annual capital cost to Medicaid would be \$159,229 in 2008 and increasing to \$525,660 in 2012.

APPENDIX A

CARDIAC CATHETERIZATION LABORATORY CERTIFICATE OF NEED REVIEW STANDARDS & METHODOLOGY

(SOURCE: DECEMBER 9, 2005 ALASKA CERTIFICATE OF NEED REVIEW STANDARDS AND
METHODOLOGIES, P. 30-31 available at <http://www.hss.state.ak.us/publicnotice/PDF/133.pdf>)

VI. Review Standards and Methodology

D. Cardiac Catheterization Services

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards in its evaluation of an application for a certificate of need for cardiac catheterization services:

1. No new cardiac catheterization laboratories will be approved in a community with existing cardiac catheterization services unless all existing adult laboratories are operating at an average of at least 75% of capacity or an average of at least 750 procedures per year.
2. The applicant for a facility that will offer pediatric cardiac catheterization demonstrates that at least 250 procedures per year will be performed
3. The applicant for a facility that will offer primary angioplasty without onsite cardiac surgery capability must have a proven and tested plan for rapid access (within 90 minutes from declaration of emergency to the patient being in a cardiac surgical operating room). Appropriate hemodynamic support capability for such a transfer must exist as well as a team of appropriately trained individuals. The ability to place an intraaortic balloon pump (IABP) and temporary transvenous pacemaker for stabilization before transport must also exist.
4. A facility requesting authorization to perform elective coronary interventions must be located within a hospital or in a laboratory attached to a hospital with onsite cardiac surgery capability. The department may approve a laboratory that is not located within a hospital or not attached to a hospital with onsite cardiac surgery capability, if the following conditions are met:
 - a. Patients with acute coronary syndromes, severe congestive heart failure, pulmonary edema due to acute ischemia, severe multi-vessel or left main disease, and severe left ventricular dysfunction associated with valvular disease are excluded.
 - b. Patients with complex (Type IIb and III) coronary lesions and other high-risk anatomic situations (only remaining coronary artery, vessel to be treated supplies more than 40% of remaining viable myocardium, etc.) are excluded. Facilities requesting approval for percutaneous

coronary intervention (PCI) services in the absence of onsite cardiac surgery must develop criteria to screen for the types of clinical and anatomic situations appropriate and inappropriate for their facility based on published criteria in the literature.

c. A plan for proper oversight must be approved by the department before approval of a certificate of need. The plan must include:

- accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO);
- membership in the American College of Cardiology - National Cardiovascular Data Registry (for benchmarking outcomes);
- an independent peer review of the program by the Society for Cardiovascular Angiography and Interventions or the American Medical Foundation for Peer Review, to be conducted once in the first six months and then annually thereafter for the first three years, to ensure that all issues related to quality assurance are monitored and addressed; and
- supplying the department with all reports and data developed within 10 working days after each is developed.

d. The laboratory director must have extensive experience performing coronary interventions (more than 500 procedures performed during their career and more than 75 procedures annually during the past two years), and must have and maintain a certificate of "Added Qualifications" in Interventional Cardiology from the American Board of Internal Medicine.

e. The laboratory must maintain a quality standard for diagnostic catheterization mortality of less than 3 per 1000 procedures and for PCI of less than 1 per 100 procedures.

5. An applicant who seeks to establish new cardiac catheterization services in a community without existing services demonstrates that the facility is likely to perform a minimum of 500 cardiac catheterizations per year by the third year after program implementation.

6. The applicant demonstrates that the facility has the capability of providing immediate transvenous pacemakers in case of cardiac arrest

Review Methodology

Several calculations are used to determine the demand for cardiac catheterization services and the number of cardiac catheterization laboratories required to meet projected demand efficiently. The department will use the following formula to determine need for cardiac catheterizations services:

~ **STEP ONE:** Determine the projected cardiac catheterization case load using the formula:

$$C=P \times UR$$

C (case load) = the number of procedures in the third year following implementation of the project

P (projected population at risk) = the official state projection for the adult population (18 years of age and older) in the third year following implementation of the project

UR (use rate) = the average annual cardiac catheterization procedures for the preceding three years per 1,000 population.

~ **STEP TWO:** Determine the number of cardiac catheterization laboratories required using the formula:

$$\text{CCLR} = (C/LC) / TO$$

C (case load) = number of cardiac catheterization procedures **LC** (laboratory capacity) = defined as 1,000 procedures per year **TO** (target occupancy) = 75% (0.75)

~ **STEP THREE:** Determine number of additional cardiac catheterization laboratories needed by subtracting number of currently existing and CON-approved laboratories from the number s found to be needed.

~ **STEP FOUR:** Determine projected cardiac catheterization laboratory need for a proposed service area by multiplying the statewide projected cardiac catheterization need by the service area share of population to be served.

$$\text{PLN}_{sa} = \text{PLN}_t \times \text{SAS}$$

PLN_{sa} = projected cardiac catheterization laboratory need for the service area **PLN_t** = total projected cardiac catheterization laboratory need for the state

SAS (service area share) = the proposed service area's current share of the population to be served, as of the most recent geographic population estimates. If there is public information about service area population changes expected over the planning horizon, such as a military base closing, or a major economic project such as a new mine, the service area share estimate may be modified with explanation to reflect the expected change.

$$\text{PBN}_{sa} = \text{PBN} \times \text{SAS}$$

SAS (service area share) = the proposed service area's current share of the population to be served, as of the most recent geographic population estimates. If there is public information about service area population changes expected over the planning horizon, such as a military base closing, or a major economic project such as a new mine, the service area share estimate may be modified with explanation to reflect the expected change.

APPENDIX B Detailed Analysis for Need Determination

Alaska Department of Health and Social Services

STEP ONE: Forecast Caseload

Caseload = Population x Use Rate

Three year average use rate calculation/1000 population (2004-2006): $UR = (5543/345,587) * 1000 = 16.04$ for patients in cath labs per 1000 population aged 18 and over (Alaska minus Interior and Mat-Su)

Three year average use rate calculation/1000 population (2004-2006): $UR = (5543/199,305) * 1000 = 27.81$ for patients in cath labs per 1000 population aged 18 and over (Anchorage Muni)

Projected use for 2010 using balance of state: $16.04 * 1000 / 368,325 = 5933$ caseload

Projected use for 2010 using Anchorage Municipality population only: $27.81 * 1000 / 214,192 = 5957$ caseload

STEP TWO: Service Area labs needed (CCLR) = (Caseload/Lab Capacity) / Target Occupancy .

$$5933/1000/.75 = 7.9 \text{ labs needed (rounded to 8)}$$

$$5957/1000/.75 = 7.9 \text{ labs needed (rounded to 8)}$$

Target use is .75 so 5933 or 5957 expected caseload implies eight cardiac cath labs are needed in Anchorage. Alaska Heart Institute data was not available (but estimated to be 520 annually).

STEP THREE: Number of additional cardiac catheterization laboratories needed: subtract number of currently existing and CON-approved laboratories from the numbers found to be needed.

$$\text{Needed} - (\text{Existing} + \text{Approved}) = 7.9 - 7 = 1 \text{ additional}$$

Seven labs are currently in operation in Anchorage . Six hospital based catheterization labs currently exist (2007): four at PAMC, two at ARH. The Alaska Heart Institute has a catheterization lab used predominantly for diagnostic services and as an overflow unit to supplement the PAMC labs.

STEP FOUR Service area share: The service area for the Anchorage cardiac catheterization labs is considered for 2010 to be the balance of the state, excluding the Interior region which will be considered the service area for the Fairbanks cath lab, and the Mat-Su which will be considered the service area for the Mat-Su cath lab. CON review criteria refer also to the “community” in which the facilities are located, which is the Anchorage Municipality, and contains 58% of the “balance of state” adult (18+) population. Use rates and projected patient counts based on the “balance of state” population show an expectation of 5908 patients per year being seen in the three Anchorage facilities with cath labs. Use rates and projected patient counts based on the Municipality of Anchorage population show an expectation of 5957 patients per year being seen in the three Anchorage facilities with cath labs.

Review of the Providence Alaska Medical Center
Certificate of a Need Application for Two
Cardiac Catheterization Laboratories

May 3, 2007

At 750 per year (75% of expected capacity), either projection amounts to a need determination for one additional cath lab for Anchorage through 2010.

APPENDIX C

Tables

(next two pages

Table 1. Catheterization Laboratory Needs Calculations for CON Review for Projected 2010 Need Using Alaska CON Use Methodology and the Anchorage Population Only

Patients									
year	PAMC	ARH	Alaska Heart Institute (Estimate based on AHI CEO "10/week")*	Total Patients Served	Use Rate/1000	18+ population Anchorage Alone (06CAG04[05, 06].xls AKDOL)	Cath Labs	Projected Need (750 per lab) (Total Patients Served in 2010 /750)	Excess (deficiency) of Labs
2003	3539	1074	520	5133			7		
2004	3401	1078	520	4999	25.29	197675	7		
2005	4203	1069	520	5792	29.16	198616	7		
2006	4142	1177	520	5839	28.96	201623	7		
Labs	4	2	1				7		
Average Use Rate									
3 year average 04-06				5543.3	27.81	199,305			
Projection									
Projected 2010				5957	27.81	214,192	7	7.9	-0.9

* Telephone conversation with Baxter Burton, CEO of AHI March 22, 2007

*the potential impact of FMH & Mat-Su cath labs on other hospitals' cath lab volume of service is unknown. Here we assume the level of use in Anchorage will not be affected. The known use in Mat-Su (250 in 12 months) has not been included in the count.

Sources: From PAMC CON Application and PAMC and ARH reports to CON Staff via emails)
 Population Estimates for 18+, 2004-2006, Alaska DOLWD table 06CAG04.xls, 06CAG05.xls, 06CAG06.xls from website

Table 2. Catheterization Laboratory Needs Calculations for CON Review for Projected 2010 Need Using Alaska CON Use Methodology including all Alaska populations except Interior and Mat-su

Patients									
year	PAMC	ARH	Alaska Heart Institute (Estimate based on AHI CEO "10/week")*	Total Patients Served	Use Rate/1000	18+ population excluding Interior & Mat-Su (06CAG04[05, 06].xls AKDOL)	Cath Labs	Projected Need (750 per lab) (Total Patients Served in 2010 /750)	Excess (deficiency) of Labs
2003	3539	1074	520	5133			7		
2004	3401	1078	520	4999	14.55	343,490	7		
2005	4203	1069	520	5792	16.79	344,892	7		
2006	4142	1177	520	5839	16.76	348,380	7		
Labs	4	2	1				7		
Average Use Rate									
3 year average 04-06				5543.3	16.04	345,587			
Projection									
Projected 2010				5933	16.04	369,868	7	7.9	-0.9

* Telephone conversation with Baxter Burton, CEO of AHI March 22, 2007

*the potential impact of FMH & Mat-Su cath labs on other hospitals' cath lab volume of service is unknown. Here we assume the level of use in Anchorage will not be affected. The known use in Mat-Su (250 in 12 months) has not been included in the count.

Sources: PAMC CON application and PAMC and ARH reports to CON Staff via emails.

Population Estimates for 18+, 2004-2006, Alaska DOLWD table 06CAG04.xls, 06CAG05.xls, 06CAG06.xls from website

Review of the Providence Alaska Medical Center
Certificate of a Need Application for Two
Cardiac Catheterization Laboratories

May 3, 2007

APPENDIX D

**OFFICE OF RATE REVIEW
ESTIMATED COST TO MEDICAID**

(next page)

STATE OF ALASKA

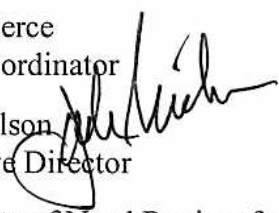
SARAH PALIN, GOVERNOR

Office: 3601 C Street, Suite 978
Anchorage, AK 99503
Mail: P.O. Box 240249
Anchorage, AK 99524-0249
Phone: (907) 334-2464
FAX: (907) 334-2220

DEPT. OF HEALTH AND SOCIAL SERVICES

OFFICE OF RATE REVIEW

MEMORANDUM

Date: March 1, 2007
To: David Pierce
CON Coordinator
From: Jack Nielson 
Executive Director
Subject: Certificate of Need Review for Providence Alaska Medical Center Two
Catheterization Laboratories

Providence Alaska Medical Center wishes to establish two Cardiac Catheterization Laboratories in their existing facility. The proposed labs would be in addition to the four Cardiac Catheterization Laboratories already in operation. Total cost for the renovation projects are estimated to be \$5,001,614. Presentation of the total cost is being established as a single project, however, two laboratories are being proposed with different implementation dates.

Approval of this certificate of need would generate a Certificate of Need (CON) add-on to the Providence Medicaid inpatient per-diem rate. This add-on would be for the facilities FY 2007-2011. Total cost of the project would be integrated into the FY 2010 base year for inclusion in the FY 2012 Medicaid rates. There will also be increased charges to the program for the newly available outpatient services generating increased Medicaid payments, but there would not be a change to the overall Medicaid outpatient reimbursement rate for the 2008-2011 rate years.

The facility only provided a three year projection of operating costs from 2007 through 2009, therefore FY 2010 through 2012 projected costs to the program are based upon the estimates given for FY 2009 and are listed below. The increase in FY 2012 is due to rebasing where operating costs are included in the inpatient and outpatient rate calculation.

Estimated Medicaid Cost (using information available in CON)

	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>
Inpatient Capital	\$26,381	\$79,144	\$79,144	\$79,144	\$79,144	\$79,144	\$79,144
Inpatient Operating	-	-	-	-	-	694,531	694,531
Outpatient Charge Increase **	\$50,166	\$239,313	\$331,575	\$331,575	\$331,575	-	-
Outpatient Capital	-	-	-	-	-	\$33,919	\$33,919
Outpatient Operating	-	-	-	-	-	\$297,656	\$297,656
Total Cost to Medicaid							
(est. with CON available information)	\$76,547	\$318,457	\$410,719	\$410,719	\$410,719	\$1,105,250	\$1,105,250

**These amounts include Capital and Operating paid through increased charges for outpatient services.

Should you have any questions please contact Joyce Seekatz at 334-2466 or me at 334-2447.