

**REVIEW OF THE ALASKA REGIONAL HOSPITAL
CERTIFICATE OF NEED APPLICATION FOR ADDITION OF
ONE NEURORADIOLOGY CATHETERIZATION
LABORATORY**

April 13, 2007



**Sarah Palin
Governor**

**Karleen Jackson, PhD
Commissioner**

**Anthony Lombardo
Deputy Commissioner**

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

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EXECUTIVE SUMMARY

Alaska Regional Hospital (“ARH”) submitted a Certificate of Need (“CON”) application to add one neuroradiology catheterization laboratory to treat cerebrovascular disease (stroke). Proposed new equipment includes a Phillips Integrated 3D Neuro Biplane Flat Detector System. If approved, the new \$2.15 million, 519 square foot project is scheduled for completion in July, 2007.

Believing it was planning an activity similar to the project proposed by ARH, Providence Alaska Medical Center (“PAMC”) submitted a CON application for cardiac catheterization services. Based upon its review of the information presented by the respective applicants, the Department has determined that the two projects represent different services. Accordingly, the Department has considered the merits of each application separately.

The Department’s decision to review the two application separately is largely based on the fact the ARH project is for the treatment of cerebrovascular (stroke) disease (a new service), while the PAMC project is for cardiac services. Further, state of the art interventional neuroradiology procedures, as proposed for use by ARH, utilize significantly different imaging systems than do cardiac catheterizations. In particular, they rely on larger “image intensifiers” and bi-plane x-ray systems with full rotational capabilities compared to the cardiac procedures. While limited neuroradiology procedures might be possible in conventional cardiac labs, the quality and capabilities of these procedures would be less than those done in labs with the neuro-specific equipment. Moreover, because of the stronger image intensifiers required in neuro-radiology suites, the use of these systems for cardiac procedures (which typically utilize ‘cine’ techniques) could expose heart patients to excessive amounts of radiation.

Recommendation: It is recommended that Alaska Regional Hospital be approved to build and equip one dedicated neuroradiological catheterization laboratory at a cost of \$2.15 million with a project completion date of December 31, 2007.

CERTIFICATE OF NEED GENERAL REVIEW STANDARDS MATRIX A

ALASKA REGIONAL HOSPITAL NEURORADIOLOGY CATHETERIZATION LABORATORY CERTIFICATE OF NEED REVIEW - April 13, 2007		
GENERAL CON REVIEW STANDARDS	Standard Met?	COMMENTS
<p><u>General Review Standard #1 -- Documented Need:</u> <i>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.</i></p>	Met	ARH meets this standard. Their application documented utilization and projected need based on the population. The applicant discussed the fact that there is no dedicated stroke program in Alaska.
<p><u>General Review Standard #2 Relationship to Applicable Plans:</u> <i>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.</i></p>	Met	This standard is met. The applicant represented that this service is included in their long range strategic plans. Further, additional information related to stroke plans for Alaska was included by the applicant in their application.
<p><u>General Review Standard #3 – Stakeholder Participation:</u> <i>The applicant demonstrates effective formal mechanisms for stakeholder participation in planning for the project and in the design and execution of service.</i></p>	Met	ARH included stakeholder participation in the planning of the project.
<p><u>General Review Standard #4 – Alternatives Considered:</u> <i>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.</i></p>	Met	ARH considered different alternatives for providing the proposed services.
<p><u>General Review Standard #5 – Impact on the Existing System:</u> <i>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</i></p>	Met	In their application, the applicant discussed the impact on the regional health care system.

<i>regions of the state.</i>		
General Review Standard #6 – Access: <i>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.</i>	Met	ARH demonstrated their project is accessible to patients, families and ancillary services.

CERTIFICATE OF NEED SPECIFIC REVIEW STANDARDS MATRIX B

ALASKA REGIONAL HOSPITAL NEURORADIOLOGY CATHETERIZATION LABORATORY CERTIFICATE OF NEED REVIEW - April 13, 2007
THERE ARE NO SPECIFIC NEURORADIOLOGY CATHETERIZATION REVIEW STANDARDS OR REVIEW METHODOLOGY

REVIEW OF THE ALASKA REGIONAL HOSPITAL CERTIFICATE OF NEED APPLICATION FOR A NEURORADIOLOGY CATHETERIZATION LABORATORY

BACKGROUND

Alaska Regional Hospital (“ARH”) has submitted a Certificate of Need application to add one neuroradiology catheterization laboratory for the treatment of cerebrovascular disease (stroke). Proposed new equipment includes a Phillips Integrated 3D Neuro Biplane Flat Detector System. If approved, the new \$2.15 million, 519 square foot suite is expected to be operational by July 2007. These treatments do not repair areas of the brain already injured by a stroke.

Since August 2006, several percutaneous endovascular treatments of intracranial aneurysms (endovascular coilings) have been available on a limited basis at ARH through their new endovascular neurosurgeon. ARH proposes to serve the following ICD 9 diagnosis and procedure codes and Medicare DRG and CPT payment groups:

- ICD-9-CM Diagnosis Code 430 – Subarachnoid hemorrhage
- ICD-9-CM Diagnosis Code 437.3 – Cerebral aneurysm, non-ruptured
- ICD-9-CM Procedure Code 39.72 – Endovascular repair or occlusion of head and neck vessels (proposed treatment)
- ICD-9-CM Procedure Code 39.51 – Clipping of aneurysm (a substitute treatment for invasive surgery)
- ICD-9-CM Procedure Code 88.41 – Arteriography of cerebral arteries
- DRG 1 – Craniotomy Age >17 with co-morbidities and complications
- DRG 2 - Craniotomy Age >17 without co-morbidities and complications
- DRG 528 – Intracranial vascular procedure with a principal diagnosis of subarachnoid hemorrhage
- CPT 61624 – Transcatheter permanent occlusion or embolization, any method (intracranial, spinal)

ARH’s long-range plan is to develop a premier Neurosciences Program and become a JCAHO Certified Primary Stroke Center. In addition to neuroradiology, ARH plans to offer neurosurgery and a stroke initiative. ARH states that neuroradiology services are

- the most advanced treatments available for stroke and have only recently become available on a limited basis in Alaska, at their hospital;
- that this non-surgical procedure eliminates the pain and intracranial edema associated with traditional neurosurgery; and
- it is a safe, effective option for most patients, and recovery and post-treatment quality of life is greatly improved.

Believing its project to be a similar activity as the project proposed by ARH, Providence Alaska Medical Center (“PAMC”) submitted a letter of intent and a subsequent Certificate of Need application for two cardiac catheterization laboratories. Although the two applications were initially slated to be reviewed concurrently, ARH requested the Department consider the ARH project separately arguing that the two projects provide different services. The following information taken from the two applications highlights the differences:

- The ARH the catheterization laboratory will be dedicated to stroke services. The PAMC catheterization laboratories will be dedicated cardiac services.
- The technology (equipment) is significantly different. The ARH biplane unit was designed primarily for neuroradiological catheterization, and the PAMC monoplane unit was designed primarily for cardiac and interventional catheterization.
- Equipment used for cardiac services would not have the clarity and power to perform all of the specific tests needed for stroke services, and the equipment for stroke services is not appropriate for cardiac services because it would expose patients to excessive radiation. (Below are two pictures that show the biplane equipment for neuroradiology (left) and monoplane for cardiac services (right).)



Allura Xper FD20/10 biplane



Allura Xper FD20 monoplane

Contacts with two interventional radiologists regarding the similarities and difference between cardiac catheterization suites and neuroradiology suites confirmed that the equipment used in the two types of procedures is significantly different and rarely interchangeable. Non-cardiac suites like neuroradiology labs rely on bigger image intensifiers than do cardiac suites. Because of the extensive use of ‘cine’ techniques in cardiac cases, the use of larger image intensifiers for cardiac cases would typically expose patients to excessive radiation. Also, neuroradiology cases

rely on biplane imaging systems with full rotational capabilities that are not found in conventional cardiac labs.^{1, 2}

A consultant hired by the Department stated: “As a result of our work on this project, we do think that neuroradiology laboratories should be considered separately from cardiac catheterization laboratories, where there is reasonable service volume.”³

After considering the information presented, the Department agrees with ARH that the two applications are different and should not be reviewed concurrently. Therefore, the Department has conducted and will issue separate reviews for each project. This review address the ARH application only.

GENERAL 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.

ARH states that the national prevalence of intracranial aneurysms in the adult population is between one and five percent, with the incidence of subarachnoid hemorrhage from ruptured intracranial aneurysm as 1 case per 10,000 persons and the peak age-specific incidence occurring in persons 55 to 60 years old.⁴ This means that between 4,683 to 23,415 adults in Alaska will have an intracranial aneurysm and that 66 will die annually from a subarachnoid hemorrhage. In 2004, there were 173 total cerebrovascular deaths in Alaska. ARH projects a need to perform two coiling procedures per week in the first year, with a subsequent 4% annual growth rate. In addition, ARH projects 25.5 neuroradiology interventional procedures per month with 1% growth annually. The applicant’s projection as to the number of procedures that ARH will perform in its laboratory three years after implementation of the project is as follows:

	2008	2009	2010
Endovascular Coiling	108	112	117
Neuro Interventional	309	312	315
Total	417	424	432

¹ Conversation between Dr. Alex Malter, DHSS Staff Physician, and Dr. Robert Sheely, Senior Interventional Radiologist, Good Samaritan Hospital, Portland Oregon. April 2, 2007.

² Conversation between Dr. Alex Malter, DHSS Staff Physician, and Dr. Robinson & associates, VMMC Interventional Radiology Group, Seattle. Washington. Feb. 28, 2007.

³ Dean Montgomery, Consultant, American Health Planning Association. E-mail. March 15, 2007.

⁴ Brisman et al, Cerebral Aneurysms, NEJM 2006; 355: 928-938.

A consultant for the Department states: “We think a neuroradiology laboratory in Anchorage, if accepted by the medical community, might generate a case load of between 550 and about 800 cases annually within two or three years.”⁵

Finding #1: ARH meets this standard. The application documented utilization, projected need based on the population, and discussed the fact there is no dedicated stroke program in Alaska.

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.*

Since Alaska does not have a specific state health systems plan that addresses neuroradiology catheterization services, the only applicable portion of this standard that relates to the application is the applicants’ long range plans. ARH’s long range plan is to develop one of the premier Neurosciences Programs in the country. In addition, the ARH program plans to become a JCAHO Certified Primary Stroke Center.

ARH provided additional statements from Alaskan publications relating to stroke and circulatory disease, including *Healthy Alaskans 2010, Take Heart Alaska, Second Edition, The Burden of Heart Disease and Stroke in Alaska: Mortality, Morbidity, and Risk Factors, July 2006 Update*. ARH states that these documents articulate Alaska’s interest in addressing stroke prevention and treatment, although no specific goals or objectives are quoted. This project fits into the Healthy Alaskans 2010 goal of reducing stroke deaths to fewer than 60 per 100,000 population and improving rapid emergency care for the prevention or reduction of stroke.

Finding #2: This standard is met because this service is included in ARH’s long range strategic plan. Further, the service may help meet objectives identified in other Alaska health planning documents with goals related to strokes.

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.*

ARH states that it has communicated closely with physician providers of this service and specifically with Marshall Tolbert, M.D. Dr. Tolbert is the endovascular neurosurgeon who

⁵ Dean Montgomery, Consultant, American health Planning Association. Email. April 3, 2007.

started practicing at ARH in August 2006 and has worked closely with them to develop this service. A letter of support shows ARH also worked with Alaska Imaging Associates.

Finding #3: The standard is 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.*

Upgrading the existing cath lab equipment and doing nothing else was an alternative considered, but ultimately rejected as an unsuitable alternative. This alternative would perpetuate timely treatment problems as stroke care would continue to be accessible only via out-of-state travel. In addition, the existing cath lab equipment is already being heavily used for cardiac cases, making it unavailable for emergency procedures. Also, if different patient needs (heart and stroke) are served by the same piece of equipment, a general, non-specific model of equipment would have to be purchased. Such equipment would not be able to meet the specific needs of neuroradiology; therefore, certain stroke interventions would not be able to be performed. Limitations on existing equipment that do not allow for optimal stroke treatment include:

- the existing equipment's large image intensifiers require close proximity access to effectively view the aneurysm, but in certain cases, the patient's head interferes with this close proximal viewing;
- the magnification available with the existing equipment may produce a "fuzzy" or "pixilated" image of the aneurysm, limiting the neurosurgeon's ability to treat; and
- existing equipment is not always available on an emergency basis because it is also used to conduct lengthy electrophysiology studies.

Finding #4: ARH has met this standard by demonstrating that they have considered different alternatives for providing the service.

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.*

ARH described how its lab will provide an alternative to surgical clipping (a more invasive neurosurgical procedure that requires opening the skull for brain surgery). ARH also described how the proposed project will allow patients to stay in Alaska for treatment, complement and bolster stroke treatment, reduce costly rehabilitation, as well as costly post-surgical clipping care.

Finding #5: ARH meets this standard.

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.*

ARH discussed the fact that this new service was just recently introduced in Alaska, and will allow patients who need this service to stay in Alaska rather than travel out of state. ARH’s Anchorage location makes it accessible to approximately 42% of the total state population.

Finding #6: This standard has been met.

SPECIFIC REVIEW STANDARDS (Neuroradiology Catheterization Services)

Neuroradiology catheterization is a new medical service within Alaska. There is not currently a dedicated neuroradiology suite located within the State of Alaska, such as the one proposed by ARH. Consequently, the Department of Health and Social Services does not have specific review standards or a specific methodology for determining the need for neuroradiology catheterization procedures. As a result, the general review standards are the only standards applicable to the application submitted by ARH. As referenced above, ARH has met the general review standards.

Notwithstanding the lack of a specific review standards and methodologies for determining need relative to neuroradiology catheterization procedures, the Department’s review concludes that there is a reasonable basis to find that a need currently exists in Alaska for neuroradiology catheterization services.

DETERMINATION OF NEED SUMMARY

A consultant for the Department indicated that the minimum service volume for neuroradiology catheterization services, within three years of program startup should be between 300 and 600 procedures per year.⁶ This same consultant estimated that a neuroradiology catheterization laboratory in Anchorage would generate between 550 and 800 cases annually within two to three years.⁷ In its application, ARH projected that its proposed project would generate 432 procedures within the third year of operation. Hospital discharge data from Washington State and Alaska was used by the Department to estimate the level of services likely to be provided to Alaska patients by the proposed project. The specificity of the applicant’s description of the target patient group made it possible to analyze the inpatient discharge rate for the relevant diagnoses and procedures being conducted with current facilities, and to make comparisons to another state. The

⁶ Dean Montgomery, Consultant. American Health Planning Association. Email. March 1, 2007.

⁷ Ibid. Email. April 3, 2007.

data showing Alaska discharges (including the Washington State discharges of Alaska patients) are included in Appendix A. Also included in Appendix A are summary discharge data from the Commonwealth of Virginia indicating age-specific use rates that are more than three times as high as Alaska's current age specific use rates. Based on this data, the Department estimates that 637 neuroradiology catheterization services would be performed within three years of program startup.

Factors that may impact the Department's estimate of neuroradiology catheterization procedures are as follows:

- A growing senior population may increase utilization;
- The Department could only document inpatient procedures offered in Alaska and in some hospitals in Washington State. It is likely that some Alaskan residents obtained these services from other states such as Oregon and California;
- The data referenced above was only for inpatient procedures. Neuroradiology catheterization services are expected to average 43% inpatient and 57% outpatient, so the outpatient procedures had to be factored in;
- Although Alaska's neuroradiology use rate is not expected to be as high as in other states (if the Virginia rate was applied to Alaska, 1,361 procedures would be expected), the low rate is expected to rise because patients going to other states such as Oregon or California have not been counted.

Finding: The need for a neuroradiological catheterization laboratory at ARH is warranted based on the applicant's meeting the general review standards; the fact that the proposed service is a new service not currently offered in Alaska, and based on the above analysis regarding the number of procedures expected to be performed over the next three years.

PUBLIC COMMENT

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 Alaska Regional Hospital neuroradiology project and the Providence Alaska Medical Center project to build two cardiac catheterization laboratories. At that time, a determination had not been made to consider these two projects separately. The Department received a total of two letters of support for the Alaska Regional Hospital 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 it is seeking to offer a different service (stroke) rather than a cardiac catheterization service.

FINANCIAL FEASIBILITY AND COST TO MEDICAID

Facility Financial Strength

ARH is a hospital that appears to be strong financially. They should have no problem financing the neuroradiology project since they have had an excess of revenues over expenses in each of the last five years listed in their application (2002-2006). Over that five-year period, ARH had \$45.1 million in excess revenues over expenditures.

The annual capital cost to Medicaid of the new ARH neuroradiology catheterization service will range from \$63,254 to \$52,195 from 2008 to 2012. There will be some significant additional charges to the Medicaid program since inpatient and outpatient operating costs were not able to be calculated due to lack of data.

Financial Feasibility: The Department's consultant states, "In terms of economic viability, it is evident that many cardiac catheterization and interventional radiology laboratories can survive reasonably well at the 200-250 procedures per year level. Of course, this is not desirable but it is the case in many communities. We would not support something less than 200 cases/procedures per year unless there were compelling reasons. But we do think that, assuming stability and quality can be assured by careful patient selection, etc.... having at least one program in Alaska (especially Anchorage)... is a compelling argument.⁸ Based on consultant information on the number of procedures to survive (200-250), the estimated number of procedures expected within three years (400-800), and the ARH excess revenues over expenditures, the project is deemed to be financially feasible.

⁸ Dean Montgomery, Consultant, American health Planning Association. Email. April 3, 2007.

APPENDIX A

Table A shows the inpatient discharges for Alaska residents from reporting Alaska and Washington state hospitals for neuroradiology and interventional radiology diagnoses and procedures identified by the applicant as those targeted to be performed in the proposed laboratory. The data source is the Alaska Hospital Discharge Data System managed by the Alaska Department of Health and Social Services through agreement with the Alaska State Hospital and Nursing Home Association, with data clearinghouse services provided by the Hospital Industry Data Institute, Inc. of Missouri. This data developed by the Department projects that 637 procedures could be performed in a neuroradiological catheterization laboratory by 2010. The use rate is considerably less than for the State of Virginia, where 1,361 procedures would be expected for the same population.

The estimate for Alaska is based on an average of 43% of the patients served expected to be inpatients and 57% expected to be outpatients based on data supplied by the applicant.

**Table A.
 Alaska Resident Inpatient Discharges
 For Selected Neuroradiology and Interventional Radiology Diagnosis and Procedure Codes***

Age Group	2001	2002	2003	2004	2005	Total	Using AK 2005 Rates		Applying
							2010	2010	VA rates
								<i>Projection including outpatient (assuming inpatient = 43% of total)</i>	2010
						2001-2005	Projection		Projection
0-17	0	1	4	6	2	13	3		107
18-44	88	80	61	73	79	381	77		367
45-64	136	95	113	109	118	571	136		446
65+	71	67	48	61	60	307	84		425
All Codes									
Total	295	243	226	249	259	1,272	274	637	1361
Population									
0-17	191,929	192,594	193,007	194,230	194,780	966,540	1,281,210	1,975,870	
18-44	257,378	256,745	255,745	256,382	254,960	1,281,210	2,573,840		
45-64	145,861	152,640	158,895	164,644	170,206	792,246	1,893,050		
65+	37,073	38,565	40,100	41,578	43,307	200,623	549,310		
Total	632,241	640,544	647,747	656,834	663,253	3,240,619	6,992,070		
Rate per 100,000									
0-17	0	0.52	2.07	3.09	1.03	1.35			VA 54.14
18-44	34.19	31.16	23.85	28.47	30.99	29.74			142.67
45-64	93.24	62.24	71.12	66.2	69.33	72.07			235.82
65+	191.51	173.73	119.7	146.71	138.55	153.02			774.12
Total	46.66	37.94	34.89	37.91	39.05	39.25			194.67

* DRGs (Diagnosis Related Groups) 1, 2, 528

ICD 9 Diagnoses 430 and 437.3
 ICD 9 39.72, 39.51,

Alaska had no primary procedure codes among these:
 Additional

Review of a Certificate of Need Application
from Alaska Regional Hospital for a Neuroradiology
Catheterization Laboratory in Anchorage

April 13, 2007

procedures	88.41	:	39.79,	38.80,	38.86,	38.64, 99.25,
			39.53,	99.25,	44.44,	99.29

APPENDIX B

COST MEMORANDUM – OFFICE OF RATE REVIEW

STATE OF ALASKA

DEPT. OF HEALTH AND SOCIAL SERVICES
OFFICE OF THE COMMISSIONER

SARAH PALIN, GOVERNOR

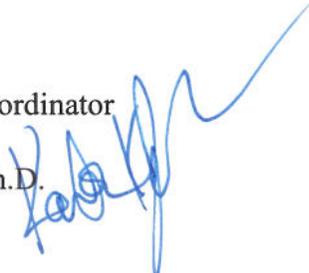
P.O. BOX 110601
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MEMORANDUM

Date: April 26, 2007

To: David Pierce
Certificate of Need Coordinator

From: Karleen K. Jackson, Ph.D.
Commissioner



Subj: Request for Additional Information
Alaska Regional Hospital/Neuroradiology Catheterization Laboratory

I have received the "Review of the Alaska Regional Hospital Certificate of Need Application for Addition of One Neuroradiology Catheterization Laboratory" dated April 13, 2007, and request that you provide additional information and clarification on the matters described below.

Completion Date:

Page 5 of the report indicates that the project will be completed by July 2007, the application states a completion date of March 2007, and the draft certificate you have provided includes a completion date of December 31, 2007. Please reconcile these different dates.

Cost to Medicaid:

Page 12 of the report indicates that the Office of Rate Review projects annual capital costs to Medicaid ranging from \$63,254 to \$52,195 and that operating costs would be "substantial" but could not be calculated due to lack of data. The attached memorandum from the Office of Rate Review does not support this statement insofar as it pertains to a different application. Please provide the correct memorandum and information indicating the magnitude, if not a detailed projection, of the annual operating costs.

Patient Outcomes and Safety:

I understand that the department has not adopted specific standards relating to neuroradiology catheterization laboratories. However, I would appreciate receiving additional information regarding any widely accepted standards for these facilities that might exist relating to patient outcomes and patient safety. Please consult with Dr. Malter on what may be appropriate in this regard. Areas of particular interest to me include:

- Standards relating to the number of procedures that must be performed to maintain proficiency;
- Standards relating to specialized medical personnel who should be available on-site or on-call at the facility;

David Pierce, CON Coordinator

April 26, 2007

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- The likely impact of providing enhanced neuroradiology services in Alaska on other aspects of the health care system including long-term care; and
- The likelihood of decreased (or increased) mortality resulting from providing these services in-state.

Please provide a written response to these questions by close-of-business Friday, May 11, 2007.

Attachment:

cc: Tony Lombardo, Deputy Commissioner, Office of Program Review
Dr. Alex Malter, Staff Physician
Pat Carr, Chief, Health Planning and Systems Development

**ADDITIONAL INFORMATION AND CLARIFICATION FOR
THE ALASKA REGIONAL HOSPITAL
NEURORADIOLOGICAL CON REVIEW - MAY 1, 2007**

Completion Date: Page 5 of the report indicates that the project will be completed by July 2007, the application states a completion date of March 2007, and the draft certificate you have provided includes a completion date of December 31, 2007. Please reconcile these different dates.

Response: The initial projected completion date submitted with the ARH application was March 2007. This date could not be met because the review was delayed 60 days to allow PAMC to submit a competing application. ARH then revised the completion date to July 2007. CON staff arbitrarily recommended an approved completion date of December 31, 2007. Staff experience is that CON application completion dates are inaccurate projections subject to change. Projects often run into problems with construction or financing that take more time than expected. If projects do not meet the time deadline they must submit a request for modification. Therefore, the Department staff usually recommends time extensions beyond the applicant's estimated completion date so that there is not a constant stream of projects submitting CON modification requests due to missed time deadlines. Staff usually recommends a time extension that is six months to a year beyond the applicants projected completion date, depending on project size and complexity, applicant experience with construction, and availability of financing.

Cost to Medicaid: Page 12 of the report indicates that the Office of Rate Review projects annual capital costs to Medicaid ranging from \$63,254 to \$52,195 and that operating costs would be "substantial" but could not be calculated due to lack of data. The attached memorandum from the Office of Rate Review does not support this statement insofar as it pertains to a different application. Please provide the correct memorandum and information indicating the magnitude, if not a detailed projection, of the annual operating costs.

Response: The correct memorandum is attached with a detailed income statement from ARH and a new cost estimate from the Office of Rate Review.

Patient Outcomes and Safety: I understand that the department has not adopted specific standards relating to neuroradiology catheterization laboratories. However, I would appreciate receiving additional information regarding any widely accepted standards for these facilities that might exist relating to patient outcomes and patient safety. Please consult with Dr. Malter on what may be appropriate in this regard. Areas of particular interest to me include:

- **Standards relating to the number of procedures that must be performed to maintain proficiency -**

Response: We were unable to locate any governing board that sets formal proficiency standards for invasive neuroradiology specialists. This is likely because these procedures are relatively new, still considered "cutting edge", and performed by a very small number of physicians and

surgeons (about 300 nationwide).

The American Society of Interventional Therapeutic Neuroradiologists (“ASTIN”) has developed some recommended guidelines regarding the technical staffing and equipment recommendations for a neuro-interventional suite, but these relate more to process and structure issues and don’t fully address the more critical quality assurance and proficiency questions.

Staff recommends that approval of this CON contain a proviso stating: “A facility performing interventional and therapeutic neuroradiology is expected to adhere to the most recent standards and guidelines developed by relevant specialty societies, including the American Society of Interventional and Therapeutic Neuroradiology (ASTIN) and the Society of Interventional Radiology (SIR). When available, standards related to the training and qualifications of interventional physicians or surgeons; maintenance of proficiency of those physicians, technical staffing, and interventional suite requirements; the necessary additional medical staff and facilities required for back-up care; and quality assurance programs should all be adhered to.”

The issue of surgical backup for these facilities is not analogous to that issue surrounding backup for interventional cardiology. First, endovascular interventional neuroradiology is often performed by a neurosurgeon as the preferred alternative to performing open brain surgery. In these cases, if complications develop during the endovascular procedure, the same surgeon doing the invasive procedure is immediately available as the appropriate “backup” specialist. More important, unlike invasive cardiology cases for which urgent surgical backup can be life saving for some patients with complications, the complications associated with invasive neuroradiology procedures will rarely if ever be amenable to emergent surgical rescue. Hence, the question of “appropriate backup” for these procedures is somewhat less germane.

- **Standards relating to specialized medical personnel who should be available on-site or on call at the facility -**

Response: The applicant states that the program is available 24 hours per day, seven days a week so there will be two teams on call - one is always available as a back-up should the first team get called in. This will allow for scheduled procedures and multiple emergencies to be covered. Team staffing will be similar to that of the cath lab including two cath lab techs and one RN for each team. The team leader will be either a board certified neuroradiologist or an interventional radiologist.

We were unable to locate any governing board that sets formal standards for staffing invasive neuroradiology catheterization laboratories. The American Society of Interventional Therapeutic Neuroradiologists has developed some recommended guidelines regarding the technical staffing recommendations for a neuro-interventional suite.

- **The likely impact of providing enhanced neuroradiology services in Alaska on other aspects of the health care system including long-term care -**

Response: The impacts will likely be positive – common conditions, post-stroke, are incapacitation, rehabilitation, and death. The availability of this new service will provide timely

treatment that will result in the avoidance of these conditions in many patients. In other words, patients who receive the coiling or stenting are generally saved from the incapacitating and long-term rehab-requiring conditions common to many stroke victims. Timely and safer treatment of stroke and neuroradiology patients are expected to lead to longer life, better quality of life, and less damage if a stroke occurs.

The economic effect on the system will likely be neutral. Although there will be increased cost for these new procedures, they may be fully mitigated by savings down the line on long-term care costs if fewer individuals enter nursing homes or are less disabled when they do. These procedures are expected to improve outcomes for some stroke patients, which might occasionally decrease demand for long-term care services. Acute care may also be reduced some since these minimally invasive procedures replace brain surgeries and therefore take less inpatient recovery time. These services are not likely to have a large effect on the system because the numbers of stroke victims will be small compared to all the other services.

- **The likelihood of decreased (or increased) mortality resulting from providing these services in-state -**

Response: Stroke is the third leading cause of death in the United States (fourth in Alaska), killing someone every three minutes. In contrast to heart disease, the stroke death rate in Alaska is about 10% higher than the national rate. Compared to the slowly declining rate of stroke death in the US, Alaska's stroke death rate has not decreased over the last 14 years.¹ This service will reduce but not eliminate mortality and morbidity (disability) from stroke. There are many procedures currently offered and their number is increasing annually. The reduction in mortality and the danger of negative result varies by procedure.

Stroke victims have a three-hour window for treatment of blood clots via clot-busting drugs from onset of symptoms or else they are subject to death or serious disability. Most people do not recognize the symptoms or do not realize that prompt treatment can save lives and reduce disability and therefore arrive at the hospital too late for this treatment. Interventional Neuroradiology stretches the treatment window to six-hours and allows specialists to place clot busting drugs directly on the clot or break up the clot mechanically. These new therapies lengthen the window of time for treatment and improve outcomes.²

This service is expected to significantly decrease post stroke disabilities for individuals being treated for acute stroke, and may prevent disabilities in patients with underlying cerebral-vascular disease who've not yet suffered strokes. Additionally, these procedures may occasionally even decrease mortality, and overall they should substantially decrease combined morbidity and mortality.

¹ *The Burden of Heart Disease and Stroke in Alaska: Mortality, Morbidity, and Risk Factors, July 2006 Update.* Published by the State Department of Health and Social Services.

² http://www.sirweb.org/news/newsPDF/IR2_stroke%20meeting_PR_1-29-04.pdf

STATE OF ALASKA

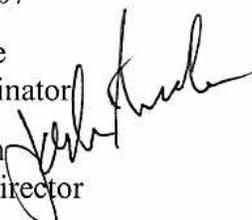
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DEPT. OF HEALTH AND SOCIAL SERVICES

OFFICE OF RATE REVIEW

MEMORANDUM

Date: March 1, 2007
To: David Pierce
CON Coordinator
From: Jack Nielson 
Executive Director
Subject: Certificate of Need (CON) Review for Alaska Regional Hospital
Interventional Neuroradiology Suite

Alaska Regional Hospital wishes to establish an Interventional Neuroradiology Suite in their existing facility. The proposed project would add to and expand the current interventional neuroradiology services for treatment of cerebrovascular disease (stroke). Total cost for the renovation project is estimated to be \$2,152,524.

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. Since the submitted application for this project does not meet this criteria, an add-on would not be applied to the current Medicaid inpatient per-diem rate.

There will be increased charges to the Medicaid program for the newly available outpatient services; however, the facility did not submit financial operating projections by which to calculate an estimate. The projected number of Medicaid outpatient 'procedures' are expected to increase annually by approximately 50. Of the total projected procedures, approximately 25% annually are expected to be Inpatient services performed with an average length of stay of one day. The annual capital cost of the new services for Medicaid procedures will be approximately \$52,000, until the facility is re-based in FY 2010. There would not be a change to the overall Medicaid outpatient reimbursement rate.

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 Per Diem Days Increase	\$38,124	\$41,332	\$44,743	\$48,442	\$52,446	-	-
Inpatient Capital	-	-	-	-	-	\$30,273	\$30,273
Inpatient Operating	<i>unknown</i>						
Outpatient Charge Increase **	\$16,441	\$21,922	\$21,922	\$21,922	\$21,922	-	-
Outpatient Capital	-	-	-	-	-	\$21,922	\$21,922
Outpatient Operating	<i>unknown</i>						
Total Cost to Medicaid							
(est. with CON available information)	\$54,565	\$63,254	\$66,665	\$70,364	\$74,368	\$52,195	\$52,195

**These amounts are capital costs paid through increased charges. Insufficient information in CON application to estimate additional outpatient charges

Should you have any questions please contact Joyce Seekatz at (907) 334-2466 or me at 334-2447.

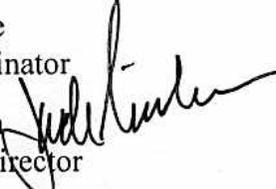
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DEPT. OF HEALTH AND SOCIAL SERVICES

OFFICE OF RATE REVIEW

MEMORANDUM

Date: May 3, 2007
To: David Pierce
CON Coordinator
From: Jack Nielson 
Executive Director
Subject: Certificate of Need (CON) Review for Alaska Regional Hospital
Interventional Neuroradiology Suite

Alaska Regional Hospital wishes to establish an Interventional Neuroradiology Suite in their existing facility. The proposed project would add to and expand the current interventional neuroradiology services for treatment of cerebrovascular disease (stroke). Total cost for the renovation project is estimated to be \$2,152,524.

Please consider this memorandum an addendum to my memo of March 1, 2007 regarding the same subject. I have amended the table of Estimated Medicaid Cost provided in the March 1 document as the result of additional information you provided on April 26, 2007. The estimated Medicaid Costs in this revised table are calculated from information provided in both the original CON application for the project and the supplemental Income Statement provided by you on April 26, 2007.

Estimated Medicaid Cost (using information available in CON and supplementary April 26, 2007 data)

	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>
Inpatient Per Diem Days Increase	\$38,124	\$41,332	\$44,743	\$48,442	\$52,446	-	-
Inpatient Capital	-	-	-	-	-	\$30,273	\$31,787
Inpatient Operating	unknown	-	-	-	-	\$394,913	\$406,365
Outpatient Charge Increase **	\$16,441	\$21,922	\$21,922	\$21,922	\$21,922	-	-
Outpatient Capital	-	-	-	-	-	\$21,922	\$23,018
Outpatient Operating **	unknown	\$156,041	\$170,444	\$186,582	\$204,638	\$197,561	\$203,290
Total Cost to Medicaid (est. with CON available information)	<u>\$54,565</u>	<u>\$219,295</u>	<u>\$237,109</u>	<u>\$256,946</u>	<u>\$279,006</u>	<u>\$644,669</u>	<u>\$664,460</u>

**2007-11 amounts are costs paid through increased charges.

**Alaska Regional Hospital
Income Statement (\$000's)**

Comprehensive Neurosciences Progr	2008	2009	2010	2011	2012
PATIENT REVENUES					
Inpatient Revenues	10,528	11,808	13,225	14,793	16,527
Outpatient Revenues	5,563	6,067	6,616	7,214	7,865
Total PATIENT REVENUES	16,091	17,874	19,840	22,006	24,392
Other Operating Income	0	0	0	0	0
Total GROSS REVENUES	16,091	17,874	19,840	22,006	24,392
Contractual Adjustments	5,466	6,192	6,997	7,891	8,880
HMO/PPO Discounts	4,799	5,313	5,879	6,500	7,184
Charity	0	0	0	0	0
Total DEDUCTIONS	10,266	11,505	12,876	14,391	16,065
TOTAL NET REVENUE	5,825	6,369	6,964	7,615	8,327
OPERATING EXPENSES					
Salaries & Wages	544	569	594	621	649
Employee Benefits	154	161	168	176	184
Supplies	2,126	2,418	2,749	3,127	3,556
Professional Fees	0	0	0	0	0
Contract Services	0	0	0	0	0
Repairs & Maintenance	58	64	70	76	83
Rents & Leases	0	0	0	0	0
Utilities	29	32	35	38	42
Insurance	18	19	20	21	22
Bad Debts	0	0	0	0	0
Non-Income Taxes	20	20	20	21	21
Other Operating Expenses	0	0	0	0	0
Total OPERATING EXPENSES	2,950	3,282	3,657	4,080	4,557
EBITDA	2,875	3,087	3,307	3,536	3,771
Depreciation	130	130	130	130	133
Goodwill Amortization	0	0	0	0	0
Other Amortization	0	0	0	0	0
Interest Expense	0	0	0	0	0
Non-Oper. Expense (Revenues)	0	0	0	0	0
Management Fees	0	0	0	0	0
Total CAPITAL & OTHER	130	130	130	130	133
PRETAX INCOME/(LOSS)	2,745	2,957	3,178	3,406	3,638
Federal & State Taxes	1,129	1,216	1,306	1,400	1,495
NET INCOME	1,617	1,741	1,871	2,006	2,142