REVIEW OF A CERTIFICATE OF NEED APPLICATION TO DEVELOP IMAGING FACILITIES IN THE MAT-SU VALLEY AND ANCHORAGE SUBMITTED BY IMAGING ASSOCIATES OF PROVIDENCE

June 26, 2008



Sarah Palin Governor

William H. Hogan Acting Commissioner

Jay C. Butler, M.D. Chief Medical Officer

State of Alaska
Department of Health and Social Services
Division of Public Health
Health Planning & Systems Development Section
Certificate of Need Program

TABLE OF CONTENTS

BACKGROUND	2
### PROJECT DESCRIPTION. ### CENERAL REVIEW STANDARDS APPLICABLE TO ALL CON APPLICABLE	2
GENERAL REVIEW STANDARDS APPLICABLE TO ALL CON	APPLICATIONS
#3 Stakeholder Participation	5
<u>♣</u>	
#5 Impact on Existing System	6
#6 Access	7
SDECIEIC DEVIEW STANDADDS EOD MACNETIC DESONANI	CE IMACINO
· · · · · · · · · · · · · · · · · · ·	
#4 Expansion of an Existing Service	13
FINANCIAL FEASIBILITY AND COST TO MEDICAID	13
PUBLIC COMMENT SUMMARY	14
DECOMMENDATION	1.4
KECUIVIIVIENDA HUN	14
APPENDICES	
APPENDIX A – Detailed Analysis for Need Determination	16
APPENDIX B - Alaska Review Standards for MRI and CT	20

CERTIFICATE OF NEED REVIEW OF AN APPLICATION FOR IMAGING FACILITIES IN ANCHORAGE AND THE MAT-SU VALLEY

BACKGROUND:

This Certificate of Need application is for two imaging facilities that have been in operation since June 2006: a 4,654 square foot facility in Anchorage, and a 6,400 square foot facility in Palmer, adjacent to the Mat-Su Regional Medical Center. The total cost of the project is \$12,775,154.

In December 2005, Imaging Associates of Providence, LLC (IAP) began construction of two imaging facilities, one located at 2000 Abbott Road in Anchorage (referred to as the Abbott Road facility in this document) and another at 2280 South Woodworth in Palmer (referred to as the Mat-Su facility). The facilities were completed in June 2006, and have been operating ever since. Imaging Associates of Providence, LLC (IAP) is a for-profit joint venture partnership between Interventional and Diagnostic Radiology Consultants (IRDC) and Providence Health System – Washington, doing business as Providence Alaska Medical Center (PAMC).

On March 21, 2006, the Mat-Su Regional Medical Center (MSRMC) submitted an appeal requesting that the Department investigate the IAP facility in Palmer because it did not go through the CON review process. In June 2006, shortly after both IAP facilities began operations, the Commissioner sent IAP a letter of determination stating that a Certificate of Need was not required for these facilities. This decision was reversed by the Commissioner on August 17, 2006 after MSRMC appealed the decision that a CON was not required. In October 2007 an administrative hearing officer upheld the Commissioner's decision that the IAP projects were required to submit a Certificate of Need application for the two facilities. IAP submitted a CON application on January 30, 2008, although they believe these projects should not be required to submit to the CON process.

The review of this project was delayed by 60 days because Alaska Regional Hospital (ARH) submitted a letter of intent to compete with the Anchorage site of these projects, but ARH did not submit a CON application before the time deadline expired.

Department staff requested and were approved a 14-day extension of the review document completion date (from June 17 to July 1, 2008) to allow for assessment of additional IAP data received on June 11 before submitting this to the Commissioner.

PROJECT DESCRIPTION:

Both facilities perform CT, MRI, X-ray, digital mammography, and ultrasound. Bone densitometry is performed only at the Mat-Su facility. The 3.0 Tesla MRI at the Abbott Road facility is specially equipped with nuclear magnetic resonance (NMR) spectroscopy capability.

NMR spectroscopy, sclerotherapy, and endovenous ablation of varicose veins are provided only in Anchorage.²

Services offered include an array of diagnostic imaging and image-guided therapeutic procedures. Diagnostic services provided include x-rays, magnetic resonance imaging (MRI), computed tomography (CT), ultrasound, bone density scans, galactography, nuclear magnetic resonance (NMR) spectroscopy, digital mammography, and a variety of ultrasound-guided therapeutic procedures. Therapeutic procedures include: endovenous ablation of varicose veins, chemical sclerotherapy of varicose veins, and variety of ultrasound-guided procedures such as paracentesis and thoracentesis. Professional services are provided through an agreement with Alaska Radiology Associates (ARA), a group of nine board-certified radiologists. IAP employs the technologists and clerical staff.

GENERAL REVIEW STANDARDS

<u>General Review Standard #1- Documented Need</u> 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.

IAP states that there is a need for the project based on the following: the population growth in each service area, increased demand nationally for the imaging services, the perceived need to increase IAP patient access to their physicians, and increased access to enhanced technology. Also, IAP states that through the project they will be able to provide higher levels of care, and a higher quality of care at a lower cost than is available at existing facilities. Citations used to support these claims include the Alaska Economic Trends report (population projections to the year 2015), and an opinion from Advance for Imaging and Radiation Therapy Professionals that states CT and MRI utilization is expected to rise by 57% and 44% respectively by year 2016.

The Department's minimum service-specific standards of 3,000 MRIs per unit and 3,000 CTs per unit are met for the Anchorage facility. Anchorage utilization patterns show that six out of eight existing non-military facilities with MRI and CT services are currently operating above the minimum use standard.⁶ Projections developed by the Department show that CT scans and MRI

¹ IAP CON Application. January 2008. Page 4.

² Ibid. Pages 4, 2.

³ Ibid. Page 50.

⁴ Ibid. Page 44.

⁵ Ibid. Page 130.

⁶ Appendix A – Detailed Analysis for Need Determination.

scans in the Anchorage service area are expected to grow to an average of 6,399 scans and 3,433 scans respectively per unit by 2011.

These standards have not been met for the Mat-Su facility. Utilization patterns show that the two MRIs and two out of three CT scanners in the Mat-Su Valley that were in operation prior to this application are currently operating below the 3,000 scan minimum use standards for MRIs and CTs. Although growth is expected, utilization in the Mat-Su Valley is not expected to reach the 3,000 scan minimum use standard for CTs and MRIs within the three-year planning horizon as required by the CON methodology. Projections developed by the Department show that the Mat-Su Valley utilization is only expected to grow to an average of 2,599 CT scans per unit and an average of 2,492 MRI scans per unit by 2011.

In addition to growth in utilization, the applicant described other factors for the Department to consider in determining need. Two factors are as follows:

- IAP physicians have a provision in their contract that precludes them from applying for privileges elsewhere, including the Mat-Su Regional Medical Center, therefore, they need their own facilities to serve patients;
- IAP will bring new radiology technology and new procedures to the communities for the first time. (Example: it is claimed that paracentesis and thoracentesis are now available in the Mat-Su Borough for the first time). 10

Exclusivity contracts that limit where radiologists can or cannot practice are not a relevant consideration under the Certificate of Need program and are not used under the current standards and methodologies to support and applicant's demonstration of need in a given service area. Although, need for new technology might be used to support a statement demonstrating the need for a service, it would depend upon the number of patients needing the service and how difficult it is to access the service. In this case, the applicant did not provide any information as to how many individuals in the Mat-Su Valley need these services and representatives of the Mat-Su Regional Medical Center stated at the public meeting that these services are already provided.

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

.

⁷ Appendix B – Alaska DHSS Review Standards for MRI and CT.

⁸ Appendix B – Alaska DHSS Review Standards for MRI and CT.

⁹ Appendix A - Alaska DHSS Detailed Analysis for Need Determination.

¹⁰ Ibid. Page 7.

relevant state plan, with appropriate federal agencies for relevant federal plans, and with appropriate communities regarding community or regional plans.

At this time, the Federal and State of Alaska governments do not have state health systems plans that address diagnostic and therapeutic radiology services. The applicant did, however, state that this project and IAP's mission were consistent with the [1984] State Health Plan goals of providing an adequate range of primary, preventative and acute care services in all communities. Neither the Anchorage nor the Mat-Su Borough areas have formal health plans that include radiology services. ¹¹

This standard should be excepted because there are no state, local, or regional health plans that address radiology services.

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

This standard is considered to be met by both IAP facilities because IAP stated that physicians participated in the planning and design of these facilities and that several local patients reviewed the proposed facility schematics. In addition, the project architect formally included patients and family members in the planning process for other similar projects to ensure they were designed to be "patient friendly." While there is no evidence that area residents were included in planning for the design and execution of services, the Department takes the view that physicians are also stakeholders, and therefore this standard was met, but only minimally. Although the Department takes the view that physicians are also stakeholders it is important to involve others besides just those with a vested interest.

<u>General Review Standard #4 – Alternatives Considered:</u> 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.

Four alternatives were outlined in the application: doing nothing, applying for privileges at facilities with available equipment not yet reaching the minimum use standard, closing one facility, and continuing to operate both facilities.

1) **Do nothing:** This option was determined to be unacceptable for the following reasons:

a) Some Alaskans would continue to receive un-timely and inappropriate diagnostic and therapeutic radiology services. However, no documentation was provided with the application to support the claims of inappropriate, un-timely service.

¹¹ Public Meeting Testimony. Elizabeth Ripley. March 12, 2008.

¹² IAP CON Application. January 2008. Page 85.

June 26, 2008

- b) Continuing with imaging services through Providence Imaging Center (PIC) and PAMC was unacceptable because both PIC and PAMC are fully utilized. As stated above, this utilization argument applies only to the Anchorage facility and is not applicable to the Mat-Su facility.
- 2) <u>Applying for privileges at other facilities in the Mat-Su Valley:</u> This option only applies to the Mat-Su Valley. It was not chosen because IAP physicians have a provision in their contract with PAMC that precludes them from applying for privileges at other facilities. This is not a prohibition from Mat-Su Regional Medical but it is a self-imposed limitation that does not allow IAP physicians to work elsewhere. This option should have been chosen in the Mat-Su Valley, where most scanners are operating below the minimum use standard and installation of new equipment creates unnecessary duplication of services.
- 3) <u>Closing one or both IAP Facilities</u> This option was determined to be unacceptable as it would be an inconvenience to patients and referring physicians as well as a hardship to IAP employees. In addition, most funds invested in the facilities would not be recoverable. IAP staff testified during the public meeting to the hardship they would have with the loss of their jobs. This is not an option that would have been considered in a normal planning process because the facility would not be operational. If a facility closes, IAP staff will work somewhere else.
- 4) <u>Build two new outpatient facilities</u>: This option was chosen because the applicant felt it is the most effective way to increase access to the services of IAP physicians in a cost-effective, high quality manner.

Some of the options listed are difficult to consider since these facilities are not in the planning phase but are actually operational. For example, amending and negotiating the existing PAMC contract to allow physicians to seek privileges at other facilities would only be necessary if one or both facilities were to close and it would be difficult to consider closing a facility when those facilities are up and running and generating revenue. So although alternatives have been considered, the standard has not been met since the facilities are operating without a valid CON and it is impossible to evaluate the relative merits of the options under the facts of this case.

<u>General Review Standard #5 – Impact on the Existing System</u> 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.

The applicant stated that the project complements existing services, provides alternatives to some services, provides some unique services, and provides needed competition in the Mat-Su Valley.

It is stated that the project complements existing services by reducing the outpatient procedure burden on hospitals, and will help hospitals by allowing them to use their scanners for

emergencies and high-intensity in-patient care. It is claimed that outpatients who are served by hospitals are forced to wait for openings since inpatients and emergencies have priority, and that these services will reduce patient waiting times.

Other impacts mentioned are: 1) the project has increased access to enhanced technology and 2) the service has brought well-trained physicians and staff to the service area and has created jobs. The applicant impact statement did not mention any potential negative or positive impact of implementation of these projects on any existing providers of the same service.

The impact statement submitted by the applicant did not specifically mention imaging service providers that already exist in Anchorage and the Mat-Su Valley. No additional information on the impact of the Anchorage project was received, but Mat-Su Regional Medical Center (MSRMC) submitted two documents regarding the impact this project would have on their facility and also spoke at the public meeting held at the University in Palmer.

On March 21, 2006, MSRMC submitted a letter to the Commissioner of Health and Social Services stating that MSRMC "may be adversely and substantially affected..." by the IAP project located in the Valley. At the public meeting held on March 12, 2008, Dr. Swank, a Radiologist representing MSRMC, states that the IAP facility in Palmer is "duplicative" and that "...duplicative services do affect the service providers already practicing in the area. The community-based hospital, Mat-Su Regional Medical Center, provides the same services in the same location and [MSRMC] is necessarily impacted by the... duplicative services..."¹³

This standard is met for the Anchorage facility only. Claims that the project complements other services and the absence of a discussion of any negative impact on existing facilities in Anchorage were not challenged by anyone in the public meetings or during the public comment period. In addition, Anchorage utilization patterns show that six out of eight non-military facilities with MRI and CT services are operating at above the minimum use standard at the current time and their use is expected to grow.

This standard is not met for the Mat-Su facility. The utilization patterns and public comments show that the project will likely have a negative impact on the existing service system. Both MRIs and two out of three CT scanners are currently operating under the minimum use standard. Although growth is expected, utilization in this region is not expected to reach or exceed the minimum use standard within the three-year planning horizon as required by the CON methodology. In addition, there were a significant number of public comments in opposition by representatives who work in the health care field in the Mat-Su Valley who feel this project provides unnecessary duplication and will have a negative impact on other providers in the region.

¹³ Public Meeting testimony. Dr. Swank. March 12, 2008. Page 41.

<u>General Review Standard #6 – Access:</u> 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.

The Anchorage facility is located at 2000 Abbott Road in Anchorage and the Mat-Su Valley facility is located at 2280 South Woodworth in Palmer. The Abbott Road facility is located on the south end of Anchorage and can be accessed by private vehicles and public transportation. The Anchorage IAP facility is 9.5 miles (17 minutes driving time) from Alaska Open Imaging, 6.6 miles (12 minutes driving time) from Alaska Regional Hospital, 5.3 miles (11 minutes driving time) from Providence Hospital and the Providence Imaging Center, 5.3 miles (9 minutes driving time) from Alaska Innovative Imaging, 4.8 miles (11 minutes driving time) from Alaska Native Medical Center, and 4.3 miles (9 minutes driving time) from Diagnostic Health Corporation. All of these facilities offer some of the same services.

The Mat-Su IAP facility is located between Palmer and Wasilla with easy access from the freeway by private vehicles. The Mat-Su facility is 0.33 miles (one minute driving time) from the Mat-Su Regional Medical Center and 7.6 miles (13 minutes driving time) from Alaska Open Imaging, which both offer similar services.

IAP states that they are often able to provide services on a same day basis from the referring physician. Their hours of operation are Monday through Friday from 6AM to 6PM, however, for patient convenience; several imaging appointments are available in the evening and on Saturdays, including MRI and mammography. Hospitals operating in both communities offer services 24-hours a day, 7 days a week for emergencies.

This standard has been met. The applicant has demonstrated that both facilities are accessible to their patients. The Anchorage facility is located in an area that is not significantly close to other similar facilities and so it enhances access to patients living in South Anchorage. The Mat-Su facility is located one minute away from MSRMC and does not enhance access for patients.

SERVICE SPECIFIC REVIEW STANDARDS

MAGNETIC RESONANCE IMAGING (MRI) SPECIFIC REVIEW STANDARDS

MRI Specific Review Standard #1: Except as provided in Review Standard 2, an applicant who seeks to establish an MRI service demonstrates the ability to provide a minimum of 3,000 MRI scans per year by the end of the third operational year, dating from the initiation of the service.

¹⁴ IAP CON Application. January 2008. Page 7.

Total average MRI scan volume for the Anchorage Municipality service area, including IAP MRI use data, was 23,190 per year for 2005-2007, and is expected to increase to 25,120 per year by 2011, based on a 5% population growth. If each existing MRI (excluding the IAP MRI) were operating at the minimum capacity level of 3,000 scans per year, the review standards would indicate that nine (9) MRIs could be justified to provide services for the population. In practice, two of the eight existing MRIs – Alaska Open Imaging and Alaska Spine Institute - are functioning below 3,000 scans per year, indicating underutilized capacity that is available. ¹⁵

IAP's Anchorage MRI, for which approval is sought, has been in limited use since June 2006, with 322 scans in 2006 and 1,045 in 2007. IAP asserts there will be expansion to 3,945 scans by 2010. The Department has developed its own projections for MRI scans in the Anchorage service area, and based on historical use, it is estimated that IAP's MRI use will be below 3,000 per scans per year (2,794) by 2011. However, IAP may be able to achieve the 3,000 scans annual standard, since the service area average will be well above the 3,000 scan standard (3,433 scans per MRI scanner by 2011), and due to its location in an expanding area of Anchorage that may be more convenient than the hospitals and other private facilities. Using the approach of total machines "allowable" which indicates 8.4 can be justified, the additional IAP machine brings the total to 9 for Anchorage and is approvable.

In contrast, in the Mat-Su Valley, the total level of use of all existing MRIs (including IAP data) is only 4,411 scans per year for which only two MRIs are justifiable under CON but there are already three MRIs in use (not including the IAP MRI), which is an average use rate of 1,473 scans per MRI per year, which is well below the minimum use level of 3,000 scans per MRI per year required to allow approval of a new MRI. MRI volume projected for the Mat-Su Valley in 2011 is 4,980 scans (an average of 1,660 per MRI unit), based on a 13% population growth, which indicates need for only two MRIs in the service area in three years.

ANCHORAGE	Avg. Annual Scans 2005- 2007	Expected number for 2011	Minimum Scans Level expected per machine	# mach- ines allowable	# machines existing or approved	# additional machines approvable
2011 estimated MRIs (+5% for population growth over 2005-07 avg)	23,190	25,142	3,000	8.4	8	1
MAT-SU VALLEY						
2011 estimated MRIs (+13% for population growth over 2005-07 avg)	4,411	4,980	3,000	1.7	3	0

¹⁵ The IAP Anchorage machine for which approval is being sought has not been counted as an available machine although the scans provided are counted since they would presumably have been conducted at another facility if the service had not been available.

¹⁶ IAP CON Application. January 2008. Page 62.

MRI Specific Review Standard #2: An applicant who seeks to establish an MRI service in a community with a population of 10,000 or less demonstrates the ability to provide a minimum of 1,000 MRI scans per year by the end of the third year, dating from the initiation of the service.

This standard is not applicable to either of the facilities, because there are more than 10,000 people living in both Anchorage and the Mat-Su Valley.

MRI Review Standard #3: No MRI service will be approved at a location that is less than 30 minutes access time of an existing MRI service performing fewer than 3,000 scans per year, or of a CON-approved, but not yet operational, MRI service.

The applicant does not meet this MRI standard in either the Anchorage or Mat-Su Valley locations and requests a waiver stating that it is inapplicable where contractual obligations prevent the physicians of one facility from accessing the equipment at another facility that may be operating below the minimum use standard.¹⁷

According to 7 AAC 07.025, under certain circumstances the Department can recommend that an exception to the standards be granted if there is an "unreasonable barrier" to services in the service area that relates to quality, availability, or accessibility of health care services. The Department believes that an exception to this standard should be made for the Anchorage IAP facility but not for the Mat-Su IAP facility based on availability and accessibility as follows:

- Most MRI equipment in the Anchorage area is operating at or above the minimum use standard.
- Projected growth within the three-year planning horizon will continue to reduce access and increase waiting times for scheduling an MRI or CT scan.
- The Anchorage facility is located in an area of town that does not have this service.
- The average number of MRI scans for all MRI scanners in Anchorage is currently above the minimum use standard and will remain so and increase within the planning horizon (2011).
- Allowing one or two scanners who are under-performing to cause disapproval of a new scanner when the average of all equipment is above the minimum use standard is an "unreasonable barrier."
- Self-imposed contractual obligations that limit the ability of physicians to work in a particular setting are a choice made by providers, not an "unreasonable barrier" that the Department needs to waive. It is more likely an "unreasonable barrier" that the contractor needs to waive.
- The claim that patients will have to "switch" providers and disrupt continuity of care if the Mat-Su facility closes is not an "unreasonable barrier" to care. Radiologists traditional roles are quite different that primary physicians. They perform specific services ordered by other

¹⁷ IAP CON Application. January 2008. Page 86.

- doctors and report the results back. They are not generally asked for specifically by name by patients, and therefore moving from one radiologist to another should not diminish care.
- There was a good deal of opposition to the Mat-Su portion of the project by Valley residents and no opposition to the Anchorage portion of the project.
- The Department's projections do not support the view that the IAP facility in the Mat-Su Valley will operate at or above the minimum use standard by the 3-year planning horizon.
- The Department's projections show that the average use of all imaging facilities in the Mat-Su Valley will be below the minimum use standard by the 3-year planning horizon, and
- The IAP facility in the Mat-Su Valley is located one minute away by car from the existing MSMRC radiology facility and therefore is not providing increased access to patients.

COMPUTED TOMOGRAPHY (CT) SPECIFIC REVIEW STANDARDS

<u>CT Review Standard #1:</u> An applicant who seeks to establish a new CT service in an urban area (population of 70,000 or more) demonstrates the ability to provide a minimum of 3,000 CT scans per year by the end of the third operational year, dating from the initiation of the service.

Total average CT scan volume for the Anchorage Municipality service area, including IAP CT use, was 48,757 per year for 2005-2007, and is expected to increase to 51,268 per year by 2011, based on population growth of 5%. If each existing CT scanner (excluding the IAP CT for which approval is being sought) were operating at the minimum capacity level of 3,000 scans per year, the review standards indicate that 17 CT scanners could be justified to provide services for the population. In practice, three of eight existing CTs – Alaska Open Imaging, Diagnostic Health (formerly Health South), and an Alaska Regional Hospital 4-slice CT that were in use at least part of 2007 – were used for fewer than the 3,000 scans per year level, indicating underutilized capacity that is available.¹⁸

The IAP's Anchorage CT machine, for which approval is sought, has been in limited use since June 2006, with 190 scans in 2006 and 586 in 2007. IAP asserts that there will be expansion to 3,105 scans by 2010.¹⁹ The Department has developed its own projections for CT scans in the Anchorage service area, and based on historical use, it is estimated that IAP's CT use will be below 3,000 per scans per year by 2011. However, IAP may be able to achieve the 3,000 CT scans standard since the service area average will be well above the 3,000 scan standard (average use is projected to be 6,399 scans by 2011), and due to its location in an expanding area of Anchorage that may be more convenient than the hospitals and other private facilities. Using the approach of total machines "allowable" which indicates 17.1 can be justified, the additional IAP

¹⁸ The IAP Anchorage machine for which approval is being sought has not been counted as an available machine although the scans provided are counted since they would presumably have been conducted at another facility if the service had not been available.

¹⁹ IAP CON Application. January 2008. Page 62.

machine brings the total to 9 for Anchorage and is approvable. It is not possible to ascertain if the market share will equal the average, but we accept that an additional CT scanner is approvable for the Anchorage Municipality service area.

In contrast, the total average use of all CT scanners in the Mat-Su Valley, including IAP use data, was 8,398 scans per year for 2005-2007, which is expected to grow to 9,482 scans per year by 2011 based on a 13% population growth.²⁰ As a result, in 2011, 3.2 CT scanners (rounded up to four) are justifiable under CON for the Mat-Su Valley. With four machines already in use, and none of them operating at the minimum level of 3,000 scans per year that is required, it is not expected that the minimum 3,000 CT scans standard for approval of a new CT scanner would be met in the Mat-Su Valley by 2011.

ANCHORAGE	Avg. Annual CT Scans 2005-2007	Expected number for 2011	Minimum Scans Level expected per machine	# machines allowable	# machines existing or approved	# additional machines approvable
2011 estimated CT scans (+5% for population growth over 2005-07 avg)	48757	51268	3000	17.1	8	9.1
MAT-SU VALLEY						
2011 estimated CT scans (+13% for population growth over 2005-07 avg)	8398	9482	3000	3.2	4	0

CT Review Standard #2: An applicant who seeks to establish a new CT service in a rural area demonstrates the ability to provide a minimum of 1,000 CT scans per year by the end of the third operational year, dating from the initiation of the service.

This standard is not applicable to either of the facilities, because both Anchorage and the Mat-Su Valley facilities are located in urban rather than rural areas.

<u>CT Review Standard #3:</u> No new CT service will be approved in a service area or at a location that is less than 30 minutes travel time of an existing CT service performing fewer than 3,000 scans per year, or of a CON-approved but not yet operational, CT service.

The applicant does not meet this CT standard in either the Anchorage or Mat-Su Valley locations and requests a waiver, stating that it is inapplicable where contractual obligations prevent the physicians of one facility from accessing the equipment at another facility that may be operating at below the minimum use standard.²¹

²⁰ (13 percent population based increase expected),

²¹ IAP CON Application. January 2008. Page 86.

According to 7 AAC 07.025, the Department can recommend under certain circumstances, that an exception to the standards be granted if there is an unreasonable barrier to services in the service area that relates to: quality, availability, or accessibility of heath care services. The Department believes that an exception to this standard should be made for the Anchorage facility, but not for the Mat-Su facility for the following reasons:

- Most CT equipment in the Anchorage area is operating above the minimum use standard
- Projected growth within the three-year planning horizon will put more strain on the system
- The IAP Anchorage facility is located in an area of town that does not have this service
- The average number of CT scans per scanner for all CTs in Anchorage is currently above the minimum use standard and will remain so and increase within the planning horizon (2011)
- Allowing one or two CT scanners who are under-performing to cause disapproval of a new scanner when the average of all equipment is above the minimum use standard is an "unreasonable barrier."
- Self-imposed contractual obligations that limit the ability of physicians to work in a particular setting are a choice made by providers, not an "unreasonable barrier" that the Department needs to waive. It is more likely an "unreasonable barrier" that the contractor needs to waive.
- The claim that patients will have to "switch" providers and disrupt continuity of care if the Mat-Su facility closes is not an "unreasonable barrier" to care. Radiologists' traditional roles are quite different that of primary physicians. They perform specific services ordered by other doctors and report the results back. They are not generally asked for specifically by name by patients, and therefore moving from one radiologist to another should not diminish care.
- There was a good deal of opposition to the Mat-Su portion of the project by Valley residents and no opposition to the Anchorage portion of the project,
- The Department's utilization projections do not support the view that the IAP facility in the Mat-Su Valley will operate above the minimum use standard by the 3-year planning horizon,
- The Department's utilization projections show that the average use of all facilities in the Mat-Su Valley be well below the minimum use standard by the 3-year planning horizon, and
- The IAP facility in the Mat-Su Valley is located one minute away by car from the existing MSMRC radiology facility and therefore is not providing increased access to patients.

<u>CT Review Standard #4:</u> An applicant who seeks to expand an existing CT service must demonstrate an average service volume of at least 4,000 CT scans annually for each existing CT scanner at the service site.

This standard is not applicable for either facility because both are new facilities seeking to continue operations, not looking for expansion of an existing service.

FINANCIAL FEASIBILITY AND COST TO MEDICAID

Facility Feasibility and Financial Strength

Imaging Associates of Providence is a for-profit joint venture partnership between Interventional and Diagnostic Radiology Consultants, LLC (IDRC) and Providence Health System-Washington doing business as Providence Alaska Medical Center (PAMC). The 50% interest in the venture that is owned by PAMC promotes financial stability. Financing was obtained from GE Financing, Milwaukee, Wisconsin. The applicant provided financial statements which show a profit of \$247,851 by Fiscal Year 2008. Reimbursements by Medicaid for the 2006 and projected though 2009 were less than 4% of facility's total revenue so the cost to Medicaid is minimal.

PUBLIC COMMENT

The written public comment period was held from February 16, 2008, to March 17, 2008. A public meeting was held on March 11, 2008 in Anchorage and an additional public meeting on March 12, 2008 in Palmer. The March 11 public meeting in Anchorage included a presentation from the IAP CEO. The IAP CEO did not appear at the March 12 public meeting in Palmer and no one from IAP presented information on the project, although they were invited to do so.

Nine people spoke at the Anchorage public meeting. All were in favor of the project and all were staff or had a connection to IAP. No one spoke in opposition to the Anchorage facility. Nineteen people spoke at the Mat-Su public meeting. Seventeen of the speakers opposed the Mat-Su IAP and two were supportive. Only three of the speakers were members of the public that were not working for MSRMC or IAP and they spoke against the project. The majority of the testimony at the public meetings, in letters and emails received by the Department, and in letters of support attached to the application addressed the Mat-Su facility and could be categorized as follows:

- The current equipment in the Mat-Su Borough is currently operating below the minimum use standard and the Mat-Su IAP facility does not meet Certificate of Need standards that would warrant approval.
- The Mat-Su IAP will have a negative impact on existing services in the Valley.
- All facilities in the Mat-Su Valley offer the same services as IAP.
- The Anchorage IAP facility provides images of the highest quality.
- IAP staff state they would be negatively impacted if either the Abbott Road or the Mat-Su facility were to close.

The Department did receive one letter from a provider that stated their patients were denied service from the Mat-Su IAP facility for inability to pay.²²

²² Email. Shawn Roberts. March 14, 2008.

RECOMMENDATION

Although neither the Anchorage nor the Mat-Su Valley IAP facilities meet all of the CON standards, an exception to the standards should be granted for the Anchorage IAP facility and it should be approved. Although there will be a few under-performing scanners in the Anchorage service area in 2011, the average of all CT and MRI scanners are currently operating at over the minimum standard and is growing. The under-performing equipment constitutes an unreasonable barrier since it is the primary reason for denial and will negatively affect service access and availability. Therefore, under 7 AAC 07.025, it is recommended that an exception to these review standards be made for the Anchorage IAP facility only, and that a Certificate of need be approved at a cost of \$5,440,184, which represents the cost of equipment, furniture, fixtures, IT, and acquisition. No completion date is required because the facility is operational.

It is recommended that the Mat-Su Valley IAP facility's request for a waiver and approval of a Certificate of Need be denied because the facility also does not meet the minimum standards for utilization, and there are no unreasonable barriers that should be met for access or availability. Unlike Anchorage, by 2011, the Mat-Su Valley service area will not on average be equal to or above the minimum standard utilization of 3,000 scans required for both CT and MRI scanners for approval of additional scanners. Therefore, there are no unreasonable barriers that would indicate that an exception to the standard be granted for the Mat-Su IAP facility. A self imposed limit on where contract physicians can practice is not considered an unreasonable barrier for the purposes of the Certificate of Need program.

²³ Certificate of Need Review. Detailed Analysis for Need Determination. Appendix A.

June 26, 2008

APPENDIX A

Alaska Department of Health and Social Services Detailed Analysis for Need Determination

Anchorage & Mat-Su MRI Data	MRI Data As of June 11, 2008										
Facility	Current Equipment		2007	2006	2005	2004	2003	2002	2001	2000	1999
Anchorage:									•		
AK Innovative Imaging	0.2 Tesla Siemens Magnetom Jazz	Not full body	,								
AK Open Imaging	0.3 Tesla Hitachi Open Unit		1,613	1,906	2096	2200	1618	Service Star	ted in Ancho	rage in 2003	
AK Reg Hosp MRI Grp									purchased b	y ARH in 199	93
AK Regional Hospital	1.5 Tesla/GE Horizon LXi Short-bore		3,099	3,372	3371	3229	3259	3823	3813	3489	3224
AK Spine Institute Imaging	1.5 Tesla GE Signa Infinity w/excite		2,618	2,401	2288	802	Service Star	ted in 2004			
ANC Fracture & Ortho Clinic	0.2 Tesla GE/Lunar E-scan Open Unit	Not full body	,								
Anchorage Diagnostic Health (previously	GEHT 1.5T Signa Excite HD MR System										
listed as HealthSouth)	with CXK4 Magnet		3,484	3,554	3476	3937	3922	3762	2955	2695	2368
Provide Alaska Medical Center 1.5 Tesla Siemens			3,000	884	Service star	ted in 2006					
Provide Alaska Medical Center	0.65 Phillips - excl use		х	Х	248						
Providence Imaging Center PIC Total	1.5 Tesla/GE Signa		3,314	3,944	4378	4385	8765	9045	8732	8157	7041
Providence Imaging Center PIC Total	Center PIC Total 0.35 T Toshiba Opart Open MRI		х	Х	no longer in	use			2066	2607	2589
Providence Imaging Center PIC Total	1.5 Tesla/GE Signa Twin		3,313	3,943	4377	4384	3245	2nd MRI Op	erational in 2	2003	
IAP Anchorage			1,045	322		Service Start	ed in June 20	2006			
Alaska Native Med Ctr	1.5 Tesla/GE Signa		3,156	3,314	3215	3296	2523	2137	1987	1606	
Anchorage Total:			24,642	23,640	23,449	22,233	23,332	18,767	19553	18554	15222
avg per machine (8)			3,080.3	3,377.1	3.349.9			,			
2005-2007 avg per machine		3,269.1	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	-,-	-,-						
2011 estimate (+5% for population	growth over 2005-07 avg)	3433									
Elmendorf AFB	1.5 Tesla/GE Signa	military	4,701	2,717		put into servi	ce 2004				
Mat On Vallance											
Mat-Su Valley:	0.05 Table Tabliba On an Hait		4 744	4.040	1075	2073	1007	0110			
AK Open Imaging	0.35 Tesla Toshiba Open Unit		1,741	1,842	1875		1867	2116	551		
IAP Mat-Su	4 O Table /Distline Organization		1,178	353	0470		ted in June 20		4457	004	005
MatSu Regional Hosp	1.0 Tesla/Phillips Gyroscan Intera		X	145	2172	2012	1401	1739	1157	884	865
MatSu Regional Hosp	1.5 Tesla GE Excite		2038	1888	Replaced Pr	nillips in 2006					
Mat-Su Borough Total:			4957	4228	4047	4085	3268	3855	1708	884	86
avg per machine (2)			2478.5	2114	2023.5						
2005-2007 avg per machine		2,205.3									
2011 estimate (+13% for population	n growth over 2005-07 avg)	2492									

ANCHORAGE				machines	# machines existing or approved	# additional machines	(2011) per
2011 estimated MRIs (+5% for population growth over 2005-07 avg)	23910	25142	3000	8.380597	8	1	2794
MATSU							
2011 estimated MRIs (+13% for population growth over 2005-07 avg)	4411	4980	3000	1.66002	3	0	1660

Facility	CT Equipment	2007	2006	2005	2004	2003	2002	2001	2000
Anchorage:									
Alaska Native MC	16 Slice GE Light Speed Pro	10,967	10,262	10162	9217	7519	6845	6224	5422
Alaska Open Imaging	16 Slice Toshiba	1,550	1,007	1171	995	297			
Alaska Regional	single slice Siemens Balance	х	863	936	879	921	875	790	736
Alaska Regional	4 slice Siemens Volume Zoom	828	7,772	8417	7903	8283		7110	6616
Alaska Regional	Siemens Sensation	7,306	,						
Diagnostic Health (was HealthSouth)	8 slice GE Light Speed	1,988	2,311	2794	2645	2666	1920	1702	
Providence	16 slice GE Lightspeed	7814	6512	9577	9968				
Providence	4 slice Toshiba			5157	5368	10850	11369	12315	9039
Providence	1 slice GE CTI			5842	6122	6631	4867		
Providence	64 Slice GE	11722	9768	New in 200	6				
Providence PIC	16 Slice GE LIGHTSPEED PRO	7452	7177	6139	3877	replaced dis	covery in 200)4	
Providence PIC	8 slice GE DISCOVERY**			replac	ced in 2004	912			
IAP Anchorage		586	190	•		Service Starte	ed in June 2006	3	
Anchorage Total:		50,213	45,862	50195	46974	38079	33746	28141	21813
avg per machine (8) not counting pr	oposed machines	6277	5733	6274					
2005-2007 avg per machine		6095		-					
2011 estimate (+5% for population gro	owth over 2005-07 avg)	6399							
Elmendorf Air Force Base Hosp	GE Litespeed	175		Dec 2007 N	New Scanne	er			
	Siemens Somotom	11101	7834						
Mat-Su Borough:		•			•	•	•	•	
c. = c. c. g							3662	3186	2687
Mat-Su Regional Hosp	4 slice Siemens Somotom	211	393	1383	1227	1011	3332	0.00	
Mat-Su Regional Hosp	4 slice Siemens Somotom	77	309	4542		3691	1898		
Mat-Su Regional Hosp	64 slice GE VCT	6678			rvice 1/2006				
IAP Mat-Su		944	323				ed in June 2006	3	
Alaska Open Imaging - Wasilla	4 Slice Toshiba	1,629	1,541	1296	1257	1010			
Mat-su total		9539	8433	7221					
avg per machine (4)		2385	2108	2407					
2005-2007 avg per machine		2300							
2011 estimate (+13% for population g	rowth over 2005-07 avg)	2599							
		ı			ı	1	1	ı	
								Expected	(Number
					#	# machines	# additional	avg scans	of
		Avg scans			machines	existing or	machines	(2011) per	Machines
ANCHORAGE		2005-2007	Expected 2	Minimum		approved	approvable		Assumed)
2011 estimated CT scans (+5% for population	growth over 2005-07 avg)	48757	51268	3000	17.1	8		5696	9
, , ,	<u> </u>								
MATSU									
2011 estimated CT scans (+13% for population	on growth over 2005-07 avg)	8398	9482	3000	3.2	4	0	2370	4

Population Estimates and Projections											
Alaska Dept. of Labor Population Estimates					Alaska Dept. of Labor Population Projections						
	2004	2005	2008	2009	2010	2011	2015				
Anchorage	277,627	277,980	282,813	283,823	286,990	290,156	293,323	296,039	306,902		
Mat-su	70,401	74,011	77,174	80,056	81,480	82,904	84,328	87,031	97,843		
		2005-6-7 Avg					Change fr	om 3-yr av	g to 2011		
Anchorage			281539					105%			
Mat-su			77080					113%			

Population

Estimates: http://www.labor.state.ak.us/research/pop/estimates/07T2.1.xls

Population

Projections: http://www.labor.state.ak.us/research/pop/projections/AkSubStatePopProj.xls

APPENDIX B

Alaska DHSS Review Standards for MRI and CT Alaska Certificate of Need Review Standards and Methodologies December 9, 2005

VII. Diagnostic Imaging Services: Review Standards and Methodology

The Department will develop and maintain data sources for measuring utilization rates and will identify regional and national norms to use in assessing the reasonableness of applicant assertions about projected levels of service.

A. Magnetic Resonance Imaging

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, as applicable, in its evaluation of an application for a certificate of need for magnetic resonance imaging:

- 1. Except as provided in Review Standard 2, an applicant who seeks to establish an MRI service demonstrates the ability to provide a minimum of 3,000 MRI scans per year by the end of the third operational year, dating from the initiation of the service.
- 2. An applicant who seeks to establish an MRI service in a community with a population of 10,000 or less demonstrates the ability to provide a minimum of 1,000 MRI scans per year by the end of the third year, dating from the initiation of the service. (Based on the estimate of a minimum of 2,500 scans/70,000 people, it is estimated that the minimum service area population for an MRI service to provide a minimum of 1,000 MRI scans per year would be 28,000 people.)
- 3. No MRI service will be approved at a location that is less than 30 minutes access time of an existing MRI service performing fewer than 3,000 scans per year, or of a CON-approved, but not yet operational, MRI service.

C. Computed Tomography

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 computed tomography (CT) services:

1. An applicant who seeks to establish a new CT service in an urban area (population of 70,000 or more) demonstrates the ability to provide a minimum of 3,000 CT scans per year by the end of the third operational year, dating from the initiation of the service.

- 2. An applicant who seeks to establish a new CT service in a rural area demonstrates the ability to provide a minimum of 1,000 CT scans per year by the end of the third operational year, dating from the initiation of the service.
- 3. No new CT service will be approved in a service area or at a location that is less than 30 minutes travel time of an existing CT service performing fewer than 3,000 scans per year, or of a CON-approved but not yet operational, CT service.
- 4. An applicant who seeks to expand an existing CT service must demonstrate an average service volume of at least 4,000 CT scans annually for each existing CT scanner at the service site.